Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K133879 - 1932 pages
COMPANY:	CAS MEDICAL SYSTEMS, INC. (CASMEDISYST)
PRODUCT:	OXIMETER, TISSUE SATURATION (MUD)
SUMMARY:	Product: FORE-SIGHT ELITE ABSOLUTE TISSUE OXIMETER
DATE REQUESTED:	Oct 19, 2015
DATE PRINTED:	Oct 19, 2015
Note:	Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

6. 510(k) Summary

APR 2 9 2014

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	CAS Medical Systems, Inc.
Address:	44 East Industrial Rd. Branford CT. 06405 USA
Contact:	Ron Jeffrey – Director, Regulatory Affairs Phone - (203) 488-6056 Fax – (203) 488-9438 Email – rjeffrey@casmed.com
Prepared:	December 16, 2013
Trade Name:	FORE-SIGHT Elite™ Absolute Tissue Oximeter
Common Name:	FORE-SIGHT Oximeter
Classification Name:	Oximeter, Tissue Saturation (870.2700) (MUD)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

EQUIVALENCE (Predicate Device)

The FORE-SIGHT Elite™ Absolute Tissue Oximeter is equivalent to the following devices:

- Nonin Model 7600 Regional Oximeter Equanox (K102715)
- FORE-SIGHT Absolute Tissue Oximeter Monitor (K112820)

DESCRIPTION

The FORE-SIGHT Elite Absolute Tissue Oximeter measures hemoglobin under the Sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation saturation in the tissue (StO2).

The Oximeter consists of a monitor unit, preamplifier assembly, and sensor. The sensor uses multiple wavelengths in the range of 660 to 900 nm to precisely measure light absorption in tissue. Sensors are sized to provide targeted penetration depths appropriate for the tissue and patient populations of interest. The monitor unit controls the measurement sequence, generating the sensor LED currents and processing the detected light signals after amplification by the dual-channel preamplifier assembly. The FORE-SIGHT algorithm determines the StO2 values for the tissue under the sensor from the light absorption values and measured patient characteristics. The monitor unit provides simultaneous measurements on up to four sensors with both numeric and real-time graphical display formats.

The monitor unit is a mains-powered device with a field-replaceable battery backup module. A touchscreen user interface allows configuration of the Oximeter including audible, on-screen, and dedicated visual alarm indicators. The monitor display can be replicated for simultaneous remote viewing through an auxiliary VGA video output. Measurement data can be exported through various interfaces such as USB, RS-232 serial or wireless communications.

FORE-SIGHT Oximeter Monitor Intended Use

The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated as follows:

When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.

FORE-SIGHT Monitor Technology Compared to Predicate Devices

The FORE-SIGHT Elite Absolute Tissue Oximeter compares substantially to the cited predicate devices in that they use fundamentally the same optical operating principle, called multi-distance diffuse reflectance spectroscopy. All cited monitors use light to examine a cross-section tissue microvasculature (a mixed bed of arterioles, capillaries and venules). The FORE-SIGHT Elite Monitor and predicate devices analyze the light that is returned after having passed through tissues. The spectroscopic analysis determines concentrations of hemoglobin in its oxygenated and deoxygenated states. All cited monitors calculate oxygen saturation which reflects the percentage of oxygenated hemoglobin in the sampled tissue.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The FORE-SIGHT Elite Absolute Tissue Oximeter compares substantially to the predicates. All have 4-channel capability, an LED light source, similar user interface features and the benefits of portability.

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The FORE-SIGHT Elite Absolute tissue Oximeter has successfully undergone extensive performance, safety, electromagnetic, clinical, software and environmental testing to ensure it has been found to be substantially equivalent to the predicate devices. In addition to the above laboratory tests, CAS has conducted a full program of individual hardware, software, systems verification and validation studies of the FORE-SIGHT monitor and sensors.

Clinical Testing to Show Substantial Equivalence

The FORE-SIGHT Elite Absolute Tissue Oximeter has successfully undergone extensive clinical validation for the indicated use. The premarket notification cites a validation report: **Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO2%) in Adult and Transitional Adolescent Subjects.**

Conclusions Drawn from Clinical and Non-Clinical Testing

Clinical evaluation, safety testing and software validation demonstrate the FORE-SIGHT Elite Absolute Tissue Oximeter is substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 29, 2014

Cas Medical Systems, Inc.
Ron Jeffrey
Director, Regulatory Affairs
44 East Industrial Rd.
Branford, Connecticut 06405

Re: K133879
Trade/Device Name: Fore-Sight Elite Absolute Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Tissue Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: March 28, 2014
Received: March 31, 2014

Dear Ron Jeffrey,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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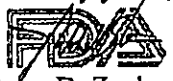
Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

K133879

Indications for Use

510(k) Number:

Device Name: FORE-SIGHT Elite™ Absolute Tissue Oximeter.

Indications for Use:

The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT Oximeter is indicated for use on adults and transitional adolescents ≥ 40 kg.

Prescription Use ✔ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.04.29 16:39:32 -04'00'

Page 1 of _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

3. 510(k) Cover Letter

K133879

FDA CDRH DMC
DEC 26 2013
Received

December 16, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Re: Traditional 510(k) NOTIFICATION – FORE-SIGHT Elite™ Absolute Tissue Oximeter

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, CAS Medical Systems, is submitting the required copies of the 510(k) notification for the FORE-SIGHT Elite Absolute Tissue Oximeter. The FORE-SIGHT non-invasive monitor is an optically based device that will continuously provide immediate measurement of absolute tissue blood oxygenation saturation and circulatory homodynamic changes. This is now an established device technology in the market and the documentation presented here represents our ninth premarket notification for this technology.

The purpose of this submission is to seek clearance for additional claims for the FORE-SIGHT Elite Absolute Tissue Oximeter. The current intended use and indications statement is:

K123700

The noninvasive FORE-SIGHT® Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with Large sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of adults and transitional adolescents ≥ 40 Kg.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

CAS will demonstrate that there is substantial equivalence regarding intended use between this proposed device and the predicates 1) Nonin Model 7600 (K102715), with a claim of blood underneath the sensor on adult and pediatric patients > 40kg., and 2) CASMED's FORE-SIGHT Elite Absolute Tissue Oximeter (K123700) predicate, indicated as stated above.

The proposed intended use and indications statement is as follows:

> *The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:*
>
> - *When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.*

The table below is supplied as suggested in the FDA Guidance Document, "Format for Traditional and Abbreviated 510(k)s," August 12, 2005.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

As part of the enclosed traditional 510(k) notification, Section 2 of this document contains a copy of a completed CDRH Premarket Review Submission Cover Sheet, while Section 4 contains the Premarket Notification 510(k) "Screening Checklist" with reference to the appropriate sections of this document that contain the required information. Additionally, the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary of Safety and Effectiveness Information can be found in Section 6 and Section 7 contains the signed truthful and accuracy certification statement. A full description of all contents for this submission can be found in the Table of Contents.

It is the understanding of CAS Medical Systems that written notification will be received from FDA if this device is subject to § 522 of the Federal Food, Drug and Cosmetic Act, i.e. Postmarket Surveillance.

The documents are prepared and submitted in accordance with the requirements of the eCopy Program for Medical Device Submissions (October 10, 2013).

The eCopy is an exact duplicate of the paper copy.

CAS Medical Systems has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, CAS Medical Systems requests that the FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b). CAS Medical Systems also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any questions about this notification, the contact person is:

Name:	Ron Jeffrey
Address:	44 East Industrial Rd. Branford, CT 06405
Telephone number:	203-488-6056
Fax number:	203-488-9438
Email:	rjeffrey@casmed.com

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs

Enclosures

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DEC 20 2013
Received

K133879

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Does the submission include clinical information?	X	
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Fax number:	203-488-9438
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Sincerely,

Ron Jeffrey
Director, Regulatory Affairs

Enclosures

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

TRADITIONAL 510(K)

FORE-SIGHT ELITE™ ABSOLUTE TISSUE OXIMETER

December 16, 2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Table of Contents

Section	Description	Page No.
1.	Medical Device User Fee Cover Sheet (form 3601)	3.
2.	CDRH Premarket Review Cover Sheet (form 3514)	6.
3.	510(k) Cover Letter	12.
4.	Screening Checklist for Traditional Premarket Notification Submissions	15.
5.	Indications for Use Statement	17.
6.	510(k) Summary	18.
7.	Truthful and Accuracy	19.
8.	Class III Summary and Certification	20.
9.	Financial Certification and Disclosure Statement(s)	21.
10.	Declarations of Conformity and Summary Reports (form 3654)	27.
11.	Executive Summary	33.
12.	Device Description	34.
13.	Substantial Equivalence Discussion	37.
14.	Proposed Labeling	40.
15.	Sterilization and Shelf Life	41.
16.	Biocompatibility	42.
17.	Software	43.
18.	Electromagnetic Compatibility and Electrical Safety	44.
19.	Performance Testing – Bench	45.
20.	Performance Testing – Animal	46.
21.	Performance Testing – Clinical	47.
22.	Risk Analysis	48.
Att. A	Product Specification (21-07-0302)	49.
Att. B	Indications for Use (ODE Format)	87.
Att. C	Proposed Labeling	89.
Att. D	Biocompatibility Reports	162.
Att. E	Software Exhibit(s) – Requirements, Specifications and Verification	220.
Att. F	Safety and EMC reports	360.
Att. G	Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO2%) in Adult and Transitional Adolescent Subjects	680.
Att. H	Risk Management (Analysis and Summary Report	706.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

1. Medical Device User Fee Cover Sheet

Attached is a signed copy of form 3601. It designates a payment of $2,585., because CAS Medical Systems, Inc. has qualified as a small business.

Payment Identification Number: (b)(4) [redacted]

Small Business Decision Number: (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

CAS MEDICAL SYSTEMS INC
44 EAST INDUSTRIAL RD
BRANFORD
CT 06405
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****3096

2. CONTACT NAME
Ron Jeffrey

2.1 E-MAIL ADDRESS
rjeffrey@casmed.com

2.2 TELEPHONE NUMBER (include Area code)
2034886056

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: (b)(4) [redacted]

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted] 18-Oct-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

10/18/13

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

2. CDRH Premarket Review Cover Sheet

The following forms (# 3514) make up the submission cover sheet.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
December 16, 2013	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: CAS Medical Systems, Inc.	Establishment Registration Number *(if known)*: (b)(4) [redacted]		
Division Name *(if applicable)*: NA	Phone Number *(including area code)*: 203-488-6056		
Street Address: 44 East Industrial Road	FAX Number *(including area code)*: 203-488-9438		
City: Branford	State / Province: Connecticut	ZIP/Postal Code: 06405	Country: USA
Contact Name: Ron Jeffrey			
Contact Title: Director, Regulatory Affairs	Contact E-mail Address: rjeffrey@casmed.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [x] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	MUD	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K102715	1	Model 7600 Regional Oximeter "Equanox"	1	Nonin Medical, Inc.
2	K123700	2	FORE-SIGHT Elite Absolute Tissue Oximeter	2	CAS Medical Systems, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Tissue Oximeter

	Trade or Proprietary or Model Name for This Device		Model Number
1	FORE-SIGHT Elite Absolute Tissue Oximeter	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K051257	2 K061960	3 K073036	4 K083892	5 K091452	6 K094030
7 K112820	8 K123700	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [x] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
MUD	870.2700	[ ] Class I [x] Class II
Classification Panel		[ ] Class III [ ] Unclassified
74 Cardiovascular		

Indications *(from labeling)*

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: CAS Medical Systems, Inc.		Establishment Registration Number: 2244861
Division Name *(if applicable)*		Phone Number *(including area code)*: 203-488-6056
Street Address: 44 East Industrial Road		FAX Number *(including area code)*: 203-488-9438
City: Branford	State / Province: Connecticut	ZIP Code: 06405 / Country: USA
Contact Name: Ron Jeffrey	Contact Title: Director, Regulatory Affairs	Contact E-mail Address: rjeffrey@casmed.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ES60601-1	AAMI	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance		01/01/2005
2	C22.2#60601-1	CSA	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance	Edition 3	01/02/2008
3	60601-1	IEC	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance	Edition 3	01/01/2005
4	60601-1-6	IEC	Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance	Edition 3	01/27/2008
5	62366	IEC	Medical Devices - Application of Usability Engineering to Medical Devices	Edition 1	10/01/2007
6	60601-1-8	IEC	Part 1-8 General Requirements for Basic Safety and Essential Performance - General Requirements, Tests and guidance for Alarm Systems in Medical Equipment and Medical Electrical Systems	Edition 2	10/25/2006
7	60601-1-2	IEC	Medical Electrical Equipment Part 1-2:General Requirements for Basic Safety and Essential Performance - collateral Standard: Electromagnetic Compatibility - Requirements for Tests	Edition 3	03/01/2007

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. 510(k) Cover Letter

December 16, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Re: Traditional 510(k) NOTIFICATION – FORE-SIGHT Elite™ Absolute Tissue Oximeter

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, CAS Medical Systems, is submitting the required copies of the 510(k) notification for the FORE-SIGHT Elite Absolute Tissue Oximeter. The FORE-SIGHT non-invasive monitor is an optically based device that will continuously provide immediate measurement of absolute tissue blood oxygenation saturation and circulatory homodynamic changes. This is now an established device technology in the market and the documentation presented here represents our ninth premarket notification for this technology.

The purpose of this submission is to seek clearance for additional claims for the FORE-SIGHT Elite Absolute Tissue Oximeter. The current intended use and indications statement is:

K123700

The noninvasive FORE-SIGHT® Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with Large sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of adults and transitional adolescents ≥ 40 Kg.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CAS will demonstrate that there is substantial equivalence regarding intended use between this proposed device and the predicates 1) Nonin Model 7600 (K102715), with a claim of blood underneath the sensor on adult and pediatric patients > 40kg., and 2) CASMED's FORE-SIGHT Elite Absolute Tissue Oximeter (K123700) predicate, indicated as stated above.

The proposed intended use and indications statement is as follows:

> *The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:*
>
> - *When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.*

The table below is supplied as suggested in the FDA Guidance Document, "Format for Traditional and Abbreviated 510(k)s," August 12, 2005.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

As part of the enclosed traditional 510(k) notification, Section 2 of this document contains a copy of a completed CDRH Premarket Review Submission Cover Sheet, while Section 4 contains the Premarket Notification 510(k) "Screening Checklist" with reference to the appropriate sections of this document that contain the required information. Additionally, the

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510(k) Summary of Safety and Effectiveness Information can be found in Section 6 and Section 7 contains the signed truthful and accuracy certification statement. A full description of all contents for this submission can be found in the Table of Contents.

It is the understanding of CAS Medical Systems that written notification will be received from FDA if this device is subject to § 522 of the Federal Food, Drug and Cosmetic Act, i.e. Postmarket Surveillance.

The documents are prepared and submitted in accordance with the requirements of the eCopy Program for Medical Device Submissions (October 10, 2013).

The eCopy is an exact duplicate of the paper copy.

CAS Medical Systems has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, CAS Medical Systems requests that the FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b). CAS Medical Systems also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any questions about this notification, the contact person is:

Name:	Ron Jeffrey
Address:	44 East Industrial Rd. Branford, CT 06405
Telephone number:	203-488-6056
Fax number:	203-488-9438
Email:	rjeffrey@casmed.com

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs

Enclosures

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions based on Guidance for Industry and FDA Staff

Title	Section	Present	N/A
MDUFMA Cover Sheet	1	√	
CDRH Premarket Review Submission Cover Sheet	2	√	
510(k) Cover Letter	3	√	
Screening Checklist for Traditional 510(k)	4	√	
Indications for Use Statement	5	√	
510(k) Summary or 510(k) Statement	6	√	
Truthful and Accuracy Statement	7	√	
Class III Summary and Certification	8	√	
Financial Certification or Disclosure Statement Form 3454 Form 3455	9	√	√
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)			√
Executive Summary	11	√	
Device Description	12	√	
Substantial Equivalence Discussion	13	√	
Proposed Labeling	14	√	
Sterilization/Shelf Life	15		√
Biocompatibility	16	√	
Software	17	√	
Electromagnetic	18	√	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Title	Section	Present	N/A
Compatibility/Electrical Safety			
Performance Testing – Bench	19		√
Performance Testing – Animal	20		√
Performance Testing – Clinical	21	√	
FORM FDA 3654, Standards Data Report for 510(k)s	10	√	
Kit Certification			√

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5. Indications for Use Statement

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.

See Attachment E for this statement in the ODE format.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

6. 510(k) Summary

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	CAS Medical Systems, Inc.
Address:	44 East Industrial Rd. Branford CT. 06405 USA
Contact:	Ron Jeffrey – Director, Regulatory Affairs Phone - (203) 488-6056 Fax – (203) 488-9438 Email – rjeffrey@casmed.com
Prepared:	December 16, 2013
Trade Name:	FORE-SIGHT Elite™ Absolute Tissue Oximeter
Common Name:	FORE-SIGHT Oximeter
Classification Name:	Oximeter, Tissue Saturation (870.2700) (MUD)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EQUIVALENCE (Predicate Device)

The FORE-SIGHT Elite™ Absolute Tissue Oximeter is equivalent to the following devices:

- Nonin Model 7600 Regional Oximeter Equanox (K102715)
- FORE-SIGHT Absolute Tissue Oximeter Monitor (K112820)

DESCRIPTION

The FORE-SIGHT Elite Absolute Tissue Oximeter measures hemoglobin under the Sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation saturation in the tissue (StO2).

The Oximeter consists of a monitor unit, preamplifier assembly, and sensor. The sensor uses multiple wavelengths in the range of 660 to 900 nm to precisely measure light absorption in tissue. Sensors are sized to provide targeted penetration depths appropriate for the tissue and patient populations of interest. The monitor unit controls the measurement sequence, generating the sensor LED currents and processing the detected light signals after amplification by the dual-channel preamplifier assembly. The FORE-SIGHT algorithm determines the StO2 values for the tissue under the sensor from the light absorption values and measured patient characteristics. The monitor unit provides simultaneous measurements on up to four sensors with both numeric and real-time graphical display formats.

The monitor unit is a mains-powered device with a field-replaceable battery backup module. A touchscreen user interface allows configuration of the Oximeter including audible, on-screen, and dedicated visual alarm indicators. The monitor display can be replicated for simultaneous remote viewing through an auxiliary VGA video output. Measurement data can be exported through various interfaces such as USB, RS-232 serial or wireless communications.

FORE-SIGHT Oximeter Monitor Intended Use

The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated as follows:

When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.

FORE-SIGHT Monitor Technology Compared to Predicate Devices

The FORE-SIGHT Elite Absolute Tissue Oximeter compares substantially to the cited predicate devices in that they use fundamentally the same optical operating principle, called multi-distance diffuse reflectance spectroscopy. All cited monitors use light to examine a cross-section tissue microvasculature (a mixed bed of arterioles, capillaries and venules). The FORE-SIGHT Elite Monitor and predicate devices analyze the light that is returned after having passed through tissues. The spectroscopic analysis determines concentrations of hemoglobin in its oxygenated and deoxygenated states. All cited monitors calculate oxygen saturation which reflects the percentage of oxygenated hemoglobin in the sampled tissue.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The FORE-SIGHT Elite Absolute Tissue Oximeter compares substantially to the predicates. All have 4-channel capability, an LED light source, similar user interface features and the benefits of portability.

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The FORE-SIGHT Elite Absolute tissue Oximeter has successfully undergone extensive performance, safety, electromagnetic, clinical, software and environmental testing to ensure it has been found to be substantially equivalent to the predicate devices. In addition to the above laboratory tests, CAS has conducted a full program of individual hardware, software, systems verification and validation studies of the FORE-SIGHT monitor and sensors.

Clinical Testing to Show Substantial Equivalence

The FORE-SIGHT Elite Absolute Tissue Oximeter has successfully undergone extensive clinical validation for the indicated use. The premarket notification cites a validation report: **Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO2%) in Adult and Transitional Adolescent Subjects.**

Conclusions Drawn from Clinical and Non-Clinical Testing

Clinical evaluation, safety testing and software validation demonstrate the FORE-SIGHT Elite Absolute Tissue Oximeter is substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

7. Truthful and Accuracy

I certify that, in my capacity as Director of Regulatory Affairs of CAS Medical Systems Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Ron Jeffrey

(Name)

December 16, 2013

(Dated)

Not assigned at this time

(Premarket Notification [510(k)] Number)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8. Class III Summary and Certification

Not applicable. The FORE-SIGHT Elite Absolute Tissue Oximeter is a class II monitor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

9. Financial Certification and Disclosure Statement(s)

The following pages contain form # 3454. Form # 3455 was not necessary.

Also enclosed here is form # 3674 a Certificate of Compliance to section 402(j) of the Public Health Service Act

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: December 31, 2015

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	
(b) (6) [redacted]	Duke University Medical Center

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Ron Jeffrey	Director, Regulatory Affairs
FIRM/ORGANIZATION CAS Medical Systems, Inc.	
SIGNATURE	DATE *(mm/dd/yyyy)* 12/05/2013

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
CAS Medical Systems, Inc.

2. Date of the Application/Submission Which This Certification Accompanies
11/01/2013

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
44 East Industrial Road

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City: Branford
State/Province/Region: Connecticut
Country: USA
ZIP or Postal Code: 06405

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*
(Tel): 203-488-6056
(Fax): 203-488-9438

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

FORE-SIGHT Elite Absolute Tissue Oximeter

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Ron Jeffrey	Director, Regulatory Affairs

12. Address

Address 1 *(Street address, P.O. box, company name c/o)* 44 East Industrial Road	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City: Branford	State/Province/Region: Connecticut
Country: USA	ZIP or Postal Code: 06405

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 203-488-6056

(Fax): 203-488-9438

14. Date of Certification

11/01/2013

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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10. Declarations of Conformity and Summary Reports

The following (5) pages contain form # 3654, one for each of the (5) national or international standards to which CASMED claims compliance. A nationally recognized test laboratory (NRTL) was used for all testing listed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ES60601-1 Medical Electrical Equipment, Part 1: General REquirements for Basic Safety and Essential Performance, 2005

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-71		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1 Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance, 2005

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1-2 Part 1-2: General Requirements for Basic Safety and Essential Performance - Electromagnetic Compatibility

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-53		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1-8 Basic Safety and Essential Performance - General Requirements, Test and Guidance for Alarm Systems

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-55		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC62366 Medical Devices - Application of Usability Engineering to Medical Devices, 2007

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-67		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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11. Executive Summary

This submission represents the ninth Pre-Market Notification for the FORE-SIGHT Device. CAS Medical began marketing tissue oximeters (MUD) for cerebral indications after our first adult cerebral market clearance K051257 was granted in December 2005.

Clearance for K061960 was granted in September 2006. This version introduced the trade name FORE-SIGHT and expanded indications to the cerebral monitoring of adults and children greater than 40 Kg as well as infants, using the large and small sensor sizes.

Our third submission cleared in February 2008 under K073036 was also for cerebral monitoring, this time adding a neonatal population of 2.5Kg and above for small sensor use. The indication remained for adults and children over 40Kg using the large sensor.

Clearance for K083892 was granted in March 2009. This version introduced the medium sensor, completing the full line of sensors, large, medium, and small. The indications for use permitted "cerebral" use on any individual but with a contraindication for use on low birth weight individuals <2.5Kg.

Our fifth submission cleared in August 2009 under K091452 was also for cerebral use with all three sensor sizes. The contraindication was removed and the small sensor became indicated for infants and neonates ≤ 8Kg.

Clearance for K094030 was granted in December 2009 expanding it use for skeletal muscle for the 5 to 50 Kg patient group using the medium sensors. The cerebral indications remained as they were from K091452.

Our seventh clearance (K112820), granted in January 2012, expanded the indications for abdominal use in neonates less than 4 Kg with the small sensor. With more validation data available, the indications for the medium sensor went from 5 to 50 Kg to 4 – 50 Kg.

The eighth clearance (K123700) introduced the FORE-SIGHT Elite Absolute tissue Oximeter to the FORE-SIGHT line. This monitor was cleared for a cerebral indication using its large sensor.

For each indication for use CAS Medical has provided clinical data to demonstrate that the FORE-SIGHT Tissue Oximeter provided accurate and reproducible monitoring measurements when compared to an appropriate reference measurement over a wide variety of patient groups.

The purpose of this Premarket Notification 510(k) submission is to obtain clearance for additional claims for the FORE-SIGHT Elite Absolute Tissue Oximeter. The current intended use and indications statement is for cerebral use whereas CASMED is seeking a broader use for non-cerebral tissue in the same patient population.

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12. Device Description

FORE-SIGHT Elite™ Absolute Tissue Oximeter - Purpose:

The FORE-SIGHT Elite Oximeter measures a single parameter of oxygenated hemoglobin under the Sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation in the tissue.

< Monitor

< Pre-Amp

< Large Sensors

Figure 1

The FORE-SIGHT Elite System:

The FORE-SIGHT Elite System (Figure 1) consists of three distinct components. None can be used independently of the others in this system.

The **Monitor** (01-06-3000/01-05-3005) contains the systems software, power supply, display, user interface, communication ports, and other electronics. The Monitor is responsible for all configuration, display, surveillance, and alarm management functions. The Monitor electronics also coordinate all measurement activities including light generation, processing of detected signals, and computation of the tissue oxygenation.

The **Dual Preamp Monitor Cable** (01-06-3100) is a reusable assembly consisting of electrical cabling, connectors, and a preamplifier circuit to pre-process the signals

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received from the sensors. Each preamp assembly connects to the monitor with a single connector, but provides the capability to monitor tissue oxygen saturation levels for two sensors. The monitor has connection ports for two preamps enabling simultaneous monitoring on up to 4 sensors.

The **Sensors** (01-07-2103) are the single use patient applied part. They connect to the Preamp Monitor Cable delivering modulated light of predetermined wavelengths into the tissue and converting the detected light into electrical signals for subsequent processing.

Figure 2 depicts a representative illustration of a Large Sensors components and full assembly.

Figure 2

Performance Specifications:

The method of %StO2 measurement is derived from a modified Beer-Lambert equation using the Near Infrared Spectroscopy (NIRS) wavelengths of 690, 735, 810 & 870 nm. The information outputted is as absolute tissue oxygen saturation (%StO2) in a measurement range of 0 to 99%. The display resolution is 1% and the data acquisition rate is approximately10Hz. The measurement refresh rate is every 2 seconds. System diagnostics are performed during a power-on self-test.

Bias ± Precision has been determined for the range 45% to 95% as follows:

Large Sensors (Somatic): 0.24 ± 5.17% to 1 SD (this submission)
Large Sensors (Cerebral): -0.14 ± 3.05% to 1 SD (cleared under K123700)

The FORE-SIGHT Monitor generates alarms for (user-selectable) high or low limit violations. Equipment and system status messages are displayed independently for each sensor and augmented with audible enunciation when appropriate.

Power is provided by input voltages of 100-240 VAC, 50-60 Hz with a field-replaceable battery module.

The operating environment is rated for 10°C to 40°c at 30% - 75% RH non-condensing. Storage conditions are rated for -20 C to 60°C with 90% RH @ 50°C to 15% RH @ 0°C

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

General Design Features:

- The monitor is transportable for use in various hospital locations;
- The monitor uses a LED light source;
- The monitor uses one size sensor to monitor adults and transitional adolescent's;
- The monitor's measurement accuracy is not affected by melanin, temperature, or perfusion;
- The monitor displays an StO_2 numeric value in the range of 01-99%;
- The monitor displays an indicator of optimal sensor placement called a Tissue Perfusion Index (TPI);
- The monitor contains an easy to read 10.4" color LCD VGA touch-screen display;
- The monitor provides a 24 hour review of historical data during or after a case;
- The monitor has modes for demonstration, servicing, programming and operating;
- The monitor provides patient data storage via USB memory sticks;
- The monitor provides a serial data output for compatibility with several third-party data review, charting, and acquisition systems;
- The monitor documentation and software, is available in multiple languages.

FORE-SIGHT Elite Models:

There are two models of the FORE-SIGHT Elite Absolute Tissue Oximeter. They are designated as part number(s) 01-06-3000 and 01-06-3005. They are identical. See figure 1.

FORE-SIGHT Accessories:

Part Number	Name	Function
01-06-3100 01-06-3005	FORE-SIGHT Elite Absolute Tissue Oximeter Dual Pre-Amp	Necessary part of the operating system. Included with monitor.
01-06-3014	FORE-SIGHT Elite Oximeter Battery Pack	For short term operation while not on mains power.
01-06-3036	User Manual on CD (English)	Included with each monitor
01-02-0395	Replacement Power Cord	Included with each monitor
01-07-2103	FORE-SIGHT Elite Large Sensor. Carton of 20.	Necessary part of the operating system. Patient contact part. Purchased separately.
01-06-0238	FS Roll Stand	A hospital grade roll stand, making the FS portable.

Full descriptive information may be found in the Project Gemini Product Specification 21-07-0302 Rev. 02. See Attachment A

Note: "Gemini" is the project name used during development. That name will appear on some documents that actually refer to FORE-SIGHT Elite Absolute Tissue Oximeter.

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13. Substantial Equivalence Discussion

For this submission there are two predicate devices. The Nonin 7600 Regional Oximeter System primarily, cleared under (K102715). Secondarily is our own device, the CASMED FORE-SIGHT Absolute Tissue Oximeter, cleared under (K123700).

PREDICATE DEVICE COMPARISON TABLE				
Device ► / Characteristic Comparison ▼	CASMED FORE-SIGHT Elite Absolute Tissue Oximeter **(Proposed)**	Nonin 7600 Regional Oximeter System (K102715)	CASMED FORE-SIGHT Elite Absolute Tissue Oximeter (K123700)	Differences and Similarities
Classifications	Class 2, 870.2700, MUD	Class 2, 870.2700, MUD	Class 2, 870.2700, MUD	Same
Parameters Monitored	Single parameter - Regional hemoglobin oxygen saturation of blood under the sensor.	Single parameter - Regional hemoglobin oxygen saturation of blood underneath the sensor.	Single parameter - Regional hemoglobin oxygen saturation of blood under the sensor.	All are single parameter monitoring devices.
Patient Population	Adults and transitional adolescents ≥ 40kg	Adult and pediatric >40 kg.	Adults and transitional adolescents ≥ 40kg	The patient populations are roughly equivalent.
Anatomical sites – all non-invasively	Blood under the sensor	Blood beneath the sensor	Brain via forehead.	The proposed device is seeking clearance for that already cleared in the predicate device(s).
Sensor type	Disposable large sensor with biocompatible patient contact surface.	Disposable, single size.	Disposable large sensor with biocompatible patient contact surface.	The FORE-SIGHT Sensors are identical.
Depth of penetration	Up to 25 mm	Up to 20 mm	Up to 25 mm	The FORE-SIGHT devices are identical.
Light source	Five wavelength near-infrared LED assembly comprising 690, 735, 770, 810, and 870 nm wavelengths. Maxim um total output energy of 50 mJ at 10 Hz repetition rate.	Four Wavelengths LED source 730,760,810, and 880 nm.	Five wavelength near-infrared LED assembly comprising 690, 735, 770, 810, and 870 nm wavelengths. Maximum total output energy of 50 mJ at 10 Hz repetition rate.	The Nonin device is similar and the FORE-SIGHT devices are identical.
Validation model	Accuracy has been demonstrated by direct validation to co-oximetry measurement of blood draws from invasive reference	It is not clear how accuracy has been demonstrated for somatic use.	Accuracy has been demonstrated by direct validation to co-oximetry measurement of blood draws from invasive reference	The validation methodology between the proposed device and the predicate CASMED device is

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PREDICATE DEVICE COMPARISON TABLE				
Device ► / Characteristic Comparison ▼	CASMED FORE-SIGHT Elite Absolute Tissue Oximeter **(Proposed)**	Nonin 7600 Regional Oximeter System (K102715)	CASMED FORE-SIGHT Elite Absolute Tissue Oximeter (K123700)	Differences and Similarities
	blood vessels in human subjects. Reference blood vessels are specific to the region monitored		blood vessels in human subjects. Reference blood vessels are specific to the region monitored	equivalent for the tissue examined.
Performance Accuracy	Cerebral – 45% - 95% ± 3.05% 1 standard deviation with large sensors Somatic – 45% - 95% ± 5.17% 1 standard deviation with large sensors	Cerebral—4.1 % (1 standard deviation) Arms with adult 8004CA sensors (unknown range) Accuracy unknown for Somatic use	Cerebral – 45% - 95% ± 3.05% 1 standard deviation with large sensors	Comparable clinical accuracy between the proposed device and the predicate device

Substantial Equivalence Discussion

CASMED has reviewed the criteria described in FDA's various Premarket Notification Guidance documents and below is a summary of the justification for substantial equivalence organized to be consistent with the decision process steps defined in FDA guidance, Description of 510(k) "Substantial Equivalence" Decision-Making Process. The predicate device(s) used to make this determination are the Nonin 7600 Regional Oximeter System (K102715) and the CASMED FORE-SIGHT Elite Absolute Tissue Oximeter, most recently cleared under K123700.

Intended Use

The FORE-SIGHT Elite Absolute Tissue Oximeter that is the subject of this 510(k) submission has the same intended use as the predicate devices, meaning it is intended for use as a tissue oximeter in any individual at risk for reduced flow or low flow ischemic states. The purpose of this submission is to seek clearance for a use in adjunct monitoring of regional hemoglobin oxygen saturation of blood underneath the sensor. CASMED is seeking clearance to indicate the monitor for use with large sensors on adults and transitional adolescents ≥ 40 Kg.

This indication that is proposed for the FORE-SIGHT Elite Absolute Tissue Oximeter does not affect the therapeutic/diagnostic effect and does not have an adverse impact on safety and effectiveness. To support the validity of this claim the necessary clinical

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evaluations have been conducted. These evaluations are based on accepted scientific methods designed to have a clinical and scientific rationale consistent with that used to support the predicate device indications. Namely, the use of reference measurements from one or more arterial and/or venous locations compared to measurements obtained by the system in the anatomical area of interest in individuals representing the same patient population (weight and maturity) for which the new indication is intended to be used. The results of the clinical evaluations conducted demonstrate that the accuracy and reproducibility of the system in measuring tissue oxygen levels for the new and modified indications are acceptable and consistent with the accuracy and reproducibility criteria used to support the current indications.

Technological Characteristics and Performance Testing

As it is evident in the table above, there are no changes to the design and technological characteristics of the FORE-SIGHT Elite Absolute Tissue Oximeter for this submission. Software comprises the only update to permit the updated indications. The software validation for these changes has been completed.

In conclusion, based upon the above considerations of intended use, indications for use, technological characteristics, and performance testing, the FORE-SIGHT Elite Absolute Tissue Oximeter meets the criteria for substantial equivalence.

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Indications for Use

510(k) Number:

Device Name: FORE-SIGHT Elite™ Absolute Tissue Oximeter.

Indications for Use:

The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT Oximeter is indicated for use on adults and transitional adolescents ≥ 40 kg.

Prescription Use ✔ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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CASMED®	Document Number 21-07-0302	Rev 02
Title: Project Gemini Product Specification		

Author: H. Triebel **Date:** 10-Oct-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

10/18/13	10·17·13	10/15/13
Product Mgr Marketing M. Aceves — Date	Operations G. Brocksieper — Date	Project Leader VSM Engineering H. Triebel — Date
10/15/13	10/16/13	10/22/13
Clinical - Applications B. Kopotic — Date	Quality Assurance Regulatory Affairs R. Jeffrey — Date	Sensor Engineering K. Duffy — Date
see attached email approval 10/23/13	10/23/13	10/18/2013
Clinical - Technical P. Benni — Date	Service L. Hottin — Date	R & D G. Gamelin — Date

CASMED®

FOR WHAT'S VITAL

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From: Benni, Paul
Sent: Wednesday, October 23, 2013 9:10 AM
To: Triebel, Harry
Subject: RE: Gemini Phase 1.5 new IFU & associated Project Documentation

These are ok
Paul

From: Triebel, Harry
Sent: Tuesday, October 22, 2013 4:51 PM
To: Benni, Paul
Subject: FW: Gemini Phase 1.5 new IFU & associated Project Documentation

Paul,

Sorry to push, but have you had a chance to review the updated Product Spec and Design Plan. If you approve of the changes, an email with that statement is all I need. Thanks.

Harry

From: Triebel, Harry
Sent: Tuesday, October 15, 2013 8:09 AM
To: Benni, Paul; Kopotic, Robert
Cc: Aceves, Mauro; Brocksieper, George; Jeffrey, Ron; Duffy, Karen; Hottin, Lenny; Gamelin, John
Subject: RE: Gemini Phase 1.5 new IFU & associated Project Documentation

Paul & Bob,

Attached are the latest Gemini/FORE-SIGHT ELITE Product Spec and Phase 1.5 Design Plan incorporating the Adult Tissue under Sensor IFU. Nothing has changes since the last emailing except to update the Revs to 02 and 00 respectively. If you could print the 1st page, sign, scan and return OR simply respond to this email with your approval, I will start the process of the circulating these 2 docs internally for the remaining approvals. Thanks in advance.

Harry

From: Triebel, Harry
Sent: Tuesday, October 08, 2013 10:33 AM
To: Aceves, Mauro; Brocksieper, George; Benni, Paul; Jeffrey, Ron; Duffy, Karen; Kopotic, Robert; Hottin, Lenny; Gamelin, John
Subject: Gemini Phase 1.5 new IFU & associated Project Documentation

To All,

To support the Gemini Phase 1.5 development, attached is the updated Product Spec -0359 as well as a new Design Plan -0302.
The Product Spec includes the following updates:

- Update IFU for new Indications for use: Adult under tissue
- Change VAC rating from 100-240 to 110 to 240;
- Change Max RH from 95 to 90%
- Section 4.9.1.1 & 4.9.1.2 change to CISPR 11 Class A
- Add new/missing design documents
- Add 21-07-0359 Gemini Phase 1.5 Design Plan (Adult Somatic IFU)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Revision History

Rev	Date	Editor(s)	Reason for Change
00	26-Mar-12	HMT	Initial Release
01	29-Oct-12	HMT	• Update to latest IFU, include Phase 1.0 reference; • Update list of Project Documents; • Add Low priority Alarms; • Change Eng, Mfg & Srv screen access by Password or USB Key; • Change to FORE-SIGHT ELITE™ to where appropriate; • Remove sections dealing with ability to turn High/Low Limits Off; • Add reference to the specific standards for Shock and Vibration; • Add new section "4.13.2.4 The system shall meet European Standard - Part 1-6 Collateral std: Usability"; • Remove Age & Weight inputs; • Update Battery icons; • Add Phase 1.5 & update Phase descriptions; • Update description of overlay Power On/Off button icon; • Update description of on-screen Alarm Silence/Reset button icon; • Update Section 4.5.1 Sensor for new Phases; • Remove Preamps in estimated cost of unit, Section 7.1;
02	10-Oct-13	HMT	• Update IFU for new Indications for use: Adult Tissue under Sensor; • Specify size of Sensors for at least Phase 1.0 and 1.5 • Change Max RH from 95 to 90%; • Section 4.9.1.1 & 4.9.1.2 change to CISPR 11 Class A; • Include new & missing Project Design documents; • Add new 21-07-0359 Gemini Phase 1.5 Design Plan (Adult Tissue under Sensor IFU); • Included Cerebral & Tissue under Sensor numeric field icons

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table of Contents

1 INTRODUCTION 5
1.1 PURPOSE OF SPECIFICATION 5
1.2 SCOPE OF SPECIFICATION 5
1.3 PROJECT OBJECTIVES 5
1.4 SCOPE OF DEVELOPMENT 5
1.5 INDICATIONS FOR USE 6
1.6 CONTRAINDICATIONS 6
1.7 REGULATORY 6
2 REFERENCE DOCUMENTS 7
2.1 AGENCY REGULATIONS, STANDARDS AND GUIDANCE'S 7
3 SYSTEM DEFINITION 11
3.1 PURPOSE AND FUNCTION 11
3.2 VITAL SIGN MONITORING FUNCTIONS 11
3.3 SYSTEM FUNCTIONS 11
3.4 ENVIRONMENTS OF USE 12
3.5 TYPE OF EQUIPMENT 12
4 PRODUCT DEFINITION 12
4.1 HUMAN FACTORS 12
4.2 USER INTERFACE 15
4.3 LABELING 16
4.4 LANGUAGES 19
4.5 SYSTEM REQUIREMENTS 19
4.6 MESSAGES 22
4.7 MONITORING 23
4.8 ENVIRONMENTAL CONDITIONS 24
4.9 ELECTROMAGNETIC COMPATIBILITY 25
4.10 ELECTRICAL AND MECHANICAL SAFETY REQUIREMENTS 25
4.11 PHYSICAL 26
4.12 ACCESSORIES 26
4.13 REGULATORY APPROVAL AND STANDARDS REQUIREMENTS 27
4.14 CLASSIFICATIONS 28
4.15 FIELD SERVICE / TECHNICAL SUPPORT FUNCTIONS 29
4.16 WARRANTY 29
5 PRODUCT ARCHITECTURE 30
5.1 SYSTEM ARCHITECTURE 30
5.2 PRODUCT INTERFACES 30
5.3 PREDICATE DEVICE(S) 30
6 DESIGN AND CONSTRUCTION 31
6.1 WORKMANSHIP 31
6.2 INTERCHANGEABILITY 31
7 CONSTRAINTS AND LIMITATIONS 31
7.1 COST 31
7.2 COMPONENT AND CONDUCTOR SPACING 31
7.3 DIAGNOSTIC TECHNIQUES 31
7.4 INDUSTRIAL DESIGN 31
7.5 TECHNOLOGICAL 31

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

7.6 FIELD SERVICE 31
8 PARTS, MATERIALS AND PROCESSES 32
8.1 ELECTRONIC AND ELECTRICAL PARTS 32
8.2 MECHANICAL PARTS 32
8.3 LABELS 32
8.4 MATERIALS 32
8.5 PROCESSES 32
8.6 MANUFACTURING PROCESS 32
9 PRODUCT ASSURANCE 33
9.1 GENERAL 33
9.2 VERIFICATION AND VALIDATION 33
9.3 DOCUMENTATION 33
10 HANDLING AND SHIPPING 35
11 TECHNOLOGICAL RISKS 35
11.1 PRODUCT PERFORMANCE & DEVELOPMENT RISKS 35

SAMPLE

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1 INTRODUCTION

1.1 PURPOSE OF SPECIFICATION

This specification exists for the purposes of:

a) Defining the scope of the CAS Next Generation Tissue Oximeter;
b) Defining the functions, performance, and interfaces of the product;
c) Determining the risks involved with the project;
d) Ensuring that all individuals involved in the project have the same understanding of the product's requirements; and
e) Provide a method of tracing the design input requirements to the design output for verification.

1.2 SCOPE OF SPECIFICATION

This document covers the entire design for Project Gemini. The various electrical, mechanical, human-factors, regulatory, and system requirements are detailed in this specification. This specification provides a means for tracing requirements through the verification and validation stages to insure that all stated requirements are met by the design implementation. The Project Gemini device[1] utilizes a 10.4" color VGA LCD Display integrated into a front bezel with a touchscreen overlay. Project Gemini shall be constructed using a metal internal enclosure with a plastic cover. Project Gemini shall incorporate a proprietary algorithm and a Sensor[2] that is placed on the body. The front panel shall allow connection to a USB memory device. The left side panel shall allow connection to the patient connections. The rear panel shall allow connection to other devices including, but not limited to: serial interface, Ethernet capability and video output. Project Gemini shall be capable of operating on AC or internal batteries. When on AC, the batteries shall be charging.

Project Gemini shall be divided into 4 Phases:

- Phase 1.0 – Adult cerebral (using Large Sensor)
- Phase 1.5 – Adult Tissue under Sensor (using Large Sensors)
- Phase 2.0 – Pediatric (using Medium Sensors)
- Phase 3.0 – Neonatal (using Small Sensors)

The Product Specifications shall capture all the design specifications associated with Phase 1 features. The Product Specifications will be updated when more Phase 1.5, 2 & 3 design specifications becomes available. If known and available, some aspects of the design related to Phase 1.5, 2 & 3 may be included in the Product Specification. Refer to latest Marketing Specifications Appendix I - PDR Phase Release Schedule and Appendix II - Software Release Schedule.

1.3 PROJECT OBJECTIVES

The objective of this project is to develop a replacement for the current FORE-SIGHT® (G1) Tissue Oximeter. The FORE-SIGHT ELITE™[3] platform shall: be lower cost, increase the number of channels (2 to 4), have a larger display, have a touchscreen interface, improved reliability of connector & mechanical design and incorporate the existing NIRS algorithm that reports absolute tissue blood oxygen saturation.

1.4 SCOPE OF DEVELOPMENT

The development of Project Gemini and Sensor will be accomplished by a dedicated CAS team. Time to market is critical and is the reason to limit initial feature and enhancements. While it is recognized that there will be additional opportunities to add features, improve performance and reduce cost, these will need to be implemented in future software releases.

---

[1] The term **Device** refers to Gemini Oximeter (Monitor) and is the Engineering Design Project name.

[2] The term **Sensor** refers the patient applied part, whereas the term **Preamp Cable** refers to the electrical cables assembly connecting the **Sensor** to the **Device**.

[3] FORE-SIGHT ELITE™ is the Product name and differentiates it from the FORE-SIGHT G1 product and accessories. The terms GEMINI and FORE-SIGHT ELITE may be used interchangeably.

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1.5 INDICATIONS FOR USE

(Phase 1.0): The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescent's ≥40 Kg.

1.6 CONTRAINDICATIONS

- The Gemini Sensor is contraindicated for use on patients with physical site area too limited for proper Sensor placement.
- The Gemini Sensor is contraindicated for use on patients with allergic reactions to electrode adhesive.
- The Sensor site must be checked at least every eight hours; if the circulatory condition or skin integrity has deteriorated, the Sensor should be applied to a different site.
- Do not adhere Sensors to underdeveloped, immature, compromised, or healing skin.
- No other contraindications are known at this time.

1.7 REGULATORY

1.7.1 Product Trade Name:
FORE-SIGHT ELITE Absolute Tissue Oximeter

1.7.2 FDA Regulatory Classification:
2

1.7.3 FDA Regulation Name:
Oximeter, Tissue Saturation

1.7.4 FDA Regulation Number:
CFR 21 part 870.2700

1.7.5 FDA Product Code:
MUD

1.7.6 FDA Premarket Notification:
New 510k required

1.7.7 Canada Device Class:
Monitor: 3, Sensors: 2, Preamp Cable: 2

1.7.8 Canada Product License(s):
(3) New or amended licenses required

1.7.9 CE Certificate (CE01416):
Suitable for this product

1.7.10 CE Certificate (CE547432):
Update with new model numbers

1.7.11 EU Product Class/Rule/Annex:
2b/Rule 10/Annex IX

1.7.12 EU Technical File:
Update required

1.7.13 EU Declaration of Conformity:
Update required

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1.7.14 GMDN Code(s):

(b)(4) [redacted]

1.7.15 Product Manufacturing Life:

(b)(4) [redacted]

1.7.16 Shelf Life:

Monitor unlimited, Sensors unlimited, but 2 years recommended

1.7.17 Lifetime of the device:

Refer to Medical Device Directive, Annex 1 #7

1.7.18 Expected Service Life:

Refer to 60601-1:2005, section 4.4 and 21-07-0304 Project Gemini Hazard Identification document, Section 3.2 Expect Service Life

1.7.19 Record Retention:

Equivalent to the life of the device and greater than 5 years

1.7.20 Software System Safety Class:

Class B - Refer to ANSI/AAMI/IEC 62304:2006, section 4.3 and to 21-07-0333 Project Gemini Main Bootloader Software Life Cycle Worksheet, 21-07-0334 Project Gemini Main Application Software Life Cycle Worksheet, 21-07-0335 Project Gemini NSAM Bootloader Software Life Cycle Worksheet, 21-07-0336 Project Gemini NSAM Application Software Life Cycle Worksheet documents.

1.7.21 Software Level of Concern:

Moderate – Refer to CDRH Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005 and 21-07-0337 Gemini Software Level of Concern Document.

2 REFERENCE DOCUMENTS

The following documents, with revision levels in effect on the date of issuance of this specification, are applicable to, and shall be considered part of this specification to the extent specified herein. Subsidiary documents, which are referenced in the applicable documents are also applicable and shall be considered part of this specification to the extent required to complete the specification of the applicable requirements.

2.1 AGENCY REGULATIONS, STANDARDS AND GUIDANCE'S

2.1.1 Food and Drug Administration (CDRH)

- The New 510K Paradigm - Alternate Approaches to 510k, March 1998;
- Deciding When to Submit a 510k for a Change to an Existing Device, January 1997;
- General Principles of Software Validation - Final Guidance for Industry and FDA Staff, January 2002;
- Guidance on the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005;
- Design Control Guidance for Medical Device Manufacturers, March 1997;
- Medical Devices; Current Good Manufacturing Practice - Quality System Regulation, October 1996.
- Labeling Regulatory Requirements for Medical Devices, August 1998;

2.1.2 Industry Standards - United States & International

- ANSI/AAMI ES 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI/IEC 60529:2004 Degrees of Protection Provided by Enclosures (IP Code)
- UL 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1:2005 w/Amendments Medical Electrical Equipment - General Requirements for Safety (3rd Edition)

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- IEC 60601-1-2:2007 Medical Electrical Equipment - General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests.
- IEC 60601-1-6:2010-01 Medical electrical equipment - General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8:2006 Medical Electrical Equipment - General Requirements for Safety – Collateral Standard: General requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60068-2-27:2008 Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
- IEC 60068-2-68:2008 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance
- IEC 61000-4-2 Ed. 2.0 b:2008 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
- IEC 61000-4-3 Amd.2 Ed. 3.0 b:2010 Amendment 1 - Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- IEC 61000-4-4 Amd.1 Ed. 2.0 b:2010 Amendment 1 - Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
- IEC 61000-4-5 Ed. 2.0 b Cor.1:2009 Corrigendum 1 - Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
- IEC 61000-4-6 Ed. 3.0 b:2008 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
- IEC 61000-4-8 Ed. 2.0 b:2009 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
- IEC 61000-4-11 Ed. 2.0 b:2004 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
- IEC 61000-3-2 Ed. 3.2 b:2009 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
- IEC 61000-3-3 Ed. 2.0 b:2008 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection
- ISO 14971:2007 Medical Devices - Application of Risk Analysis Management to Medical Devices
- ISO 13485:2003 Quality Systems - Medical Devices
- ISO 10993-1:2009 Biological evaluation of medical devices
- ANSI/AAMI/IEC 62366:2007, Medical devices - Application of usability engineering to medical devices
- ANSI/AAMI/IEC 62304:2006 Medical Device Software Life Cycle Processes
- Directive 2002/96/EC of the European Parliament and of the Council WEEE directive
- CAN/CSA-C22.2 No. 50501.1:2008 Safety Standard for Medical Devices. Note: Obtained through US safety testing (ETL/UL)
- International Safe Transit Association (ISTA) Pre-shipment Test Procedures, Project 1-A
- BS EN 55011:2009+A1:2010 Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement

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2.1.3 CAS Medical Documents

Design Inputs:

- Project Gemini Product Profile
- Project Gemini Marketing Requirements

Procedures:

- QSP1005 Engineering Change Procedure
- QSP1010 Product Labeling
- QSP1015 Product Regulatory File
- QSP1017 Regulatory Requirements
- QSP1019 Clinical Investigation
- QSP1025 Product Planning and Risk Management
- QSP1026 Risk Management
- QSP4001 Product Design Procedure
- QSP4002 Software Life Cycle Procedure
- QSP4003 Process Validation
- QSP4004 System Performance Report (SPR), Product Request (PR) Procedure
- QSP4005 Printed Circuit Board (PCB) Fabrication and Assembly Procedure
- QSP4006 Compliance Requirements for the EU Directive on the Restriction of the Use of Certain Hazardous Substances (RoHS) in Electrical and Electronic Equipment
- QSP4007 Design Verification and Validation
- QSP4008 Product Specifications Procedure
- QSP4009 Product Usability Process Procedure
- QSP4010 Design For Manufacturing & Assembly Guideline Procedure

Design Documentation:

- 21-07-0300 Gemini Project Schedule
- 21-07-0301 Gemini Design Plan
- 21-07-0302 Gemini Product Specification
- 21-07-0303 Gemini Risk Management Plan
- 21-07-0304 Gemini Hazard Identification
- 21-07-0305 Gemini Monitor & Preamp dFMEA Analysis
- 21-07-0306 Gemini Risk Analysis
- 21-07-0307 Gemini Risk Management Summary
- 21-07-0308 Gemini Usability Specifications and Requirements
- 21-07-0309 Gemini System Controller Board Programmer Reference
- 21-07-0310 Gemini Mechanical Design Overview
- 21-07-0311 Gemini Prototype Plan
- 21-07-0312 Gemini GUI Specifications
- 21-07-0313 Gemini NIRS Signal Acquisition Module (NSAM) Reference Guide
- 21-07-0314 Gemini Large Sensor Specifications
- 21-07-0315 Gemini Medium Sensor Specifications
- 21-07-0316 Gemini Small Sensor Specifications
- 21-07-0317 Gemini Download & Eng/Mfg/Srv GUI Specifications
- 21-07-0318 Gemini 1-Wire Memory Device Specifications: Boards
- 21-07-0319 Gemini NSAM Serial Protocol Specifications
- 21-07-0321 Gemini Residual Risk(s) Judged Acceptable and the Disclosure Process

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- 21-07-0322 Gemini Philips VueLink Translation Document
- 21-07-0323 Gemini Software Icons Specifications
- 21-07-0324 Gemini Main Bootloader Software Requirement Specifications
- 21-07-0325 Gemini Main Application Software Requirement Specifications
- 21-07-0326 Gemini NSAM Bootloader Software Requirement Specifications
- 21-07-0327 Gemini NSAM Application Software Requirement Specifications
- 21-07-0328 Gemini Main Bootloader Software Architecture & Specification
- 21-07-0329 Gemini Main Application Software Architecture & Specification
- 21-07-0330 Gemini NSAM Bootloader Software Architecture & Specification
- 21-07-0331 Gemini NSAM Application Software Architecture & Specification
- 21-07-0332 Gemini 1-Wire Memory Device Specifications: Sensors
- 21-07-0333 Gemini Main Bootloader Software Life Cycle Worksheet
- 21-07-0334 Gemini Main Application Software Life Cycle Worksheet
- 21-07-0335 Gemini NSAM Bootloader Software Life Cycle Worksheet
- 21-07-0336 Gemini NSAM Application Software Life Cycle Worksheet
- 21-07-0337 Gemini Software Level of Concern Document
- 21-07-0338 Gemini Software V&V History
- 21-07-0339 Gemini Software Revision History
- 21-07-0340 Gemini Sensor dFMEA Analysis
- 21-07-0341 Gemini Obsolescence Plan for FORE-SIGHT G1
- 21-07-0342 Gemini USB Patient Data File Storage Format
- 21-07-0343 Gemini Displayed Message Priority Assignment Document
- 21-07-0344 Gemini Help Screen Specifications
- 21-07-0345 Gemini Scientific Data Serial Output Protocol
- 21-07-0346 Gemini 4-Ch Comma Separated Value Serial Output Format
- 21-07-0347 Gemini Sensor Monitoring and Memory Capabilities
- 21-07-0348 FS-Elite Sensor Test Fixture Requirements
- 21-07-0349 Gemini Sensor dFMEA Analysis
- 21-07-0352 FS-Elite Preamp Test Fixture Requirements
- 21-07-0353 FS-Elite Sensor Test Fixture Architecture and Operation
- 21-07-0354 Gemini Programming 1-Wire PCB PC-Application Requirements
- 21-07-0355 Gemini/FORE-SIGHT ELITE GUI Text Translations (Fre, Spa, Dut, Ger, Ita, Rus)
- 21-07-0356 Gemini/FORE-SIGHT ELITE Sensor Simulator Requirements
- 21-07-0357 FORE-SIGHT ELITE Pre-Release Clinical Field Studies
- 21-07-0358 Gemini Research Mode Guidelines
- 21-07-0359 Gemini Phase 1.5 Design Plan

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3 SYSTEM DEFINITION

Section	Customer Needs / Intended Use	Performance Requirements	PLAN
3.1	**PURPOSE AND FUNCTION**		
3.1.1	The System[5] will be applied for a specific set of patient populations Product Profile[6]	Refer to the Indications For Use (section 0, page 6)	Marketing planning and strategy
3.1.2	The System will be operated by a wide range of Users Product Profile	For use as prescribed by physicians, physician assistants, registered nurses, certified registered nurse anesthetists, clinical specialists, clinical investigators or other qualified medical personnel trained in the use of the equipment	Marketing planning and strategy
3.1.3	The System will be operated by a wide range of User profiles Product Profile	The User profile shall include: • Adult (e.g., > 21 years old OR required experience) • Ability to read text on screen & labels from < 2' distance • Able to read simple screen prompts in Oximeter's currently-selected language as well as User Manual • Able to perform simple interface tasks (touchscreen, connections) with left or right hand • Able to apply appropriate Sensor to selected monitoring site successfully • Professional clinician responsible for patient care • Trained (in person or via User manual) in the proper operation of the Gemini Oximeter • Average degree of aging-related short term memory impairment or age-related reduced hand/finger dexterity	Marketing planning and strategy
3.2	**VITAL SIGN MONITORING FUNCTIONS**		
3.2.1	The System shall report absolute tissue blood oxygen saturation values Mktg Req 2.A[7]	The product shall monitor and display up to 4 channels of a patient's local tissue blood oxygen saturation for the following patient types: • Phase 1.0 Adult cerebral using large Sensors • Phase 1.5 Adult Tissue under Sensor using Large Sensors • Phase 2.0 Pediatric using Medium Sensor • Phase 3.0 Neonatal using Small Sensors Refer to the most current Project Gemini FDA submission and approved Indications For Use (IFU)	21-07-0338 Gemini Software V&V History Gemini Project FDA submission
3.2.2	The System shall present notification of patient and equipment status Mktg Req 6.A, 6.D	Gives notification of patient and system status via visual indication and audible tones	21-07-0338 Gemini Software V&V History
3.3	**SYSTEM FUNCTIONS**		
3.3.1	The System shall have provide a graphical user interface (GUI) Mktg Req 7.all	The User Interface consists of: • Backlit Color LCD Display • Power and Equipment/Patient state LEDs • Touchscreen interface	21-07-0338 Gemini Software V&V History
3.3.2	The System shall display tissue blood oxygen saturation values as a numeric and trended waveform Mktg Req 4.A, 6.C, 7.B.j	The product shall monitor and display up to 4 channels of a patient's local tissue blood oxygen saturation	21-07-0338 Gemini Software V&V History
3.3.3	The System shall use single use Sensors	Sensors are intended to be applied to a single patient	21-07-0338 Gemini Software V&V

[4] Design Inputs are based upon the approved Product Profile and Marketing Requirements (refer to Section 2 REFERENCE DOCUMENTS).

[5] The System refers to the Oximeter, Preamp Cable(s) and Sensor(s), while the term Device refers to the Oximeter itself.

[6] Refer to Gemini Product Profile document for additional details for Customer Needs and Intended Uses

[7] Mktg Req X.Y.Z - Refer to Gemini Marketing Requirements Phase 1 (unless otherwise noted), Section X, Sub-Section Y, Paragraph Z

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	Mktg Req 17.C		History
3.4	**ENVIRONMENTS OF USE**		
3.4.1	The System shall be used in professional medical facilities Product Profile	Environments include, but are not limited to, operating room (OR), anesthesia, intensive care unit (ICU) , post anesthesia care unit (PACU) , EP and Cath labs	Marketing planning and strategy
3.5	**TYPE OF EQUIPMENT**		
3.5.1	The System shall be mobile as well as stationary Mktg Req 1.B, 1.C, 3.A, 3.B	Equipment is intended to be stationary (including wall or pool mount arm), affixed to a roll stand or carried by hand	21-07-0338 Gemini Software V&V History

4 PRODUCT DEFINITION

SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.1	**HUMAN FACTORS**		
4.1.1	**User Controls**		
4.1.1.1	The controls shall be ergonomically designed Mktg Req 7.A, 7.B.a-j, 7.C	The arrangement of the User Controls shall allow the user to use a single hand to operate the Device The User Controls shall be positioned so that they do to not interfere with any cables	21-07-0338 Gemini Software V&V History
4.1.1.2	There shall be a "On / Standby" power switch Mktg Req 7.C	The "On / Standby" switch shall have a Power button symbol (circle with line IEC 60417-5010) near it. The switch shall turn the Device on and off when connected to AC or while on battery and no AC When the Device is connected to AC power, the Device is fully operational in "On" mode, but only the battery charger is operational in "Standby" mode When the Device is NOT connected to AC power, the Device is fully operational in "On" mode, but is completely powered off in "Standby" mode	21-07-0338 Gemini Software V&V History
4.1.2	**Displays Indicators**		
4.1.2.1	The display shall be easily viewed from several angles Mktg Req 6.B, 6.E, 7.F	The LCD shall have a wide viewing angle > 45° all 4 angles The LCD display shall have anti-glare characteristic Numerics shall be readable from 12 feet away	21-07-0338 Gemini Software V&V History
4.1.2.2	There shall be a AC indicator located on the front panel Mktg Req 7.D	The AC indicator shall be illuminated whenever the Device is connected to AC (regardless of battery state)	21-07-0338 Gemini Software V&V History
4.1.2.3	The display shall present patient and equipment information Mktg Req 6.C, 6.D, 6.E, 7.B.a-j	The display shall use a 10.4" (diagonally measured) Color, VGA display (640 x 480 pixels) using 256 color palette The background color for normal operations shall be black	21-07-0338 Gemini Software V&V History
4.1.2.4	There shall be a brightness adjustment for the display Mktg Req 6.B	There shall be a minimum of 4 levels of user selectable brightness adjustments for the LCD	21-07-0338 Gemini Software V&V History
4.1.2.5	The display shall present the current battery state Mktg Req 7.E	There shall be on screen icon to indicate the state of the battery: • Not present • Charging • Discharging, possibly various states of discharge • Low Battery condition • Depleted Battery condition	21-07-0338 Gemini Software V&V History
4.1.2.6	There shall be an area to display the current time & date Mktg Req 6.A	The device shall incorporate the use of a battery-backed, non-volatile Real Time Clock (RTC), settable by the User The time shall be displayed in 24-hour format: 2-digit hours and 2 digit minutes (e.g., 11:34, leading zeros) The date shall be displayed as a 2-digit day, 3-letter abbreviated month and 2-digit year (e.g., 02-Jun-11, leading zeros)	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.1.2.7	There shall be an area to display the Patient ID Mktg Req 6.A	The device shall allow the user to enter a Patient ID via a QWERTY keyboard. The keyboard shall include A-Z, 0-9 & _ Patient ID shall be optional - not needed to save data Patient ID shall be used to help define Patient data file name	21-07-0338 Gemini Software V&V History
4.1.2.8	The Device shall be have an area to display numerics that are easily read at a distance of up to 15' Mktg Req 6.E, 7.B.a,e,i,j	The Device shall be able to display a maximum of four (4) numeric values: 1 numeric for each channel (①, ②, ③, ④) along the right side of the display Each numeric shall be 2-digits (leading space), 2 dashes "- -" if the value is invalid (no Sensor, Sensor off patient, etc.) The Numeric digits shall be 0.5" minimum in height (15' readable) The numeric for each channel shall have an associated color representing the location of the Sensor The color of the numerics (and traces) shall be the same color as the primary color of the Sensor location icons Each numeric shall have an associated Trace There shall be an area in each numeric to display a choice of Left/Right indicator (near body icon) Area in each numeric section to display a reference saturation value Numeric field shall include icons for the channel number Numeric field shall include the alarm limit values and icons for the TPI for channels with valid body locations Sensor location icons shall be displayed in the Numeric field: **Phase 1.0:** **Left** **Right** Cerebral/Brain **Phase 1.5** Tissue under Sensor Arm Flank Legs	21-07-0338 Gemini Software V&V History
4.1.2.9	The Device shall be have an area to display the signal strength for each channel Mktg Req 7.B.e	A Tissue Perfusion Index (TPI) consisting of 4 ascending height bars shall be visible near the channel Numeric TPI Bars shall be white (outlines/filled in) on black background Low/no bars indicates poor tissue perfusion, while higher bars indicates better tissue perfusion	21-07-0338 Gemini Software V&V History
4.1.2.10	There shall be an area to display the trace for each value Mktg Req 6.C	Traces shall have fixed scales with reference marks/values along the left side of the traces All traces shall have the same sweep speed (View) When one preamp is installed 2 overlapping traces and 2 individual numerics may be displayed When two preamps are installed 2 pairs of overlapping traces and 4 individual numerics may be displayed When a numeric is invalid, the trace shall be the same color as the background (blank)	21-07-0338 Gemini Software V&V History
4.1.2.11	There shall be an area to display each channel's Patient and Channel conditions Mktg Req 6.A	Patient and Channel conditions shall be displayed in a message area associated with each channel's numeric at all times (normal mode) Patient and Channel conditions shall have priority alarms status based on Risk Analysis Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.1.2.12	There shall be an area to display the System Status Mktg Req 6.A	The System status shall be displayed in a dedicated area, visible on screen at all times (normal mode) System status shall have priority alarms status based on Risk Analysis High Priority System conditions shall be displayed as white text on a red background Medium Priority System conditions shall be displayed black text on yellow background Low Priority System conditions shall be displayed yellow text on black background Informational System conditions shall be displayed white text on black background Mixed priority conditions (High, Medium, Low & information) shall only display the highest Priority System condition Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History
4.1.2.13	Icons should be used where possible Mktg Req 7.B.a,e	Icons should be used in place of text where possible to limit translations Icons should be of sufficient size and should be designed so that their interpretation is intuitive	21-07-0338 Gemini Software V&V History
4.1.3	**Audible Indicators**		
4.1.3.1	Audible tones shall be generated to indicate various conditions Mktg Req 7.B.f,g	The Device shall generate High Priority tones for High Priority conditions The Device shall generate Medium Priority tones for Medium Priority conditions The Device shall generate Low Priority tones for Low Priority conditions Mixed priority conditions (High, Medium & Low) shall only generate the High Priority tones Mixed priority conditions (Medium & Low) shall only generate the Medium Priority tones User selectable Volume Adjustments – User is not allowed to turn volume to OFF Audio Silence capabilities shall be implemented to allow for temporary suspension of Audio tone generations Audio tones shall meet IEC 60601-1-8 requirements Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History
4.1.4	**Device Patient Connector Receptacles**		
4.1.4.1	Device Patient connectors shall be located for ease of use Mktg Req 5.A	Device Patient connector(s) shall be on the left side of the Device (looking at front of Device) The Device Patient connectors will be identified with the associated Channel number (e.g., ①, ②, ③, ④) near the connections	21-07-0338 Gemini Software V&V History
4.1.4.2	Device Patient connections shall connect to the Preamp Cable Mktg Req 14	Device Patient connectors shall withstand a minimum of 750 Preamp Cable insertions	21-07-0338 Gemini Software V&V History
4.1.4.3	The Device Patient connection should be unique Mktg Req 14	Mechanical keying may be used to avoid accidental connection of other cables using the Device Patient connector	21-07-0338 Gemini Software V&V History
4.1.5	**External Interfaces**		
4.1.5.1	The Device may be powered by AC Mktg Req 9.F, 9.G, 9.H	The Device shall use a universal power supply to allow voltage input from 100 to 240 VAC, 50 or 60 Hz without any user selection The fuses are accessible without opening the housing, but are not accessible w/o first removing the AC power cord. (Per IEC 65)	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
		AC Power input shall be by means of EN60320 (IEC320) C14 connector on rear of Device, suitable for attachment of medical grade power cord equipped with EN60320 C13 receptacle and a plug suitable for the country of destination	
4.1.5.2	The Device shall provide two (2) RS-232 serial Interface connections Mktg Req 10.D	Two (2) dedicated bi-directional RS-232 connections shall be located on the rear panel of the Device The RS232 interfaces will be DTE connections using DB9 plugs. Each connector will provide 4-40 threaded standoffs for jackscrew retention	21-07-0338 Gemini Software V&V History
4.1.5.3	The Device shall provide basic serial protocols Mktg Req 8.C, 10.E, 10.Fa-d	The Device shall provide a Philips VueLink protocol selection on either RS-232 port (refer to 4.1.5.2) The Device shall provide a Comma Separated Valve (CSV) protocol selection on either RS-232 port (refer to 4.1.5.2) The Device shall provide a CAS ATE protocol selection on either RS-232 port (refer to 4.1.5.2) The Device shall provide support for printing STS and FS Data	21-07-0338 Gemini Software V&V History
4.1.5.4	The Device shall provide 1 Ethernet connection Mktg Req 10.A	The Device shall have the capability for a 10Base-T/100Base-T Ethernet connection The Ethernet connection shall be a RJ45 jack located on the rear panel	21-07-0338 Gemini Software V&V History
4.1.5.5	The Device shall provide connection to USB Memory devices Mktg Req 10.B	The Device shall provide a primary USB Host port ("A" connector) for use only with Flash Memory 'sticks' having no power or data connection other than the Host Port. The Primary USB connection shall be located on front of Device The Device shall provide a Secondary USB Host port ("A" connector) for use only with devices requiring having no power or data connection other than the Host Port. A Secondary USB connection shall be located on rear of Device	21-07-0338 Gemini Software V&V History
4.1.5.6	The Device shall provide a Video output Mktg Req 10.C	The Device shall provide an VGA standard video output port (DE15) DFU shall stipulate connection to Video output shall be to a Medical Grade display or video device	21-07-0338 Gemini Software V&V History
4.1.5.7	The Device shall provide an optional wireless feature Mktg Req, Beyond Phase 1	The Device may be configured with a factory-installed optional Bluetooth capability. The Device may be configured with a factory-installed optional WiFi (802.11 b/g/n) capability.	21-07-0338 Gemini Software V&V History
4.2	**USER INTERFACE**		
4.2.1	The user interface shall use a touchscreen Mktg Req 7.A	The touchscreen interface shall allow the user to touch images on the LCD and perform an action A minimum number of touches shall be used to navigate and alter any user selectable feature	21-07-0338 Gemini Software V&V History
4.2.2	The user interface shall allow the user to configure the Device Mktg Req 7.Bb-k, 8.B	The User Interface software shall use the following features (similar to Microsoft 'Windows"), including but not limited to • Patient – Patient Setup, Patient ID • Limits – High, low and differential limits • View – Horizontal time scale, TUT threshold and display • Events – Place and manage list of events • Data – Patient Data transfer to USB • Setup – Time/Date, brightness, etc.	21-07-0338 Gemini Software V&V History
4.2.3	There shall be a "Silence / Reset" touchscreen target area always available on the screen Mktg Req 7.B.g	The "Silence / Reset" target shall have an audio silence symbol (e.g., speaker with single/dual dashed or solid diagonal line on it) Touching the target shall disable or enable the temporary (2-Min) audio silence function	21-07-0338 Gemini Software V&V History
4.2.4	The Device shall have a Normal Mode of operations	The Device shall display 2 channels and waveforms, as well as associated channel information	21-07-0338 Gemini Software V&V

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Mktg Req 4.A, 6.E	The Device shall display 4 channels (when monitoring more than 2 channels) and waveforms, as well as associated channel information	History
4.2.5	The Device shall have an Engineering (Eng) Menu Mktg Req, Appendix II	Engineering personnel can access an Eng Menu by use of a specific password or USB Key The Eng Menu shall allow the Device to be examined for Eng related issues	21-07-0338 Gemini Software V&V History
4.2.6	The Device shall have a Manufacturing (Mfg) Menu Mktg Req, Appendix II	Engineering personnel can access an Mfg Menu by use of a specific password or USB Key The Mfg Menu shall allow the Device to be examined for manufacturing related issues	21-07-0338 Gemini Software V&V History
4.2.7	The Device shall have a Service (Srv) Menu Mktg Req, Appendix II	Engineering personnel can access an Srv Menu by use of a specific password or USB Key The Service Menu shall allow the Device to be examined for service related issues	21-07-0338 Gemini Software V&V History
4.2.8	The Device shall have a Demo Mode(s) Mktg Req, Appendix II	The text "Demo" shall be shown prominently on the display while the Device is in Demo Mode The Device shall enter the Demo Mode and remain in Demo Mode until one of the following occurs: • Power is cycled • Demo exited by de-selecting "Demo Mode" • Preamp connected w/non-Demo sensors connected	21-07-0338 Gemini Software V&V History
4.2.9	The display text in Normal Mode user shall be easily understood Mktg Req 7.F, 12.A Mktg Reg, Appendix I	Normal Modes of operation shall present text that is concise and appropriate for the intended audience Text shall be multi-language selectable with provisions for multiple Language to be stored in the device – The following languages shall be available (both for GUI and IFUs)	21-07-0338 Gemini Software V&V History
	Phase 1.0 & 1.5 Mandatory:	English, Spanish, French, Italian, German, Dutch, Russian (1.5)	
	Desired:	Polish, Finnish, Swedish, Norwegian, Danish, Portuguese, Turkish, Arabic	
	Phase 2.0 Mandatory:	Polish, Finnish, Swedish, Norwegian, Danish, Portuguese, Turkish, Arabic	
	Desired:	Japanese, Chinese, Korean	
	Phase 3.0 Mandatory:	Japanese, Chinese, Korean	
4.2.10	The display text seen by Service / Mfg / Eng Menu user shall be easily understood menus Mktg Req, Appendix II	Srv, Mfg & Eng Menus shall present text that is concise and appropriate for the intended audience Srv, Mfg & Eng Menu text shall be in English only	21-07-0338 Gemini Software V&V History
4.3	**LABELING**		
4.3.1	**Labeling Requirements for IEC 60601-1 Section six**		
4.3.1.1	There shall present any required markings on the outside of the Device and also in Device DFU[8] Regulatory Standards Requirement	Markings on the outside of the Equipment and also referenced in the Device DFU shall meet IEC 60601-1 Section Six a) Indication of Origin: **CAS Medical Systems, Inc.** **Branford, CT, USA 06405** b) Connection to the supply rated supply voltage(s) or range(s) **100-240 VAC** c) Supply frequency **50/60 Hz** d) Power input **1.5A RMS (max) @ 115 VAC**	21-07-0338 Gemini Software V&V History

[8] DFU – Refers to Directions For Use, e.g., could be single page or multi-page User Manual

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
		e) Symbols for Device classification from IEC 60601-1 Section Five Degree of Protection against Electrical Shock **Input - Type BF** BF defib symbol, IEC 60417 - 5334 f) Type and rating of fuses accessible **listed in Device DFU and next to fuses** g) Symbol of Equipotentiality, IEC 60417-5021	
4.3.1.2	There shall be markings for European Deviations Product Profile	Warnings and instructions for use should be printed in all languages prior to shipping to the corresponding country	Marketing planning and strategy
4.3.1.3	There shall be markings for Korean Deviations Product Profile	Accompanying documents shall be in Korean as well as DFUs and appliance marking related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417, prior to shipping units to Korean	Marketing planning and strategy
4.3.1.4	There shall be markings on the inside of the equipment and also referenced in the Device DFU Regulatory Standards Requirement	Markings on the inside of the Device and also referenced in the Device DFU shall meet IEC 60601-1 Section Six a) Presence of high voltage accessible parts IEC Symbol IEC 60417 - 5036 located on or around power supply (if required) b) Battery type (if required) c) Protective earth terminal (if required)	21-07-0338 Gemini Software V&V History
4.3.2	**Labeling Requirements for the Medical Device Directive (for CE marked devices)**		
4.3.2.1	The Device shall provide Labeling associated with Medical Device Directive (Reference Annex 1, Section 13.3) Regulatory Standards Requirement	(a) The name or trade name and address of the manufacturer and the name and address of the authorized representative of the manufacturer established within the EC Community • Manufacturer: **CAS Medical Systems, Inc.** **44 East Industrial Road** **Branford, Connecticut 06405** **USA** (b) The details strictly necessary for the user to identify the Device and the contents of the packaging (c) Where appropriate, an indication that the Device is for single use (ISO 7000-1051) (d) Any special storage and/or handling conditions: • Storage / Transport Temperature: -20°C to +60°C (-4°F to +140°F) • Storage / Transport Humidity: 15%RH to 90%RH (non-condensing) (e) Any special operating instructions (f) Any warnings and/or precautions (g) Year of manufacture (can be part of a SN) – Symbol for "DATE OF MANUFACTURING" to be put in Device DFU to explain SN format (h) The CE mark and control number (i) Detachable components shall be identified with "CAS" PN (j) The symbol for "attention" ISO 7000-0434 shall be placed wherever the User should see directions for use (k) The symbol "REF" shall be placed wherever a re-order number appears (l) The word "LOT" within a box shall be placed wherever a lot number is indicated (m) The symbol "SN" proceeding any serial number	21-07-0338 Gemini Software V&V History
4.3.3	**Labeling Requirements General**		
4.3.3.1	The Device shall use Special Labels when required	Devices intended for clinical investigation will be clearly labeled and will comply with all applicable standards and requirements	21-07-0338 Gemini Software V&V

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Regulatory Standards Requirement		History
4.3.3.2	Labels should be easy to read / understand, legible and durable Regulatory Standards Requirement	Labels shall be made with as large a font possible, using permanent ink, whenever possible; label ink shall not easily be removed by common cleaning	21-07-0338 Gemini Software V&V History
4.3.3.3	The Device shall have labels for the Patient Connectors Mktg Req 4.A	Label contains channel number dark text on light background Label is located on side panel of Device, near patient connectors	21-07-0338 Gemini Software V&V History
4.3.3.4	The Device shall have a label[9] for the FORE-SIGHT ELITE™ brand name Standard CAS product Labeling	The image contains FORE-SIGHT ELITE™ logo - dark text w/4 green ascending size circles on light background The image is located on the top front area of Device	21-07-0338 Gemini Software V&V History
4.3.3.5	The Device shall have a label for the CASMED© brand name Standard CAS product Labeling	The image contains CASMED© logo – Dark text on light background The image is located on the top front area of Device	21-07-0338 Gemini Software V&V History
4.3.3.6	The Device shall have a Serial Number label Regulatory Standards Requirement	Label contains part number, serial number, and barcode(s) information using standard CAS SN Labels & colors Label is located on the rear panel of the Device The serial number will contain information on date of manufacture and be assigned in accordance with QSP1007	21-07-0338 Gemini Software V&V History
4.3.3.7	The Device shall have a NRTL label Regulatory Standards Requirement	Label contains part NRTL symbol & a control number Label is located on the rear panel of the Device	21-07-0338 Gemini Software V&V History
4.3.3.8	The Device shall have the required Non Equipotential, Warning and Caution labels Regulatory Standards Requirement	A label contains BF defib symbol IEC 60417–5334, example: A label containing the symbol for "Caution" ISO 7000-0434 - dark icon on light background, example: A Label shall be located on the front of Device, near the USB connection A Label shall be located on the rear panel of Device, near the USB connection A label containing the symbol for "Warning" ISO 7010:2003-W001 - dark icon on Yellow background, example: A Label shall be located on the left side of Device, near the Patient connection	21-07-0338 Gemini Software V&V History
4.3.3.9	The Device shall have the required refer to User Manual (DFU) label(s) Regulatory Standards Requirement	A label contains the IEC 7010-M002 "Follow Instructions for use" – Blue background with white icon, Example: A label shall be located on the rear of the monitor A label shall be located on the bottom of the preamp A label contains the IEC 7010-M002 "Follow Instructions for use" – Black background with white icon, Example: A label shall be located on the Sensor pouch	21-07-0338 Gemini Software V&V History
4.3.3.10	The Device shall have a label for the AC Rating Regulatory Standards Requirement	Label contains correct AC ratings per 4.3.1.1- dark icon/text on light background Label is located on rear panel of the Device near the power entry module	21-07-0338 Gemini Software V&V History
4.3.3.11	The Device shall use a Warranty Void label to indicate when unauthorized service was done Standard CAS product Labeling	Label contains text "WARRANTY VOID IF DAMAGED" – Standard CAS label Label is located on an overlapping enclosure seam The label may be underneath a plastic cover.	21-07-0338 Gemini Software V&V History

[9] The term "Label" refers to a physical applied label or an image imprinted on a physical surface

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.3.3.12	There shall be a Device User Manual Regulatory Standards Requirement Mktg Reg , 12.A	The User Manual for the device shall include the following: • Provide a brief troubleshooting guide for selected conditions • Use the standard CAS electronic CD manual format • Be made available electronically via the Internet at a later time • Contain section with all warnings and cautions identified in this specification and associated project documentation • Shall be included with the Device (shipping container)	21-07-0338 Gemini Software V&V History
4.3.3.13	There shall be a Device Quick Reference Guide Mktg Reg , 12.A	A Quick Reference Guide may instruct the user with the basic operation of the device and may be included with the Device	21-07-0338 Gemini Software V&V History
4.3.3.14	Sensor cartons shall include a Sensor Directions for Use Regulatory Standards Requirement Mktg Reg , 12.A	A Direction for Use for each size Sensor, shall be included with the Sensor Cartons	21-07-0338 Gemini Software V&V History
4.3.3.15	The Preamp Cable shall have the required labels Regulatory Standards Requirement	Label contains Manufacturers name and reorder PN	21-07-0338 Gemini Software V&V History
4.3.3.16	The Preamp cable shall indicate that it is multiple use (do not discard) Regulatory Standards Requirement Mktg Req 17.C	Label contains "Do not throw away" text with waste basket in circle w/single slash - dark text on light background, example: Label shall be located on the cable	21-07-0338 Gemini Software V&V History
4.3.3.17	The Device shipping container shall have the required labels Regulatory Standards Requirement	These labels will be identified by product type A Serial Number label shall be available on outside of sealed box The shipping container will have a contents label on outside of the sealed box containing: Company name, transport & storage conditions and CE & Authorized Representative label Label(s) will have dark text on light background	21-07-0338 Gemini Software V&V History
4.3.3.18	The Device shall have the required WEEE (waste) label Regulatory Standards Requirement	Label contains the "crossed-out wheeled bin" WEEE symbol - dark text on light background, example: Located on rear panel of the Device	21-07-0338 Gemini Software V&V History
4.3.3.19	The Device shall have the required warning and caution labels Regulatory Standards Requirement	All appropriate Warning and Caution labels shall meet UL requirements for character height (7/64th), durability, adhesion and visibility.	21-07-0338 Gemini Software V&V History
4.3.3.20	The Device shall have the required EC Rep symbol Regulatory Standards Requirement	Located on the shipping carton and in Device DFU EC Rep label shall be dark text on light background	21-07-0338 Gemini Software V&V History
4.4	**LANGUAGES**		
4.4.1	**Labels (markings) and printed text**		
4.4.2	Device DFU shall be available in various languages Standard CAS product Labeling Mktg 12.A, Appendix II	Device DFU shall be available in multi-languages – Initial Languages to be defined by Mktg prior to release Additional translations of the Device DFU shall be completed as required after the initial release	21-07-0338 Gemini Software V&V History
4.4.3	Sensor DFU shall be available in various languages Standard CAS product Labeling Mktg 12.A, Appendix II	Sensor DFU shall be available in multi-languages – Initial Languages to be defined by Mktg prior to release Additional translations of the Sensor DFU shall be completed as required after the initial release	21-07-0338 Gemini Software V&V History
4.5	**SYSTEM REQUIREMENTS**		
4.5.1	**Sensors**		
4.5.1.1	The Device shall use be able to monitor Cerebral sites for Adult patients	Standard CAS disposable Large Sensor will be used to monitor Adult Cerebral sites for Adult patients Refer to 21-07-0314, Large Sensor Specifications	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Mktg Req 17.A, 2.A, PRD release Phase 1.0 Release	Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	
4.5.1.2	The Device shall use be able to monitor Tissue under Sensor in Adult patients Mktg Req 17.A, 2.A, PRD release Phase 1.5 Release	Standard CAS disposable Large Sensor will be used to monitor Adult Tissue under Sensor sites for Adult patients Refer to 21-07-0314, Large Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.3	The Device shall use be able to monitor Cerebral and Tissue under Sensor in Pediatric patients Mktg Req 17.A, 2.A, PRD release Phase 2.0 Release	Standard CAS disposable Medium Sensor will be used to monitor Cerebral and Tissue under Sensor sites for Pediatric patients Refer to 21-07-0315, Medium Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.4	The Device shall use be able to monitor Intestine sites on Pediatric patients Mktg Req 17.A, 2.A, PRD release Phase 2.0 Release	Standard CAS disposable Medium Sensor will be used to monitor Intestine sites on Pediatric patients Refer to 21-07-0315, Medium Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.5	The Device shall use be able to monitor Cerebral sites for Neonatal and small Pediatric patients Mktg Req 17.A, 2.A, PRD release Phase 3.0 Release	Standard CAS disposable Small Sensor will be used to monitor Cerebral sites for Neonatal and small Pediatric patients Refer to 21-07-0316, Small Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.6	The Device shall use be able to monitor Abdominal sites on Neonatal patients Mktg Req 17.A, 2.A, PRD release Phase 3.0 Release	Standard CAS disposable Small Sensor will be used to monitor Abdominal sites on Neonatal patients Refer to 21-07-0316, Small Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.7	The Device shall use be able to monitor Intestine sites on Pediatric patients Mktg Req 17.A, 2.A, PRD release Phase 3.0 Release	Standard CAS disposable Medium Sensor will be used to monitor Intestine sites on Pediatric patients Refer to 21-07-0315, Medium Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.8	The System shall be optimized for various patient groups Mktg Req 7.B.c, 17.D-O	The System requires only the entry of the patient's body location of the Sensor (non-unused body location = valid location) Sensors shall have a unique ID readable by the Device	21-07-0338 Gemini Software V&V History
4.5.1.9	The Sensors shall be packaged for sale and distribution Mktg Reg 17.C, 17.M	The Sensors shall be packaged for individual use The Sensors shall be packaged as non-sterile The Sensor size coding on the Sensor top and pack-outs use FORE-SIGHT G1 size color scheme	21-07-0338 Gemini Software V&V History
4.5.1.10	The Sensors shall have noise immunity Mktg Reg 16.A, 16.B	The Sensors shall have the same level of noise immunity as the FORE-SIGHT G1 product The Sensors shall have the same level of protection from ESU "Bovie Interference"	21-07-0338 Gemini Software V&V History
4.5.1.11	The Sensors shall be as small and flexible as possible Mktg Reg 17.F, 17.G, 17.K, 17.N	The Sensor shall present a low profile to minimize pressure points if Sensor is positioned under the weight of the patient Sensor construction should conform to the attachment site without applying excessive force and the construction should not cause the part to lift from the patient The Sensor shall be able to conform to curved surfaces of patient The attachment area shall be no larger than FORE-SIGHT G1 Sensors; could be smaller and more flexible if possible The lead exit for Large and Medium Sensors preferred in-line with Sensor pad The release liner shall be required to be removed from the Sensor to apply the Sensor to the patient	21-07-0338 Gemini Software V&V History
4.5.1.12	The Sensors shall have a long shelf life	The Sensor shall have a minimum 24 month shelf life	21-07-0338 Gemini Software V&V

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[redacted]

SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Mktg Req 17.O		History
4.5.1.13	(b)(4) [redacted] Mktg Req 17.N		21-07-0338 Gemini Software V&V History
4.5.1.14	Ability to identify channel near each Sensor Mktg Req 17.N	Label on preamp cable near Senor connection allows User to easily identify preamp channel	21-07-0338 Gemini Software V&V History
4.5.2	**Preamp Cable**		
4.5.2.1	The Preamp Cable shall connect to the Device Mktg Req 14.A-E, 15.A-D	The Preamp Cable shall be 4m ±3.175% in length An optional longer Preamp Cable may be made available (~6.5m) The Preamp Cable shall have a unique ID readable by the Device The Device shall require 2 Preamp Cables, each Preamp Cable supplies input for 2 channels The Preamp Cable (box and cables) shall be grayish/off-white in color The Preamp Cable shall be able to withstand a 300lb roll-over (on the cable only) while being as flexible as possible The Preamp Cable may have provisions to limit the number/time of monitor connections The Preamp Cable to Device connection shall provide a positive locking mechanism that is easily connected and disconnected Each Preamp Cable Device connectors shall withstand at least (b) [redacted] insertions	21-07-0338 Gemini Software V&V History
4.5.2.2	The Preamp Cable shall connect to the Sensor Mktg Req 14.J, 15.D	The Preamp Cable to Sensor connection shall be as small or smaller that the FORE-SIGHT G1 connection The Preamp Cable to Sensor connection shall provide a positive locking mechanism that is easily connected and disconnected The Sensor connector shall disconnect from the preamp cable with a maximum 8 lb inline pull/breakaway force The Preamp Sensor connection shall be able to withstand a fluid cleaning (wipe down) The Preamp Cable connectors shall withstand at least (b) [redacted] insertions w/Sensors (b)(4) [redacted] The Preamp Sensor Cable shall have a means for identifying the active channel	21-07-0338 Gemini Software V&V History
4.5.2.3	The Preamp Cable should be able to lie on a bed without falling off Mktg Req 14.H-I, 14.K, 15.A-B	The Preamp Cable shall provide a means to attach to a fixed object (bed, sheets, etc.)	21-07-0338 Gemini Software V&V History
4.5.3	**Characterized**		
4.5.3.1	The Sensors shall be characterized for all known sizes Mktg Req 17.N	Sensors shall be characterized in the manufacturing process; wavelengths, power etc. The Device requires no factory or field calibration Functional verification procedure to be provided in Device DFU	21-07-0338 Gemini Software V&V History
4.5.3.2	Internal Printed Circuit Boards (PCBs) should be able easily serviced Mktg Req 13.A	Device PCBs shall have Manufacturing and Service information stored on the board	21-07-0338 Gemini Software V&V History
4.5.4	**Power Interfaces**		
4.5.4.1	The Device shall have the ability to operate from a battery Mktg Req 9.A-E	The Device shall operate on the fully changed battery for approximately ½ hour (4-channels) In the event of AC power failure, the Device shall switch to battery operations without interruption A fully discharged battery shall take no more than 5 hours to become > 90 % charged with the Device connected to AC	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN[4]
		The Device will be installed with a Battery Cut-off feature that will disconnect the Battery from the system when the battery voltage falls below a set threshold - This will reduce the possibility of deep discharge of the battery The batteries shall be user accessible via a tool (screwdriver) The Device may be operated (on AC) without a battery installed	
4.5.5	**Transportability**		
4.5.5.1	The System shall be transportable (as well as being stationary) Mktg Req. 1.C, 3.A-B	The Device is designed to be placed on a shelf, or affixed to wall or pole mount The Device may also be mounted on a roll stand	21-07-0338 Gemini Software V&V History NRTL results located in Project DHF[10]
4.5.5.2	The System shall have a handle Mktg Req 1.C	Design & position to be selected such as to encourage proper carrying with natural and comfortable wrist position	21-07-0338 Gemini Software V&V History
4.5.6	**Cleaning**		
4.5.6.1	The Device shall be capable of being easily cleaned Mktg Req 1.E-F	The Device may be disinfected with a cleaning solution (e.g., 70% isopropyl alcohol, 10% bleach & water or CaviCide-like solutions) Wipe down with cloth dampened with clean water There shall be a caution statement to not immerse or sterilize Complete cleaning information provided in Device DFU Also refer to section 4.14.1.4	21-07-0338 Gemini Software V&V History
4.5.6.2	The Preamp Cable(s) shall be capable of being easily cleaned Mktg Req 14.I, 15.C	The Preamp Cable may be disinfected with a cleaning solution (e.g., 70% isopropyl alcohol, 10% bleach & water or CaviCide-like solutions) Wipe down with cloth dampened with clean water There shall be a caution statement to not immerse or sterilize Complete cleaning information provided in Device DFU Also refer to section 4.14.1.4	21-07-0338 Gemini Software V&V History
4.5.7	**Audible Noise**		
4.5.7.1	The Device should generate minimal sounds Mktg Req 9.I	The Device may generate low-level sounds inherent with its operation due to the function of internal components such as inductors, relays, and fan(s) The maximum allowable inherent sounds shall be < 38 dBA, at 1 meter, TWA	21-07-0338 Gemini Software V&V History
4.6	**MESSAGES**		
4.6.1	**Alarm Limit Messages**		
4.6.1.1	The Device shall have the ability to set generate messages for High/Low Limit violations Mktg Req Appendix II	Alarm Limit violation shall have priority alarms status based on Risk Analysis Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History
4.6.1.2	The Device shall have factory default Alarm limits Mktg Req 7.B.f	The default Low Alarm Limits shall be 50% The default High Alarm Limits shall be 90% The default Alarm delay shall be 0 sec	21-07-0338 Gemini Software V&V History
4.6.1.3	The Device shall allow for setting of limits within a set range Mktg Req 7.B.f	Low Limit range shall be 2 to 93 % in 1% increments High Limit range shall be 7 to 98 % in 1 % increments There always be 5% difference between channel High & Low limits	21-07-0338 Gemini Software V&V History
4.6.1.4	The Device shall present equipment statuses Mktg Req 6.A, 6.D	Equipment status Alarms shall have priority alarms status based on Risk Analysis Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History

[10] DHF – Design History File for Project Gemini retained by the Regulatory Affairs/Quality Assurance group

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.6.1.5	The Device shall present channel status Mktg Req 6.A, 6.D	Channel status Alarms shall have priority alarms status based on Risk Analysis Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History
4.6.1.6	The Device shall present High priority system messages Mktg Req 6.A	The product shall display an appropriate High Priority messages in the Equipment and/or Channel message area A front panel LEDs shall flash red when a high priority condition is present High Priority messages may be output to all external communications ports configured for protocols supporting alarm codes (CSV, ATE, Philips VueLink, Philips IntelliBridge)	21-07-0338 Gemini Software V&V History
4.6.1.7	The Device shall present Medium priority system messages Mktg Req 6.A	The product shall display an appropriate Medium Priority messages in the Equipment and/or Channel message area A front panel LEDs shall flash yellow when a Medium priority condition is present (unless a High priority condition) Medium Priority messages may be output to all external communications ports configured for protocols supporting alarm codes (CSV, ATE, Philips VueLink, Philips IntelliBridge)	21-07-0338 Gemini Software V&V History
4.6.1.8	The Device shall present Low priority system messages Mktg Req 6.A	The product shall display an appropriate Low Priority messages in the Equipment and/or Channel message area A front panel LEDs shall indicate yellow when a low priority condition is present (unless a High or Medium priority condition) Low Priority messages may be output to all external communications ports configured for protocols supporting alarm codes (CSV, ATE, Philips VueLink, Philips IntelliBridge)	21-07-0338 Gemini Software V&V History
4.6.1.9	The Device shall present Informational system messages Mktg Req 6.A	The product shall display an appropriate Informational messages in the Equipment and/or Channel message area Informational messages may be output to all external communications ports configured for protocols supporting alarm codes (CSV, ATE, Philips VueLink, Philips IntelliBridge)	21-07-0338 Gemini Software V&V History
4.6.1.10	The Device labeling shall make available troubleshooting advice Regulatory Standards Requirement	There shall be a section in the Device DFU that has a brief section dedicated to common troubleshooting	21-07-0338 Gemini Software V&V History
4.7	**MONITORING**		
4.7.1	**Measurement**		
4.7.1.1	The Device shall provide a means to measure absolute tissue blood oxygen saturation values Mktg Req 4.A	The Device shall employ a modified Beer-Lambert Near Infrared Spectroscopy (NIRS) algorithm	21-07-0338 Gemini Software V&V History
4.7.1.2	The Device shall display a computed value Mktg Req 4.A	The computed value shall be the absolute tissue oxygen saturation (StO_2)	21-07-0338 Gemini Software V&V History
4.7.1.3	The Device shall have a specified measurement range Mktg Req 4.A	The measurement range shall be: 0 to 99 %	21-07-0338 Gemini Software V&V History
4.7.1.4	The System shall have a specified accuracy Mktg Req 4.A	The accuracy shall be specified for each Sensor and IFU combination (refer to FDA 510(k) clinical data for stated accuracy)	21-07-0338 Gemini Software V&V History
4.7.1.5	The Device shall have a specific numeric resolution Mktg Req 4.A	The numeric resolution of the Device shall be: 1%	21-07-0338 Gemini Software V&V History
4.7.1.6	The Device shall have a specific data rate Mktg Req 4.A	The Device acquisition rate: ≥ 1.0 Hz The Device numeric update rate: minimum 0.5 Hz	21-07-0338 Gemini Software V&V History
4.7.1.7	The Device shall be able to present Collected Data	The Device shall be capable of starting and stopping Data collection	21-07-0338 Gemini Software V&V

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Mktg Req 7.B.h, 8.B	The Device shall be capable of storing patient data to USB for review with graphing PC application tool	History
4.7.1.8	The Device shall be able to present STS Collected Data Mktg Req 7.B.h, 10.E	STS data collection accumulates the amount & time for values between 1 and 99% - Collection shall be automatic The minimum supported database output formats shall be Congenital Heart Surgery (v3.0), General Thoracic Surgery (v. 2.2), and Adult Cardiac Surgery (v2.73) The Device shall be capable of displaying and printing the collected STS Data	21-07-0338 Gemini Software V&V History
4.7.1.9	The Device shall be able to present FS Collected Data Mktg Req 7.B.h, 10.E	FS Data collection accumulates the amount & time for values between 1 and 99% The Device shall be capable of displaying and printing the FS Collected data	21-07-0338 Gemini Software V&V History
4.7.1.10	The Device shall be able capture data from multiple patients and store through power cycles Mktg Req 8.A, 9.D	The Device shall be capable of storing the equivalent ~20 days of patient data (assuming 0.5 Hz rate) into internal, non-volatile memory. The number of files shall be limited only by the amount of available memory for Patient data. Stored data shall be capable of exporting individual Patient files to USB memory stick	21-07-0338 Gemini Software V&V History
4.8	**ENVIRONMENTAL CONDITIONS** (Refer to Reference Section 2 for latest standard revisions/dates)		
4.8.1	**System Operating Environment**		
4.8.1.1	The System shall have a specified: High Operating temperature Low Operating temperature Regulatory Standards Requirement	 IEC 60601-1 §10.2, +40°C (+104°F) continuous IEC 60601-1 §10.2, +10°C (+50°F) continuous	NRTL results located in Project DHF
4.8.1.2	The System shall have a specified Operating humidity, non-condensing Regulatory Standards Requirement	IEC 60601-1 §10.2, 30 to 75% RH, non-condensing	NRTL results located in Project DHF
4.8.2	**Device Operating Environment**		
4.8.2.1	The Device shall have a specified: Level of Fluid ingress Regulatory Standards Requirement	IEC 60529 IPX0 min Phase 1, IPX1 by Phase 2	NRTL results located in Project DHF
4.8.2.2	The Device shall have a specified: Solid foreign object ingress Regulatory Standards Requirement	IEC 60529 IPX0 min Phase 1, IPX1 by Phase 2	NRTL results located in Project DHF
4.8.3	**Device Storage Environment**		
4.8.3.1	The Device shall have a specified: High Storage temperature Low Storage temperature Regulatory Standards Requirement	 IEC 60601-1 §10.1, +60°C (+140°F) IEC 60601-1 §10.1, -20°C (-4°F)	NRTL results located in Project DHF
4.8.3.2	The Device shall have a specified Storage humidity, non-condensing Regulatory Standards Requirement	IEC 60601-1 §10.1, 15%RH to 90%RH, non-condensing	NRTL results located in Project DHF
4.8.4	**Sensor Storage Environment**		
4.8.4.1	The Sensor shall have a specified: High Storage Temperature Low Storage Temperature Regulatory Standards Requirement	 IEC 60601-1 §10.1, +32°C (+90°F) IEC 60601-1 §10.1, +10°C (+50°F)	NRTL results located in Project DHF
4.8.4.2	The Sensor shall have a specified Storage humidity, non-condensing	IEC 60601-1 §10.1, 15%RH to 90%RH, non-condensing	NRTL results located in Project DHF

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Regulatory Standards Requirement		
4.8.5	**System Mechanical Environment**		
4.8.5.1	The Device and Sensor shall have a specified Immunity to mechanical shock Regulatory Standards Requirement	IEC 60068-2-27:2008 Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	NRTL results located in Project DHF
4.8.5.2	The Device and Sensor shall have a specified Immunity to mechanical random vibration Regulatory Standards Requirement	IEC 60068-2-68:2008 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	NRTL results located in Project DHF
4.8.5.3	The Device shall have a specified flammability Regulatory Standards Requirement	The Device shall meet at IEC 60601-1 standard	NRTL results located in Project DHF
4.9	**ELECTROMAGNETIC COMPATIBILITY**		
4.9.1.1	The System shall have a specified immunity to Radiated emissions Regulatory Standards Requirement	IEC 60601-1-2, BS EN 55011 – CISPR 11 Class A	NRTL results located in Project DHF
4.9.1.2	The System shall have a specified immunity to Conducted emissions Regulatory Standards Requirement	IEC 60601-1-2, BS EN 55011 – CISPR 11 Class A	NRTL results located in Project DHF
4.9.1.3	The System shall have a specified immunity to ESD Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-2, Level 3 6kV contact, 8kV air discharge	NRTL results located in Project DHF
4.9.1.4	The System shall have a specified immunity to Radiated immunity Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-3, 3 V/m for 26 to 1000 MHz	NRTL results located in Project DHF
4.9.1.5	The System shall have a specified immunity to Fast Transients Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-4, 2 kV power lines, 1 kV I/O lines > 3 meters	NRTL results located in Project DHF
4.9.1.6	The System shall have a specified immunity to Fast Surges Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-5, 0.5 kV (differential), 2 kV (common mode)	NRTL results located in Project DHF
4.9.1.7	The System shall have a specified immunity to Conducted signals Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-6 10 kHz – 100 MHz, curve #3, modulated; 3 V, 150 kHz to 80 MHz, modulated	NRTL results located in Project DHF
4.9.1.8	The System shall have a specified immunity to Magnetic fields Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-8 5 cm for 30 Hz to 100 kHz; 3 A/m at 50/60 Hz	NRTL results located in Project DHF
4.9.1.9	The System shall have a specified immunity to Voltage dropout	IEC 60601-1-2, IEC 61000-4-11 10 ms, 100 ms, 500 ms, 2 s; 0%,40%, and 70% of input voltage	NRTL results located in Project DHF
	Regulatory Standards Requirement		
4.9.1.10	The System shall have a specified immunity to Harmonics Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-3-2	NRTL results located in Project DHF
4.9.1.11	The System shall have a specified immunity to Flicker Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-3-3	NRTL results located in Project DHF
4.9.1.12	The System shall have a specified immunity to Quasi static fields Regulatory Standards Requirement	Determination made that above testing is equivalent / exceeds requirements of this test 2 kVaP/VaR $_{,p}$ at 0.5 Hz sine-wave modulation	NRTL results located in Project DHF
4.10	**ELECTRICAL AND MECHANICAL SAFETY REQUIREMENTS**		
4.10.1	The System shall have a specified Enclosure leakage current Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.10.2	The System shall have a specified Patient risk current Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF
4.10.3	The System shall have a specified Patient defibrillator withstand Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF
4.10.4	The System shall have a specified Enclosure surface temperature Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF
4.10.5	The System shall have a specified Construction Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF
4.11	**PHYSICAL**		
4.11.1	**Size and Weight** (Device only)		
4.11.1.1	The Device should be light weight Mktg Req 1.B	The Device should weigh ≤ 15 lbs (7kg)	21-07-0338 Gemini Software V&V History
4.11.1.2	The Device should be <10" in height Mktg Req 1.A	The Device should be ≤ 10 in (26 cm) tall (excluding handle)	21-07-0338 Gemini Software V&V History
4.11.1.3	The Device should be <13" in width Mktg Req 1.A	The Device should be ≤ 13 in (33 cm) wide	21-07-0338 Gemini Software V&V History
4.11.1.4	The Device should be <9" in depth Mktg Req 1.A	The Device should be ≤ 9 in (23 cm) deep	21-07-0338 Gemini Software V&V History
4.11.2	**Cooling** (Device only)		
4.11.2.1	The Device should be able to dissipate Heat generated by internal components Regulatory Standards Requirement Mktg Req 9.I	The Device shall have venting holes as well as an internal fan(s) Adequate clearance shall be maintained above and alongside the Device to allow sufficient airflow for cooling The Device shall be able to effectively dissipate at least 60 watts (205 BTU/hrs) using forced air cooling (fan(s)) and 10 watts (35 BTU/hrs) using passive cooling (no fan(s) operating)	21-07-0338 Gemini Software V&V History
4.11.3	**Stability** (Device only)		
4.11.3.1	Device shall not move easily when the user controls are operated Mktg Req 7.A	The Device shall be equipment with non-skid feet	21-07-0338 Gemini Software V&V History
4.11.4	**Shipping** (Device only)		
4.11.4.1	The System shall be packaged for shipping Standard CAS product Labeling	Simple, low-cost, logical shipping package with as few pieces as possible	21-07-0338 Gemini Software V&V History
4.11.5	**Styling** (all)		
4.11.5.1	The Device shall have a forgiving texture Mktg Req 1.E, 15.C, 17.I	The Device shall present a surface that hides minor imperfections and signs of normal use The surface of the device shall be smooth and present seams or gaps as narrow as possible for easy cleaning	21-07-0338 Gemini Software V&V History
4.11.5.2	The Device should be durable Mktg Req 1.E, 14.G-H, 15.C-D, 17.I	The Device chassis and case shall be constructed to provide the maximum strength throughout the life of the product The User Control components shall be chosen to provide the maximum number of operations throughout the life of the product	21-07-0338 Gemini Software V&V History
4.11.6	**Color** (all)		
4.11.6.1	The Device and Cables shall be light in color Mktg Req 1.D, 14.B, 17.I	The front & rear of the Device case shall be white The Preamp Cable and Sensors should be white or Cool Gray Cable connections colors should blend and not contrast with the Device, Preamp Cable and Sensors	21-07-0338 Gemini Software V&V History
4.12	**ACCESSORIES**		

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.12.1	**Device Accessories**		
4.12.1.1	The System shall provide a means to verify proper operation Mktg Req 13.B	The Device shall be capable of connecting each channel to a CAS designed Sensor Simulator The Sensor Simulator shall present signals similar in magnitude to those generated by actual Sensors applied to a patient's tissue that produce a known and stable StO_2 value	21-07-0338 Gemini Software V&V History
4.12.1.2	The System shall provide a means for mounting on standard hospital equipment Mktg Req 3.A	The device shall provide GCX-compatible mounting features for securing to roll stands, articulating arms, etc.	21-07-0338 Gemini Software V&V History
4.12.1.3	The System shall provide a means to generate analog signals Mktg Req 10.F.d	The device shall interface to FORE-SIGHT G1 Analog Output device Configured to accept FORE-SIGHT G1 or Gemini CSV protocol	21-07-0338 Gemini Software V&V History
4.13	**REGULATORY APPROVAL AND STANDARDS REQUIREMENTS** (Refer to Reference Section 2 for latest standard revisions/dates)		
4.13.1	**United States of America**		
4.13.1.1	The System must meet FDA clearance to market substantially equivalent Device Regulatory Standards Requirement	Code of Federal Regulation – 21 CFR part 807 (refer to CAS QSP1017)	Refer to FDA 510k clearance letter
4.13.1.2	The System must meet Underwriters Laboratory or equivalent Regulatory Standards Requirement	UL 60601-1 Listed, USA/Canada	NRTL results located in Project DHF
4.13.1.3	The System must meet the General Principal of Software Validation – Final Guidance for Industry and FDA staff Regulatory Standards Requirement	CDRH	NRTL results located in Project DHF
4.13.2	**European Union**		
4.13.2.1	The System shall have the CE Mark Regulatory Standards Requirement	93/42/EEC Medical Device Directive (MDD)	NRTL results located in Project DHF
4.13.2.2	The System shall meet the European Standard – General requirements for safety Part 1 Regulatory Standards Requirement	IEC 60601-1	NRTL results located in Project DHF
4.13.2.3	The System shall meet the European Standard – Part 1-2 Collateral std: electro-magnetic compatibility. Regulatory Standards Requirement	IEC 60601-1-2	NRTL results located in Project DHF
4.13.2.4	The system shall meet European Standard – Part 1-6 Collateral std: Usability Regulatory Standards Requirement	IEC 60601-1-6	NRTL results located in Project DHF
4.13.2.5	The System shall meet the European Standard – Part 1-8 General requirements, tests and guidance for Alarm systems in medical Electrical Equipment and Medical Electrical Systems Regulatory Standards Requirement	IEC 60601-1-8	NRTL results located in Project DHF
4.13.2.6	The Sensor patient contact surface shall meet the Biological testing of medical and dental materials and devices Regulatory Standards Requirement	ISO 10993-1	Biocompatibilities results located in Project DHF

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION	Functional Requirements	SPECIFICATION	PLAN[4]
4.13.2.7	The System shall meet the International Organization for Standardization – Application of Risk management to Medical Devices Regulatory Standards Requirement	ISO 14971	NRTL results located in Project DHF
4.13.2.8	The System shall meet the use of non-hazardous materials in the Device, cables and accessories Mktg Req 19.A Regulatory Standards Requirement	Directive 2002/95/EC of the European Parliament and of the Council RoHS directive	NRTL results located in Project DHF
4.13.2.9	The System shall meet the proper disposal of the Device, cables and accessories Regulatory Standards Requirement	Directive 2002/96/EC of the European Parliament and of the Council WEEE directive	NRTL results located in Project DHF
4.13.3	**Canada**		
4.13.3.1	The System shall meet the Medical Device safety Regulatory Standards Requirement	Product licensing CMDR	Refer to appropriate Country's documentation
4.13.3.2	The System shall meet the Health Canada license Bureau Regulatory Standards Requirement	Product licensing CMDR	
4.14	**CLASSIFICATIONS** (Refer to Reference Section 2 for latest standard revisions/dates)		
4.14.1	**IEC 60601-1** (reference clause)		
4.14.1.1	The System shall meet the Type of protection against electrical shock (5.1) Regulatory Standards Requirement	Equipment energized from an external power source Class I / Internal Power Source	NRTL results located in Project DHF
4.14.1.2	The System shall meet the Type of protection against electrical shock (5.2) Regulatory Standards Requirement	Type BF Equipment, Type B protection against Electric Shock with Floating Applied Part	NRTL results located in Project DHF
4.14.1.3	The Device shall meet the Degree of protection against harmful ingress of water (5.3) Regulatory Standards Requirement	Drip proof equipment, IPX1 protection against the harmful ingress of water (IPX0 min Phase 1, IPX1 by Phase 2)	NRTL results located in Project DHF
4.14.1.4	The System shall have Methods of disinfection (5.4) Regulatory Standards Requirement	The Device and Preamp Cable may be disinfected with a cleaning solution such as 70% isopropyl alcohol or 10% bleach. Wipe down with cloth dampened with clean water or commercial disinfecting solutions including but not limited to: • Aspeti-Wipe™ • 3M™ Quat #25 • Metrix CaviCide® • Phenolic germicidal detergent solution (per manufacturer's recommendations) • Quaternary ammonium germicidal detergent solution (per manufacturer's recommendations) Device DFU shall indicate not to immerse or sterilize the Device or the Preamp Cable The device cleaning instructions may include the following statement "*Follow recommended cleaning and disinfecting procedures per your institution's guidelines, with use of methods such as those outlined by the Association for Professionals in Infection Control & Epidemiology (APIC) or the World Health Organization (WHO).*"	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.14.1.5	The System shall meet the Degree of safety of application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide Regulatory Standards Requirement	The Device DFU indicates the equipment is not suitable for use in the presence of a flammable anesthetic gas mixture with air, oxygen, or nitrous oxide	21-07-0338 Gemini Software V&V History
4.14.1.6	The System shall have a Mode of operation (6.1) Regulatory Standards Requirement	Continuous Operation	NRTL results located in Project DHF
4.15	**FIELD SERVICE / TECHNICAL SUPPORT FUNCTIONS**		
4.15.1	**Documentation**		
4.15.1.1	The System may provide a Service Manual Standard CAS product Labeling	Available prior to the expiration of the warranty on the first production units (available after initial release) Shall contain at a minimum, the following sections – • Installation procedure • Preventative maintenance procedure • Safety test procedure • Technical specifications • Schematics and detailed drawings • Troubleshooting procedure • Replacement parts list • Service accessory parts list • RMA return/Shipping information	21-07-0338 Gemini Software V&V History
4.15.1.2	The System shall be field repairable Standard CAS product Labeling	The Device will be field repairable down to an FRU level by Authorized CAS trained personnel The Preamp Cable shall not be repairable in the field – except by authorized CAS Service centers	21-07-0338 Gemini Software V&V History
4.15.2	**Installation**		
4.15.2.1	The System does not need calibration when installed Mktg Req 17.N	No calibration is required at installation Any written installation procedure shall be provided to verify proper operation in the Device User Manual	21-07-0338 Gemini Software V&V History
4.15.3	**Troubleshooting**		
4.15.3.1	The System shall provide field troubleshooting procedure Mktg Req 13.C	Shall be provided in the Device User manual to attempt to identify failing or faulted FRD (Field Replaceable Device) The system will be field repairable down to an FRU level by Authorized CAS trained personnel	21-07-0338 Gemini Software V&V History
4.15.3.2	The System shall provide visual reporting of any failure Mktg Req 13.C,	If any power-up test, or any periodic test fails, a failure message shall be displayed stating the Device needs service	21-07-0338 Gemini Software V&V History
4.15.4	**Preventative Maintenance**		
4.15.4.1	The System shall provide procedures for Preventative Maintenance Mktg Req 13.A, 13.B, 13.C	The Device DFU shall provide procedures for Safety tests The Device DFU shall indicate the interval and procedure for periodic Device functional verification The Device DFU & Service Manuals shall indicate the interval and procedure for periodic Device and Preamp Cable cleaning Software Service reminders may be enabled to remind Users about Service intervals (beyond Phase 1)	21-07-0338 Gemini Software V&V History
4.16	**WARRANTY**		
4.16.1.1	The System shall have a warranty Standard CAS product Labeling	The following CAS Warranty apply – 2 year minimum on the Device 6 months on batteries 90 days on Preamp cable	21-07-0338 Gemini Software V&V History

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

5 PRODUCT ARCHITECTURE

5.1 SYSTEM ARCHITECTURE

Project Gemini architecture uses the following components:

- Project Gemini Device consists of:
  - Chassis: internal metal cage and Plastic enclosure
  - Main Ctrl Board: Main app – GUI, Threshold detection, communications, USB
  - NSAM Board: NSAM App, signal acquisition and processing
- Dual Preamp Cable: up to 2 per System, 1 Preamp Cable for 2 channels
- Sensors: 2 per Dual Preamp Cable (1 per channel)

5.2 PRODUCT INTERFACES

5.2.1 Patient Interfaces

Project Gemini will allow connection only to Gemini Preamp Cable and Sensors.

Project Gemini will not be backwards compatible with the FORE-SIGHT G1 Preamp Cable or Sensors

5.2.2 Serial Interfaces

- Serial interfaces are RS232 DTE through DB9 plugs.
- Project Gemini will connect to a Philip's Vital Signs device using their proprietary interface protocol (VueLink or IntelliBridge).
- Project Gemini will communicate with other devices using Comma Separated Values (CSV) or CAS ATE Protocols.

5.2.3 USB Interfaces

Project Gemini shall provide storage and retrieval of patient information and system software and parameters.

5.2.4 Ethernet Interface

Project Gemini shall provide an interface for patient information exchange.

5.3 PREDICATE DEVICE(s)

Predicate devices include the following monitors:

CAS FORE-SIGHT - Tissue Oximeter, Model MC-2000 Series

Somanetics INVOS - 2 wavelength LED NIRS monitor

Nonin EQUANOX – 3 and 4-wavelength LED NIRS monitors

***Hamamatsu NIRO 200, 200*-NX, and 300** - 3 wavelength laser and LED Oximeters

Spectros T-Stat VLS 303 - Microvascular Tissue Oximeter

Hutchinson Technologies InSpectra - *StO_2 Tissue Oxygenation Monitor*

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6 DESIGN AND CONSTRUCTION

Project Gemini will be designed to meet or exceed the standards referenced in Section 2.1 of this document regarding the safe use for medical instrumentation when the Device is used in a manner that is consistent with the operation and environment according to its intended use.

6.1 WORKMANSHIP

Production units will be built to the exact specifications as dictated by the assembly documentation using quality components, the cGMP and the QSR.

6.2 INTERCHANGEABILITY

All replaceable major components of Project Gemini shall be identified with a CAS part or assembly number. All parts or assemblies with the same assembly number shall be interchangeable, independent of the revision of the assembly.

Once the product is released, any change to a part or assembly that makes it no longer backward compatible with existing assemblies will require generation of a new part number for the affected assembly.

7 CONSTRAINTS AND LIMITATIONS

The following factors constrain or limit the latitude of the product development described by this specification.

(b)(4)

[redacted]

7.2 COMPONENT AND CONDUCTOR SPACING

The spacing for each component and conductor will be in accordance with the manufacturers recommended guidelines and satisfying all safety creepage and clearance requirements. Consideration will also be given to components requiring room for heat dissipation of power devices, separation of analog and digital signals and power planes to maintain as high a signal to noise ratio as possible, and other layout guidelines as recommended by the Device manufactures.

7.3 DIAGNOSTIC TECHNIQUES

Project Gemini shall use the following diagnostic techniques:

(a) Checksums in ROM (startup self-test)

(b) Verification of SRAM integrity (startup self-test)

(c) Checksums on all packets transmitted via the serial interface between host microprocessor and the individual modules (whenever available)

(d) Automated test software to allow control of many Device functions

(e) Performing periodic system checks ensure circuit integrity

(f) Electronic and physical of all PC boards shall include provision for ATE

7.4 INDUSTRIAL DESIGN

The industrial design of Project Gemini shall provide for the functional, operational and human engineering requirements of this specification and conform to the standards referenced in Section 2 of this document.

7.5 TECHNOLOGICAL

No technological constraints exist for the design and manufacture of this product.

7.6 FIELD SERVICE

No field serviceable parts - other than replacement of the battery (within a pack).

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8 PARTS, MATERIALS AND PROCESSES

8.1 ELECTRONIC AND ELECTRICAL PARTS

Wherever possible, the electrical parts used shall be UL-listed and CE-marked for the intended application. All electronic parts shall be consistent with conservative derating values. Guidelines for derating are as follows:

(b)(4) [redacted]

Wherever practical, the electronic parts shall be selected from the CAS standard parts and from associated lists of preferred or high usage parts.

8.2 MECHANICAL PARTS

Mechanical parts such as connectors shall be evaluated for suitability and reliability. All components shall be constructed of materials known to be suitable for the application and specified environments of use.

8.3 LABELS

All labels on the devices should be clear and easy to read. All labels and adhesives thereof shall be constructed of materials known to be suitable for the application and specified environments of use. Caution and Warning labels shall meet UL requirements for character height, durability, adhesion and visibility.

8.4 MATERIALS

The Device and Preamp Cable shall be constructed of materials known to be suitable for the application and expected environments. Materials shall meet the requirements of the following specifications:

IEC 60601-1	Safety of Medical Electronic Equipment - General Requirements Part 1
UL 60601-1	Medical Electrical Equipment Part 1: General Requirements for Safety
UL 94	Test for Flammability of Plastic Materials for parts in Devices and Appliances

The Sensor shall be constructed of materials known to be suitable for prolonged patient contact.

8.5 PROCESSES

All special processes will be detailed by specifications and procedures included in the product documentation package. These specifications and procedures shall contain or reference QA and inspection requirements.

8.6 MANUFACTURING PROCESS

Project Gemini shall be manufactured in accordance with standard CAS manufacturing process procedures.

The Sensor may be manufactured outside CAS, but in accordance with standard CAS manufacturing procedures.

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9 PRODUCT ASSURANCE

9.1 General

Each requirement shall be verified, either by analysis, inspection or test(s) as outlined in this document or referenced documents.

9.2 Verification and Validation

Verification procedures are to be conducted in accordance with applicable QSPs.

Testing and validation requirements are to be defined in applicable QSP specification and protocols.

9.3 Documentation

9.3.1 Drawings

Drawings will be produced using available drafting capabilities in a manner appropriate with their intended use.

Drawings may be available in either paper or machine readable formats.

Drawings will be maintained as released documents under formal change control per QSP1005: Engineering Change Procedure.

There shall be a Device Master Record (DMR), which shall list all applicable assemblies and their subassemblies, reference drawings, schematics, source control drawings and specifications.

9.3.2 Software

The software shall be documented in accordance with the appropriate CAS Engineering Software Standards as set forth in QSP4002. After release, revisions shall be under formal change control.

9.3.3 Instruction Manuals

All DFUs (e.g., Device & Sensor) shall comply with applicable QSP procedures concerning instrument manuals. The manuals will address the requirements set forth in the Medical Device Directive and in IEC 60601-1.

DFUs shall be designed to be understood by the personnel at the level of training at which the equipment are to be used.

9.3.3.1 IEC 60601-1, General Requirements for Safety, (6.8) Accompanying Documents

a) General Requirements

- Instructions for use
- Technical description
- Company name and address
- Classifications (type of protection against shock, degree of protection against shock, degree of protection against ingress of water, disinfection method, degree of safety of application in presence of flammable gases, and mode of operation)
- Meaning of all figures, symbols and warning statements and abbreviations used.

b) Instructions for use – General information (as applicable)

- Device function and intended application
- How to operate
- Explanation of the function of controls, displays, signals, sequence of operation, connection and disconnection of detachable parts and accessories and replacement of consumables.
- Information regarding potential electromagnetic or other interference between Device and other devices and advice on avoidance.
- An indication on recognized accessories, and parts or materials if they can degrade safety.
- Instruction and frequency for cleaning, preventive maintenance, maintenance and safe performance of routine maintenance.
- Instruction and frequency of preventive maintenance (where it can be performed by others).
- Explanation of the meaning of symbols, warning statements and abbreviations shown on the Device.

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

- Signal outputs and input connections intended for specific equipment shall be called out
- Details about cleaning, disinfecting, and sterilizing patient contact equipment parts
- Identify any risks, and advice on minimizing risks associated with disposal of waste products, residues, etc. and of Device and its accessories at end of useful life.

c) Technical description (as applicable)

- Describes all data which are essential for safe operation
- Data mentioned in IEC 60601-1 sub clause 6.1
- Describe characteristics of equipment such as ranges, accuracy, precision of displayed values (or where that information can be found)
- Any particular measures or conditions for installation or start up.
- Where types and ratings of fuses, external to Device, are not apparent, they will be included
- Instructions for replacement of interchangeable or detachable parts subject to deterioration during normal use.
- For repairable parts of equipment, a statement that supplier will make available (on request) circuit diagrams, parts list, descriptions, calibration information, etc. for the benefit of qualified technical users.
- Explain permissible environmental conditions for transport and storage as stated on package labeling

9.3.3.2 IEC 60601-1-2, Electromagnetic Compatibility Requirements and Tests, (6.8.201) Instructions for Use

Note: Only the requirements not already called out in 8.3.3.1 are here.

a) Instructions for use (as applicable)

- Include a statement that the Device needs special precautions regarding EMC and ESD and needs to be installed and put into service according to EMC information provided
- Include a statement that portable and mobile RF comm. equipment can affect the Device

b) Technical description (as applicable)

- Include a list of cables, transducers and other accessories that are specified for compliance with EMC requirements
- Include a warning that the use of accessories, transducers and cables other than those specified, may result in increased emissions or decreased immunity of the Device
- Include a declaration of conformity (table 201) showing compliance with electromagnetic emissions
- Include a declaration of conformity (table 202) showing compliance with electromagnetic immunity
- Include a warning that the Device and Device system should not be used adjacent or stacked with other equipment, and should that be unavoidable, the Device and system configuration should be observed verifying normal operation. If a safe configuration has been predetermined, a description or list of configurations may be provided
- Include a justification for each compliance level lower than 60601 test level
- Include a declaration of conformity (table 204) showing compliance with electromagnetic conducted and radiated immunity
- Include an informational (table 206) showing separation distances between Device and mobile and portable RF comm. devices
- Include each frequency or frequency band of reception; the preferred frequency or frequency band, if applicable; and the bandwidth of the receiving section of the Device in those bands
- Include a warning that other equipment may interfere with the Device or system even if the other equipment complies with CISPR emissions requirements
- Include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the effective radiated power

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

9.3.3.3 Labeling – Regulatory Requirements for Medical Devices (par. 1040.10)

Note: Only the requirements not already called out in 8.3.3.1 and 8.3.3.2 are here.

a) General requirements

9.3.3.4 Other FDA general instructions for labeling

Note: Only the requirements not already called out in 8.3.3.1, 8.3.3.2 and 8.3.3.3 are here.

a) Instructions for use

- Include the Rx statement for prescription devices – "Federal law restricts this Device to sale by or on the order of a health care professional";

10 HANDLING AND SHIPPING

Handling and shipping shall be in accordance with CAS Manufacturing department SOPs.

Prior to FDA clearance, domestic shipments shall contain proper labeling for Investigational Devices.

Special environmental requirements for the safe transport and handling, including temperature and humidity limits, will be clearly indicated on the external Device packaging. The shipping carton labeling will also include a description of the package contents.

11 TECHNOLOGICAL RISKS

11.1 PRODUCT PERFORMANCE & DEVELOPMENT RISKS

The following performance & development risks[11] have been identified at this time:

1. **Clinical Data** - Time frame to acquire and verify all clinical patient data (Adult, Pedi & Neo with Large, Medium and Small Sensors) for requested indications is challenging. Clinical results may also demonstrate inferior performance to FORE-SIGHT G1. Use of FORE-SIGHT G1 as validation reference versus invasive blood measurements may not satisfy requirements of the FDA. Pre-IDE submission with protocol and validation plans to reduce risk but may delay start of clinical work.
2. **Usability** - IEC60601-1 3rd Edition requires a Validated Usability Process. There may be a risk that the UI interface is unacceptable to the majority of Users and require UI modifications, which may not be accomplished within the timeframe.
3. **Sensor Construction** - Flex circuit (not hand wired) to emitter and detector components may pose a challenge to be manufactured reliability, consistently and economically.
4. **Touchscreen Interface** - Size of on-screen targets for touchscreen will need to be large enough to touch with an adult finger; may limit amount of info on screen; interface with PEG unknown for touchscreen but should be able to emulate a mouse click.
5. **Screen Size** - Larger screen (assumed 10.4" diagonal) will need to display 4 channels of info as well as equipment, Sensor, patient info.
6. **Screen Resolution** - Same resolution as FORE-SIGHT G1; proposed (640 x 480) should be capable of displaying CJK and Cyrillic characters; may have char memory limitations, even with expanded memory to achieve 20K of CJK char in multiple fonts.
7. **SW Development Tools** - The FORE-SIGHT G1 SW development tools (CodeWarrior, MQX and PEG) have gone through several upgrades and revisions to improve performance and add new features so may not be totally compatible with FORE-SIGHT G1 code. Porting of FORE-SIGHT G1 code may take longer than anticipated.

[11] Risks are not listed in any particular order or priority.

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8. **USB** - Using MQX USB driver may pose a challenge; desire to allow increase use of different size and Mfg of USB memory devices; changing releases of development environment and changes to and automatic to Microsoft operating systems may cause delays to determine fixes or workarounds.
9. **Physical Characteristics** - Keeping the outside dimensions of the monitor to a minimum while creating a full metal enclosure inside.
10. **Preamp** - Smaller electrical Sensor connections will need to be custom; reduction in preamp weight size (to minimum) may be a challenge; moving of some preamp components back to monitor may pose some risk.
11. **LED Array** - 5 LED array may pose some design risk to get a small geometry. Broad spectral output and uncertainty in wavelength may limit precision of system, preventing equivalent performance with the FORE-SIGHT G1 monitor. (b)(4) [redacted] (b)(4) [redacted]
12. **Sensor Construction** - The success of high throughput sensor manufacture depends on a robust high throughput test fixture. This is uncharted territory for us and could take longer to complete or be more difficult than anticipated. The flex circuit (not hand wired) to emitter and detector components may pose a challenge to be manufactured reliability, consistently and economically. Large number of electrical connections to sensor may complicate cable design and impact mechanical or electrical performance. High-current signals used to drive LEDs introduce crosstalk with sensitive photodiode circuits in sensor, cabling, and preamp and may increase cost, complexity, and limit sensitivity of sensor for patients with high absorption.
13. **Cable Connections** - Preamp cable to monitor and preamp cable to Sensor connections as well as preamp cable length need to be acceptable in real clinical scenarios. Verifying acceptability of the cable retention mechanism (i.e., clip) could be done simultaneously.
14. **Connectivity** - Selecting and implementing the correct methods to communicate with other devices and the inter system connectivity landscape can change quickly.
15. **Market Risk** - Acceptance of LED-based design may require additional clinical preference testing or delay sales of system until experience base established.
16. **Signal Generation and Acquisition Design** - Edge-detection design susceptible to coherent crosstalk from high-current LED transitions. Design places tighter constraints on performance of components such as sensor, cabling, and PCB layout within the signal path.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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14. Proposed Labeling

Note – Some Elite labeling refers to the "project" name Gemini. They are one and the same.

Part number and name
21-22-3000 FORE-SIGHT Elite Absolute Tissue Oximeter User Manual (DRAFT 01Xa)
21-05-0240 FORE-SIGHT Elite Sales Sheet and Specification rev.02 (2- pages front and back)
21-01-1978 FORE-SIGHT Gemini Rear Panel label (has Rx symbol) rev.02
21-01-1979 Gemini Patient Connection Label rev. 01
21-01-2017 FORE-SIGHT Elite 01-06-3000 US Serial Number Label rev.01
21-01-2018 FORE-SIGHT Elite 01-06-3005 OUS Serial Number Label rev.01
21-01-1981 FORE-SIGHT Elite US Monitor Contents Label rev.0
21-01-2020 FORE-SIGHT Elite OUS Monitor Contents Label rev.0
21-01-1980 FORE-SIGHT Elite Battery Contents Label rev.0
21-01-1982 Gemini Battery Label rev.0
21-01-2003 FORE-SIGHT Elite Battery Pack Mfg. Label rev.01
05-02-0194 FORE-SIGHT Elite Large Sensor Directions For Use (DRAFT rev.03)
05-02-0188 FORE-SIGHT Printed Pouch Stock FORE-SIGHT Elite Large Sensor rev.02
05-02-0190 Carton Label FORE-SIGHT Elite Large Carton of 20 rev.02
01-06-3100 13 Elite Dual Pre Amp Bottom Label
21-01-2008 Dual Pre Amp Label, FORE-SIGHT Elite rev. 02
21-01-1801 Pre Amp Box Serial No. Label rev. 01
21-01-1966 Do Not Discard Label for Pre-Amp monitor cable rev. 0
01-06-3100 22 Contents Label, FORE-SIGHT Elite Absolute Tissue Oximeter Dual Pre Amp rev.A

(See examples in Attachment C)

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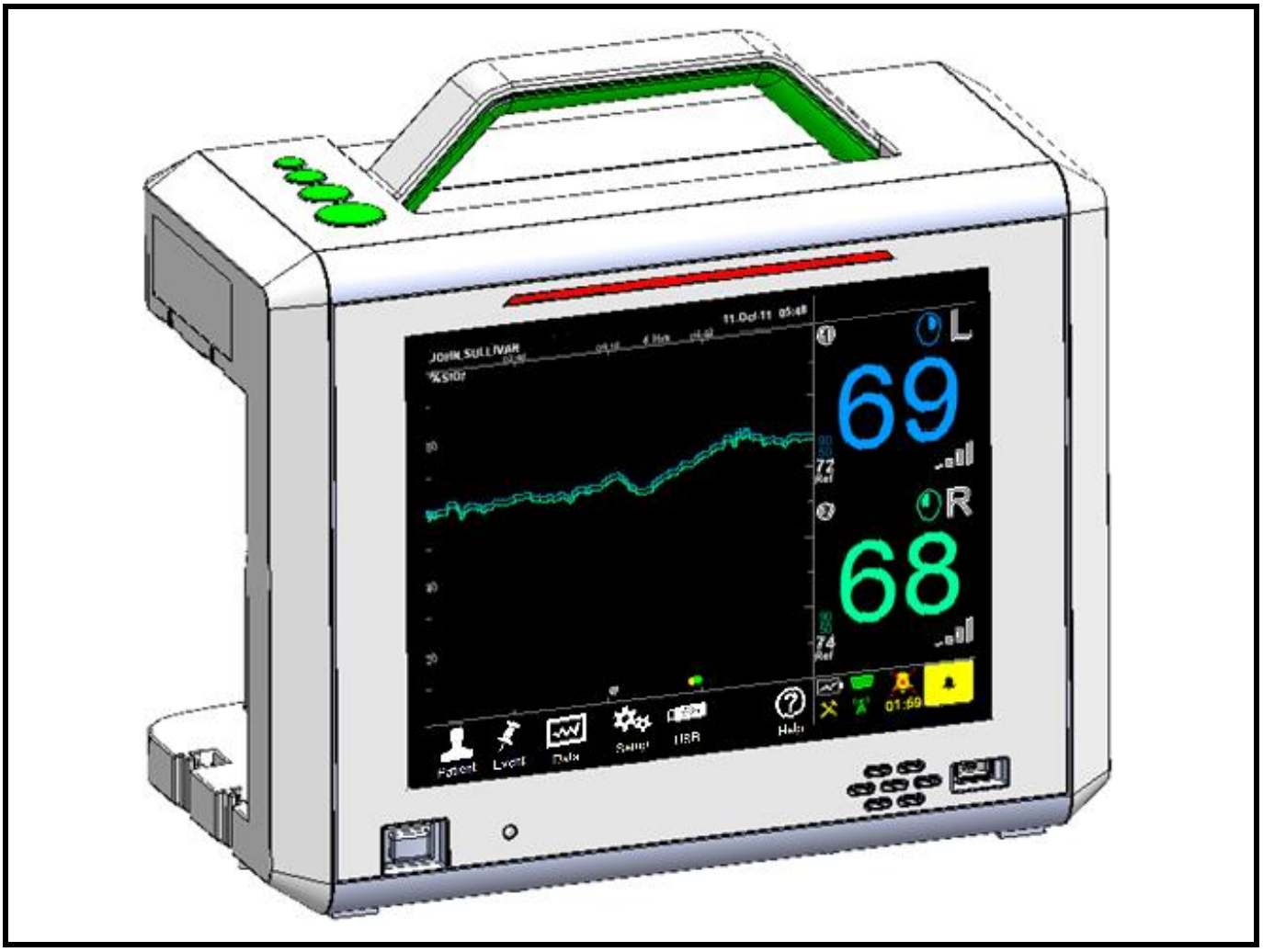
FORE-SIGHT ELITE™
Absolute Tissue Oximetry



User Manual

CE 0086

CASMED®
FOR WHAT'S VITAL

This User Manual describes the features and operations of FORE-SIGHT ELITE Oximeter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Overview

Trademarks

Trademarked names appear throughout this document. Instead of inserting a trademark symbol with each mention of the trademarked name, the publisher states that it is using the names only for editorial purposes and to the benefit of the trademark owner with no intention of improperly using that trademark.

CASMED® is a registered trademark of CAS Medical Systems, Inc.

FORE-SIGHT ELITE™ is a trademark of CAS Medical Systems, Inc.

Contact Addresses

CAS Medical Systems, Inc. 44 East Industrial Road Branford, CT 06405 U.S.A. Phone: in the US: (800) 227-4414 +1 (203) 488-6056 Fax: +1 (203) 488-9438 E-Mail: custsrv@casmed.com sales@casmed.com techsrv@casmed.com Web: www.casmed.com	**EC REP** MediMark® Europe 11 rue E. Zola 38100 Grenoble. France

Please contact the distributor in the country of purchase if product information or service should be required.

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Manufacturer's Declaration of Conformity

Manufacturers Declaration of Conformity
Electronic Emissions and Immunity

The FORE-SIGHT ELITE Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Oximeter should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment
RF emissions – CISPR 11	Group 1	The Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions – CISPR 11	Class A	The Oximeter is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions	Complies	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Level 3	Level 3	The Oximeter is designed for use in controlled environments only. Per OSHA guidelines for operating rooms, the area must employ adequate static electricity controls. The relative humidity should be maintained at about 50%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	The Oximeter is designed for use in controlled environments only. Per OSHA guidelines for operating rooms, the Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) mode ±2 kV line(s) to earth mode	±0.5 kV line(s) to line(s) mode ±2 kV line(s) to earth mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If user of the Oximeter requires continued operation during power mains interruptions, it is recommended that the Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the A.C. mains voltage prior to application of the test level.

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FORE-SIGHT Elite Oximeter

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The FORE-SIGHT ELITE Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Oximeter should insure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. ***Recommended separation distance:*** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and *d* is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1 At 80 MHz and 800MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is effected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Oximeter is used exceeds the applicable RF compliance level above, the Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Oximeter.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Oximeter

The Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	Separation distance according to frequency of transmitter (Meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters operating at a maximum output power not listed above, the recommended separation distance *d* in meters can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.
Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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CE Marking Information

Compliance The FORE-SIGHT ELITE Oximeter bears the CE mark CE-0086 indicating conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive.

Exceptions None

Conventions Used in this Manual

Warning: Directions that warn of conditions that put the patient or the caregiver at risk.

Caution: Directions that help to avoid damaging the Oximeter or losing data.

Note: Directions that make it easier to use the Oximeter, something not readily apparent.

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General Information

This manual is an integral part of the product and describes its intended use. Compliance with the manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety. Refer to Symbols starting on page 43 for additional information.

The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers.

CAS Medical Systems, Inc., (CASMED) is responsible for the effects on safety, reliability, and performance of the product only if:

- Assembly, operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by CASMED.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The device is used in accordance with the instructions for use.
- All publications conform to the product specifications and applicable IEC publications on safety and essential performance of electro-medical equipment as well as with applicable UL requirements and AHA recommendations valid at the time of printing.

For complete warranty information, refer to the Warranty Policy located on page 48.

The CASMED quality management system complies with the international standards ISO 13485 and the Council Directive on Medical Devices 93/42/EEC.

The parts of the Oximeter include the Oximeter, Preamp cable(s), Battery Pack, AC power Cord and Sensor(s). Refer to Oximeter on page 52.

The accessories for the Oximeter include, but are not limited to: USB Flash Drive, $St0_2$ Simulator and mounting hardware. Refer to Accessories on page 52

Note: Due to continuing product innovation, specifications in this manual are subject to change without notice.

Warning: Before using the Sensors and Oximeter for the first time, please read the information given in Safety section, starting on page 12 and the directions for use provided with the Sensors.

In the U.S. the following **Caution** applies: Rx only

Caution: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

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About This Manual

This User Manual describes the features and operation of the FORE-SIGHT ELITE Oximeter.

Manual Purpose

This manual contains the instructions necessary to operate the Oximeter safely and in accordance with its functions and intended use.

Note: All illustrations in this manual are provided as examples only. They may not necessarily reflect your monitoring setup or data displayed on your Oximeter.

Intended Audience

This manual is written for clinical professionals. Clinical professionals are expected to have working knowledge of medical procedures, practices, and terminology as required for monitoring of critically ill patients.

Warning: For continued safe use of this equipment, it is necessary that the listed instructions be followed. Nothing in this user guide is intended to override procedures and regulations imposed at the institutional level or above. Hospital's quality system, privacy rules, or other legal or policy requirements may govern whether and how to implement any specific procedure in this manual.

Training

Training on this Oximeter for the safe and effective use of the primary operating functions can be provided through CAS Medical Systems. Refer to Contact Addresses on page 2 for e-mail and phone number information.

CAS Medical Systems recommends in-service training on the Oximeter after the initial installation or whenever a new User intends to operate the device. No periodic retraining should be required. Training can also be provided when updates to the system are provided or whenever a User may be unfamiliar with the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Revision History

This manual has a revision number located at the bottom of each page. It changes whenever the manual is updated.

Rev-00-Xi	Oct/2013
Rev 01-Xa	Nov/2013

Read this manual carefully before patient use of the Oximeter

CASMED reserves the right to make changes to this manual and improvements to the product it describes at any time without notice or obligation.

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Contents

Overview **2**
Trademarks 2
Contact Addresses 2

Manufacturer's Declaration of Conformity **3**
CE Marking Information 5
Conventions Used in this Manual 5
General Information 6
About This Manual 7
Manual Purpose 7
Intended Audience 7
Training 7
Revision History 8

Safety **12**
Indications for Use 12
Contraindications 12
Installation and Setup 13
Device Handling 15
Safety Checks 15
Monitoring 16
Initial Inspection 17
Oximeter Checklist 17
Patient Environment 18
Oximeter Classifications of Electrical Insulation 18

Basic Operations **19**
Introduction 19
Getting Started 19
Physical Configuration 20
Front View 20
Rear View 21
Side View 22
Oximeter Controls 23
On / Off Button 23
Touchscreen 23
Oximeter Display 24
Parts of the Display Screen 24
Starting the Oximeter 25
Turning the Oximeter On 25
Touchscreen Navigation 25
Patient/Case Menu 25
Alarm Limit Menu 25
Start Patient Monitoring 26
Connecting Preamp Cable 26
Connecting Sensor to Preamp Cable 27
Preparing Patient 28
Applying Sensor 28
Sensor Selection Guide 29
TPI Indicator 29
Stop Patient Monitoring 30
Removing Sensor 30
Disconnecting Sensor from Preamp Cable 30
Disconnecting Preamp Cable (Optional) 30

DRAFT COPY

Monitoring the Patient 31
Controlling Alarm Volume & Limits 31
Adjusting Alarm Volume & Limits 31
Alarm Volume 31
High & Low Limits 31
Saving Alarm Volume and Limits 32
Responding to Alarms 33
Alarm LEDs 33
System Messages 33
Channel Messages 35
Philips IntelliVue Messages 37

Cleaning 38
Cleaning the Oximeter 38
Cleaning Preamp Cables 38
Cleaning Sensors 38

Maintenance 39
Maintenance Intervals 39
Waste Electrical and Electronics Equipment (WEEE) 39
Fuse Replacement 40
AC Fuse Replacement 40
PC Board Fuse Replacement 41
Battery Maintenance 42
Installing/Removing the Battery Pack 42

Appendix 43
Symbols 43
Symbols on Front of Oximeter 43
Symbols on Left Side of Oximeter 43
Symbols on Rear of Oximeter 43
Symbols on Display of Oximeter 44
Symbols on Battery Pack 46
Symbols on Oximeter Packaging 46
Symbols on Preamp 46
Symbols on Preamp Packaging 46
Symbols on Sensor Packaging 47
Warranty Policy 48
Oximeter Configuration Record 49
Specifications 49
Parts 52
Oximeter 52
Accessories, Detachable Parts and Materials 52
Philips IntelliVue/VueLink Accessories and Options 53

DRAFT COPY

Figures

Figure 1: Patient Environment 18
Figure 2: Front View 20
Figure 3: Rear View 21
Figure 4: Side View 22
Figure 5: Major Areas of Display 24
Figure 6: 1st Level buttons 25
Figure 7: Connecting Preamp Cable 26
Figure 8: Preamp top label, Ch1 & Ch2 Preamp connected 27
Figure 9: Preamp top label, Sensor connected to Ch1 27
Figure 10: Sensor Selection Guide 29
Figure 11: AC Fuse Placement 40
Figure 12: System Control Board Fuse Locations & Ratings 41
Figure 13: NSAM Board Fuse Placement 41

Tables

Table 1: System Messages 34
Table 2: Channel Messages 36
Table 3: Oximeter Messages on Philips IntelliVue 37

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Safety

The operator must comply with the following **Warnings**, **Cautions**, and **Notes** to guarantee safe operation of the Oximeter.

Additional **Warnings**, **Cautions**, and **Notes**, which apply to specific parameters, are listed in the sections that pertain to each parameter.

Indications for Use

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced-flow or no-flow ischemic states and is indicated for use as follows:

When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescent's ≥40 Kg.

Contraindications

- The FORE-SIGHT ELITE sensor is contraindicated for use on patients with physical site area too limited for proper sensor placement.
- The FORE-SIGHT ELITE sensor is contraindicated for use on patients with allergic reactions to sensor adhesive.
- The sensor site must be checked at least every eight hours; and if the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.
- Do not adhere sensors to underdeveloped, immature, compromised, or healing skin.
- No other contraindications are known at this time.

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Installation and Setup

Warning: The Oximeter is to be operated by qualified personnel only. Failure to read this manual, accessory direction for use, all precautionary information, and specifications could result in injury.

Warning: The Oximeter needs special precautions if it is placed close to a strong EMC transmitter such as X-ray, ESU or MRI devices. There is a risk that these signals could interfere with the Oximeter resulting in disruption of performance of this device. For continued protection against this risk, replace the AC power cord only with one provide by CASMED. Authorized CASMED or biomedical engineering personnel should replace the AC power cord.

Warning: To reduce the risk of injury, do not move or place the Oximeter in any position that might cause it to fall on patient, bystander or operator.

Warning: As with all medical equipment, carefully route and secure all cables to reduce the risk of patient entanglement or strangulation.

Warning: Do not lift or pull the Oximeter by any cable, or place the Oximeter or accessories in any position that might present a risk that the Oximeter may fall on the patient, bystander or operator.

Warning: The proper assembly of the various mounting solutions cannot be assured for structural integrity. There is risk that a damaged or improperly assembled Oximeter mounting solution may fall on patient, bystander or operator.

Warning: Do not come into contact with patients during defibrillation otherwise serious injury or death could result.

Warning: To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

Warning: The Oximeter is defibrillator-proof. It may remain attached to the patient during defibrillation, but the readings may be inaccurate during use and up to twenty (20) seconds thereafter. For proper protection against the effects of a cardiac defibrillator only CASMED supplied Preamp cables and Sensors shall be used.

Warning: Do not come into contact with patients during defibrillation. Otherwise serious injury or death could result.

Warning: Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

Warning: Avoid placing anything in front of the Oximeter that will cause the speaker output to be muffled.

Warning: Avoid placing the Oximeter where the controls can be changed by the patient.

Warning: Do not use the Oximeter for any purpose other than specified in this manual. Doing so will invalidate the Oximeter's warranty.

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Warning: Do not connect more than one patient to an Oximeter.

Warning: *Leakage Current Test* - When interfacing with other equipment, qualified biomedical engineering personnel must perform a test for leakage current before using it with patients. Serious injury or death could result if the leakage current exceeds applicable standards.

Warning: Patient Safety – If a Sensor is damaged in any way, discontinue use immediately.

Warning: The Oximeter is not "Category AP or APG Equipment."

Warning: Isolation of product from mains can only be achieved by removal of external AC power cord. If the integrity of the protective earth conductor is in doubt, the Oximeter may be operated from the internal batteries by disconnecting the AC power cord completely from the Oximeter. Do not position the Oximeter in a position that makes it difficult to remove the external AC power cord.

Warning: Do not place Sensor over poorly perfused tissues. Avoid uneven skin surfaces for best adhesion. Do not place sensor over sites with ascites, cellulitis or edema.

Warning: Do not position Sensor under the weight of the patient. Prolonged periods of pressure (such as taping over the Sensor or the patient lying on a Sensor) transfers weight from the Sensor to the skin, which can injure skin and reduce Sensor performance.

Warning: Measurements may be affected in the presence of strong electromagnetic sources such as electro-surgery equipment and measurements may be inaccurate during use of such equipment.

Caution: The USB connector accommodates a CASMED USB Flash Drive; do not connect any other USB type device or cable.

Caution: Qualified biomedical engineering personnel only must interface monitoring equipment with other types of medical equipment. Be certain to consult manufacturers' specifications to maintain safe operation.

Caution: Avoid placing either side of the Oximeter against objects that would restrict air flow through the air intakes and exhausts (other side).

Note: In the event that the location of the selected tissues cannot be palpated or visualized, confirmation by ultrasound or x-ray is recommended.

Note: The Oximeter is designed for continuous operation.

Note: The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

The Oximeter can remain connected to the patient during cardiac defibrillation. All applied parts are "Type BF Defibrillation Proof."

The Oximeter has been designed to promote patient safety. All equipment parts are protected against the effects of the discharge of a defibrillator. No separate actions are required when using this equipment with a defibrillator.

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Device Handling

Warning: Do not, under any circumstances, perform any liquid cleaning while the Oximeter or AC power cord while the Oximeter is being used to monitor a patient. The Oximeter must be turned off, Sensors removed from the patient and the AC power cord disconnected before servicing or cleaning the Oximeter. There is a risk of serious injury or death if this procedure is not followed.

Warning: If the Preamp Cable should become grossly contaminated with blood or other bodily fluids, it should be discarded to reduce the risk of contamination and cross infection.

Caution: Pressing the front display touchscreen with a sharp or pointed instrument may permanently damage the membrane. Press the touchscreen using only your finger.

Caution: Do not attempt to sterilize, gas sterilize or autoclave the Oximeter or accessories.

Note: There are no known risks with common disposal of equipment or accessories; however, the disposing of accessories should follow in accordance with local hospital policies. The user should ensure these policies do not conflict with any local, state, or federal guidelines.

Safety Checks

Warning: There is a risk of an explosion hazard if a damaged Oximeter or accessory is used in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

Warning: Inspect the cables and Sensors for damage prior to operation. If any damage is noted, the cables or Sensor should not be used until it has been serviced or replaced. There is a risk that these damaged parts could reduce the performance of the Oximeter or present a safety hazard.

Warning: Liquids must not be allowed to enter the device. There is a risk of electric shock or device malfunction if liquids enter a device. If the Oximeter or Preamp is accidentally wetted, take it out of operation. It should be thoroughly dried (minimum 1 hour) and have it checked by a service technician before it is used again.

Warning: The operator should not perform any servicing except as specifically stated in this manual.

Warning: If the accuracy of any value displayed on the Oximeter is questionable, determine the patient's vital signs by alternative means. The functions of the Alarm system for monitoring of the patient must be verified at regular intervals and whenever the integrity of the product is in doubt, periodically test all functions.

Warning: Only use CASMED-supplied accessories with this Oximeter. CASMED-supplied accessories ensure patient safety and preserve the integrity, accuracy, and electromagnetic compatibility of the Oximeter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Caution: If the Oximeter fails to respond, do not use it until the situation has been corrected by authorized CASMED personnel.

Caution: Inspect the Oximeter and accessories for damage prior to operation. If any damage is noted, the Oximeter or accessory should not be used until it has been serviced. Only personnel authorized to do so by CASMED should repair the Oximeter. Refer to Contact Addresses on page 2 for e-mail and phone number information.

Monitoring

Warning: If the accuracy of any value displayed on the Oximeter is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly. Failure to comply may lead to injury.

Warning: The Sensor site must be inspected at least every eight hours; to reduce the risk of inadequate adhesion, circulation, and skin integrity. If the circulatory condition or skin integrity has deteriorated, the Sensor should be applied to a different site.

Warning: The Sensor is designed for single patient use, and is not to be reprocessed. There is risk of contamination and cross infection from used sensors. The disposing of accessories should follow in accordance with local hospital and institution policies.

Warning: *Conductive Connections* - Extreme care must be exercised when applying Sensors. Sensor circuits are conductive and it is very important that the Sensor does not come into contact with other grounded, conductive parts. Such contact would bridge the patient's isolation and cancel the protection provided by the Sensor.

Warning: Interfering substances: Elevated levels of Carboxyhemoglobin (COHb) or methemoglobin (MetHb) may lead to inaccurate measurements. Intravascular dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings. Other factors that may affect the accuracy of measurement include: myoglobin, hemoglobinopathies, anemia, pooled blood under the skin, interference from foreign objects in Sensor path, Bilirubinemia, externally applied coloring (tattoos) or birthmarks.

Warning: Sensors are not sterile and therefore should not be applied to sites with compromised skin integrity. Exercise caution when applying Sensors to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.

Warning: Failure to apply Sensors properly may cause incorrect measurements. Misapplied Sensors or Sensors that become partially dislodged may cause either over- or under-reading of oxygen saturation.

Warning: Do not modify or alter the Oximeter or Sensor in any way. Alterations or modification may affect performance and/or accuracy.

Warning: *Electrocautery* – To prevent unwanted skin burns; apply electrocautery electrodes as far as possible from all other Sensors, a distance of at least 15 cm (6 in.) is recommended.

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Note: For patients experiencing complete bilateral ECA occlusion, measurements may be lower than expected.

Note: Body location does not change any settings for output of the Oximeter, but is used to improve measurement accuracy.

Initial Inspection

Before unpacking the Oximeter, inspect the packaging for damage. If there are any signs of damage to the package, a claim should be filed immediately with the shipping agent. It is the receiver's responsibility to notify the carrier's local office to arrange for the pickup of the damaged items. Save the damaged shipping carton as evidence.

Contact your distributor, CASMED sales representative, or CASMED to report external damage and to arrange for repair or replacement of damaged equipment.

The shipping carton should contain the items listed below. Unpack the Oximeter and account for each item. Inspect each item for signs of external damage, dents, cracks, scratches, etc. If an item is missing or damaged, contact your distributor, CASMED sales representative, or CASMED.

Refer to Contact Addresses on page 2 for e-mail and phone number information.

Record the serial number and date of purchase at the back of this manual.

Oximeter Checklist

- 1 FORE-SIGHT ELITE Oximeter
- 1 FORE-SIGHT ELITE Preamp Cable
- 1 FORE-SIGHT ELITE User Manual
- 1 Hospital Grade AC power cord

Warning: Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Grade".

Note: The Oximeter is shipped with the appropriate line cord for the country and voltage being used.

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Patient Environment

The Oximeter has been tested with specific parts of the system used within the patient environment (see Figure 1 below).

These parts are:

- The Oximeter
- Appropriate accessories as listed under Parts, on page 52, at the back of this manual.
- AC power cord

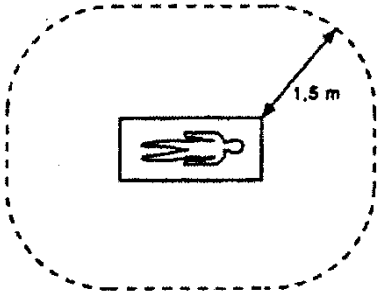

Figure 1: Patient Environment

Oximeter Classifications of Electrical Insulation

The Oximeter (with integrated AC power supply) is a Class I device.

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Basic Operations

Introduction

The Oximeter is pre-configured to measure absolute tissue oxygen saturation.

The Oximeter detects oxygenation changes in biological tissue mainly at the microcirculation level (capillary, arteriole, and venula) based on different absorption characteristics of the chromophores oxyhemoglobin (HbO_2) and deoxyhemoglobin (Hb) in the near-infrared spectrum. A biological spectroscopic window exists at the wavelength range 660–940 nm in which Hb and HbO_2 can be differentiated and measured. Tissue oxygen saturation (StO_2) is determined from the ratio

$$((HbO_2)/(HbO_2 + Hb)) \times 100\%$$

The Oximeter uses LED Technology to project light into tissue to measure oxygen saturation.

The Oximeter is equipped with a rechargeable backup battery pack that allows the Oximeter to be used independently from an external power source.

Refer to the Battery Maintenance section on page 42.

Getting Started

Before operating the Oximeter, the user should be thoroughly familiar with the following:

- **Warnings** and **Cautions** in the Safety section starting on page 12.
- Physical configuration of the Oximeter, page 20.
- Content and use of the Oximeter display, page 24.
- Procedures described in this guide, pages 26 and following,
- Use the Oximeter, starting on page 23.
    1. Set up the Oximeter for the patient (optional). See page 26.
    2. Connect the Preamp Cable(s) to the Oximeter. See page 26.
    3. Connect the Sensors(s) to the Preamp Cable(s). See page 26.
    4. Affix the Sensor(s) to the patient. See page 27.
    5. Begin monitoring. See page 26.

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Physical Configuration

Front View

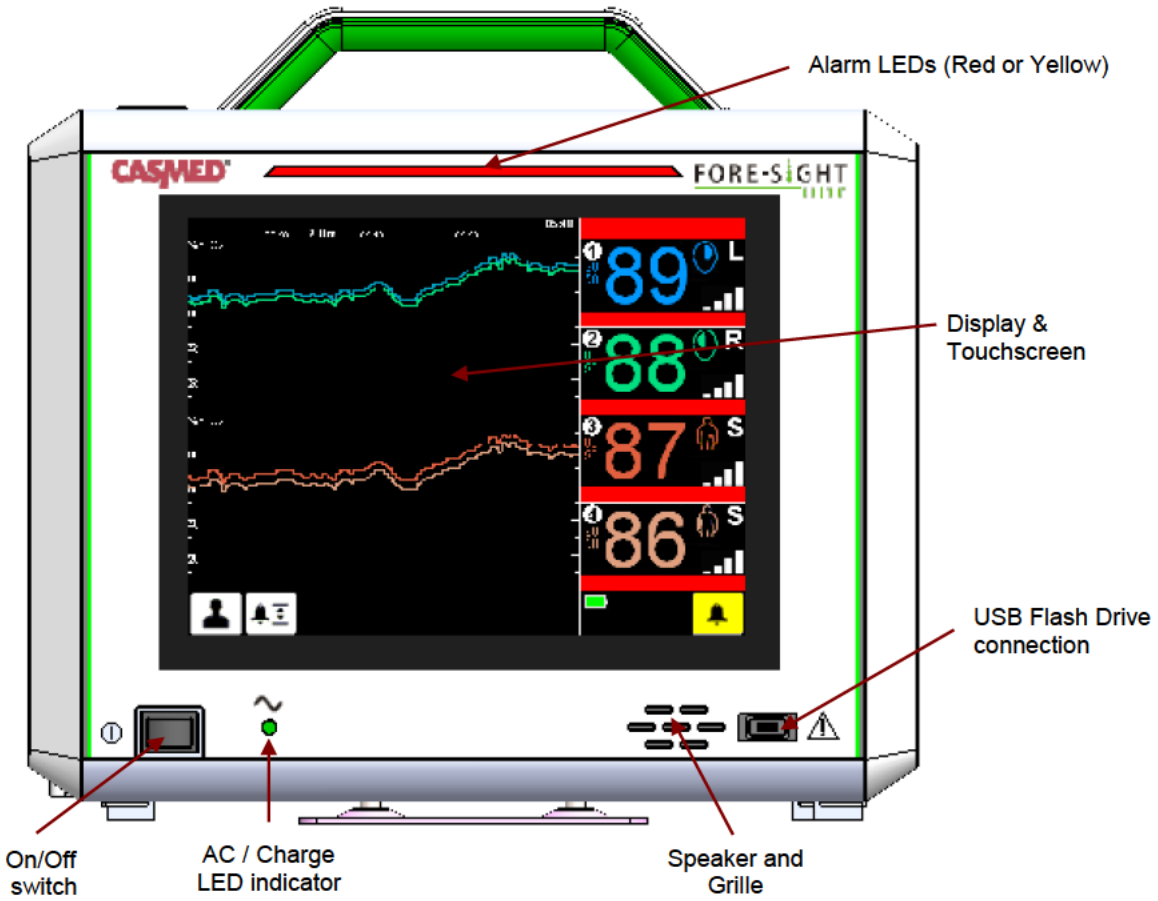

Figure 2: Front View

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Rear View

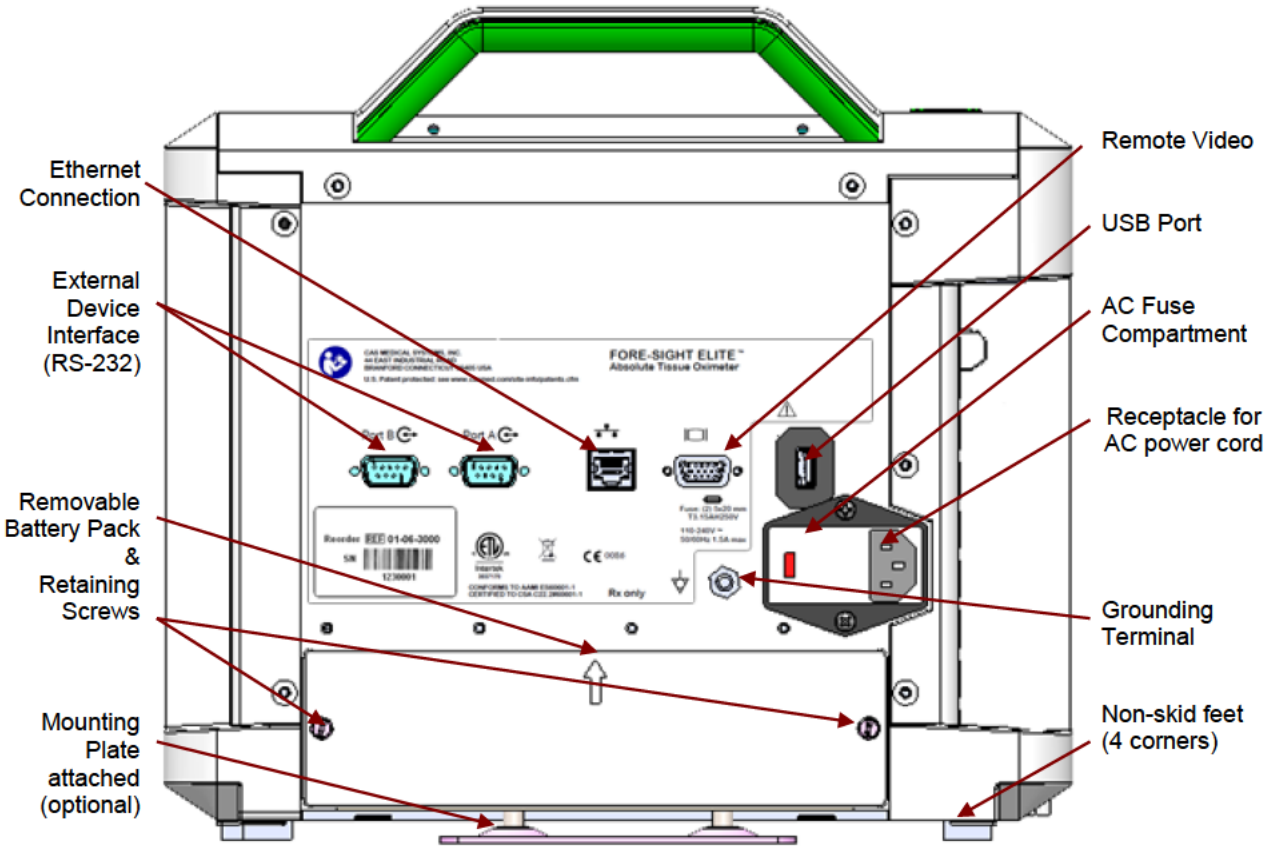

Figure 3: Rear View

Note: The Ethernet connection is for the use of CASMED service personnel only.

Note: The 4 non-skip feet may be removed (feet are attached with sticky tape) to make installation with the various mounting solutions easier.

Note: The Grounding Terminal can provide a connection between the Oximeter and the potential equalization bus-bar of the electrical installation.

When using the Grounding Terminal, the line cord shall not incorporate a potential equalization conductor.

Refer to IEC 60601-1 for additional information.

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Side View

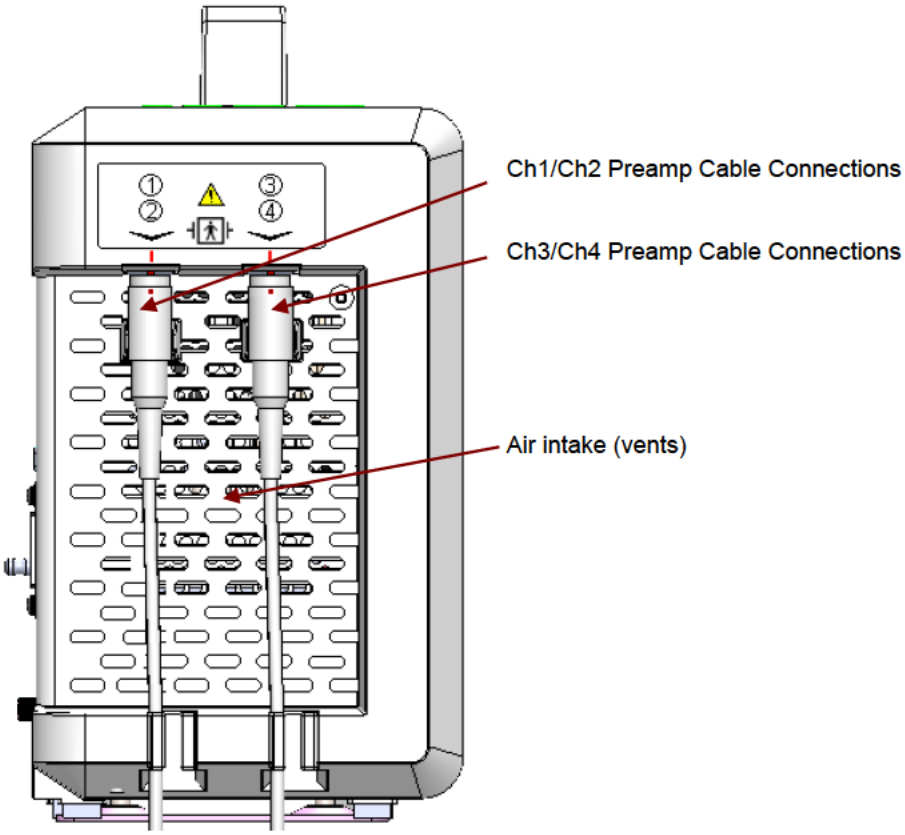

Figure 4: Side View

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Oximeter Controls

On / Off Button

Press the On / Off button to switch from Off to On.

Press the On / Off button to switch from On to Off.

The Oximeter will remain Off when connected to AC power and the On / Off button is not pressed

Touchscreen

The touchscreen gives the user access to on-screen Oximeter functions.

The user can:

- Silence Audio Alarms
- Navigate through all menu selections
- Choose optional settings
- Enter data

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Oximeter Display

Parts of the Display Screen

The major indicators on the Oximeter display are shown in Figure 5 below.

Note: The Major Areas of the Oximeter display illustrate all the areas of the display and certain settings presented may not represent actual display configurations.

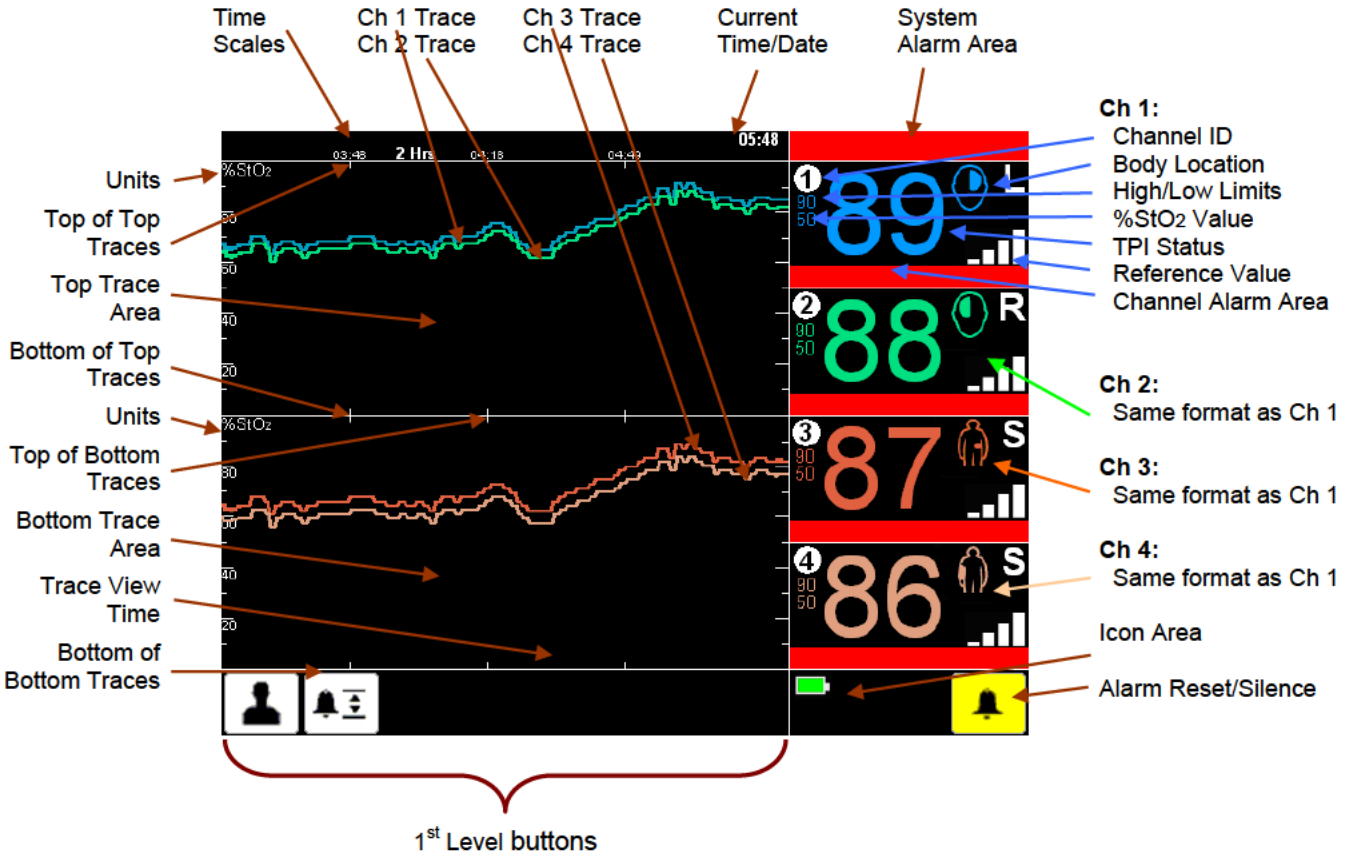

Figure 5: Major Areas of Display

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Starting the Oximeter

Turning the Oximeter On

Note: The Oximeter may be turned on before or after connecting cables and Sensors.

To turn the Oximeter on:

1. Plug the AC power cord into a power outlet.

Note: The Oximeter is equipped with a removal battery pack that allows the user to turn the Oximeter on without plugging it into an outlet. The battery status indicator shows the state of charge in the form of a colored battery icon on the display. Refer to the Battery Maintenance section on page 42.

2. Push the On / Off switch on the front of the Oximeter. The Oximeter will power on within a few seconds.

While the software initializes, a splash screen and a set of diagnostic tests are displayed. When the diagnostic tests are done the Oximeter will switch to the main screen, and is ready to begin normal operation.

Touchscreen Navigation

The user can control the operations of the Oximeter through the touchscreen system (see Figure 6 below). The procedures in this manual make frequent reference to the touchscreen system. This section explains how to navigate through it.

Figure 6: 1st Level buttons

The following paragraphs briefly describe what can be done from the various menus.

This section serves as an orientation to the touchscreen system.

Specific procedures making use of the touchscreen system are found in later sections of this manual.

Patient/Case Menu

The Patient/Case menu lets the user select the body locations of the sensors on the Patient.

Alarm Limit Menu

Touching the Alarm Limit icon allows user change each Channel's High & Low Alarm Limit.

Note: Powering the Oximeter off and on (for any period of time) will retain the last saved High & Low Limits.

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Start Patient Monitoring

Connecting Preamp Cable

Preamp Cables (see Figure 7, below) connect the Oximeter to the Sensors. Preamp Cables are reusable.

Note: Preamp Cables can remain connected to the Oximeter between uses.

Note: Preamp Cables should be replaced when they no longer properly functioning. Keep track of cable installation date and usage. See Parts on page 52 for reorder information.

To connect the Preamp Cables to the Oximeter:

1. Remove the Preamp Cable from the packaging.
2. Position the Preamp connector under the desired Oximeter Preamp connector (1&2 or 3&4). The Preamp connector housing may rest on the Guides under each Oximeter connection.
3. Line-up the alignment marks (red dots) on the Preamp Cable and Oximeter Preamp Receptacle. The Preamp Connector may be placed in the Oximeter Receptacle and rotated until the Preamp connectors inserts further.
4. Gently push the Preamp Cable Connector straight up into the Oximeter Preamp Receptacle, the Preamp Connector should snap into place.
5. Pull down gently on the Preamp cable to make sure the Preamp Connector has fully snapped into place.

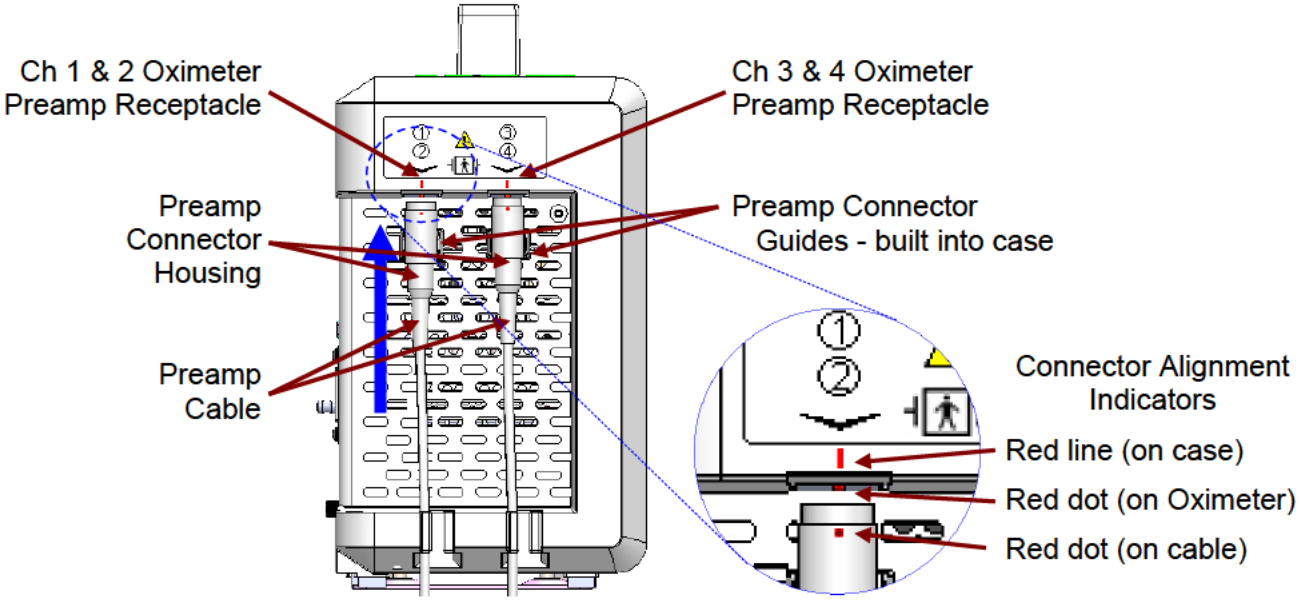

Figure 7: Connecting Preamp Cable

6. The small box at the far end of the Preamp cable contains indicators that will illuminate when the Preamp and Sensors are connected. The indicators will denote Preamp channel assignment 1, 2, 3 or 4.

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The Preamp plastic housing has a top label (refer to Figure 8) to indicate Channel Identification as well as Sensor connection status. Each Channel identification contains 2 LEDS; 1 green, 1 white

When a Preamp cable is connected to the Oximeter, the appropriate pair of white Channel ID LEDs (① ② or ③ ④) will be lit.

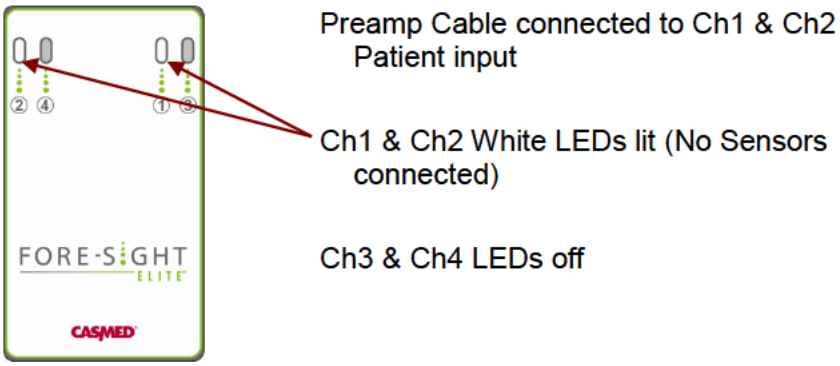

Figure 8: Preamp top label, Ch1 & Ch2 Preamp connected

Connecting Sensor to Preamp Cable

Sensors connect the Preamp Cables to the patient.

Caution: The Sensor is designed for single patient use, and is not to be reprocessed. Use a new Sensor for every patient and discard after use.

To connect a Sensor to the Preamp Cable:

1. Remove Sensor from its packaging.
2. Position the Sensor connector in front of the Preamp Sensor connector.
3. Line-up the alignment marks on the Sensor and Preamp Sensor connector.
4. Gently push the Sensor connector straight into the Preamp Sensor connector, the connector should snap into place.

The Channel ID LED on the preamp housing will change to green when a Sensor is connected (refer to Figure 9).

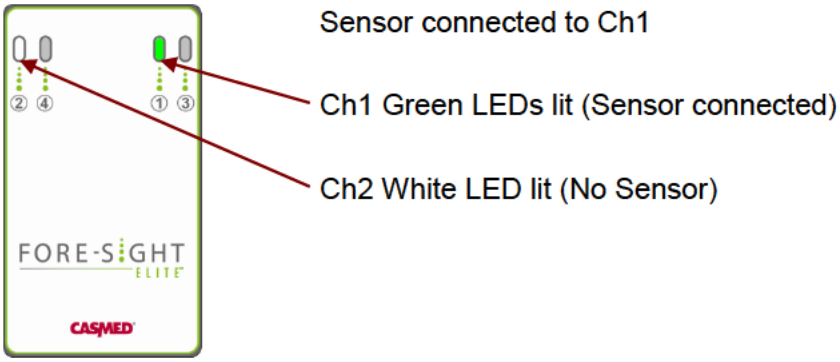

Figure 9: Preamp top label, Sensor connected to Ch1

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Preparing Patient

To prepare the patient's skin for placement of the Sensor:

1. Make sure the skin area where the Sensor is to be placed is clean, dry, intact and free of powder, oil or lotion.
2. If necessary, shave hair from skin at chosen site.
3. Use an appropriate cleanser to gently clean the intended Sensor site. Allow the skin to dry completely before applying the Sensors.

Applying Sensor

Caution: Sensors should not to be placed on high density hair areas.

Caution: The Sensor must be flush with clean, dry skin. Any debris, lotion, oil, powder, perspiration, or hair that prevents good contact between the Sensor and the skin will affect the validity of the data collected and may result in an alarm message.

Note: Skin pigmentation does not affect the validity of collected data. The Oximeter compensates automatically for skin pigmentation.

Note: For cerebral applications, If possible, locate the Sensor away from the midline of the forehead or over a sinus cavity.

Note: Refer to Figure 10: Sensor Selection Guide below to help select the proper Sensor for the patient.

Apply Sensor using the instructions provided in the Sensor kit package.

1. Be sure that all cables are fully connected and Sensors are placed correctly on the patient's skin.
2. Use the clip/hook near the Preamp to secure the cable to prevent the cable from being pulled away from the patient.

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Sensor Selection Guide

Cerebral & Skeletal Muscle Applications

kg	40-60	>60
10-18 yrs		L
> 18 yrs	L	L
lbs	88-132	>132

Figure 10: Sensor Selection Guide

L – Large Sensor

TPI Indicator

A 4-bar indicator of the Tissue Perfusion Index (TPI) represents the amount of hemoglobin in the tissue under a Sensor and is displayed near the $St0_2$ value (see Symbols on Display of Oximeter on page 44).

The TPI level is useful for the initial placement of a Sensor or for assessing an existing Sensor site:

Initial Placement:

- Without removing the white protective paper, hold the Sensor on the selected monitoring site.
- Slide the Sensor over the target sensing area until the highest TPI level is achieved.
- Visually note the Sensor position and remove & discard the protective paper prior to affixing the Sensor.

Routine Assessment:

- In normal operation, the TPI level should be 3 to 4 bars.
- If the TPI level changes to 2 bars, the user should verify proper Sensor contact and assess the site for reliability (e.g., edema is more present).
- For subjects that become hemodiluted during monitoring, a decrease in the TPI level is likely (e.g., during initiation of cardiopulmonary bypass).
- If 1 bar is present, the Sensor must be moved to a location with a higher TPI level. After 10 seconds this condition may trigger a warning message and $St0_2$ values will become dashes.

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Stop Patient Monitoring

Removing Sensor

Carefully peel the Sensor from the patient to avoid damaging the skin.

Discard the adhesive Sensors.

Disconnecting Sensor from Preamp Cable

To remove a Sensor from the Preamp Cable:

1. Grasp the Sensor connector of desired Preamp Cable to be disconnected.
2. Gently pull the Sensor connector straight out until the Sensor connector disengages from the Preamp Sensor connector.

When the Sensor is disconnected from the Preamp, the associated Channel ID LED on the Preamp housing will change back to white (refer to Figure 8).

3. Discard the Sensor.

Disconnecting Preamp Cable (Optional)

To remove a Preamp Cable from the Oximeter (see Figure 7 on page 18):

1. Grasp the housing of the connector (near The Oximeter Preamp Receptacle) of desired Preamp Cable to be disconnected.
2. Gently pull straight down on the Preamp Cable connector housing until the Preamp Cable connector disengages from the Oximeter Preamp Receptacle.

When the Preamp cable is disconnected from the Oximeter, all Channel ID LEDs on the Preamp housing will turn off.

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Monitoring the Patient

This section assumes that you are familiar with the front panel controls (see Figure 2: Front View on page 20) and the parts of the display screen (see Figure 5: Major Areas of Display on page 24).

Controlling Alarm Volume & Limits

The user can disable audible alarms by pressing the Alarm Silence / Reset button on the Oximeter front panel. Pressing the button disables the audio associated with all alarms for two (2) minutes. This does not affect the visual alarms. See Responding to on page 33 for a list of alarm conditions.

One the two minute audio disable time reaches zero, the audio will be re-enabled, assuming an alarm condition is still present.

The user can re-enable the audible alarms by pressing the Alarm Silence / Reset button on the Oximeter front panel when the audio is currently being disabled.

The user can set the High and Low Alarm limits of acceptable percentages on each channel independently.

The Oximeter shall annunciate an alarm when the Numeric value is below the Low limit or above the High limit. The Oximeter shall generate an alarm sound at the selected volume, indicate an alarm limit violation (text) in the Numeric field as well as flashed the Alarm LEDs at the top of the front display.

Adjusting Alarm Volume & Limits

To view or change the Alarm Volume or Alarm Limits:

1. Touch the Alarm Limit icon on the Main menu (see Figure 6 on page 25).
2. Touch the High/Low Limit icon and the High/Low Limit screen should appear

Alarm Volume

To adjust the Alarm Volume perform the following:

1. Touch the target area entitled “Volume”.
2. A selection of available Alarm Volumes will appear.
3. Touch the desired Alarm Volume, the selection shall be outlined for as long as the selection is touched.
4. Release the selection. The selected Volume shall be updated in the Volume target area.

High & Low Limits

To adjust the Alarm Limits perform the following:

1. Touch the target area entitled “High Limit” to adjust the High limit or “Low Limit” to adjust the Low limit

Note: Each High & Low limit selections shall be adjacent (to the left) of the corresponding channel Numeric

2. Numeric buttons (0-9, accept & backspace) will appear.
3. Enter a 2-digit limit

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The Backspace button may be used to delete the last entered digit

4. After the 2nd digit is entered, the Accept icon should be available, touch to accept.

   If the value entered is valid, the value shall be updated as the appropriate High or Low Alarm Limit (depending on which selection was made) and the numeric buttons shall disappear.

   OR

   If the value entered is invalid, the value shall be displayed as red and the numeric buttons shall remain. The value must be deleted and re-entered as a valid value before proceeding.

Caution: Setting the High Alarm limit to an extreme high value can render the High Limit detection ineffective.

Caution: Setting the Low Alarm limit to an extreme low value can render the Low Limit detection ineffective.

Note: The alarm delay for High and Low limits remains constant during any alarm condition. The alarm delay High and Low limits are factory set to 0 and cannot be altered.

Note: The High Limit cannot be set less than the Low Limit (for the same channel). The Low Limit cannot be set greater than the High Limit (for the same channel). There is always 5% difference between the Low and High limits (same channel).

Saving Alarm Volume and Limits

Once the Alarm Volume and High/Low limits have been entered, perform the following to save them:

Touch Accept icon to accept this Alarm Limit changes.

OR

Touch Cancel icon to discard this channel's Alarm Limit changes.

Note: For proper identification of the Alarm signals generated by the Oximeter, the operator should be positioned directly in the front of the Oximeter, facing the front panel.

Note: To test the Alarm operation, connect a $St0_2$ simulator (available through CASMED) to the patient connection of the Oximeter. Set the High Alarm limits to at least 1% less than the current displayed value and verify the activation of the High limit detection. Reset the High Alarm limits to the desired level. Set the Low Alarm limits to at least 1% more than the current displayed value and verify the activation of the Low limit detection. Reset the Low Alarm limits to the desired level. Testing of the Alarm operation should be done at least once every 6 months.

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Responding to Alarms

Alarm LEDs

High Priority Alarms will flash the Red Alarm LEDs, refer to Figure 2.

High Priority Alarms will be generated over any Medium Priority alarms.

Medium Priority Alarms will flash the Yellow Alarm LEDs.

Medium Priority Alarms will be generated over any Low Priority alarms.

Low Priority Alarms will also turn on the Yellow Alarm LEDs.

Low Priority Alarms will be generated over any Informational alarms.

All Alarm Messages are displayed in the following order:

- High Priority messages will be displayed before any Medium Priority message.
- Medium Priority messages will be displayed before any Low Priority message.
- Low Priority messages will be displayed before any Informational message.

System Messages

Table 1 lists the System Messages in order of priority, the conditions they signify, and the recommended action you should take.

System condition message appear in the System Alarm area, refer to Figure 5 for additional information.

Message	*Condition*	*Recommended Actions*
Medium Priority Alarms (Black on Yellow) - listed highest to lowest		
System Error E##	Internal component failure E##, ## indicates type of Error	If condition persists, contact CASMED customer service
Depleted Battery	Battery needs to be recharged	Plug Oximeter into AC outlet
Internal Temp	Unit is above upper operating temperature	If condition persists, contact CASMED customer service
Low Priority Alarms (Yellow on Black) - listed highest to lowest		
Low Battery	Battery needs to be recharged	Plug Oximeter into AC outlet
Port *X* Comm Lost	Communications problem with bi-directional wired device *X* indicates Port A or B	Inspect the Serial cable connections Make sure the Serial cable connectors are properly engaged Verify the Serial settings are correct Verify target device is turned on and actively displaying information
Informational Alarms (White on Black) - listed highest to lowest		
Connect to AC	AC power loss, Oximeter operating on Battery power	Plug Oximeter into AC outlet Make sure outlet is powered

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Message	Condition	Recommended Actions
Faulty System Fan	Operation of fan faulty	Check for free flow of temperate air around Oximeter Move Oximeter away from wall or other obstruction Move it to a cooler area If condition persists, contact CASMED customer service
Faulty Battery	Battery Pack is incapable of operating unit w/o AC	If condition persists, contact CASMED customer service to replace Battery Pack
Unknown Battery	Problem with Battery Pack Memory or Temp device	If condition persists, contact CASMED customer service to replace Battery Pack
Set Time/Date	Time & Date not set Clock Battery not capable of retaining Time & Date values	Enter Setup screen and set correct Time & Date If condition persists, contact CASMED customer service to replace Clock Battery
Faulty USB/VGA	Problem with VGA and USB Ports	If condition persists, contact CASMED customer service
Faulty Serial Port	Problem with RS-232 ports	If condition persists, contact CASMED customer service
Faulty Front USB	Problem with Front USB Port	If condition persists, contact CASMED customer service
Faulty Rear USB	Problem with Rear USB Port	
Faulty Clock Battery	RTC Battery not capable of storing Time & Date values	If condition persists, contact CASMED customer service

Table 1: System Messages

Note: Priorities of these Alarm Conditions are Factory configured and cannot be altered by the user.

A High Priority auditory signal is characterized by 10 audio pulses repeated every 10 seconds at a frequency of 970 Hz.

A Medium Priority auditory signal is characterized by 3 audio pulses, repeated every 20 seconds at a frequency of 575 Hz.

The Low Priority auditory signal is characterized by 1 pulse at a frequency of 575 Hz.

There is no auditory signal associated with Informational messages, only visual.

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Channel Messages

The message area at the bottom of each Numeric field and are associated with that Channel. Table 2 lists the Channel Messages in order of priority, the conditions they signify, and the recommended action you should take.

Channel condition message appear in the Channel Alarm area(s), refer to Figure 5 for additional information.

Message	*Condition*	*Recommended Actions*
High Priority Alarms (White on Red)		
High StO^2	Reading exceeds user-selected High alarm limit	Assess the patient and physiologic Oximeter to verify the condition and then respond accordingly
Low StO^2	Reading is below user-selected Low alarm limit	Assess the patient and physiologic Oximeter to verify the condition and then respond accordingly
Medium Priority Alarm (Black on Yellow) - listed highest to lowest		
Faulty Preamp	Preamp Cable is defective	If condition persists, contact CASMED customer service to replace Preamp Cable
Preamp Disconnected	Preamp cable has become disconnected	Connect Preamp cable to Oximeter
Faulty Sensor	Sensor is defective	Replace disposable Sensor if necessary
Sensor Disconnected	Sensor has become disconnected	Connect Sensor to Preamp
Sensor Over Temp	Temperature under Sensor is > 41°C	Cooling of patient or environment may be required
Signal out of Range	Sensor on inappropriate object	Remove Sensor from inappropriate object and place on patient
Check under Sensor	Tissue under Sensor may have fluid accumulation/edema	Check patient for edema under Sensor When tissue condition returns to normal range (e.g. patient is no longer edematous)
High Ambient Light	Sensor is not in correct contact with patient	Check that Sensor is in direct contact with skin
Low Priority Alarm (Yellow on Black) - listed highest to lowest		
Incorrect Sensor Size	Sensor is not compatible with the specified Body Location	Use the Sensor recommended for the specified Body Location
External Interference	Interference from outside source	Move Sensor away from interfering source
Sensor Under Temp	Temperature under Sensor < 8 °C	Warming of patient or environment may be required
Informational Alarms (White on Black) - listed highest to lowest		
Ambient Light	Ambient light approaching maximum value	Check that the Sensor is in direct contact with skin
Set Body Location	Sensor connected with no body location assigned	Set Body location for channel

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Message	*Condition*	*Recommended Actions*
Connect Preamp	Connect Preamp to start monitoring channels	Connect Preamp to Oximeter
Connect Sensor	Connect Sensor to start monitoring channel	Connect Sensor to Preamp
Acquiring Data	Channel is acquiring data	Normal operation Wait for message to clear

Table 2: Channel Messages

Note: Priorities of these Alarm Conditions are Factory configured and cannot be altered by the user.

A High Priority auditory signal is characterized by 10 audio pulses repeated every 10 seconds at a frequency of 970 Hz.

A Medium Priority auditory signal is characterized by 3 audio pulses, repeated every 20 seconds at a frequency of 575 Hz.

The Low Priority auditory signal is characterized by 1 pulse at a frequency of 575 Hz.

There is no auditory signal associated with Informational messages only visual.

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Philips IntelliVue Messages

Table 3 below lists the conversion of High, Medium and Low Priority System and Channel Alarm Messages displayed on the Oximeter to the Alarm Message displayed on the Philips IntelliVue:

Oximeter Message	Philips IntelliVue Message
High StO_2	High rSO_2-# [1]
Low StO_2	Low rSO_2-# [1]
System Error Exx Internal Temp Depleted Battery Low Battery	FS Sys Warning
Diff Ch *x* & Ch *y* [2]	Diff StO_2
Faulty Preamp [3] Faulty Sensor	FS-# [1] Error
Preamp Disconnected [3] Sensor Disconnected Sensor Over Temp Signal out of Range Check under Sensor High Ambient Light	FS-# [1] Warning
Incorrect Sensor Size External Interference Sensor Under Temp	FS-# [1] Chk Sensor

Table 3: Oximeter Messages displayed on Philips IntelliVue

Note: Only High, Medium and Low Priority System and Channel Alarm Messages are displayed on the Philips IntelliVue.

Note: Alarm messages displayed the Oximeter may appear different on the Philips IntelliVue due to text length limitations.

[1] # Represents the corresponding Patient Data Channel 1, 2, 3 or 4
[2] Differential Alarm message Ch *x* & Ch *y*, where *x* & *y* represent Patient Data Channel 1, 2, 3 or 4, e.g., ***Diff Ch1 & Ch 2***
[3] Preamp messages will present 2 VueLink messages, 1 for each Preamp channel: 1 & 2 or 3 & 4

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Cleaning

Warning: The Oximeter is designed to be cleaned with soft cloths dampened with cleaning solutions. If the Oximeter or Preamp is accidentally wetted, take it out of operation. It should be thoroughly dried (minimum 1 hour) and have it checked by a service technician before it is used again.

Caution: Do not open the Oximeter to clean it.

Caution: Do not use abrasive cleaners, isopropyl alcohol or organic solvent for cleaning. Use of these cleaners can cause damage, stiffness and brittleness to the Oximeter's surface and to cables and wires.

Cleaning the Oximeter

Examine the Oximeter's case for damage and check the AC power cord for bent or broken prongs, cracks or fraying. Neither the Oximeter nor the AC power cord should be used if damaged. If any damage is noted, contact the appropriate service personnel. Refer to Contact Addresses on page 2 for e-mail and phone number information.

- **Housing:** The Oximeter surfaces may be disinfected using a soft cloth dampened with a 10% (1:10) solution of chlorine bleach in tap water. When all of the surfaces have been disinfected, wipe the entire surface of the Oximeter using a soft cloth dampened with fresh water to remove any trace amounts of residue and/or fumes.
- **Display:** Clean the display window using a soft, lint-free cloth sprayed with an alcohol free glass cleaner. The use of paper towels is not recommended as it may scratch the surface.

Thoroughly wipe off any excess cleaning solutions

Cleaning Preamp Cables

Clean the Preamp Cable using a soft cloth dampened with a 10% (1:10) solution of chlorine bleach in tap water. Do not use alcohol.

Cleaning Sensors

Sensors are not design to be cleaned and/or re-used.

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Maintenance

Warning: No modification of this equipment is allowed.

Caution: Service performed by unauthorized personnel could be damaging to the Oximeter and may void the warranty. For service, contact your CASMED Representative. Refer to Contact Addresses on page 2 for e-mail and phone number information.

The only Oximeter parts requiring preventive inspection and maintenance are the AC Fuse Replacement on page 40 and the Battery Maintenance on page 42.

CASMED will make available on request circuit diagrams, component parts lists, to assist CAS Authorized Service personnel.

Maintenance Intervals

Preventive maintenance of the Oximeter is an important function that should be performed routinely to ensure safe and efficient Oximeter operation. The following maintenance intervals are recommended:

- **Oximeter:** No user calibration is required
- **Battery Pack:** Should be replaced every 2 years

Caution: To maintain proper battery charge, plug the Oximeter into mains power when not in use. Failure to do so may diminish the service life and function of the battery.

Waste Electrical and Electronics Equipment (WEEE)

To facilitate the sound treatment of WEEE, information will be made available for current CASMED products upon request. EU distributors and treatment facility personnel may contact techsrv@casmed.com to obtain relevant information.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Fuse Replacement

Warning: Before changing any fuse, turn power off, remove battery pack and unplug the AC power cord.

Warning: For continued protection against fire hazard, replace only with identically rated fuses.

Warning: The Oximeter has multiple fuses located inside the Oximeter and Battery Pack. These fuses are not user replaceable. These fuses should only be replaced by CAS Authorized Service personnel.

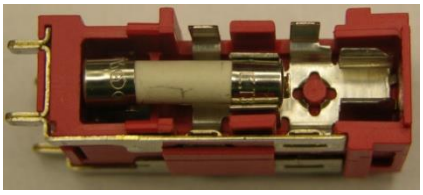
AC Fuse Replacement

The Oximeter has a dual fuse AC power input receptacle. Both AC lines are fused.

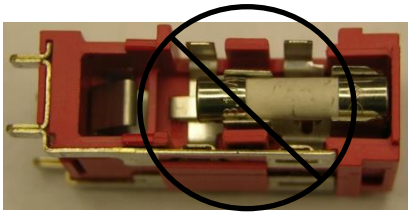
A fuse may need to be replaced if the Oximeter is plugged into an electrical outlet but the AC Power indicator is not illuminated.

To replace the AC power fuses, proceed as follows:

- Turn the Oximeter off and disconnect the AC power cord.
- Using a small screw driver, open the fuse cover on the AC Fuse Compartment (see Figure 3 on page 21).
- Using a small screw driver, pull out the red fuse holder from the AC Fuse compartment.
- Remove the suspect fuse.
- Place the new fuse into the fuse holder as indicated by the orientation (see Figure 11 below).
- Repeat this process for the fuse on the other side of holder.
- Insert the fuse holder back into the power input receptacle (the fuse holder can be inserted in either orientation).
- Close the fuse cover on the AC Fuse Compartment.
- There should be an audible click when it is secured.
- Reconnect the AC power cord back to the Oximeter.



Correct Placement



Incorrect Placement

Figure 11: AC Fuse Placement

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PC Board Fuse Replacement

The Oximeter has fuses located inside the Oximeter.

Below are the locations and ratings for the fuses on the System Control Printed Circuit Board Assembly, CAS PN 03-59-0402:

Ref Des	Rating
F3	F5.00A/125V
F2	F5.00A/125V
F1	F5.00A/125V
F4	F2.00A/125V
F5	F250mA/125V

Figure 12: System Control Board Fuse Locations & Ratings

Below are the locations and ratings for the fuses on the NSAM Printed Circuit Board Assembly, CAS PN 03-50-0450:

Ref Des	Rating
F2	F250mA/125V
F4	F250mA/125V
F1	F2.00A/125V
F3	F125mA/125V
F5	F125mA/125V

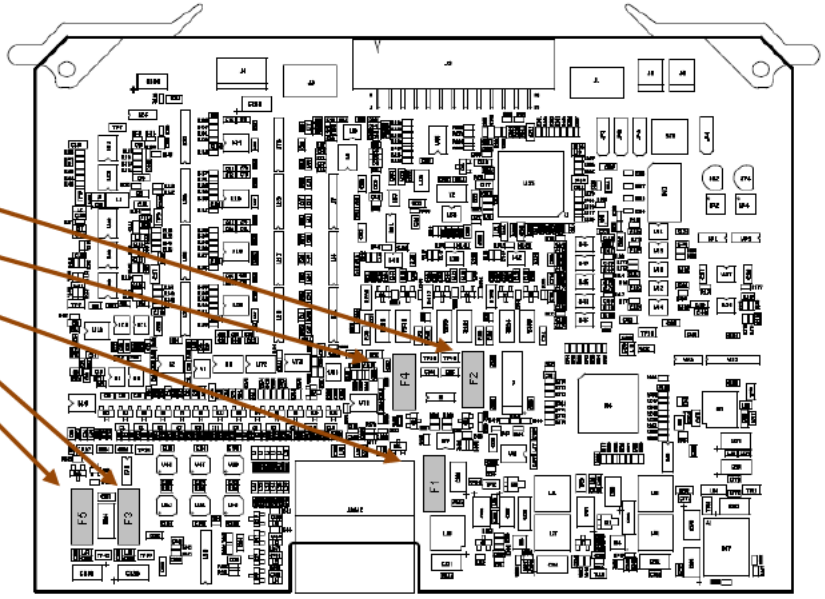

Figure 13: NSAM Board Fuse Placement

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Battery Maintenance

The Battery Pack provides power to operate the Oximeter for up to a half hour (on a new, fully charged battery).

To properly maintain the battery charge level and prolong battery life, the Oximeter should be connected to AC power at all times.

As with all batteries, the capacity will diminish over time. It is recommended that properly maintained batteries be replaced by CASMED service every 2 years.

If Oximeter will not operate for more than 10 minutes on battery power prior to the 2 year replacement interval, then the Oximeter should be returned to CASMED for service and battery replacement.

Installing/Removing the Battery Pack

Warning: Use only the battery pack that is listed in the Accessories, Detachable Parts and Materials section on page 52.

The Battery Pack in the Oximeter is designed to be easily replaced. Turn the Oximeter Off and remove the AC power cord whenever removing or installing a battery pack.

To remove a Battery Pack:

1. Locate the Battery Pack – bottom area of rear of Oximeter (see Figure 3).
2. Loosen the retaining screws on either side of the Battery Pack.
3. Grasp the retaining screws of the battery pack and pull the Battery Pack slightly out of the Oximeter - this will disconnect the Battery pack electrically from the Oximeter.
4. Gently slide the Battery pack out of the remainder of the Battery compartment of the Oximeter.

To reinstall a Battery Pack:

1. Position the Battery Pack with the arrow on outside cover facing up and the two side tabs towards the top of the pack.
2. Gently slide the Battery pack in to the Battery compartment of the Oximeter until a slight resistance if encountered.
3. With equal force on both sides of the Battery Pack, push the Battery Pack into the Battery compartment until the outside of the Battery Pack is flush with the rear of the Oximeter.

Caution: If significant resistance in encountered, do not force the Battery Pack into the Battery compartment. Ensure the arrow on outside cover facing up and the two side tabs towards the top of the pack.

4. Tighten the retaining screws on either side of the Battery Pack. Do not over tighten the screws.
5. With the AC power cord disconnected, press the front panel power button and verify the Oximeter will power on with the Battery Pack installed
6. Reconnect the AC power cord back to the Oximeter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Appendix

Symbols

The following is a summary of all symbols used on the Oximeter and accessories. Symbols may occur on the product or on its packaging. Symbols shall be black unless otherwise indicated.

Symbols on Front of Oximeter

AC power indicator / Charge mode enabled (Green circle)

On / Off

Caution

Symbols on Left Side of Oximeter

(Near the Oximeter Patient Connections)

Patient connections are Type BF

Warning (Yellow background)

Symbols on Rear of Oximeter

Caution

Potential Equalization Post (Grounding Terminal)

This symbol appears here instead of on the Oximeter. The first two digits of the Oximeter's serial number indicate the year of manufacture in the 21st century.

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Indicates this Oximeter is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

Alternating current

Communication port, RS-232 Connector

Video port, VGA Connector

Follow instructions for use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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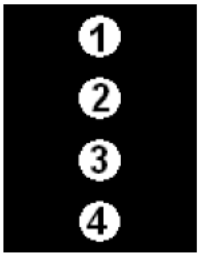
Symbols on Display of Oximeter

Audio Disable State

Temporary Audio Disabled (Yellow bell w/red dotted X) - Indication the Alarm Audio is temporarily disabled

Channel Indicators



Channel 1 (Black number on White circle background)

Channel 2 (Black number on White circle background)

Channel 3 (Black number on White circle background)

Channel 4 (Black number on White circle background)

Body Locations

Left Brain - Frontal lobe (Blue). Position over the left eyebrow, but below the hairline (higher up is best to avoid air sinus).

Left Arm Muscle - (Tan). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

Left Flank Muscle - (Tan). Position over the lateral abdominal wall below the rib cage (rib margins should be palpable or too much adipose or edema maybe present).

Left Leg Muscle - (Tan). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

Right Brain - Frontal lobe (Green). Position over the right eyebrow, but below the hairline (higher up is best to avoid air sinus).

Right Arm Muscle - (Orange). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

Right Flank Muscle - (Orange). Position over the lateral abdominal wall below the rib cage (rib margins should be palpable or too much adipose or edema maybe present).

Right Leg Muscle - (Orange). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

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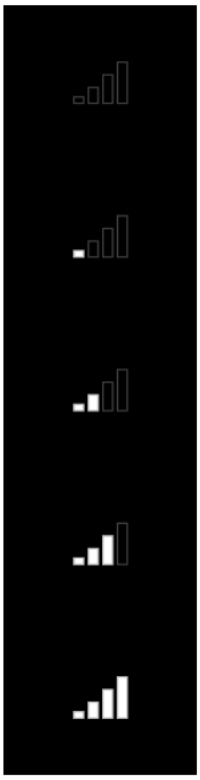
TPI Indicators



NONE (four empty Gray bars) No Sensor or Preamp connected or Sensor and Preamps connected, but Sensor off patient.

POOR (one White-filled bar & three empty Gray bars) Indicates that the Sensor should be moved as monitoring will soon stop. After 10 seconds, this condition triggers the "Check tissue under Sensor" message and $St0_2$ values become two dashes, "--".

FAIR (two White-filled bars & two empty Gray bars) If seen when first placing the Sensor, reposition to achieve a GOOD or EXCELLENT level. If TPI reduces to FAIR during monitoring, verify that the Sensor is well adhered and assess the site for reliability, e.g., edema.

GOOD (three White-filled bars & one empty Gray bar) For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site.

EXCELLENT (four White-filled bars) Ideal monitoring state. For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site.

Actions

Accept (Green) - Accepts changes and return to previous menu.

Cancel (Red) - Discards changes and return to previous menu.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Symbols on Battery Pack

Caution

Recycling suggested

Indicates this Battery pack contains lead (Pb) and is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

Symbols on Oximeter Packaging

Symbol used to indicate the minimum and maximum storage and transport Temperatures.

Refer to Storage/Transport Environment on page 50.

Symbol used to indicate the minimum and maximum relative humidity for storage and transport.

Refer to Storage/Transport Environment on page 50.

Symbol used to indicate the minimum and maximum atmospheric pressure for storage and transport.

Refer to Storage/Transport Environment on page 50.

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Fragile, handle with care

This end up

Symbols on Preamp

Follow instructions for use

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Indicates this Preamp is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

Do not Discard
Intended for Multiple use

Found on the Preamp cable
(Black text & symbol on Green background)

Symbols on Preamp Packaging

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Indicates this Preamp is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

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Symbols on Sensor Packaging

Rx only	In the U.S. the following **Caution** applies
NON STERILE	Non-Sterile
	Storage and transport temperatures
	Use only once
PVC	PVC Free
	Follow instructions for use
Latex	Latex free
	Do not cut or trim Sensor
	Do not apply prolonged pressure to the Sensor
	Manufacturer
LOT	Lot number
CE 0086	The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

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Warranty Policy

All products are sold by CASMED, under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this product directly from CASMED or CASMED's Authorized Distributors as new merchandise and are extended to the first buyer thereof, other than for resale.

The CASMED FORE-SIGHT ELITE Oximeter is warranted for a period of twelve (12) months. All products, if applicable, are warranted to be free from functional defects in materials and workmanship and to conform to the description of the product contained in the User Guide, published specifications, and accompanying labels and/or inserts, provided that the same is properly operated under conditions of normal use in accordance with applicable safety and regulatory requirements, and that replacements and repairs are made in accordance with the instructions provided by CASMED.

The same warranty conditions are made for a period of twelve (12) months with respect to the battery. A ninety (90) days warranty is provided for non-disposable accessories such as reusable Preamp Cables and other accessories provided by CASMED as part of the original purchase. CASMED warrants disposable or single-patient-use products, including Sensors for out-of-box failure only. Where the accessory is not a CASMED manufactured product, the manufacturer's own warranty applies. Warranty of accessories purchased separately from listed suppliers will be the responsibility of such listed suppliers. Damage to any part through misuse, neglect, or accident, or by affixing any accessories or attachments other than CASMED manufactured accessories or attachments, is not covered by this warranty.

The foregoing warranties shall not apply if the product has been configured, modified, adjusted or repaired other than by CASMED or by persons expressly authorized by CASMED, or not in accordance with written instructions provided by CASMED, or if the product has been subjected to misuse, negligence, or accident.

CASMED reserves the right to perform warranty service operations in its own factory, at an authorized repair facility, or at the customers' site. The sole and exclusive obligation of CASMED and Buyer's sole and exclusive remedy under the above warranties, is limited to repairing or replacing, free of charge, a product which is reported in writing or via telephone to CASMED has a Return Material Authorization (RMA) number assigned and which is returned during normal business hours, transporting charges prepaid to:

CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405 USA

Telephone:	+1 203 488 6056
Fax:	+1 203 488 9438
E-mail:	custsrv@casmed.com

CASMED SHALL NOT BE OTHERWISE LIABLE FOR ANY DAMAGES INCLUDING, BUT NOT LIMITED TO, INCIDENTAL DAMAGES, CONSEQUENTIAL DAMAGES OR SPECIAL DAMAGES.

THERE ARE NO EXPRESS OR IMPLIED WARRANTIES WHICH EXTEND BEYOND THE WARRANTIES HEREINABOVE SET FORTH. CASMED MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCT OR PARTS THEREOF.

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Oximeter Configuration Record

Serial Number: _____

Date of Purchase: _____

Specifications

Physical Dimensions and Weight

H × W × D: (without feet)	10 in (25.4 cm) × 12 in (30.5 cm) × 9 in (22.9 cm)
Weight:	13.2 lbs (5.9 kg)

Operating Environment

Operating temperature:	10°C (50°F) to 40°C (104°F)
Humidity:	30 to 90% RH, non-condensing
Altitude:	-1,000 ft (106 kPa) to 10,000 ft (68 kPa)

Oximeters may not meet performance specifications if stored or used outside temperature and humidity ranges. When moving an Oximeter from a storage location, wait at least one hour prior to use to allow it to adjust to room temperature.

Measurement

Method:		Modified Beer-Lambert Law Near Infrared Spectroscopy (NIRS)
Information output:		Absolute saturation of tissue oxygenation (StO_2)
Measurement range:		0 to 100%
Display resolution:		1%
Data rates:		Acquisition ≤ 100 Hz, numeric display = .5 Hz
Accuracy:	**Cerebral**	Accuracy not determined < 45%. Oximeter may not be accurate at saturations below 45%.
	Large Sensors	45% to 95%: ±3.05% to 1 standard deviation
	Skeletal Muscle	Accuracy not determined < 45%. Oximeter may not be accurate at saturations below 45%.
	Large Sensors	45% to 95%: ±5.17% to 1 standard deviation

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Patient Alarms

Adjustable alarms:	High, Low limits for Ch1, Ch2, Ch3 & Ch4
Alarm indicators:	• Visual • Audible • Text in Channel alarm message window
Audible sound pressure @ 100% Volume	High Priority Alarms: >56db (Fast A) @ 1m in front of Oximeter Medium Priority Alarms: <56db (Fast A) @ 1m in front of Oximeter

Patient Parameter	**Low (Default 40%)**	**High (Default 90%)**
Range: Ch1, Ch2, Ch3, Ch 4	5 to 90%	10 to 95%

Low limits cannot be set above the associated high limit.
High limits cannot be set lower than the associated low limit.
There is a min of 5% difference between the Low and High limit values at any time.

Display

Display:	LCD display of measurement results, instructions, troubleshooting messages, waveforms, and signal strength bar.
Numerics:	1 corresponding to each channel

Storage/Transport Environment

Storage Temperature:	-20°C (-4°F) to 60°C (149°F)
Transport Temperature:	-20°C (-4°F) to 60°C (149°F)
Humidity:	15 to 90% RH, non-condensing
Altitude:	-1,000 ft (106 kPa) to 10,000 ft (68 kPa)

Power

External AC power:	100 to 240 VAC, 50/60 Hz, 1.5A Max (1.5A to 0.75A) Fuse rating: T3.15AH250V (two provided)
Chassis leakage current:	100 µA (maximum)
Heat dissipation:	60 watts (205 BTU/hr)
Battery:	Sealed lead-acid battery
Charge Time:	6 hours
Operating Time:	0.5 hour (minimum with new and properly maintained battery)

Note: The life of batteries is influenced by actual use, temperature, charging & discharging cycles, and mechanical abuse.

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Serial Interface

Interface type:	Bi-directional serial communication
Speed:	User-programmable
Signal level:	RS-232C
Data length:	8 bits
Start bit:	1 bit
Stop bit:	1 bit
Parity:	None
Flow control:	None

Standards

Oximeter comply with the following requirements:

CE marking according to Directive 93/42/EEC
IEC 60601-1:2005
IEC 60601-1-2:2007
IEC 60601-1-6:2010
IEC 60601-1-8:2006
ANSI/AAMI ES 60601:2005
ANSI/AAMI IEC 62366:2007
CAN/CSA C22.2 #60601-1

U.S. Patent protected: see www.casmed.com/site-info/patents.cfm

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Parts

Contact our Customer Service department or see our website for the latest product information. Refer to Contact Addresses on page 2 for e-mail and phone number information.

Oximeter

Catalog No.	Description
01-06-3000	(1) FORE-SIGHT ELITE Oximeter
Provided With:	(1) FORE-SIGHT ELITE Dual Preamp (1) FORE-SIGHT ELITE Battery Pack (1) FORE-SIGHT ELITE User Manual (on CD) (1) Hospital Grade AC power cord (country specific) (1) Service Card & Sleeve

Accessories, Detachable Parts and Materials

Catalog No.	Description
01-02-0395	Replacement power cord, North America
01-02-0384	Replacement power cord, U.K.
01-02-0385	Replacement power cord, Australian
01-02-0386	Replacement power cord, European
01-06-3100	FORE-SIGHT ELITE Dual Preamp
01-06-3011	FORE-SIGHT ELITE USB Flash Drive
01-06-3014	FORE-SIGHT ELITE Battery Pack
01-06-3036	FORE-SIGHT ELITE User Manual on CD
01-07-1110	FORE-SIGHT ELITE $St0_2$ Simulator
01-07-2103	FORE-SIGHT ELITE Large Sensor Carton (20 sensors)
01-06-0231	Giraffe®[4] Dovetail Attachment
01-06-0232	FORE-SIGHT 3 inch Utility Basket for 01-06-0234, 01-06-0235 or 01-06-0236 Arms
01-06-0233	FORE-SIGHT 6 inch Utility Basket for 01-06-0234, 01-06-0235 or 01-06-0236 Arms
01-06-0234	FORE-SIGHT 16 inch Arm Wall Mount
01-06-0236	FORE-SIGHT 16 inch Arm Pole Mount
01-06-0238	FORE-SIGHT Roll Stand, with basket & Handle
01-06-0239	FORE-SIGHT ELITE GCX Mounting Plate Kit
The following part require the 01-06-0231 Giraffe Dovetail Attachment:	
01-06-0235	8 inch Arm Giraffe Bed Mount

[4] Giraffe® is a registered trademark of GE Healthcare

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Philips IntelliVue/VueLink Accessories and Options

Description - Purchased directly from Philips:

Philips VueLink Module AUXPLUS PN: M1032A #A05

Philips Interface Cable PN: M1032A #K6C, M1032-61699

Philips contact information:

www.medicalphilips.com	Web
medical@philips.com	E-Mail

Catalog No.	Description
01-06-2133	**FORE-SIGHT** VueLink Extension Cable

Warning: Connection of the Oximeter to a Philips Patient Monitor could result in previously unidentified risks to Patients, or Operators and the User should identify, analyze, and control such risks.

Warning: Changes in the Oximeter to a Philips Patient Monitor connection including changes to configuration, additional or deletion of items and updating or upgrading of equipment could introduce new risks that may require new analysis.

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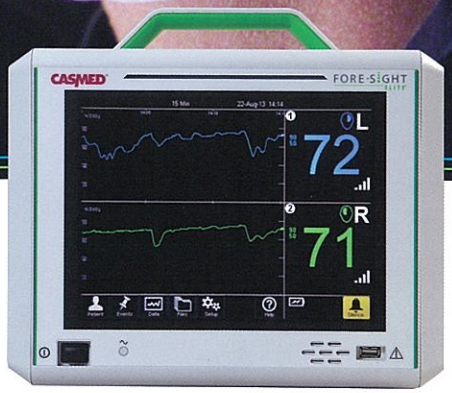
"It doesn't make sense, every other parameter indicates good cerebral oxygenation."

Logic dictates that acceptable blood pressure and pulse oximetry readings correlate to adequate oxygenation in the brain. But logic doesn't apply to desaturation events. The only way to be truly certain and avoid the risks associated with these events is accurate cerebral oximetry.



INTRODUCING FORE-SIGHT ELITE™

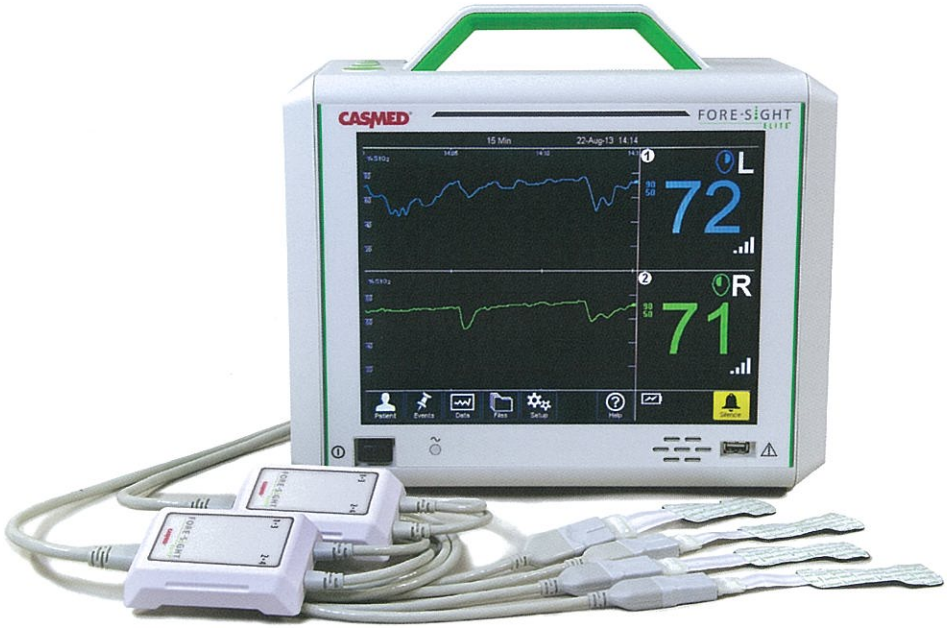
With the introduction of ELITE, CASMED has taken tissue oximetry to the next level and is making it easier than ever to get the kind of accurate and actionable readings you can trust. Building upon the proven accuracy of the FORE-SIGHT algorithm, the ELITE is the first and only FDA cleared tissue oximeter featuring 5 wavelengths of near-infrared light for greater accuracy and enhanced tissue recognition. ELITE is next generation technology designed to deliver a level of confidence that other conventional parameters can not match.

FORE-SIGHT ELITE™
Absolute Tissue Oximetry
from CASMED®

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Desaturation events may defy logic, they don't have to defy detection.



Experience the enhanced performance and ease of use with FORE-SIGHT ELITE to optimize brain protection

- First and only FDA cleared tissue oximeter utilizing a 5th wavelength of near-infrared light to reduce patient variability
- Enhanced FORE-SIGHT algorithm improves accuracy to unprecedented levels (3.05% A_{rms})[1]
- Eliminates the need for pre-induction baseline reading
- Detects otherwise unnoticed cerebral desaturation events
- Wide range of connectivity options with VGA output, Philips IntelliBridge, and EMR Systems

Preamp Cable

P/N: 01-06-3100

Large Sensor

P/N: 01-07-2103 (20 sensors/case)
Adult Cerebral: ≥ 40kg

Monitor Specifications

Absolute Tissue Oxygen Saturation
Range: 0 to 99%
Dimensions: 30.5 cm (12 in) X 25.4 cm (10 in) X 22.9 cm (9 in)
Weight: 5.9 kg (13.2 lbs)

Call our Customer Service toll-free number (800) 227-4414 to contact your local sales representative.

BSI Product is CE Marked

ISO 13485 Certificate Number FM 72259

44 East Industrial Road, Branford, CT 06405 USA
800.227.4414 | www.casmed.com

FORE-SIGHT Absolute Tissue Oximetry ELITE™ from CASMED®

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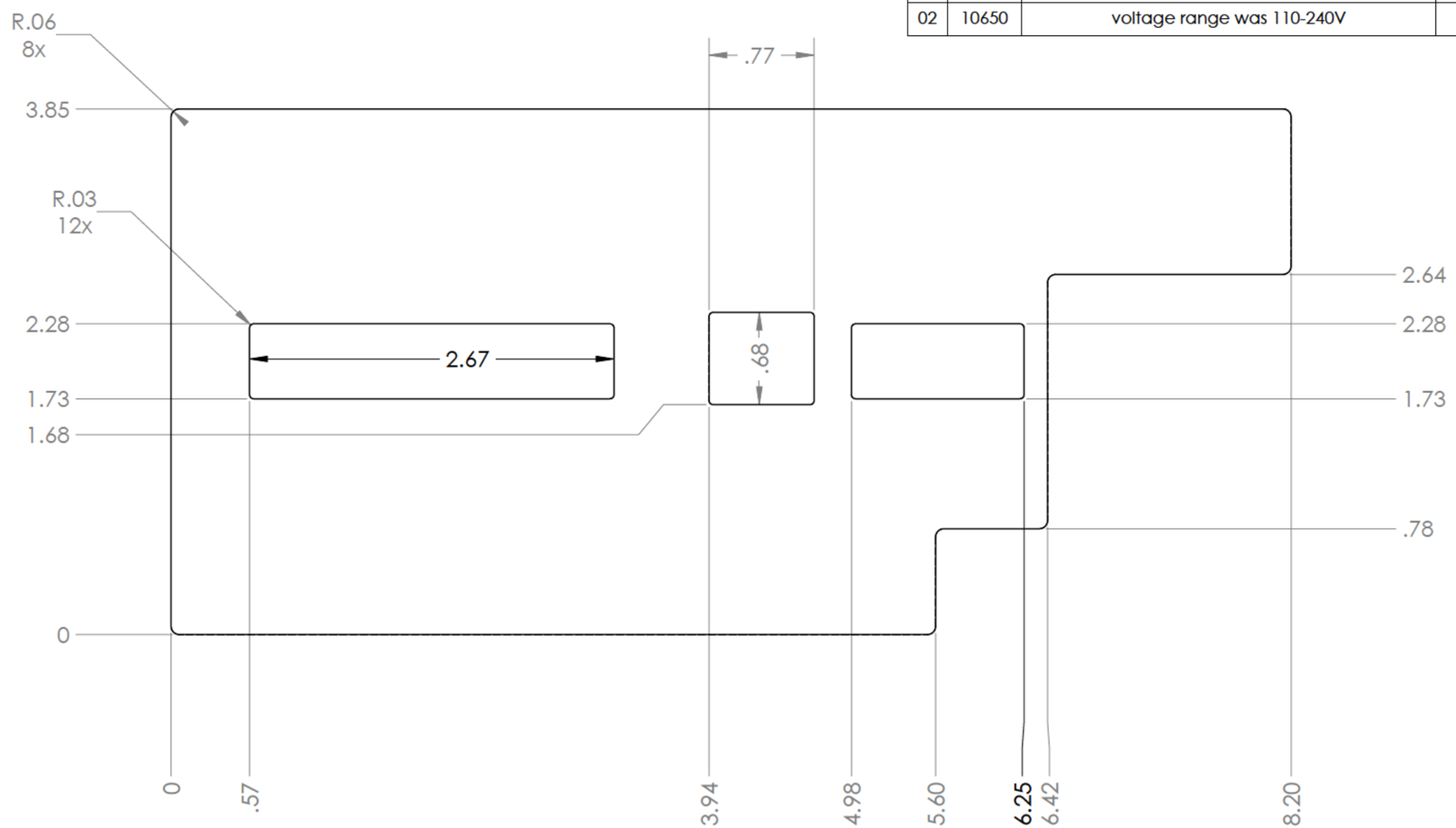
1) Validated accuracy for cerebral measurements on adults ≥40kg

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

21-05-0240 Rev 02

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN #	DESCRIPTION OF CHANGE	BY	DATE	APPROVED
00	10425	INITIAL RELEASE . WAS REV XB	MCC	9-4-2012	HT
01	10497	Interchanged position of "Port A" & "Port B	MCC	2-28-2013	mcc
02	10650	voltage range was 110-240V			



NOTES:

1. MATERIAL: 7MIL LEXAN, VELVET, #8B35
2. ADHESIVE WITH BACKING 3M 468MP
3. GRAPHIC COLORS:
   BACKGROUND OPAQUE PMS WHITE
   GRAPHICS IN BLACK COLOR EXCEPT FOR
   PERSON READING BOOK IN PMS BLUE 287

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—	FS–ELITE
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	±	N/A
2 PLACE DECIMALS	±	.01
3 PLACE DECIMALS	±	.005
ANGLES	±	1°0'

DRAWN	MCC	DATE	4-10-2012
CHECKED	M.Mancini	DATE	9-4-2012
ENGINEER	H.Triebel	DATE	9-4-2012

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTES
FINISH: —

CASMED® FOR WHAT'S VITAL

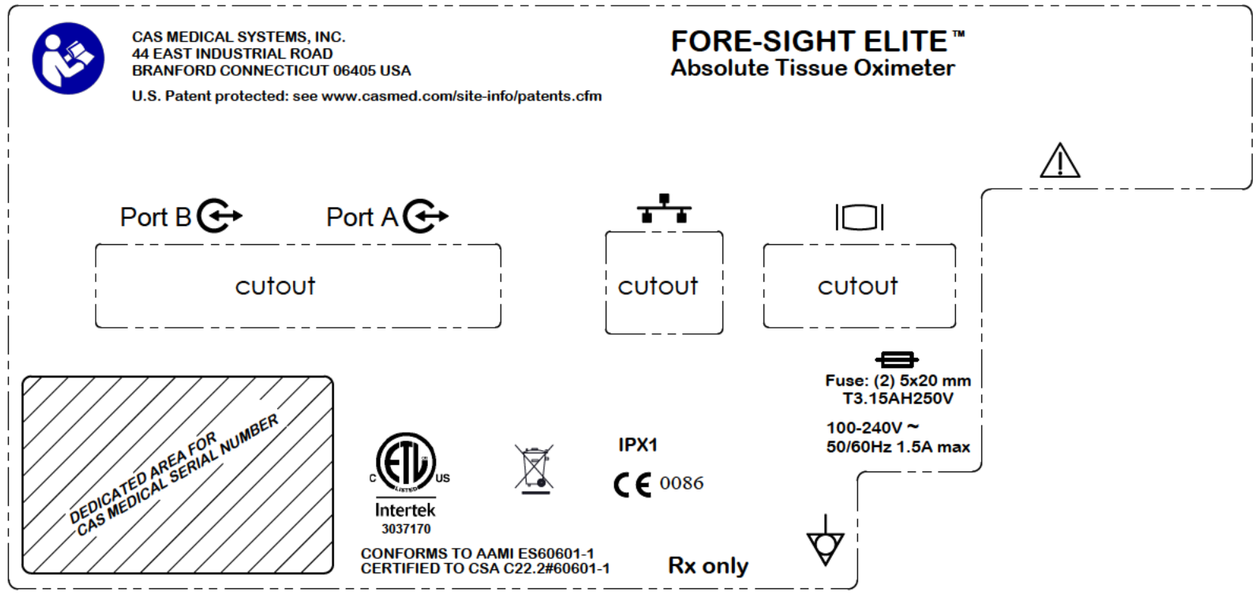
TITLE: **GEMINI REAR PANEL LABEL**

SIZE	DWG. NO.	REV
B	21-01-1978	02

SCALE: 1:1 | DO NOT SCALE DRAWING | SHEET 1 OF 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015



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—	FS–ELITE
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	±	N/A
2 PLACE DECIMALS	±	.01
3 PLACE DECIMALS	±	.005
ANGLES	±	1°0'

DRAWN	DATE
CHECKED	DATE
ENGINEER	DATE

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH

CASMED® FOR WHAT'S VITAL

TITLE: **GEMINI REAR PANEL LABEL**

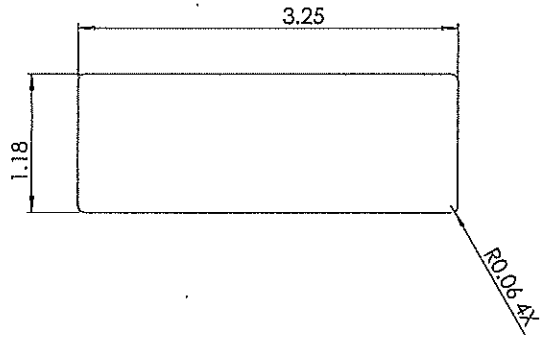
SIZE	DWG. NO.	REV
B	21-01-1978	02

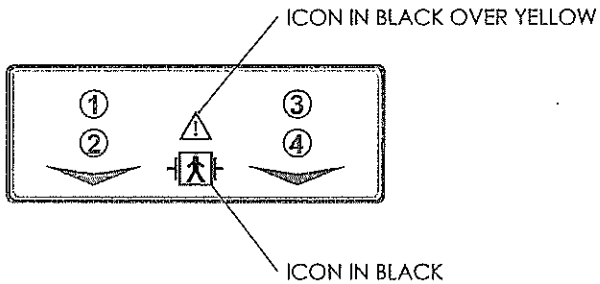
SCALE: 1:1 | DO NOT SCALE DRAWING | SHEET 2 OF 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	BY	DATE	APPROVED
01	10437	INITIAL RELEASE ADDS CAUTION ICON, DEFIB.-PROOF ICON WAS IN COOL GREY 11U			





NOTES:

1. MATERIAL: AUTOTEX V-150, 6 MILS TEXTURED, VELVET POLYESTER
2. ADHESIVE WITH BACKING 3M 468MP
3. GRAPHIC COLORS:
   BACKGROUND OPAQUE PMS WHITE
   GRAPHICS BLACK, YELLOW, PMS GREEN 368U, & PMS COOL GREY 11U

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NEXT ASSY	USED ON
—	

APPLICATION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	±	N/A
2 PLACE DECIMALS	±	.01
3 PLACE DECIMALS	±	.005
ANGLES	±	1°0'

DRAWN Michael Chenoli DATE 10-5-12
CHECKED [illegible] DATE 10/5/12
ENGINEER Michael Chenoli DATE 10-5-12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL | FINISH

CASMED® FOR WHAT'S VITAL

TITLE: GEMINI PATIENT CONN LABEL

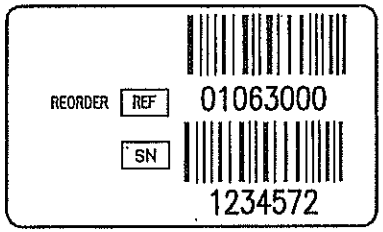
SIZE	DWG. NO.	REV
B	21-01-1979	01

SCALE: 1:1 | DO NOT SCALE DRAWING | SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE		11/12	HMT
01	10479	ADD PN BAR CODE		4/13	4/10/13



EXAMPLE ONLY

NOTES:

1. MATERIAL: METALIZED POLYESTER, 1.2" x 2.0"
2. PRINT COLOR: Black using 21-01-1814 Ribbon
3. ARTWORK: 21-01-2017.btw
4. Make labels using BarTender Software and ZEBRA printer
5. Annotate label if required

Dwg Filename: 21012017-R01

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01-06-3000	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN	MARK MANCINI	DATE	10/11/12
CHECKED	MARK MANCINI	DATE	10/11/12
ENGINEER	HARRY TRIEBEL	DATE	10/15/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTES	SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE: FS ELITE US 01-06-3000 SN Label

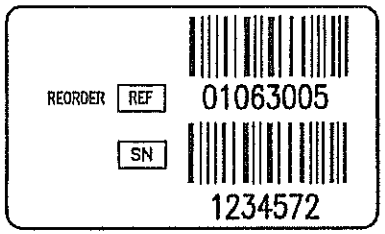
SIZE	DWG NUMBER	REV
A	21-01-2017	01

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE		11/12	HMT
01	10479	ADD PN BAR CODE		4/13	4/10/13



EXAMPLE ONLY

NOTES:

1. MATERIAL: METALIZED POLYESTER, 1.2" x 2.0"
2. PRINT COLOR: Black using 21-01-1814 Ribbon
3. ARTWORK: 21-01-2018.btw
4. Make labels using BarTender Software and ZEBRA printer
5. Annotate label if required

Dwg Filename: 21012018-R01

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01-06-3005	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN	MARK MANCINI	DATE	10/11/12
CHECKED	MARK MANCINI	DATE	10/11/12
ENGINEER	HARRY TRIEBEL	DATE	10/15/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTES	SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE: FS ELITE OUS 01-06-3005 SN Label

SIZE	DWG NUMBER	REV
A	21-01-2018	01

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE			

MANUFACTURED BY: CAS MEDICAL SYSTEMS, INC.
44 EAST INDUSTRIAL ROAD
BRANFORD, CT 06405 USA
(800) 227-4414 (203) 488-6056

REORDER REF 01-06-3000

FORE-SIGHT ELITE
TISSUE OXIMETER - US

CONTENTS	QUANTITY
MONITOR	1 EA.
ACCESSORY KIT	1 EA.

CE 0086

NOTES:

MATERIAL: Direct Thermal Label
Radist 4x3 Perf (179)

PRINT COLOR: BLACK

ARTWORK: 21-01-1981.btw

Make labels using BarTender Software and ZEBRA printer

Annotate label if required

Dwg Filename: 21011981-R00

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01-06-3000	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± 1/16
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN DATE 10/12/12
CHECKED DATE 10/12/12
ENGINEER DATE 10/15/12

DO NOT SCALE - WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTES
FINISH: SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE: FS ELITE US 01-06-3000 Contents Label

SIZE	DWG NUMBER	REV
A	21-01-1981	00

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE			

MANUFACTURED BY:
CAS MEDICAL SYSTEMS, INC.
44 EAST INDUSTRIAL ROAD
BRANFORD, CT 06405 USA
(800) 227-4414 (203) 488-6056

REORDER REF 01-06-3005

FORE-SIGHT ELITE
TISSUE OXIMETER – OUS

CONTENTS	QUANTITY
MONITOR	1 EA.
ACCESSORY KIT	1 EA.

CE 0086

NOTES:

MATERIAL: Direct Thermal Label
Radist 4x3 Perf (179)

PRINT COLOR: BLACK

ARTWORK: 21-01-2020.btw

Make labels using BarTender Software and ZEBRA printer

Annotate label if required

Dwg Filename: 21012020-R00

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NEXT ASSY	USED ON
01-06-3005	FS

APPLICATION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± 1/16
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN DATE 10/12/12
CHECKED DATE 10/12/12
ENGINEER DATE 10/12/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTES
FINISH: SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE: FS ELITE OUS 01-06-3005 Contents Label

SIZE: A | DWG NUMBER: 21-01-2020 | REV: 00

SCALE: 1:1 | SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE			

MANUFACTURED BY: CAS MEDICAL SYSTEMS, INC.
44 EAST INDUSTRIAL ROAD
BRANFORD, CT 06405 USA
(800) 227-4414 (203) 488-6056

REORDER REF 01-06-3014

FORE-SIGHT ELITE BATTERY PACK

CONTENTS	QUANTITY
BATTERY	1 EA.

CE 0086

NOTES:

MATERIAL: Direct Thermal Label
Radist 4x3 Perf (179)

PRINT COLOR: BLACK

ARTWORK: 21-01-1980.btw

Make labels using BarTender Software and ZEBRA printer

Annotate label if required

Dwg Filename: 21011980-R00

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01-06-3000	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± 1/16
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN DATE 10/12/12
CHECKED DATE 10/12/12
ENGINEER DATE 10/12/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTES
FINISH: SEE NOTES

CASMED® FOR WHAT'S VITAL

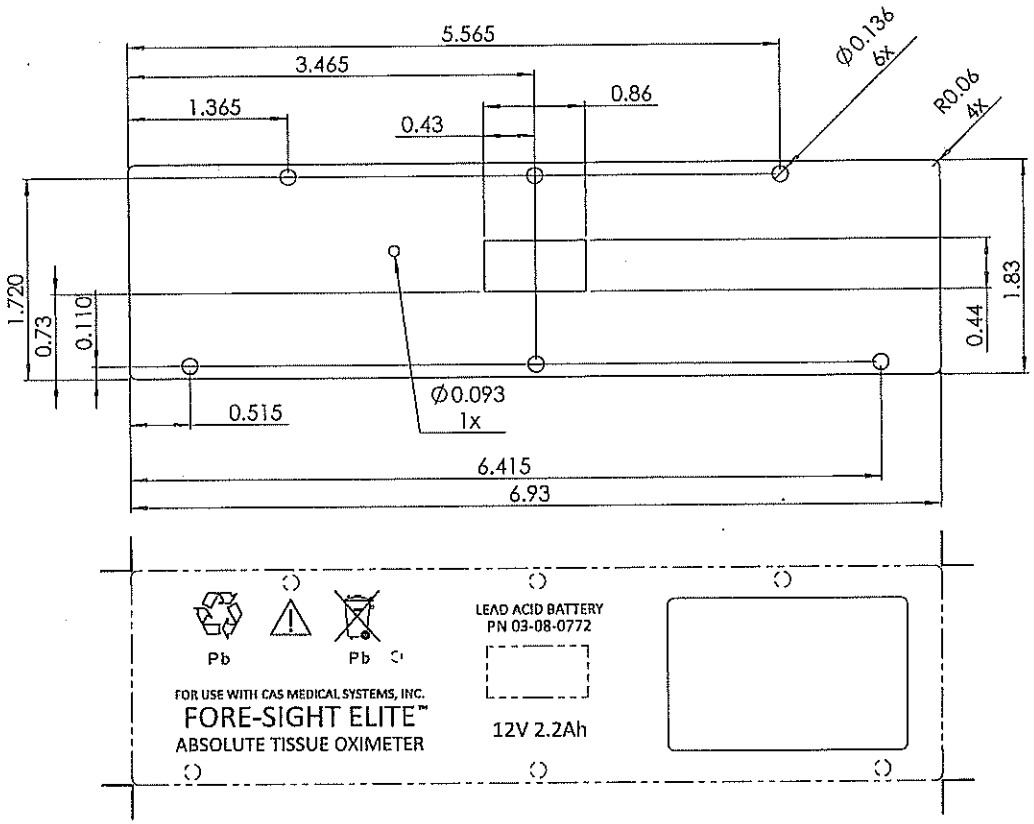
TITLE: FORE-SIGHT ELITE Battery Contents Label

SIZE	DWG NUMBER	REV
A	21-01-1980	00

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015



NOTES:

1. MATERIAL: AUTOTEX V-150, 6 MILS TEXTURED, VELVET POLYESTER
2. ADHESIVE WITH BACKING 3M 468MP
3. GRAPHIC COLORS:
   BACKGROUND OPAQUE PMS WHITE
   GRAPHICS IN PMS COOL GREY 11U

REV	ECN #	DESCRIPTION OF CHANGE	BY	DATE	APPROVED
00	10425	INITIAL RELEASE. WAS REV XD			

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NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	±	N/A
2 PLACE DECIMALS	±	.01
3 PLACE DECIMALS	±	.005
ANGLES	±	1°0'

DRAWN MGC DATE 9/4/2012
CHECKED DATE 9/4/2012
ENGINEER DATE 9/4/2012

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL | FINISH

CASMED. FOR WHAT'S VITAL

TITLE: GEMINI BATTERY LABEL

SIZE	DWG. NO.	REV
B	21-01-1982	00

SCALE: 1:1 | DO NOT SCALE DRAWING | SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE			
01	10517	ADD BATTERY MFG DATE TO LABEL		4/13	4/4/13

BATTERY–PACK MFG DATE XX/XX/XX
(mm/dd/yy)

WARNING – Use of unapproved batteries will invalidate the product's warranty and may result in serious safety consequences for the patient and user

BATTERY MFG DATE XX/XX/XX
(mm/dd/yy)

NOTES:

1. MATERIAL: 8200S METALIZED POLYESTER
   44A–UN1978 Cils International, 1.2" x 2.0"
2. PRINT COLOR: Black using 21–01–1814 Ribbon
3. ARTWORK: 21–01–2003.btw
4. Make labels using BarTender Software and ZEBRA printer
5. Annotate label if required

Dwg Filename: 21012003–R01

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03–08–0772	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN	M.A. Mancini	DATE	10/11/12
CHECKED	M.A. Mancini	DATE	10/11/12
ENGINEER	H. Triebel	DATE	10/12/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTES	SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE
FS ELITE Battery Pack Mfg Label

SIZE	DWG NUMBER	REV
A	21–01–2003	01

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Large Sensor - Directions for Use

Warnings

Assess the Sensor site at least every 8 hours, or more often as required by the institution's protocol.
Remove Sensor if the circulatory condition or skin integrity has deteriorated.
Do not lay patient on Sensor or cable.
Do not attach Sensor to skin with unapproved devices, such as headbands, tapes, hats, etc.
Do not place Sensor or accessories over eyes, nose, or mouth.
Do not cut the Sensor. Cutting the Sensor will result in risk of injury to the patient.
Do not use in an MRI environment.

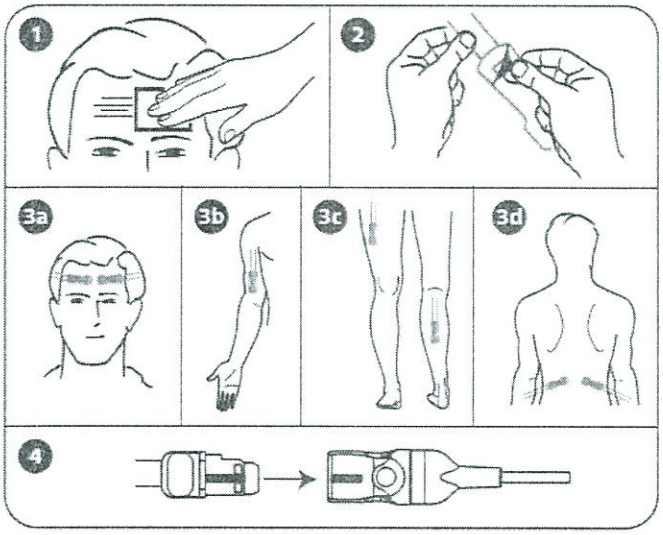
Cautions

Avoid positioning Sensor over hair or air sinus.
Avoid attaching Sensor to sites with excess adipose, ascites, or edema.
The materials used in the manufacture of the Sensor were not designed for reuse. Reuse may cause the Sensor not to perform as intended.

Instructions

1. Remove the Sensor from the package. Carefully inspect the Sensor for damage. Discard and replace Sensor if damage is found.
2. Select Sensor location on the monitor and patient.
   - Cerebral Use: Select the site on the forehead above the eyebrow and just below the hairline where the Sensors will be linearly aligned.
   - Somatic Use: Select the site that provides the ideal access to the desire skeletal muscle tissue (over biceps, brachioradialis, deltoid, quadriceps, tibialis, soleus, external oblique or latissimus dorsi, below the rib cage).
3. Clean and dry Sensor site. (1)
4. Remove white backing from the Sensor. (2)
5. Apply Sensor to patient. (3a,3b,3c,3d)
6. Insert the connector straight into the Preamp Sensor connector until it snaps into place. (4)
7. For further instructions on how to begin monitoring, consult the User Manual.

For use with FORE-SIGHT ELITE Absolute Tissue Oximeter. Refer to FORE-SIGHT ELITE User Manual for additional instructions



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

PRINTER NOTES:
Purple, orange and yellow keylines
DO NOT PRINT

PMS 368C

FORE-SIGHT ELITE™

Absolute Tissue Oximetry

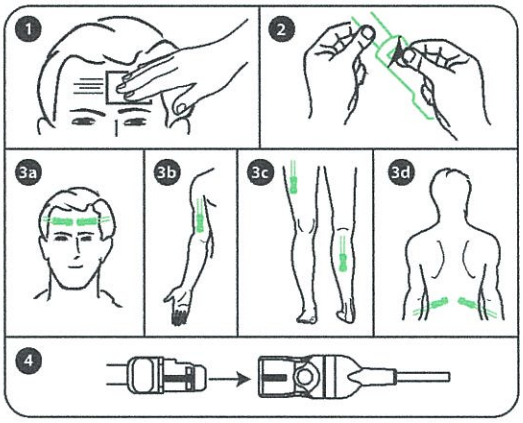
LARGE SENSOR

x1

REF 01-07-2103

≥ 40 kg

SP: Sensor Grande
FR: Capteur Grand
PT: Sensor Grande
IT: Sensore Grande
TR: Büyük Sensör
NL: Grote Sensor
DE: Großer Sensor
RU: Большой Сенсор
DA: Stor Sensor
EL: Μεγάλου Μεγέθους
PL: Duży Czujnik
FI: Suuri Anturi
NO: Stor Sensor
CS: Velký snímač
SV: Stor Sensor
SK: Návod na použitie
HU: Kis méretű érzékelő
AR: مستشعرات كبيرة
CN: 大号探头
JP: 大型センサー



Rx only NON STERILE 50°F 10°C 90°F 32°C CE 0086

PVC Latex

Notice: This kit is sold under the following U.S. Patents and foreign equivalents for single patient use only: 6,456,862; 7,047,054; 7,072,701; 7,313,427. U.S. Patents Pending.

(01) 1 0609538 72103 5

CASMED®
44 East Industrial Road,
Branford, CT 06405 USA
www.casmed.com
800.227.4414

05-02-0188 REV03
04-02-0194

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

FORE-SIGHT ELITE™

Absolute Tissue Oximetry

x20

LARGE SENSORS

REF 01-07-2103

≥ 40 kg

SP: Sensor Grande	NL: Grote Sensor	PL: Duży Czujnik	SK: Návod na použitie
FR: Capteur Grand	DE: Großer Sensor	FI: Suuri Anturi	HU: Kis méretű érzékelő
PT: Sensor Grande	RU: Большой Сенсор	NO: Stor Sensor	AR: مستشعرات كبيرة
IT: Sensore Grande	DA: Stor Sensor	CS: Velký snímač	CN: 大号探头
TR: Büyük Sensör	EL: Μεγάλου Μεγέθους	SV: Stor Sensor	JP: 大型センサー

EC REP

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11 rue E. Zola 38100
Grenoble. France

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Branford, CT 06405 USA
www.casmed.com
800.227.4414

05-02-0190 REV02
21-01-2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

MW P/N: LB1059

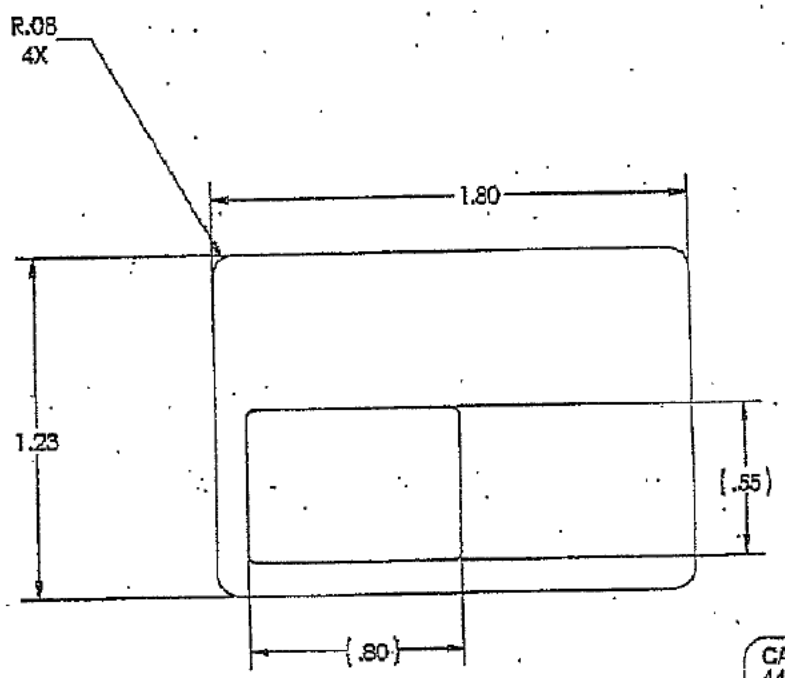
PART NAME: LABEL REV: B

DATE INITIATED: 7/3/12 BY: H. SCHNOBRICH CHK BY: BILL WHELAN

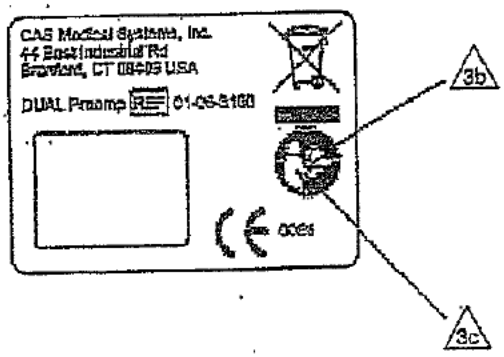
DESCRIPTION: DUAL PREAMP BTM LABEL

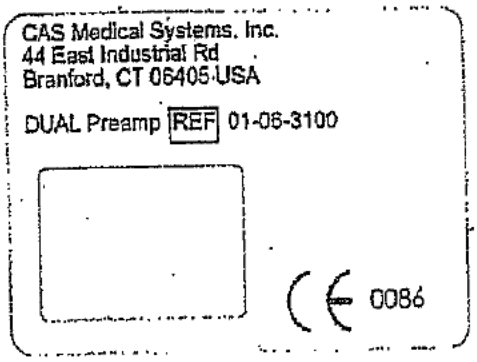
M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
ST.PAUL STAMP WORKS	M	MINNE065-33047-2



9 of 25





NOTES:

1. MATERIAL: .002" MATTE SILVER MYLAR
2. ADHESIVE: .001" ACRYLIC FLEXCON V-23
3. COLOR:
   a. TEXT BLACK
   b. BACKGROUND, "INST. FOR USE" SYMBOL (ISO-7010-M002): BLUE, PMS 287
   c. ICON, "INST. FOR USE" SYMBOL: WHITE

REV	DATE	INITIALS	DESCRIPTION
B	10/17/12	BW/JS	SEE ECN #2135
A	7/27/12	BN	RELEASED

REVISIONS

1 OF 1

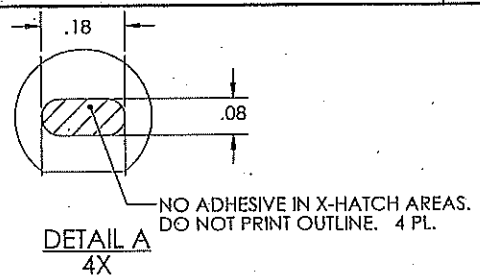
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

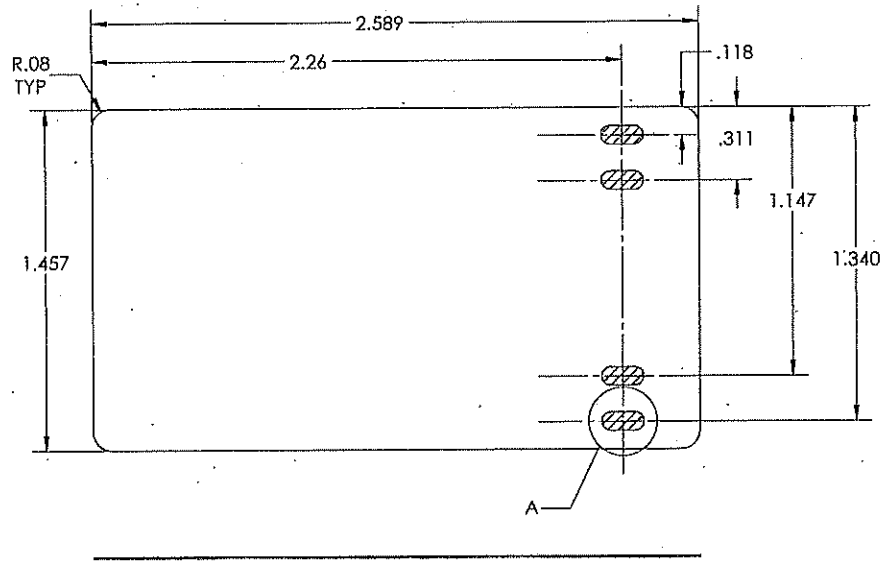
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

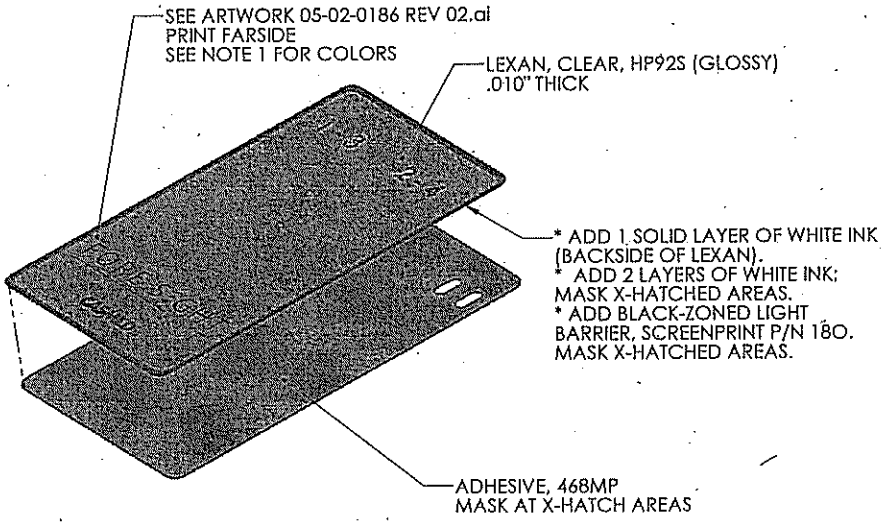
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

REVISIONS

REV.	ECN #	DESCRIPTION	DRAFTER	DATE	APPROVED
00	10408	NEW RELEASE			
01	10429	CHANGE ARTWORK TO MOVE CHANNEL DESIGNATIONS; REMOVE 'NO BORDER AROUND WINDOWS' NOTE			
02	10515	CHANGE SEQUENCE OF NUMBERS. CHANGE ARTWORK AND CONSTRUCTION TO IMPROVE AESTHETICS; ELIMINATE GREEN BORDER	RA	4/10/13	







NOTES:

1. GRAPHICS COLORS:
   - BACKGROUND COLOR: OPAQUE WHITE.
   - NUMBERS: BLACK
   - GREEN DOTS AND 'ELITE': PMS 368 U
   - RED 'CASMED' LOGO: PMS 193 U
   - OTHER TEXT AND BORDER: PMS COOL GREY 11U
2. FINAL PRODUCT TO BE RoHS COMPLIANT.
3. ARTWORK REGISTRATION TO LABEL: +/- .015"

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NEXT ASSY	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .010
ANGLES	± 1°0'

DRAWN	RABRAMS	DATE	09/30/11
CHECKED	K.DUFFY	DATE	6/15/12
ENGINEER	RABRAMS	DATE	6/15/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTES	SEE NOTES

CASMED® FOR WHAT'S VITAL

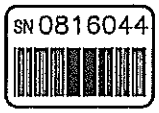
TITLE PREAMP. TOP LABEL WITH DEADFRONT

SIZE	DWG NUMBER	REV
B	21-01-2008	02

SCALE 4:1 SHEET 1 OF 1

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	8137	NEW RELEASE			
01	9337	ADDITION OF BARCODE TO LABEL	LD	11/14/08	[illegible]



LASER PRINTER
(EXAMPLE ONLY)

NOTES:

1. MATERIAL: 1/2 x 3/4" METALIZED POLYESTER LASER LABEL
   # AL4-9200-5
2. PRINT COLOR: BLACK
3. ARTWORK: 21-01-1801.btw
4. FOLLOW LABEL PROCEDURE WP2054
   * FOUND IN "BARTENDER" IN THE FORE-SIGHT FOLDER
   * LABEL IS PRINTED ON A LASER PRINTER ON MATERIAL SPECIFIED ABOVE.
   * 8 DIGIT SERIAL NUMBER USED IN FORMAT: YYMMXXXX WHERE "XXXX" IS A SEQUENTIAL NUMBER.
   * BAR CODE REQUIREMENTS

Dwg Filename: 21011801-R01

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03-08-0695F	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN	Donna LeMontague	DATE	01/22/07
CHECKED	Ron Jeffrey	DATE	01/26/07
ENGINEER	Gus Lopez	DATE	01/26/07

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTE #1	N/A

CASMED® FOR WHAT'S VITAL

TITLE
PREAMP BOX SERIAL NUMBER

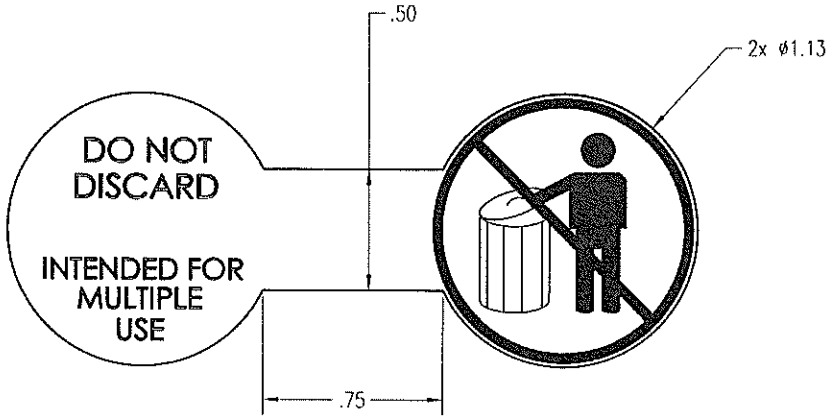
SIZE	DWG NUMBER	REV
A	21-01-1801	01

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10050	NEW RELEASE			



NOTES:
1.MATERIAL:3M 7908 LABEL MATERIAL
2.COLORS:TEXT AND GRAPHICS–BLACK
BACKGROUND–PMS 368 GREEN

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NEXT ASSY	USED ON
03-08-0760CF	FS
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN R.ABRAMS DATE 07/20/2010
CHECKED DATE 7/30/10
ENGINEER DATE 7/30/10

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTE
FINISH: N/A

CASMED® FOR WHAT'S VITAL

TITLE: NEUROSAT DO NOT DISCARD LABEL
MONITOR CABLE LABEL

SIZE: B | DWG NUMBER: 21-01-1966 | REV: 00
SCALE: 1:1 | SHEET 1 OF 1

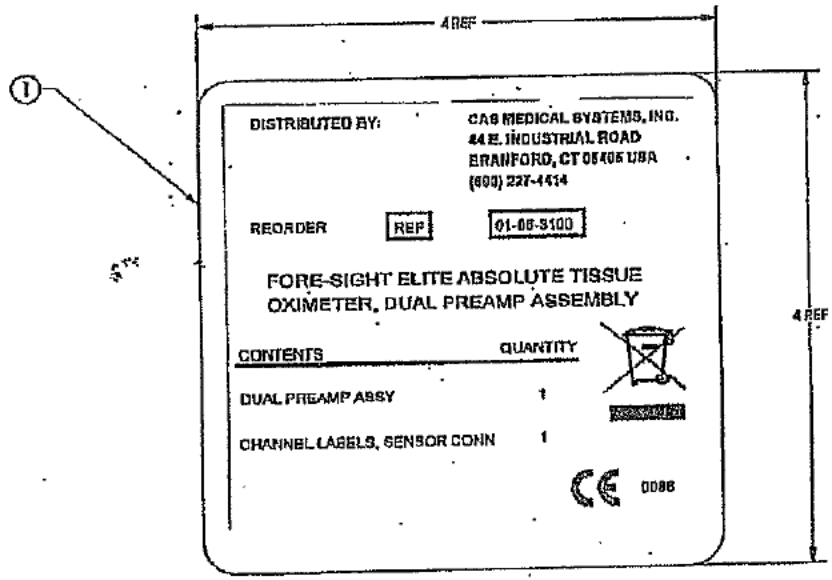
Dwg Filename: 21011966-R00

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REVISIONS			
REV	DATE	INITIALS	DESCRIPTION
A	10/9/12	SS	RELEASED FOR PRODUCTION

PARTS LIST						
ITEM	QTY	DESCRIPTION	SERIES	PART NO	COLOR	MATERIAL
1	1	BLANK LABEL		LB471	WHITE	



NOTES:

1) BLACK TEXT ON WHITE BACKGROUND

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PROJECTION

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO

DRAWN BY B.WHELAN	DATE 10/1/12	[redacted] (b)(4)	
APPROVED BY S. Sjoquist	DATE 10/9/12	TITLE LABEL, BAG FOR C726	SCALE N/A REV A
MANUFACTURING	DATE 10/9/12		
QUALITY	DATE 10/9/12	CASMED	SHEET 1 OF 1 DWG NO LB1076

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15. Sterilization and Shelf Life

No part of the FORE-SIGHT Elite™ Absolute Tissue Oximeter system or its accessories is sterilized.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

16. Biocompatibility

SENSOR BIOCOMPATIBILITY DATA

Note: Conditions of contact per ISO 10993-1: Intact skin for a prolonged period.

All sensor assemblies have been used on subjects during clinical trials. There are no reported incidents of adverse reaction. The information below represents the large Elite sensor.

Sensor Component	Testing	Pass / Fail	Documentation Enclosed & Comment
(b)(4) [redacted]	- CAS arranged lab testing May 2012	Pass	Cytotoxicity Report # SDWH-2012-20304; Skin Sensitization Report # SDWH-2012-20305 and 6; Skin Irritation Report # SDWH-2012-20307.
Sensor bottom surface foam adhesive	Complete skin safety testing done by adhesive manufacturer 3M	Pass	(b)(4) [redacted] In addition, this material has been used on CAS predicate devices for 6-years without incident.
(b)(4) [redacted]	Manufacturer Lab testing and CASMED Lab testing for Cytotoxicity	Pass	(b)(4) [redacted] In addition, this exact material has been used on CAS predicate devices for 6-years without incident.
Sensor top cover (b)(4) [redacted]	Complete skin safety testing done by vendor (b)(4) [redacted]	Pass	(b)(4) [redacted] Technical Reference Guide. Pg. 14 Biocompatibility.
(b)(4) [redacted]	Complete skin safety testing done by (b)(4) [redacted] (b)(4) [redacted]	Pass	(b)(4) [redacted] – Biocompatibility Data Summary.
Molded connector housing – (b)(4) [redacted] (b)(4) [redacted]	Complete skin safety testing done by vendor (b) [redacted]	Pass	Sabic Biocompatibility Statement and Test Reports
Sensor Gasket	Complete skin safety testing done by foam manufacturer 3M	Pass	(b)(4) [redacted] (b)(4) [redacted] Biocompatibility Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

证书编号：2010100305S

TESTING
CNAS L2954

Testing Center of Sanitation & Environment technic Institute, Soochow University, Test Report

Report Number: SDWH-2012-20304

Sample Name: (b)(4) [redacted]

Test Performed: Cytotoxicity Test

Sample Supplier: (b)(4) [redacted]

Testing Center of Sanitation & Environment Technic Institute, Soochow University
Add: No.199 Ren'ai Road, Suzhou Industrial Park, China Tel: 0512-65880038
Fax: 0512-65880038 PC: 215123

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TABLE OF CONTENTS

Page number

Title Page....1

Table of Contents....2

Supplementary Explanation....3

Signature Page....4

1.0 Summary....5

2.0 Introduction....5

3.0 Test System and Test System Management....5

4.0 Justification for Selection of Test System....5

5.0 Materials....5

6.0 Test Method....6

7.0 Results....7

8.0 Conclusion....9

9.0 Record Storage....9

10.0 Confidentiality Agreement....9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SUPPLEMENTARY EXPLANATION

1. If the analysis report requires modification please raise the matter within 15 days of receiving the report, otherwise the request for modification will not be accepted.
2. The test report is void without test center's seal.
3. The test report is only valid when signed by the persons who edited, checked and approved it.
4. Any erasure renders the report null and void.
5. The test result is only valid for the sample provided.
6. The copyright of analysis report is reserved by the analysis center. If a copy is required, please get permission from the center first. Only complete copies of the test report may be made.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Testing Center of Sanitation & Environment Technic Institute

Soochow University

Test Report

Sample name	(b)(4) [redacted]
Sample supplier	[redacted]
Model No./Size	Not Supplied
Lot No	Not Supplied
Part Number	P/N：52-0560
The information above is provided by sample supplier.	
Test Performed	Cytotoxicity Test
Receiving Date	Feb 10, 2012
Technical Initiation Date	Feb 14, 2012
Technical Completion Date	Feb 17, 2012
Sample Image	[redacted]

Edited by: Gu Yunlan

Checked by: [illegible]

Approved by: Zhang Tongcheng

Testing Center of Sanitation & Environment technic Institute, Soochow University

Date: [illegible] 2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

1.0 Summary

The test article (b)(4) [redacted] was evaluated in a cytotoxicity test in accordance with the ISO 10993-5:2009: Tests for In Vitro Cytotoxicity The testing test article extract was added to growth media containing L-929 cells, and then incubated in 96 well plates for 24h at 37℃ in 5% CO_2. Intracytoplasmic granulation and cell lysis were observed in the test article extract-treated cells. The MTT method was used to determine the potential cytotoxicity. The results showed that the cytotoxicity ratio of the 100 % extract of the test article extract was 88.9%, the 50 % extract of the test article extract was 90.5% the negative control was 96.1%, and the positive control cytotoxicity ratio was 1.9%.This meant that the cytotoxicity test was valid and the test article extract had no toxicity to L-929 cells in this study.

2.0 Introduction

The test article was evaluated for cytotoxicity in accordance with ISO 10993-5:2009: Tests for In vitro Cytotoxicity. The purpose of this study was to determine the potential cytotoxicity of the test article extract to L-929 cells.

3.0 Test System and Test System Management

L-929 mouse fibroblast cells, (American Type Culture Collection CCLI (NCTC clone 929), were obtained from American. The cells were grown in Minimal Essential Media (MEM) with 10% fetal bovine serum (10% FBS). Cells were seeded into the 96-well cell culture plates, and incubated at 37℃ in a humidified incubator with 5% CO_2 to obtain a confluent monolayer of cells prior to use. Aseptic procedures were used in the handling of cell cultures.
Personnel: Associates involved were appropriately qualified and trained.

4.0 Justification for Selection of Test System and Route of Administration

Mammalian cell culture monolayer, L-929 mouse fibroblast cells (American Type Culture Collection CCLI (NCTC clone 929), were used. In vitro mammalian cell culture studies have been used to historically evaluate the cytotoxicity of biomaterials of medical device.
The test article was extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system. This was the optimal route of administration available in this test system as recommended in the ISO 10993-5 guidelines.

5.0 Materials

5.1 Control Articles
5.1.1 Negative Control:
Name: High density polyethylene
Lot No: H0F046
Physical State: Solid

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Color: White
Stability: Stable at room temperature
Storage Conditions: Room temperature

5.1.2 Positive Control:
Name: MEM medium, with addition 10% FBS and 0.5 % phenol (Lot No: 862839)
Physical State: Liquid
Color: Red/Pink
Stability: Stable
Storage Conditions: 4 ± 2 ℃

5.1.3 Blank Control:
Name: MEM medium (Lot No: 862839), with addition 10% FBS
Physical State: Liquid
Color: Red/Pink
Stability: Stable
Storage Conditions: 4 ± 2 ℃

5.2 Equipments
Autoclaves (SDWH-327)
CO_2 Incubator (SDWH-021)
Inverted microscope (SDWH-037)
Super clean working desk (SDWH-047)
Refrigerator (SDWH-448)
Power Wave XS Microplate Reader (SDWH-312).

5.3 Reagents
MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide) (Lot No: 0793)
FBS (Lot No: 8143029)
Trypsinase (Lot No: 774748)
Penicilline, Streptomycin sulfate (Lot No: 773135)
MEM (Lot No: 862839)
99.9%Isoopropanol (Lot No: T20101123).

5.4 Cell Strain
L-929 mouse fibroblast cells, American Type Culture Collection CCLI (NCTC clone 929).. L929 mammalian fibroblast cells are storaged at -80℃ by SDWH.

6.0 Test Method

6.1 The test article Extracts Preparation
The sterilized test article was put into a culture flask, and MEM medium (10%FBS) was then added, finally the flask was sealed, and the sample was extracted at 37℃ and 5% CO_2 for 24h to obtain the

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sample extract. The blank control, negative control and positive control were prepared simultaneously by the same extraction method.

Extraction ratio	Actual sampling	Extraction conditions	The pH value of the final extract	Whether the extract is clear or not
$6cm^2$: 1ml	$42cm^2$: 7.0ml	37℃, 5% CO_2,24 h	7.0	Clear

6.2 Control Preparation

Negative control: High density polyethylene +MEM medium, with10% FBS and 37℃,5% CO_2 for 24 hours.

Positive control: MEM medium, with 10%FBS and 0.5 % phenol and 37℃,5% CO_2 for 24 hours.

Blank control: MEM medium, with 10% FBS and 37℃,5% CO_2 for 24 hours.

6.3 Cell Culture

L929 cells were cultured in MEM medium, supplemented with 10% FBS at 37℃ in a humidified atmosphere of 5% CO_2. L929 cells were digested by using 0.5% trypsin containing EDTA.The single-cell suspension was diluted to 1×10^5 cells/ml. The suspended cells were dispensed at 100μl per well in 96-well plates. After the cells grew to form a monolayer, the original culture medium was discarded, The 96 well plates were then treated with 100μl of the test article extract. Control wells were treated with , positive control solution and negative control solution. Five replicates of each test and control article were tested.

6.4 Cell Morphological Observation and Evaluation of Cytotoxicity

The test article and control article treated plates were incubated for 24 hours at 37℃ in a humidified atmosphere of 5% CO_2. Cell morphology was evaluated to verify that the monolayer was satisfactory. A 50μl aliquot of MTT (1mg/mL) was added to each well. The cells were incubated for 2 hours at 37℃ in a humidified atmosphere of 5% CO_2. The liquid in each well was tipped out and 100 μl 99.9% isopropanol was added to each well to suspend the cell layer.

Test article extract suspensions were evaluated with a dual-wavelength spectrophotometer, with the measurement wavelength at 570 nm and reference wavelength at 650 nm. The blank controls, negative controls and positive controls were tested as described in the above method.

The cell cytotoxicity ratio of the negative control group, positive control group and sample group were determined by the following formula:

The cell cytotoxicity ratio=[$\bar{O}D570$-$\bar{O}D650$] of sample group(or [$\bar{O}D570$-$\bar{O}D650$] of positive control group)/ [$\bar{O}D570$-$\bar{O}D650$] of blank control group×100%.

7.0 Results

The observation of the morphology in this experiment are showed Table 1.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Table 1 Observation of the Cell morphology

Group	Before inoculation	Before exposed to the test group in 96-well plates	24h after exposed to the test group in 96-well plates
blank	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
negative control			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
positive control			Nearly complete or complete destruction of the cell layers.
100% test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
75% test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
50% test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
25% test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.

Results in this experiment are showed Table 2.

Table2 : Results of the Cell Vitality

Group	$\bar{OD}$570±SD	Viability.%
blank	0.589±0.013	100%
negative control	0.575±0.009	96.1%
positive control	0.011±0.001	1.9%
100% test article extract	0.531±0.007	88.9%
75% test article extract	0.536±0.009	89.6%
50% test article extract	0.542±0.014	90.6%
25% test article extract	0.562±0.016	93.9%

According to ISO 10993-5:2009, if viability is reduced to < 70 % of the blank, it has a cytotoxic potential. The 50 % extract of the test sample should have at least the same or a higher viability than

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the 100 % extract, otherwise the test should be repeated.
The test article extract was mixed a suspension of L-929 cells, and then incubated for 24 hours at 37℃ in a humidified atmosphere of 5% CO_2.The MTT method was used to measure the cytotoxicity ratio, and the result for the 100 % test article extract was 88.9%.

8.0 Conclusion

Under the conditions of this study, the results showed the test article extract had no toxicity to L-929 cells.

9.0 Record Storage

All raw data pertaining to this study and a copy of the final report are retained in designated SDWH archive.

10.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

证书编号：2010100305S

TESTING
CNAS L2954

Testing Center of Sanitation & Environment technic Institute, Soochow University, Test Report

Report Number: SDWH-2012-20305

Sample Name: (b)(4) [redacted]

Test performed: Skin Sensitization Test (the Guinea Pig Maximization Test)

Sample Supplier: (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TABLE OF CONTENTS

Page number

Title Page....1

Table of Contents....2

Supplementary Explanation....3

Signature Page....4

1.0 Summary....5

2.0 Purpose....5

3.0 Materials....5

4.0 Test System....6

5.0 Justification of Test System....6

6.0 Animal Management....6

7.0 Experimental Procedure....6

8.0 Results....8

9.0 Conclusion....8

10.0 Record Storage....9

11.0 Confidentiality Agreement....9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUPPLEMENTARY EXPLANATION

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4. Any erasure renders the report null and void.
5. The test result is only valid for the sample provided.
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Testing Center of Sanitation & Environment technic Institute

Soochow University

Test Report

Sample name	(b)(4) [redacted]
Sample supplier	[redacted]
Size	Not supplied
Lot No	Not supplied
Part Number	P/N: 52-0560
	The information above was provided by sample supplier.
Test performed	Skin Sensitization Test (the Guinea Pig Maximization Test)
Receiving Date	2012-02-10
Technical Initiation Date	2012-02-20
Technical Completion Date	2012-03-16
Sample Image	[redacted]

Edited by: _____

Checked by: _____

Approved by: Zhang Tongcheng

Testing Center of Sanitation & Environment technic Institute, Soochow University

Date: _____ 2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

1.0 Summary

A guinea pig maximization test (ISO 10993-10:2010) of sample (b)(4) [redacted] was conducted to evaluate the potential for delayed dermal contact sensitization. The method of Magusson and Kligman (1970) was adapted for 0.9% sodium chloride solution test article extract.

The extract of the test article was intradermally injected and occlusively patched to ten guinea pigs in an attempt to induce sensitization. Following a recovery period, the original ten test and five control animals received a challenge absorbent gauze patch (2.5 cm×2.5 cm) of the test article extract and the control vehicle. In addition the test article was applied to the same animals. All sites were scored at 24h and 48h after patch removal.

Under the conditions of this study, the test article extract and the test article showed no signification evidence of causing delayed dermal contact sensitization in the guinea pig.

2.0 Purpose

A guinea pig maximization test identified below was conducted to evaluate the potential to cause delayed dermal contact sensitization.

3.0 Materials

3.1 Sample and Control Preparation

For each phase of this test, a ratio according to the table below (test article to volume of vehicle) was used for the test extract. The test article was extracted in 0.9% sodium chloride.

Extraction ratio	Actual sampling	Extraction conditions	The pH value of the final extract	Whether the extract is clear or not
$6cm^2$: 1ml	$60cm^2$: 10ml	37 ℃,72 h	6.2	Clear

The vehicle (without the test article) was similarly prepared to serve as the control.

3.2 Equipments

Electric-heated thermostatic water bath (SDWH-418),Autoclave (SDWH-048),Balance (SDWH-306), Electronic scale (SDWH-442).

3.3 Regents

0.9% sodium chloride (SC) (Lot No: 111022 3-1)
Freund's Adjuvant,Complete liquid (Lot No: 021M8728)
10% sodium dodecyl sulfate (10%SDS) (Lot No: F20090922)

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4.0 Test System

Species: Healthy young adult albino guinea pigs of either sex form a single outbred strain, weighing 300g to 500g at the start of the test shall be used. If female animals are used, they shall be nulliparous and not pregnant.
Source: Provided by Wuxi Huishan Jiangnan Experimental Animal Center <Permit Code: SCXK (SU) 2009-0005>.
Acclimation Period: 7 days .
Number of Animals: 15.

5.0 Justification of Test System

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, 1-chloro-2,4-dinitrobenzene (DNCB) has been substantiated at SDWH with this method. The average dermal scoring for the Positive controls was 1.9, see SDWH-2011-22434, completed on Jan 6, 2012.

6.0 Animal Management

Husbandry: Refer to ISO 10993-2:2006.
Food: Animal foods were provided by Wuxi Huishan Jiangnan Experimental Animal Center.
Water: Drinking water met the sanitary standard.
Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date.
Environment: The room Temp will be monitored daily. The temperature will be controlled within 20-26℃. The room humidity will be controlled within 30%-70%.The light cycle is controlled for 12hours' light and 12hours' dark.
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.

7.0 Experimental Procedure

7.1 Intradermal induction phase I

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.
Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.
Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%) was injected into the control animals with an emulsion of the blank liquid with adjuvant.

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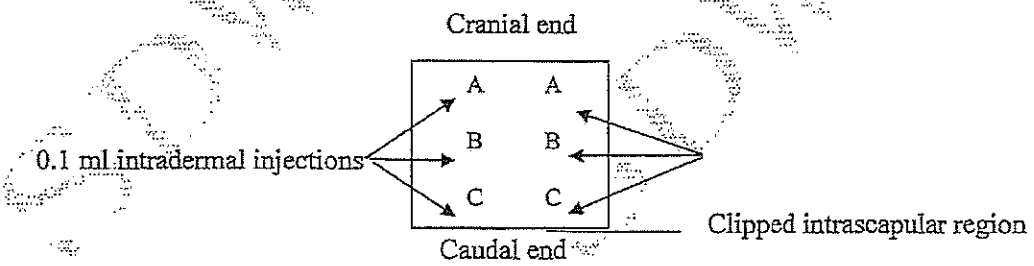

Figure 1 Location of intradermal injection sites

7.2 Topical induction phase Ⅱ

Seven days after completion of the intradermal induction phase, the test sample was administered by topical application to the intrascapular region of each animal, using a patch of area approximately 8cm^2 (filter paper or absorbent gauze), so as to cover the intradermal injection sites. The concentration selected in intradermal induction phase Ⅰ for Site B was used. The patches were secured with an occlusive dressing. The dressings and patches were removed after 48h.
The control animals were treated similarly, using the blank liquid alone.

7.3 Challenge phase

At 14 days after completion of the topical induction phase, all test and control animals were challenged with the test sample. The test sample and a vehicle control were administered by topical application to sites that were not treated during the induction stage, such as the upper flank of each animal, using appropriate patches soaked in the test sample at the concentration selected in the intradermal induction phase Ⅰ for site C. Dilutions of this concentration were also applied to other untreated sites in a similar manner. Occlusive dressings were used to secure areas treated. The dressings and patches were removed after 24h.

7.4 Observation of animal

The appearance of the challenge skin sites of the test and control animal were observed after 24h and 48h removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions.
The skin reactions for erythema and oedema were observed and graded according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval .It is highly recommended that reading be done without knowledge of the treatment, in order to minimize bias in the evaluation of the results.

7.5 Evaluation of results

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animal. If grades of 1 or greater are noted in control animal, then the reactions of test animal which exceed the most severe reaction in control animals are presumed to be due to sensitization. If the response is equivocal, re-challenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in the test and control animal.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

8.0 Results

Individual results of dermal scoring for the challenge appear in Table 2. Clinical Observations: All animals appeared clinically normal throughout the study.

Table 2 Guinea pig Sensitization Dermal Reactions – Challenge

Animal Number/ Group	Topical induction phase II		Hours following patch removal (h)		Weight (g)	
	Left	Right	24	48	Before injection	After experiment
1 Test	0	0	0	0	329	373
2 Test	0	0	0	0	318	384
3 Test	0	0	0	0	306	370
4 Test	0	0	0	0	322	377
5 Test	0	0	0	0	323	377
6 Test	0	0	0	0	315	381
7 Test	0	0	0	0	304	370
8 Test	0	0	0	0	327	382
9 Test	0	0	0	0	319	369
10Test	0	0	0	0	330	385
11Negative control	0	0	0	0	322	388
12Negative control	0	0	0	0	306	372
13Negative control	0	0	0	0	300	368
14Negative control	0	0	0	0	308	358
15Negative control	0	0	0	0	323	377
16 Positive control	3	3	2	2	304	369
17 Positive control	3	3	2	2	326	384
18 Positive control	3	3	2	2	311	372
19 Positive control	3	3	1	2	314	377
20 Positive control	3	3	2	2	303	365

Note: The data of positive control come from SDWH 2011-22434.

9.0 Conclusion

Under the conditions of this study, the test article extract and the test article showed no significant evidence of causing delayed dermal contact sensitization in the guinea pig.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

11.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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证书编号：2010100305S

TESTING
CNAS L2954

Testing Center of Sanitation & Environment technic Institute, Soochow University, Test Report

Report Number: SDWH-2012-20307

Sample Name: (b)(4) [redacted]

Test performed: Skin irritation Test

Sample Supplier: (b)(4) [redacted]

Testing Center of Sanitation & Environment technic Institute, Soochow University
Add: No.199 Ren'ai Road, Suzhou Industrial Park, China Tel: 0512-65880038
Fax: 0512-65880038 PC: 215123

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TABLE OF CONTENTS

Page number

Title Page....1

Table of Contents....2

Supplementary Explanation....3

Signature Page....4

1.0 Summary....5

2.0 Introduction....5

3.0 Test System....5

4.0 Justification of Test System....5

5.0 Animal Management....5

6.0 Experimental Procedure....6

7.0 Result....7

8.0 Conclusion....8

9.0 Record Storage....8

10.0 Confidentiality Agreement....8

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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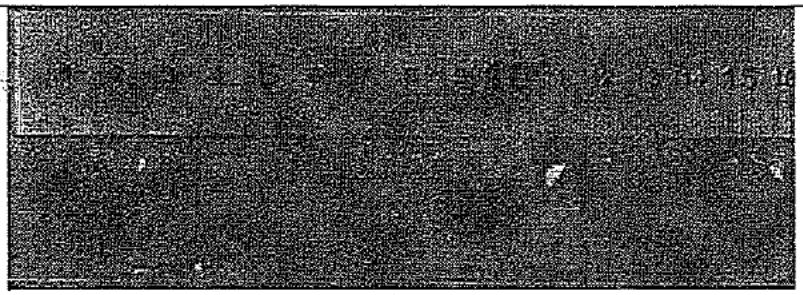
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Testing Center of Sanitation & Environment technic Institute
Soochow University
Test Report

Sample name	(b)(4) [redacted]
Sample supplier	[redacted]
Size	Not supplied
Lot No	Not supplied
Part Number	P/N: 52-0560
The information above was provided by sample supplier.	
Test performed	Skin irritation Test
Receiving Date	Feb 10, 2012
Technical Initiation Date	Feb 20, 2012
Technical Completion Date	Feb 26, 2012
Sample Image	

Edited by: Tang Yu.

Checked by: Pengfei

Approved by: Zhang Tongchao

Testing Center of Sanitation & Environment technic Institute, Soochow University

Date: 检测中心 2012

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1.0 Summary

The test article, (b)(4) [redacted] was evaluated for skin irritation in accordance with the ISO 10993-10:2010 Tests for irritation and skin sensitization. The skin responses on application sites in 1h, 24h, 48h and 72h respectively after removal the patches were observed and recorded. The tissue reaction was graded for erythema and oedema according to the classification system given in Table 1. According to what was observed, the response of skin on testing side does not exceed that on the control side. The primary irritation index for the test article was calculated to be 0 (The positive irritation index was 6.1; see SDWH-2012-20205, regent is 20% sodium dodecyl sulfate). The test result showed that the applied sample does not induce irritation to rabbit skin.

2.0 Introduction

The test article was evaluated for skin irritation in accordance with the guidelines of the ISO 10993-10:2010 Tests for irritation and skin sensitization. This study was to determine the potential skin irritation after the sample applied to the animal back.

3.0 Test System

Species: Healthy young adult albino rabbits of either sex form a single strain.
Breed: New Zealand white (single strain).
Source: Provided by Animal Center, SDWH <Permit Code: SYXK (SU) 2007-0035>.
Body Weight Range: Not less than 2 kg.
Age: Young adult.
Acclimation Period: 7 days.
Number of Animals: Three.

4.0 Justification of Test System

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current ISO 10993-10:2010 testing standards. The rabbit is widely used for this purpose and relative ranking of irritant scores can be determined.

5.0 Animal Management

Husbandry: Refer to ISO 10993-2:2006.
Food: Animal foods were provided by Wuxi Huishan Jiangnan Experimental Animal Center.
Water: Provided by Sanitary Standard for drinking water.
Housing: Animals were individually housed in stainless steel suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environment: The room Temp will be monitored daily. The temperature will be controlled within 20-26℃. The room humidity will be controlled within 30%-70%.The light cycle is controlled for

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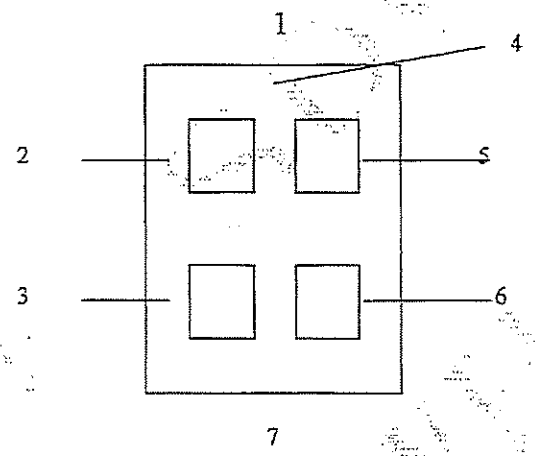
12hours' light and 12hours' dark.
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused, animals free from irritation or other dermatological lesions that could interfere with the test were selected.

6.0 Experimental Procedure

6.1 Sample and Control Preparation: Clip the test and control sample (gauze) into 2.5cm×2.5cm.

6.2 Use only animals with healthy intact skin. Fur is generally clipped within 24h of testing on the backs of the animals a sufficient distance on both sides of the spine for application and observation of all test sites(approximately 10×15cm)



1- Cranial end, 2- Test site, 3- Control sits, 4- Clipped dorsal region, 5- Control area, 6- Test area, 7- Caudal end

Figure1 Location of skin application sites

Apply the samples of the test material directly to the skin on each side of each rabbit as shown in Figure 1.Similarly, apply the control samples to each rabbit, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4h. At the end of the contact time, remove the dressing.

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 and Table 2 for each application site at each time interval. Record the appearance of each application site at 1h, 24h, 48h and 72h following removal of the patches. Use only 24h, 48h, and 72h observations for calculation. For each animal add together the primary irritation scores for the test material for both erythema and oedema at each time point and divide the total number of observations. Add together the irritation scores of all animals and divide by the total number of animals. This value is the cumulative irritation index.

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7.0 Results

According to what observed, the response of skin on testing side does not exceed that on the control side. Thus, it is identified as grade 0. See table 2.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Total possible score for irritation	8
Irritation Response Categories in the Rabbit	
Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

NOTE: Other adverse changes at the skin sites were recorded and are reported

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Table 2 Dermal Observations

Rabbit No.	Group		Interval (hours)			
			1	24	48	72
1	Test	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
2	Test	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
3	Test	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
4	Positive control	Erythema	2.0	3.0	3.0	3.0
		Oedema	2.0	4.0	4.0	2.0
5	Positive control	Erythema	2.0	3.0	3.0	3.0
		Oedema	2.0	4.0	3.0	2.0
6	Positive control	Erythema	2.0	3.5	3.0	3.0
		Oedema	2.0	3.5	3.0	2.0

Note: Positive control performed once every six months, the positive irritation index was 6.1; see SDWH-2012- 20205.

8.0 Conclusion

The test result shows that of the applied sample does not induce irritation to skin.

9.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

10.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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证书编号：2010100305S

TESTING
CNAS L2954

Testing Center of Sanitation & Environment technic Institute, Soochow University, Test Report

Report Number: SDWH-2012-20306

Sample Name: (b)(4) [redacted]

Test performed: Skin Sensitization Test (the Guinea Pig Maximization Test)

Sample Supplier: (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

TABLE OF CONTENTS

		Page number
Title Page		1
Table of Contents		2
Supplementary Explanation		3
Quality Assurance Statement		4
Verification of Study Process		5
Signature Page		6
1.0	Summary	7
2.0	Purpose	7
3.0	Materials	7
4.0	Test System	8
5.0	Justification of Test System	8
6.0	Animal Management	8
7.0	Experimental Procedure	8
8.0	Results	10
9.0	Conclusion	11
10.0	Record Storage	11
11.0	Confidentiality Agreement	11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUPPLEMENTARY EXPLANATION

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Testing Center of Sanitation & Environment technic Institute

Soochow University

Test Report

Sample name	(b)(4) [redacted]
Sample supplier	[redacted]
Size	Not supplied
Lot No	Not supplied
Part Number	P/N: 52-0560
	The information above was provided by sample supplier.
Test performed	Skin Sensitization Test (the Guinea Pig Maximization Test)
Receiving Date	2012-02-10
Technical Initiation Date	2012-02-20
Technical Completion Date	2012-03-16
Sample Image	[redacted]

Edited by: _____

Checked by: _____

Approved by: Zhang Tongcheng

Testing Center of Sanitation & Environment technic Institute, Soochow University

苏州大学卫生与环境技术研究所 检测中心

Date: Mar 9 2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.0 Summary

A guinea pig maximization test (ISO 10993-10:2010) of sample (b)(4) [redacted] was conducted to evaluate the potential for delayed dermal contact sensitization. The method of Magusson and Kligman (1970) was adapted for SO solution test article extract.

The extract of the test article was intradermally injected and occlusively patched to ten guinea pigs in an attempt to induce sensitization. Following a recovery period, the original ten test and five control animals received a challenge absorbent gauze patch (2.5 cm×2.5 cm) of the test article extract and the control vehicle. In addition the test article was applied to the same animals. All sites were scored at 24h and 48h after patch removal.

Under the conditions of this study, the test article extract and the test article showed no signification evidence of causing delayed dermal contact sensitization in the guinea pig.

2.0 Purpose

A guinea pig maximization test identified below was conducted to evaluate the potential to cause delayed dermal contact sensitization.

3.0 Materials

3.1 Sample and Control Preparation

For each phase of this test, a ratio according to the table below (test article to volume of vehicle) was used for the test extract. The test article was extracted in SO.

Extraction ratio	Actual sampling	Extraction conditions	The pH value of the final extract	Whether the extract is clear or not
$6cm^2$: 1ml	$60cm^2$: 10ml	37 ℃,72 h	5.8	Clear

The vehicle (without the test article) was similarly prepared to serve as the control.

3.2 Equipments

Electric-heated thermostatic water bath (SDWH-418),Autoclave (SDWH-048),Balance (SDWH-306), Electronic scale (SDWH-442)

3.3 Regents

100%Sesame oil (SO) (Lot No: 2010/07/26 TZH)
Freund's Adjuvant,Complete liquid (Lot No: 021M8728)
10% sodium dodecyl sulfate (10%SDS) (Lot No: F20090922)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

4.0 Test System

Species: Healthy young adult albino guinea pigs of either sex form a single outbred strain, weighing 300g to 500g at the start of the test shall be used, If female animals are used, they shall be nulliparous and not pregnant.
Source: Provided by Wuxi Huishan Jiangnan Experimental Animal Center <Permit Code: SCXK (SU) 2009-0005>.
Acclimation Period: 7 days.
Number of Animals: 15.

5.0 Justification of Test System

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, 1-chloro-2,4-dinitrobenzene (DNCB) has been substantiated at SDWH with this method, The average dermal scoring for the Positive controls was 1.7, see SDWH-2011-22435, completed on Jan 6, 2012.

6.0 Animal Management

Husbandry: Refer to ISO 10993-2:2006.
Food: Animal foods were provided by Wuxi Huishan Jiangnan Experimental Animal Center.
Water: Drinking water met the sanitary standard.
Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date.
Environment: The room Temp will be monitored daily. The temperature will be controlled within 20-26℃. The room humidity will be controlled within 30%-70%.The light cycle is controlled for 12hours' light and 12hours' dark.
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.

7.0 Experimental Procedure

7.1 Intradermal induction phase I

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.
Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.
Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%) was injected into the control animals

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with an emulsion of the blank liquid with adjuvant.

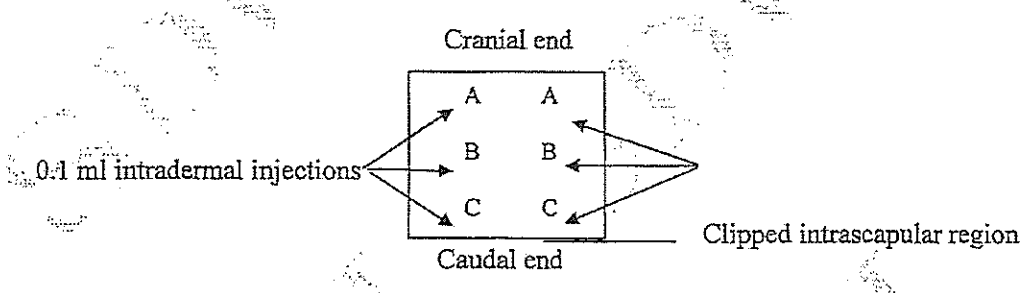

Figure 1 Location of intradermal injection sites

7.2 Topical induction phase II

Seven days after completion of the intradermal induction phase, the test sample was administered by topical application to the intrascapular region of each animal, using a patch of area approximately 8cm^2 (filter paper or absorbent gauze), so as to cover the intradermal injection sites. The concentration selected in intradermal induction phase I for Site B was used. The maximum concentration that could be achieved in intradermal induction phase I did not produce irritation, when the area was pretreated with 10% sodium dodecyl sulfate massaged into the skin 24h before the patch was applied. The patches were secured with an occlusive dressing. The dressings and patches were removed after 48h.

The control animals were treated similarly, using the blank liquid alone.

7.3 Challenge phase

At 14 days after completion of the topical induction phase, all test and control animals were challenged with the test sample. The test sample and a vehicle control were administered by topical application to sites that were not treated during the induction stage, such as the upper flank of each animal, using appropriate patches soaked in the test sample at the concentration selected in the intradermal induction phase I for site C. Dilutions of this concentration were also applied to other untreated sites in a similar manner. Occlusive dressings were used to secure areas treated. The dressings and patches were removed after 24h.

7.4 Observation of animal

The appearance of the challenge skin sites of the test and control animal were observed after 24h and 48h removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions.

The skin reactions for erythema and oedema were observed and graded according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval .It is highly recommended that reading be done without knowledge of the treatment, in order to minimize bias in the evaluation of the results.

7.5 Evaluation of results

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization,

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provided grades of less than 1 are seen in control animal. If grades of 1 or greater are noted in control animal, then the reactions of test animal which exceed the most severe reaction in control animals are presumed to be due to sensitization. If the response is equivocal, re-challenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in the test and control animal.

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

8.0 Results

Individual results of dermal scoring for the challenge appear in Table 2. Clinical Observations: All animals appeared clinically normal throughout the study.

Table 2 Guinea pig Sensitization Dermal Reactions – Challenge

Animal Number/ Group	Topical induction phase II		Hours following patch removal (h)		Weight (g)	
	Left	Right	24	48	Before injection	After experiment
1 Test	0	0	0	0	318	378
2 Test	0	0	0	0	309	375
3 Test	0	0	0	0	324	390
4 Test	0	0	0	0	313	367
5 Test	0	0	0	0	305	366
6 Test	0	0	0	0	307	357
7 Test	0	0	0	0	322	377
8 Test	0	0	0	0	316	370
9 Test	0	0	0	0	304	364
10Test	0	0	0	0	323	378
11Negative control	0	0	0	0	318	378
12Negative control	0	0	0	0	325	380
13Negative control	0	0	0	0	313	367
14Negative control	0	0	0	0	310	370
15Negative control	0	0	0	0	311	377
16 Positive control	3	3	1	2	321	385
17 Positive control	3	3	2	2	305	367
18 Positive control	3	3	2	2	314	373
19 Positive control	3	3	1	1	328	391
20 Positive control	3	3	2	2	310	369

Note: The data of positive control came from SDWH 2011-22435.

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9.0 Conclusion

Under the conditions of this study, the test article extract and the test article showed no significant evidence of causing delayed dermal contact sensitization in the guinea pig.

10.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

11.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

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3M

PRODUCT CLINICAL DATA SUMMARY

(b)(4) [redacted]

Effective: September 2010

The adhesive used on this tape has been subjected to the following safety evaluations:

In Vitro Cytotoxicity

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO_2 for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis.
The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

MEM Elution

An additional *in vitro* study was conducted to evaluate for potential cytotoxic effects following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37 degrees C for 24 hours. The negative control, reagent control and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37 degrees C in the presence of 5% CO_2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25mm x 25mm sections of the test article and control article were topically applies to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application
There was very slight to well defined erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.9. The response of the test article was categorized as slight.

Guinea Pig Sensitization

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig based on the requirements of ISO 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was occlusively patched to the intact skin of ten animals for 6-8 hours, three times a week over a 3 week period. The control article was similarly patched to 5 animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test and control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. 3M Study 011346 (all)

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In addition, earlier studies using a similar adhesive have shown the following results:

Repeated Insult Patch Test (Draize) in Humans
Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. 3M Study # MRFE 03009.
Results: No evidence of induced contact sensitization.

21-day Cumulative Irritation in Humans
Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. 3M Study # 01789.
Results: Consistent with responses characteristic of adhesive materials; within historically acceptable levels for surgical tapes.

The use of the term "hypoallergenic" has come to indicate a product that is non-sensitizing to the general public. The hypoallergenic claim for this product is supported by clinical evaluation using the repeated insult patch test in humans, commonly known as the Draize test. This protocol involves repeated application of samples on 200 healthy volunteers for a 2- to 3-week induction period, followed by a 2-week rest period and a challenge application. To be termed hypoallergenic, 3M Medical Specialties products are required to show no evidence of sensitization potential under these test conditions.

It is the responsibility of our customers to determine the final suitability of our products for their application.

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(b)(4) [redacted]

Typical Product Properties

(b)(4) [redacted]

PROPERTY	TEST METHOD	VALUE
PHYSICAL		
Density, lb. / ft³ (kg /m³)	ASTM D 3574-95, Test A	15 (240)
Tolerance, %		± 10
Thickness, inches (mm)		0.125 - 0.500 (3,18 - 12,70)
Tolerance, %		± 10
Standard Color (Code)		Black (04)
Compression Force Deflection, psi (kPa) Typical psi (kPa)	0.2" / min. Strain Rate Force Measured @ 25% Deflection	0.3 - 3.5 (2 - 24) 2 (14)
Hardness, Durometer, Shore "O", Shore "A"	ASTM D 2240-97	2 -
Compression Set, % max.	ASTM D 1667-90 Test D @ 73°F (23°C) ASTM D 3574-95 Test D @ 158°F (70°C) ASTM D 3574-95 Test J/Test D autoclaved 5 hrs @ 250°F (121°C)	2 10 5
Resilience by Vertical Rebound, %	ASTM D 2632-96	4
Dimensional Stability, % max. change	22 hrs @ 176°F (80°C) in a forced-air oven	± 5
Tensile Strength, Min. psi (kPa), Typical psi (kPa)	ASTM D 3574-75 Test E	15 (103) 30 (207)
Tensile Elongation, % min., Typical	ASTM D 3574-75 Test E	120 205
Tear Strength, Min. pli (kN/m), Typical pli (kN/m)	ASTM D 264-91 Die C	4 (0.7) 5 (0.9)
ELECTRICAL AND THERMAL		
Dielectric Constant, K' ("DK")	ASTM D 150 measurements at 72°F (22°C) relative humidity 50% for 24 hrs.	1.48
Dielectric Strength, volts/mil	ASTM D 149-97a	50
Dissipation Factor, tan D ("DF")	ASTM D 150-98	0.04
Volume Resistivity, ohm-cm	ASTM D 257-99	8×10^{11}
Surface Resistivity, ohm/sq.	ASTM D 257-99	10×10^{11}
Thermal Conductivity, W/m-C (BTU-in./hr/ft²-F)	ASTM C 518-98	-
Coefficient of Thermal Expansion		$2.3 - 3.1 \times 10^{-4}$ in./in./°C

Please see reverse side for additional data.

The world runs better with (b)(4) [redacted]

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(b)(4) [redacted] Continued

PROPERTY	TEST METHOD	VALUE
Density, lb. / ft^3 (kg /m^3)	ASTM D 3574-95, Test A	15 (240)
TEMPERATURE RESISTANCE		
Recommended Constant Use, max.	SAE J-2236	194°F (90°C)
Recommended Intermittent Use, max.	ASTM D 746-98	250°F (121°C)
Embrittlement	ASTM D 746-98	-4°F (-20°C)
Cold Flexibility	MIL-P-12420D 1991 @ -40°F (40°C)	-
FLAMMABILITY AND OUTGASSING		
Flammability	UL 94HBF (File E20305) (Pass ≥) MVSS 302 (Pass ≥) CSA Comp HBF (File 188149) (Pass ≥)	- - -
Fogging	SAE J-1756 3 hrs @ 212°F (100°C)	Pass
Outgassing, Total Mass Loss (TML) %	ASTM E 595-93 24 hrs @ 257°F (125°C) @ <7x10^{-3} Pa	1.73
Outgassing, Collected Volatile Condensable Materials (CVCM) %		0.14
Outgassing, Water Vapor Regain (WVR) %		0.71
ENVIRONMENTAL		
Gasketing and Sealing	UL JMST2 (Consisting of UL50 and UL508) CAN/CSA – C22.2 No. 94-M91	File MH15464
Water Absorption, High Humidity Exposure, % weight gain, typical	AMS 3568-95	2
Water Absorption, Immersion Testing, % weight gain, typical	ASTM D 570-95	34
UV Resistance	ASTM G 53-95	-
Ozone Resistance	GM 4485P-95	-
Corrosion Resistance	AMS 3568-91	-
Mildew/Bacteria Resistance	ASTM G 21	Good
Staining	ASTM D 925	No Stain
Skin Contact Irritation	Primary Skin Irritation Test (FHSA)	Pass

The information contained in this data sheet is intended to assist you in designing with (b)(4) [redacted] *It is not intended to and does not create any warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose or that the results shown on the data sheet will be achieved by a user for a particular purpose. The user should determine the suitability of* (b)(4) [redacted] *for each application.*

Notes:
1. All metric conversions are approximate.
2. Additional technical information is available.

(b)(4) [redacted]

3049-0503-0.6C, Publication # 17-036

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Micro Laboratories, Inc.

World Cla *ing Services*

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AGAR OVERLAY CYTOTC
TEST REPORT

Client: CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405

: #: 05-02163
028944
eived: 04/18/05

Report to: Ron Jeffrey

Sample Description: (2) Sample #3 NIRS Probe Material – Foam

Cell Line: L929 (L-008) **Pass #:** 6 **Date Plated:** 04/15/05 **Plate Size:** 60 X 15mm
Cell Density: Monolayer **Plated By:** JEG **MTL SOP#:** 2020IL rev 004
Extract Ratio: 1cm^2 agar surface **2X MEM:** Lot #: 05-342, exp. Date 6/10/05, e: 04/19/05, exp. date: 4/26/05

Sample Applied By: SSK **Date:** 04/20/05 **Time:** 4:20pm
Dye Applied By: MAC **Date:** 04/21/05 **Time:** 4:30pm
Plates Graded By: MAC **Date:** 04/21/05 **Time:** 5:35pm

Results:

Sample	Reactivity Grade		
24 Hour Reading:	Pl	Plate 2	Plate 3
Sample #3 NIRS Probe Material – Foam pad		2	2
Positive Control: Latex Rubber Lot #04-1140		4	4
Negative Control: USP Plastic Lot #05-302		0	0
Test Blank: All normal, healthy cells		0	0

Comments: The sample meets the requirements of the test if none of monolayer exposed to the sample shows greater than a mild reactivity (Grade 2).

Conclusion: The sample tested "mildly induced" cytotoxicity after 24 . The results as stated on this report are exclusive to the product defined in the "Sample Descriptio n. This report may not be reproduced, except in full, without the expressed written consent of M st Laboratories, Inc.

Reserve: The remaining sample(s) will be held at MicroTest Lab ories for 30 days following the final report completion date and then discarded, unless ed in writing by the client.

Analyst: Sheida Kouzehkanani D 05/05

Sheida S. Kouzehkanani, B.S.
Group Leader, Laboratory Technician II

NOTE: All service Undertaken Subject to the following General Policy: MICROTEST LABORATORIES, INC. Reports are Submitted For Exclusive Use of The Clients to Whom they are addressed. Their Significance is Subject to the Adequacy and Representative Character of the samples and to the Comprehensiveness of the Tests, Examination or Surveys Made. No Quotations from MICROTEST LABORATORIES, INC., Reports or use of MICROTEST LABORATORIES, INC., Name is Permitted Except as Expressly Authorized in writing. The liability of MICROTEST LABORATORIES, INC., with respect to services rendered shall in no event exceed the amount of the invoice.

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TEST REPORT

Sample #05-02163

Analyst: Michelle Coach — 25Apr05

Michelle Coach, M.B.A., B.S., RM (NRM)
Senior Supervisor, Microbiology Laboratory

Approved by: Dennis Champagne — 26Apr05

Dennis Champagne, RM (NRM)
Director of Laboratory Services

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DuPont Medical Packaging

TECHNICAL REFERENCE GUIDE

DUPONT

The miracles of science™

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1 Introduction 1

2 Why DuPont™ Tyvek® is unique 3

3 DuPont™ Tyvek® vs. medical-grade papers: a comparison of properties 5

4 Compatibility with sterilization methods 9

Aging studies 15

6 Guidelines for printing on DuPont™ Tyvek® 21

Processing/troubleshooting guidelines 24

Glossary of medical packaging terms 27

9 Guide to some common industry acronyms 31

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

INTRODUCTION

1

DuPont™ Tyvek® for medical packaging delivers trusted protection

Since its introduction to the industry more than 40 years ago, DuPont™ Tyvek® brand protective material has been recognized as a standard of excellence for medical packaging. Tyvek® earned this distinction because it provides a higher degree of protection for medical devices and supplies than any other porous material used for sterile packaging applications.

The unique structure of Tyvek® gives it inherent advantages over other materials. Specifically, Tyvek® offers:

Outstanding resistance to microbial penetration

In test after test, Tyvek® held out bacterial spores and test particles better than other porous packaging materials—even under the most rigorous conditions. What's more, a long-term shelf-life study proved conclusively that Tyvek® can maintain sterility for at least five years if package integrity is not compromised. The photomicrographs shown here illustrate how bacteria are trapped on the fiber surfaces of Tyvek®.

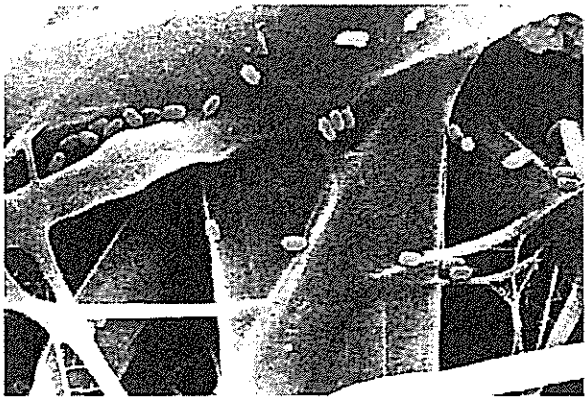
Superior tear strength and puncture resistance

The tough, continuous fibers of Tyvek® protect package integrity from both product breakthrough inside and rough handling outside. Tyvek® is so tough, it resists punctures—even from the irregular or sharp edges of many surgical devices.

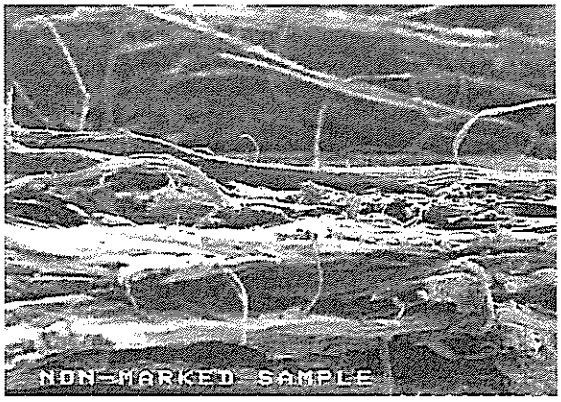
Clean peel

Because the structure of Tyvek® makes it low-linting, virtually no airborne particles are generated when packages are opened. This clean peel minimizes the risk of introducing particulates into a clean environment.

Figure 1. Scanning electron micrographs (SEMs) of Tyvek®.
The unique structure of Tyvek®, which creates a tortuous path with substantial lateral movement, results in superior microbial barrier properties.



Microbes trapped on fiber surfaces of Tyvek®
(500x magnification)



Cross-sectional view of Tyvek®
(500x magnification)

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1

Compatibility with a broad range of sterilization methods

Only DuPont™ Tyvek® is compatible with all of the most commonly used sterilization methods. No matter which process you use: ethylene oxide (EtO), gamma, electron-beam, steam (under controlled conditions) or newer methods, such as the Sterrad® Sterilization System, Tyvek® will retain its protective properties, color and flexibility.

Bioburden

The process of manufacturing Tyvek® allows only short periods of time when the sheet is subject to airborne particulates and microbes; therefore, the bioburden on the surface of Tyvek® is very low. This low bioburden does not add significantly to the required sterilization time. Measured as colony forming units (cfu) per ft^2, the typical bioburden for Tyvek® 2FS™ is 62; for Tyvek® 1059B is 93; and for Tyvek® 1073B is 80.

Ideal fit with environmental goals

As for ecological responsibility, Tyvek® is an excellent choice. This lightweight, durable material is an effective way to conserve resources and demonstrate environmental stewardship. It is lightweight for the performance delivered and is recyclable. It can also be cleanly incinerated or easily landfilled. Due to its porous structure, if compressed, Tyvek® would have less than half its thickness. In the United States, Tyvek® can be recycled at more than 70 facilities nationwide that accept flexible high-density polyethylene (HDPE) with the SPI #2 symbol. In Europe, Tyvek® is produced on a site under verified environmental management policy according to ISO 14000 (EMAS). It can be recycled at local recycling facilities that accept polyethylene waste according to local legislation. The items sent for recycling must not have been in contact with any hazardous substance. There are also several facilities in Asia Pacific that will accept Tyvek® for recycling. For more information, visit **www.MedicalPackaging.DuPont.com**. Visit **www.MSDS.DuPont.com** for a copy of the Material Safety Data Sheet (MSDS).

An industry and technology leader

The DuPont Medical Packaging Team, backed by the vast resources of DuPont, is committed to developing new, cost-effective solutions and providing the support you need to ensure that end-users receive the highest quality medical packaging available. As leaders in the industry, we are dedicated to sharing information and expertise on topics ranging from industry standards and regulatory compliance to technical issues and quality.

We developed a seminar series to help the industry stay on top of standards, regulations and new technologies. In addition, members of our team regularly participate on American Society for Testing and Materials (ASTM-International), International Organization for Standardization (ISO), European Committee for Standardization (CEN), as well as in industry activities, such as the Sterile Barrier Association (SBA, formerly known as ESPA), Association of periOperative Registered Nurses (AORN) Congress, Institute of Packaging Professionals (IoPP), European Medical Devices and Technology Industry Association (EUCOMED) and International Safe Transit Association (ISTA). And, because we want to help future packaging engineers, we established a scholarship program at some of the top packaging science schools.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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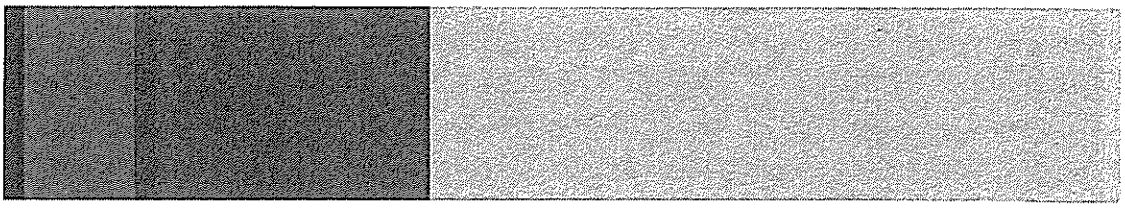

Biocompatibility

Biocompatibility testing using industry accepted test methods was performed on samples of DuPont™ Tyvek® 1073B, 1059B and 2FS™ before and after exposure to sterilization. Methods included: ethylene oxide (EtO), gamma irradiation, electron beam irradiation and STERRAD®. The results of the testing indicate that all of the styles of Tyvek® are biocompatible.

Table VI. Sample exposure results for Tyvek® 1073B, 1059B and 2FS™.

Test Performed	Unsterilized	Ethylene oxide (EtO)	Gamma Irradiation (25-35 kGy)	Electron Beam Irradiation (25-35 kGy)	STERRAD
Determination of Extractives from Olefin Polymers[3]			Below maximum allowable percentage		
Hemolysis-Rabbit Blood-ISO[2,4]			Non-hemolytic		
L929 MEM Elution Test-USP[8]			Non-cytotoxic		
ISO-Rabbit Pyrogen Test (Material Mediated)[1,2]			Non-pyrogenic		
Kligman Maximization Test-ISO (CSO and NaCl extracts)[2,7]			Non-allergenic		
Systemic Injection Test-ISO[1,2]			No biological reaction		
Primary Skin Irritation Test-ISO[7]			Non-irritant		
Short Term Intramuscular Implantation Test-ISO (14 and 28 days)[5,6]			Non-irritant		
USP Class VI Test[9]			0% sensitization		

Note: Biocompatability tests are currently underway for Tyvek® Asuron®.

Tests were based on the following references:

1. Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity, *EN/ISO 10993-1995*
2. Biological Evaluation of Medical Devices-Part 12: Sample Preparation and Reference Materials. *EN/ISO 10993-12, 1997*
3. *21 CFR 177. 1520, Olefin Polymers, Federal Register, Title 21, Chapter 1, 1997.*
4. Biological Evaluation of Medical Devices-Part 4: Selection of Tests for Interactions with Blood, *ISO 10993-4, 1992*
5. Biological Evaluation of Medical Devices-Part 6. Tests for Local Effects After Implantation, *ISO 10993-6, 1995*
6. *ASTM Section 13, Volume 13.01 Medical Devices, Designation: F 981-93, 1994*
7. Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Sensitization, *EN/ISO 10993-10, 1996*
8. *United States Pharmacopoeia 25, National Formulary 20, 2002, <87>* Biological Reactivity Tests, In Vitro.
9. *United States Pharmacopoeia 25, National Formulary 20, 2002, <88>* Biological Reactivity Tests, In Vivo.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

tSummary of Biocompatibility data for the adhesive used in (b)(4) [redacted]

Cytotoxicity study– The method used was the ISO Agarose Overlay Method (Solid); the study does comply with ISO 10993-5. The test article was a dry acrylic pressure sensitive adhesive made from the liquid resin. The adhesive (1 cm x 1 cm portions) was dosed as provided (no extraction). The results of this study showed no cell lysis or toxicity.

Skin Irritation Study – The test guidelines met FIFRA/TSCA requirements. The test article was the liquid resin (not dry adhesive). Therefore, no extraction was necessary. The results of this study showed minimal indication of skin irritation.

Dermal Sensitization Study – The test guideline was the Buehler method (closed-patch repeated insult study in guinea pigs). The test article was the liquid resin (not dry adhesive). The adhesive (1 in x 1 in portions) was applied as provided (no extraction). The study was conducted under EPA TSCA Good Laboratory Practices. The result of this study showed that the tape did not cause dermal sensitization. Statistically the results indicated that it is likely to state with 95% confidence it will be tolerated by no less than 98.29% and by as much as 100% of the population at risk.

**This data is provided by our supplier.*

This toxicology summary is intended only as a guide and should not be construed as a warranty. All implied warranties are expressly disclaimed, including without limitation any warranty of merchantability and fitness for use. All users of the material are responsible for assuring that it is suitable for their need, environment and end use. As such, final approval must be confirmed in an appropriate manner on the end use product. All data is subject to change, as DermaMed deems appropriate.

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Tel: 330-633-8216 * Fax: 330-633-2461

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(b)(4) [redacted]

DermaMed Coatings Company, LLC
Product Specification UNCONTROLLED COPY
Product No: (b)(4) [redacted]
Issue Date: September 6, 2005
Revision Date: May 9, 2006

5.0 TRACEABILITY

Material traceability must comply with current Good Manufacturing Practices. Each shipment of material will contain a lot number, which is traceable through production records. Certification will accompany each shipment.

6.0 PRODUCT SAFETY:

Product safety data sheets are contained on file regarding adhesives.

7.0 STORAGE CONDITIONS:

Product should be stored at temperatures between 50-80°F.

8.0 STANDARD LABELING:

Materials will have core labeling stating part number, roll number, lot number, width, and linear feet per roll. *Note: Any additional labeling requirements by customer should be noted at time of order entry.*

9.0 BIOCOMPATIBILITY/SAFETY INFORMATION

9.1 Cytotoxicity-Pass

9.2 Primary Dermal-Pass

9.3 Buehler Sensitization-Pass

All biocompatibility testing performed is required to satisfy FDA/GMP requirements.

It is the responsibility of the consumer to determine that the product is safe, lawful and technically suitable for the intended.

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

DermaMed Coatings Company, LLC
Product Specification UNCONTROLLED COPY
Product No: (b)(4) [redacted]
Issue Date: September 6, 2005
Revision Date: May 9, 2006

1.0 MATERIAL DESCRIPTION:

Single coated 1 mil white pearlized BOPP film with a medical grade acrylic pressure-sensitive, adhesive supported by a 54# release liner.

2.0 PRODUCT CONTENTS:

2.1 (b)(4) [redacted]

2.2

2.3 Backing –Coated one side having a basis weight of 54 lb.

3.0 ROLL DIMENSIONS:

3.1 Length – 2,000 linear feet

3.2 Width - Maximum 59 inch

3.3 Core - 3 inch inside diameter

4.0 PRODUCT REQUIREMENTS:

4.1 Physical Properties:

PEEL (PSTC-1): > 900 gm/inch average
(Preliminary data of initial samples submitted.)

4.2 Splices:

Splices are "functional", meaning that the splice on the tape and liner is intended for continuous process conditions.

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

Biocompatibility Statement for (b)(4) [redacted]

This letter is provided as a response to your request for information on the biocompatibility of (b)(4) [redacted]

While biocompatibility tests have not been performed for all available colors in this grade, (b)(4) [redacted] has subjected samples of (b)(4) [redacted] from typical production lots of (b)(4) [redacted] ("natural") molded within the processing guidelines to certain biocompatibility tests specified by the United States Pharmacopeia (USP) or described by ISO 10993, "Biological Evaluation of Medical Devices", which is the guideline for biocompatibility developed by the International Organization for Standardization (ISO). The ISO 10993 tests were also consistent with the guidance provided by the US Food and Drug Administration (FDA) regarding use of the ISO 10993 standard. These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity test, 7. Sensitization test, and 8. Physico-chemical test. The purpose of these tests is to provide our customers with data to help them determine the suitability of the subject resin, for use as containers or accessories for parenteral preparations. The samples of (b)(4) [redacted] ubjected to the ISO 10993 tests passed each of these tests and met the criteria for USP Class VI / ISO 10993.

Although the specific color of interest to you has not been subjected to these tests, we believe that if tested, the results of such tests would yield results similar to those described above. The basis for this belief is that it seems unlikely that the presence of small amounts of colorants, in a tightly bound form in the inert resin matrix, would cause any change in the results of these tests.

The medical device manufacturer and the drug packager are in the best position to know the details of the intended conditions of use. It is incumbent upon the device manufacturer or drug packager to carry out the appropriate biocompatibility tests to assure safety, efficacy, and regulatory compliance. (b)(4) [redacted] considers the determination of suitability of (b)(4) [redacted] for a medical device to be the responsibility of the device manufacturer and the drug packager. (b)(4) [redacted] **does not recommend and will not support the use of any** (b)(4) [redacted] **in medical devices intended to remain continuously in the human body for longer than 29 days.**

Because of the potential for chemical incompatibility between (b)(4) [redacted] and materials used in components comprising the application or present in the end-use environment, it is recommended that appropriate chemical compatibility be conducted with all components under intended conditions of use and reasonably foreseeable misuse.

To assist in the review of the use of (b)(4) [redacted] for medical devices and drug packages with the appropriate FDA regulatory personnel, we maintain both a Device Master File (MAF-1575) and Drug Master File (b)(4) [redacted] ith the FDA. The DMF contains detailed formulation information and test data on certain (b)(4) [redacted] Plastics considers this information proprietary and does not divulge it without a properly executed secrecy agreement. The FDA holds this information in confidence, but with our specific authorization will review it on behalf of a specific company's application or submittal for the purpose of rendering an opinion about the safety and suitability of the proposed usage.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

I trust that this information will adequately satisfy your needs. Should you have questions, or require additional information, please contact me via e-mail: patrick.rodgers(b)(4) [redacted]

In the name of the manufacturer,

(b)(4) [redacted]

(b)(4) [redacted]

Patrick A Rodgers

Patrick A. Rodgers

(b)(4) [redacted]

Washington, WV 26181
United States

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted] continues to strive for excellence in customer support. As part of ongoing efforts to address increasing customer requirements, we are further aligning our "healthcare product" portfolio to meet these needs. This alignment will also simplify product identification of "healthcare products" for our customers. These "healthcare products" are subject to formula lock and a stringent management of change process.

As part of this effort, the following current products (Old Names) have been changed to the corresponding new product names (New Names). This is a grade-name and color-name change only – the formulation, specification and manufacturing process remains unchanged:

(b)(4) [redacted]

(b)(4) [redacted]

The "healthcare product" nomenclatures, specified below, contain the letter "H" in both grade names and color names to signify their inclusion in the (b)(4) [redacted] "Healthcare product" portfolio. As such, these resin products are subject to the following (b)(4) [redacted] Plastics' "Healthcare Product" Policy:

- Easily identifiable "healthcare product" nomenclature: (b)(4) [redacted]
- Biocompatibility assessed (according to ISO10993 or USP Class VI)
- Food Contact compliance for most "healthcare products"
- FDA Drug Master File and/or Device Master File listing (Letter Of Authorization provided as needed)
- (b)(4) [redacted] "healthcare products" are subject to formula lock and stringent management of change process (ask your (b)(4) [redacted] representative for more details)

These processes support typical healthcare customer needs and regulatory requirements regarding change management for plastic materials used in medical devices or drug packaging.

Please be advised that (b)(4) [redacted] will no longer provide biocompatibility information for the old product names. Biocompatibility information will only be available for the new product nomenclature.

Please do not hesitate to contact (b)(4) [redacted] if you have any further questions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

In the name of the manufacturer,

(b)(4) [redacted]

Patrick A. Rodgers

Patrick A. Rodgers

(b)(4) [redacted]

Washington, WV 26181
United States

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Technical Information Sheet

(b)(4) [redacted]

Effective: February 2007
Supersedes all previous specifications

Features and Benefits:

- Hypoallergenic Pressure Sensitive Adhesive
- Soft & Cushioning
- Highly Conformable
- ETO & Gamma Compatible
- Good Adhesion to Skin
- Opaque Ivory Color

Composition:

Tape Caliper	22.5 mils (0.6 mm) Polyvinyl Chloride Foam Tape
Backing	20 mils (0.5 mm) Ivory PVC Closed-cell Foam
Adhesive	Acrylate, designed for medical/surgical applications
Release Liner	65 lb. Super-calendered Kraft paper, silicone on one side (4.0 mil/0.1 mm)

Typical Properties+:

Adhesion to Steel, 180° Peel	8 ounces/inch width (2.2 N/25 mm width) (227 gm/25 mm width)
Liner Release	17 gm/inch width (17 gm/25 mm width)
Visual Defects	May include pock marks and pinholes (maximum 0.063 inch /1.6 mm diameter) - allowed up to 10 per square yard

+3M test methods are available upon request.

Roll Description: Tape supplied on 3 inch (76 mm) diameter cores.

Length, Maximum	210 yards (192 m) ± 2%
Width, Maximum	48 inch (122 cm) ± 1/16 in (1.5 mm)

Splices: Splices on the tape are intended for continuous processing.

Roll Width	**Maximum Number of Splices per Roll**
≤ 8 inch (20 cm)	3 per 72 yd (66 m)
	4 per 150 yd (137 m)
	5 per 210 yd (192 m)

Information on the splice frequency in roll widths greater than 8 inch (20 cm) is available upon request.

Packaging and Recommended Storage:
Product as supplied in original packaging will maintain stated properties for a period of two years from date stamped on shipping container when stored at temperatures between 50-80°F (10-27°C) and a relative humidity between 40-60 percent.

Please see reverse side for important product, safety and warranty information.

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Product and Safety Information: User is solely responsible for determining the suitability of 3M samples and products for the intended use including any necessary safety or toxicity assessment. 3M will provide Material Safety Data Sheets and results of toxicity testing upon request. In every case before using any product in full scale production users should conduct their own tests to determine to their own satisfaction whether the product is of acceptable quality and is suitable for their particular purposes under their own operating conditions.

Notice: Nothing contained herein shall be construed to imply the nonexistence of any relevant patents or to constitute a permission, inducement or recommendations to practice any invention covered by any patent, without authority from the owners of this patent.

Warranty Information

All statements, technical information and recommendations herein are based on tests 3M believes to be reliable, but the accuracy or completeness thereof is not guaranteed. 3M warrants only that products will meet 3M's specifications at the time of shipment to the customer. 3M does not offer any other warranty and does not warrant the performance, safety or such other characteristics of Products in combination with other materials. 3M specifically DOES NOT warrant Products for any intended or unintended uses (whether or not foreseeable); for compatibility or suitability with other components or compatibility with any methods of manufacture or conversion. The foregoing warranty is made in lieu of all other warranties, expressed or implied, including the implied warranties of merchantability, fitness for a particular purpose and freedom from non-infringement.

Limitation of Remedies: If products are proven not to meet 3M's specifications, the sole and exclusive remedy available and 3M's only obligation shall be, at 3M's option, to replace such quantity of Products which are proven out of specification or to refund the purchase price paid for Products.

Limitations of Liabilities: The remedies provided herein are exclusive remedies against 3M for any alleged or actual nonconformance to specifications or defect or other failure in products or for 3M's performance of its supply obligations. Under no circumstances is 3M liable for any direct, indirect, incidental, special or consequential damages (including lost profits) in any way related to the product under any theory of law including, but not limited to, negligence and strict liability.

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International Locations

Argentina
3M Argentina S.A.C.I.F.I.A.
Tel.: 54-11-4339-2400
Fax: 54-11-4339-2640

Australia
3M Health Care
Tel: 1 300 363 878
Fax: 1 800 060 888

Belgium
3M Belgium N.V./S.A.
Tel: 32-2-722-5111
Fax: 32-2-720-0225

Brazil
3M DO Brasil Ltda.
Tel: 55-19-864-7171
Fax: 55-19-864-7848

Canada
3M Canada
Tel: 800 364-3577
Fax: 800 341-4630

Chile
3M Chile S.A.
Tel: (56-2) 4103000
Fax: (56-2) 4103400

China
3M China Ltd.
Tel: 86-21-6275-3535
Fax: 86-21-5208-2205

Colombia
3M Colombia S.A.
Tel: 57-1 4108585
Fax: 57-1 4161677

Czech Republic
3M Cesko s.r.o.
Tel: +420-261 380 111
Fax: +420-261 380 110

Denmark
3M a/s
Tel: 45-43-48-0100
Fax: 45-43-96-8596

Dominican Republic
3M Dominicana
Tel: (809) 530-6560 X499
Fax: (809) 530-2960

Finland
Suomen 3M Oy
Tel.: 358-9-52-521
Fax: 358-9-512-29-44

France
Laboratoires 3M Santé
Tel: 33-1-3031-8376
Fax: 33-1-3031-8378

Germany
3M Medica
Tel: 49 2131 14 40 00
Fax: 49 2131 14 49 99

Hong Kong
3M Hong Kong Ltd.
Tel: (852) 2806 6111
Fax: (852) 2234 6044

Hungary
3M Hungária Kft.
Tel: (36-1) 270-7777
Fax: (36-1) 320-0951

India
3M India Ltd.
Tel: 0091-80-2223 1414
Fax: 0091-80-22231450

Indonesia
PT 3M Indonesia
Tel: (62-21) 520 3401
Fax: (62-21) 520 3106

Italy
3M Italia SPA
Tel: +39 2 7035-2406
Fax: +39 2 7035-2484

Japan
3M Health Care Ltd.
Tel: 81-3-3709-8289
Fax: 81-3-3709-8754

Kazakhstan
3M Representation Office
Tel: +7 3272 509 944
Fax: +7 3272 509 573

Korea
3M Korea Ltd.
Tel: 82-2-3771-4286
Fax: 82-2-786-2825

Malaysia
3M Malaysia Sdn. Bhd.
Tel: 6-03-7806 2888
Fax: 6-03-7806 2902

Mexico
3M México, S.A. de C.V.
Tel: +52-55-5270-0400
Fax: +52-55-5270-0433

Middle East
3M Gulf Ltd.
Tel: 971-4-3670-777
Fax: 971-4-3670-699

The Netherlands
3M Nederland B.V.
Tel: 31-715-450-450
Fax: 31-715-450-212

New Zealand
3M New Zealand
Tel: 64-9-444 4760
Fax: 64-9-443 7885

Peru
3M Peru S.A.
Tel: 511-224-2728
Fax: 511-224-3171

Philippines
3M Philippines
Tel: (632) 8133781 to 95
Fax: (632) 8145873 to 74

Poland
3M Poland Sp.z o.o.
Tel: (48 22) 739 60 00
Fax: (48 22) 739 60 01

Portugal
3M Portugal
Tel: 351-21-3134500
Fax: 351-21-3134680

Russia
3M Russia
Tel: 7 (495) 784-74-74
Fax: 7 (495) 784-74-75

Singapore
3M Technologies (S) Pte. Ltd.
Tel: 65-6450-8866
Fax: 65-6455-2130

Sri Lanka
3M Lanka (Pvt.) Ltd.
Tel: (94) 11 2785701
Fax: (94) 11 4410083-4

Spain
3M España, S.A.
Tel: 34-91-321-6000
Fax: 34-91-321-6002

Sweden
3M Svenska AB
Tel: +46-8-92 21 00
Fax: +46-8-92 24 22

Switzerland & Eastern Europe
3M (Schweiz) AG
Tel: +41 44 724 92 44
Fax: +41 44 724 94 80

Thailand
3M Thailand Ltd.
Tel: (66)2 260 8577 Ext 175
Fax: (66)2 261 7535

Taiwan
3M Taiwan Ltd.
Tel: 886-2-2704-9011
Fax: 886-2-2706-0355

Turkey
3M Turkey
Tel: 9 (0212) 3507777
Fax: 9 (0212) 2821742

Ukraine
3M Ukraine
Tel: +380 44 490 57 77
Fax: +380 44 490 57 75

United Kingdom & Ireland
3M Health Care Ltd.
Tel: 44-1509-611-611
Fax: 44-1509-237-288

Venezuela
3M Manufacturera Venezuela
Tel: 58-241-8391911
Fax: 58-241-8391928

Viet Nam
3M Viet Nam Ltd.
Tel: 84 8 640986
Fax: 84 8 641024

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3M Center, Building 275-5W-05
St. Paul, MN 55144-1000 USA
Tel.: 800 228-3957

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Medical Specialties
3M Skin and Wound Care Division
3M Center
St. Paul, MN 55144-1000
651 733 1110

PRODUCT CLINICAL DATA SUMMARY

(b)(4) [redacted]

Effective: September 2010

The adhesive used on (b)(4) [redacted] as part of another tape construction, has been subjected to the following safety evaluations:

In Vitro Cytotoxicity

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO_2 for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis.
The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

MEM Elution

An additional *in vitro* study was conducted to evaluate for potential cytotoxic effects following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37 degrees C for 24 hours. The negative control, reagent control and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37 degrees C in the presence of 5% CO_2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25mm x 25mm sections of the test article and control article were topically applies to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application
There was no erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

Guinea Pig Sensitization

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig based on the requirements of ISO 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was occlusively patched to the intact skin of ten animals for 6-8 hours, three times a week over a 3 week period. The control article was similarly patched to 5 animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test and control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. 3M Study 011344 (all)

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Medical Specialties
3M Skin and Wound Care Division
3M Center
St. Paul, MN 55144-1000
651 733 1110

PRODUCT CLINICAL DATA SUMMARY

(b)(4) [redacted]

Effective: September 2010

In addition, earlier studies using the same adhesive have shown the following results:

Repeated Insult Patch Test (Draize) in Humans
Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States.
Results: No allergic contact dermatitis observed.

21-day Cumulative Irritation in Humans
Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States.
Results: Consistent with responses characteristic of adhesive materials.

The adhesive used in this product has been shown to be hypoallergenic. The use of the term "hypoallergenic" has come to indicate a product that is non-sensitizing to the general public. The hypoallergenic claim for this product is supported by clinical evaluation using the repeated insult patch test in humans, commonly known as the Draize test. This protocol involves repeated application of samples on 200 healthy volunteers for a 2- to 3-week induction period, followed by a 2-week rest period and a challenge application. To be termed hypoallergenic, 3M Medical Specialties products are required to show no evidence of sensitization potential under these test conditions.

It is the responsibility of our customers to determine final suitability of our products for their application.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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17. Software

In accordance with FDA's Guidance for the content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005, the FORE-SIGHT Elite Absolute Tissue Oximeter is categorized as a Moderate Level of Concern. This designation is appropriate because failures or latent design flaws in this adjunct monitor could lead to an erroneous diagnosis or a delayed or unnecessary medical treatment.

The FORE-SIGHT ELITE Oximeter firmware is comprised of (b)(4) [redacted] The Main Application processor and the NIRS Signal Acquisition Module (NSAM) Application processor. The Main Application processor is responsible for displaying the acquired absolute tissue oxygen saturation value (as a numeric & trace), generating alarm signals based on current conditions, interfacing with the remote equipment and the User via a touchscreen to configure the Oximeter (refer to CAS Document 21-07-0325). The NSAM Application processor is responsible for controlling the LEDs on the sensor at the patient site, acquiring the corresponding signals and computing an absolute tissue oxygen saturation value (refer to CAS Document 21-07-0327).

The software has undergone validation to verify the software functions and the data algorithm supporting the large sensor somatic tissue capability. All verification and validation testing was successfully completed and no new hazards were identified. The software requirements and report for the validation are:

- Gemini Main Application Software Requirements 21-07-0325
- Gemini NSAM Application Software Requirements 21-07-0327
- Gemini Main Application Software Architecture 21-07-0329
- Gemini NSAM Application Software architecture 21-07-0331
- Gemini Main Application Software (Life Cycle) 21-07-0334
- Gemini NSAM Application Software (Life cycle) 21-07-0336
- FORE-SIGHT Elite Software Validation Report with Plan VaR 120019
- Project Gemini Product Specification 21-07-0302.

These documents may be found in Attachment A (Product Specification) and E.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Error - Couldn't merge file with following reason - PdfReader not opened with owner password
09002621816ea02c.pdf
System attempted to attach the file. Please look at attachments to open this file manually.

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Author: P. Swanke, H. Triebel **Date:**[1] 05-Feb-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

2/6/13 Project Leader Date	2/6/13 Software Eng[2] Date
2/6/13 Regulatory Affairs Date	

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Form Revision History

00 – Initial release

Document Revision History

00 – Initial release
01 – Update Hazard/Risk Section numbers – Age/Weight feature/risks removed from RMF docs, Update list of Main Bootloader Verification plans

PURPOSE

The following Software Life Cycle Worksheet[3] shall be completed by the Project Leader early in Stage 4 with information obtained from Design Inputs (Product Specifications, Marketing Requirements or SPRs) and information gathered from Software Eng(s) involved in the design. A final review of this Software Life Cycle Worksheet shall be performed in Stage 7 prior to the Product Release.

1. Introduction – Describe the Project/Product

This document covers the Software Life Cycle of the Project Gemini's Main Application software. The Main Application will perform Graphical User Interface (GUI), obtain and display computed values from the NSAM for all channels, provide Serial communications with external devices and allow for upgrading of the NSAM Bootloader and Application.

[1] Date: Refers to date the Information on this form was last fully updated and **not** the revision of the form itself (see footer)

[2] The Form may be altered to include approvals for additional Software Engs

[3] This form may be modified by the addition of other fields. Fields should **not** be removed, and unused fields should be indicated as Not Applicable (NA) along with a justification if necessary.

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Overall Software System Safety Class[4]:	☐ Class A: No injury or damage to health is possible
	☒ **Class B: Non-serious injury is possible**
	☐ Class C: Death or serious injury is possible

Rational: IFU: The prospective clinical value of data from the FORE-SIGHT Oximeter has not been demonstrated in disease states and these data should not be used as a sole basis for diagnosis or therapy. Warning in the User manual: The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. High/Low Alarm Limit violations are High priority alarms.

Software items with lower Safely Class than Overall Software System (see above): **None**

Software Item: **Auxiliary / Debug port functionality** Class: A

Rationale: Does not affect safety / data collection, it is used for debugging purposes only Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

[4] Software System Safety Class is defined in ANSI/AAMI/IEC 62304 Standard

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Other Software Development processes used and not described in 21-07-0017 - Software Style Guidelines:	**None**

Design Input: Documents:	☒ Product Specifications:	**21-07-0302, Gemini Product Specifications**
	☐ Marketing Requirements:	
	☐ SPRs:	
	☐ Other:	

Design Outputs Software Documents:	**21-07-0325, Gemini Main App SW Requirements**
	21-07-0329, Gemini Main App SW Architecture
	Details the requirements of the Main Application to perform basic GUI
	functions, obtain and display computed values from the NSAM for all
	channels, provide Serial communications with external devices and allow for
	upgrading of the Main Bootloader and Application

Verification Documents:	Gemini Main App - System Verification Plan
	Gemini Main App - Integration Verification Plan:
	Gemini Main App: Main & Task Creation Integration Plan
	Gemini Main App: MQX Related/Common Drivers Integration Plan
	Gemini Main App: 1-Wire Integration Plan
	Gemini Main App: Shell & Debug Integration Plan
	Gemini Main App: Utilities Integration Plan
	Gemini Main App: Peg Integration Plan
	Gemini Main App - Main Screen Verification Plan
	Gemini Main App - Medium & Low Priority Alarm Annunciation Verification Plan
	Gemini Main App - Alarm Silence Verification Plan
	Gemini Main App - System Message Verification Plan
	Gemini Main App - Alarm Limit Layout Verification Plan
	Gemini Main App - Alarm Volume Verification Plan
	Gemini Main App - Hi/Lo Alarm Limits Verification Plan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Gemini Main App - Alarm Limit Delays Verification Plan
	Gemini Main App - Alarm Annunciation Verification Plan
	Gemini Main App - Numeric field Verification Plan
	Gemini Main App - Trace Area Verification Plan
	Gemini Main App - Patient menu Verification Plan
	Gemini Main App - Date/Time Menu Verification Plan
	Gemini Main App - Battery Condition Verification Plan
	VaP 120018, Gemini / FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan
	VaP 120019, Gemini / FORE-SIGHT ELITE Software PEMS Validation

Config Management:	☒ New Project & Files ☐ Use Concurrent Versions System (CVS) files: From Build _____ Rev: _____ ☐ Use DocControl Archive files: From Build Rev:

For each Software build, describe the Tools and Environment (Mfg, Name, Rev, etc.):

Software	Tools & Environment Used to Build Software
(b)(4) [redacted]	

Complete the following if the Overall Software System is Class C ☐ or N/A ☒

Standards: **N/A**

Method: **N/A**

Other Problem Resolving processes not used or described in QSP4004 - System Performance Reports (SPR), Product Request (PR): **Yes** - (b)(4) [redacted]

Complete the following if the Overall Software Systems is Class B ☒, C ☐ or N/A☐:

Integration Test Plan: 1) Main App: Main & Task Creation Integration Plan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2) Main App: MQX Related/Common Drivers Integration Plan
3) Main App: 1-Wire Integration Plan
4) Main App: Shell & Debug Integration Plan
5) Main App: Utilities Integration Plan
6) Main App: Peg Integration Plan

Project Risk Management:	Risk Management Plan:	**21-07-0303, Gemini Risk Management Plan**
	Hazard Identification:	**21-07-0304, Gemini Hazard Identification**
	dFMEA Analysis:	**21-07-0305, Gemini Monitor dFMEA Analysis**
	Risk Analysis:	**21-07-0306, Gemini Risk Analysis**
	Risk Management Summary:	**21-07-0307, Gemini Risk Management Summary**
	Other:	

SW Risk[5]	Control Measures / VeR Plan [6]
4.1.2.1 Poorly assembled or damaged monitor creates a broken electrical connection causing heat to be generated in Medical Device resulting in thermal injury (burns) at contact site	(b)(4) [redacted] (b)(4) [redacted] Verification Plan
4.1.2.5 Thermal failure of plastic bezel before end of expected service life of Medical Device creates an exposed electrical connection allowing for personal contact resulting in electrical shock	(b)(4) [redacted] (b)(4) [redacted] Verification Plan
4.1.2.7 Batteries are subjected to over-charging that produces excessive heat that increases the ambient temperature causing device readings to be incorrect resulting in a lack, delay or over treatment of patient	(b)(4) [redacted] (b)(4) [redacted] Verification Plan
4.1.3.6 Patient moves/turns or loss of adhesion due to perspiration or inadequate placement causing Sensor to move from original position causing sensor to cover nose or mouth resulting in suffocation or injury	(b)(4) [redacted] Verification Plan

[5] Refer to 21-07-0304 Gemini Hazard Identification & 21-07-0306 Gemini Risk Analysis for additional information

[6] All Control Measures are verified by specific Verification Plans as well as VaP 120018, Gemini / FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SW Risk[5]	Control Measures / VeR Plan [6]
4.3.1.1 Medical Device is inoperable due to susceptibility of electromagnetic fields (EMC) from other devices causing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Sustained noisy conditions will blank numeric & recover when noise is removed Gemini Main App - Numeric field Verification Plan
4.3.4.1 Medical Device is inoperable due to extreme temperature, humidity or atmospheric pressure causing device readings to be incorrect resulting in a lack, delay or over treatment of patient	(b)(4) [redacted] Gemini Main App - System Message Verification Plan
4.5.1.1 Medical device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Body location for Sensor prominently indicated on display Sensor body location saved Gemini Main App - Numeric field Verification Plan Gemini Main App - Patient menu Verification Plan
4.5.1.2 Poorly designed medical device labeling leads to an incorrect interpretation and lack of understanding resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display Tissue Perfusion Index (TPI) shall be displayed on the main screen for each channel and values described under a Help menu Any icons or abbreviations used are consistence with medical industry standards Gemini Main App - Numeric field Verification Plan
4.5.2.1 Medical Device used with inappropriate accessory allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Software detection of connection to an approved accessory or external medical device Gemini Main App - Main Screen Verification Plan
4.5.3.1 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display Sensor body location saved Gemini Main App - Numeric field Verification Plan Gemini Main App - Patient menu Verification Plan
4.5.4.1 Medical Device used by unskilled/ untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & values Gemini Main App - Numeric field Verification Plan
4.5.4.2 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Body location of Sensor prominently indicated on display Sensor body location saved Gemini Main App - Numeric field Verification Plan Gemini Main App - Patient menu Verification Plan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SW Risk[5]	Control Measures / VeR Plan [6]
4.5.5.1 Medical Device used by unskilled/ untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & value Gemini Main App - Numeric field Verification Plan
4.5.5.2 Medical Device used with an inappropriate Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display Sensor body location saved Gemini Main App - Numeric field Verification Plan Gemini Main App - Patient menu Verification Plan
4.5.6.2 Medical Device used with an inappropriate size Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Error messages displayed Gemini Main App - System Message Verification Plan
4.5.6.3 Software performance issue in Medical Device allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Periodic system checks Gemini Main App - System Message Verification Plan
4.5.7.1 Medical Device used in an inappropriate manner with incompatible consumables/accessories allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Software recognition application for detection of connection to an approved medical device Gemini Main App - System Message Verification Plan
4.5.10.1 Alarm Volume altered to lowest setting, allowing user to miss the Alarm tones resulting in a lack, delay or over treatment of patient	Alarm Volume cannot be turned off Lowest Alarm volume setting still audible in normal use environment Alarm message and alarm icons visible on screen Always visible Alarm LED Gemini Main App - Alarm Volume Verification Plan Gemini Main App - Alarm Silence Verification Plan Gemini Main App - Alarm Annunciation Verification Plan
4.5.10.2 Display brightness altered to lowest setting, allowing user to not see Alarm message resulting in a lack, delay or over treatment of patient	Always visible Alarm LED Alarm annunciation always includes audio tones regardless of display brightness Brightness cannot be turned off Lowest brightness setting still allows viewing of screen in normal use environment Gemini Main App - Alarm Silence Verification Plan Gemini Main App - Alarm Annunciation Verification Plan

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SW Risk[5]	Control Measures / VeR Plan [6]
4.6.1.1 Medical Device presents information that are mistaken/ misinterpreted for actual values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Parameter name & units displayed adjacent to Numeric value TPI displayed on the main screen for each channel & values Gemini Main App - Main Screen Verification Plan Gemini Main App - Numeric field Verification Plan
4.6.1.2 Arrangement of front panel controls allows user to incorrectly configure Medical Device for current type patient leading to incorrect readings and inaccurate diagnoses resulting in a lack, delay or over treatment of patient	User interface uses touchscreen with icons Menu interface driven by touchscreen allow for navigation & selection Current selections on screen are highlighted to indicate location Feature state indicated by checkbox, numeric value or outline Gemini Main App - Main Screen Verification Plan Gemini Main App - Patient menu Verification Plan Gemini Main App - Date/Time Menu Verification Plan
4.6.2.1 Abbreviations used with the Medical Device allow for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Parameter name & units displayed adjacent to Numeric value Gemini Main App - Numeric field Verification Plan
4.6.3.1 Medical Device displays ambiguous or unclear states that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid information shall be presented as dashes & messages Limit violation & Equipment alarm messages displayed TPI displayed on main screen for each channel & values Gemini Main App - Numeric field Verification Plan Gemini Main App - Hi/Lo Alarm Limits Verification Plan Gemini Main App - Numeric field Verification Plan
4.6.3.2 Wrong size Sensor used on an inappropriate type/size patient allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display Sensor body location saved TPI displayed on the main screen for each channel & value Gemini Main App - Numeric field Verification Plan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SW Risk[5]	Control Measures / VeR Plan [6]
4.6.4.1 Medical Device displays ambiguous or unclear settings that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid information shall be presented as dashes & messages Limit violation & Equipment alarm messages displayed TPI displayed on main screen for each channel & values Gemini Main App - System Message Verification Plan Gemini Main App - Numeric field Verification Plan
4.6.5.1 Erroneous or lack of visual information (e.g., limited viewing angle of display) on Medical Device that allows for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Unit provides brightness adjustments for improved visibility in varying light conditions Periodic Power Supply checks Highly visible numerics & traces due to high contrast of color Gemini Main App - System Message Verification Plan Gemini Main App - Numeric field Verification Plan Gemini Main App - Trace Area Verification Plan
4.6.6.1 Lack of audible feedback on Medical Device that allows for missing Alarm conditions causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Audible output may be allowed to be turned down, and not turned off Visual indicators remain even if audio is muted/silenced Gemini Main App - Alarm Volume Verification Plan Gemini Main App - Alarm Annunciation Verification Plan
4.7.1.1 Internal data transfer is erroneous allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Periodic RS232 checks – packet checksum Communications between NSAM & Main ctrl board uses checksum'ed information Invalid received data not used/displayed Lack of continuous missing data will cause system alarm Gemini Main App - System Message Verification Plan
4.7.1.2 Calculated FS Data is collected erroneous due to a software performance issue allowing FS Data readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Software calculations for FS Data Collection are based on simple algorithms FS Data transfer to USB Patient data file or snapshot/print feature Gemini Main App - System Message Verification Plan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SW Risk[5]	Control Measures / VeR Plan [6]
4.7.1.3 Medical Device readings are transmitted erroneously due to a software performance issue or faulty connection allowing remote readings to be incorrect causing inaccurate diagnoses resulting in wrong course of patient treatment leading to ischemic or hypoxic injury	Periodic RS232 checks – Protocol check Serial output protocol based on documented format Gemini Main App - System Message Verification Plan
4.7.2.1 Medical Device readings are displayed erroneously due to lack/delay of specifications of maintenance checks allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Periodic hardware checks (Power Supply, Memory, USB, VGA & RS232) Gemini Main App - System Message Verification Plan
4.7.4.1 Re-use of disposable, single-use Sensor (e.g., by user reprocessing, or non-removal of release liner on adhesive type Sensors) allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Software recognition software for detection of connection to an approved medical device Gemini Main App - System Message Verification Plan
4.7.5.1 Medical Device controls become inoperable due to age/use & not allowing user to enter proper patient data or forced to use existing patient case allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Periodic power supply checks TPI displayed on the main screen for each channel & values Gemini Main App - System Message Verification Plan Gemini Main App - Numeric field Verification Plan
4.7.5.2 Medical Device LCD become partially inoperable due to age/use & not allowing user to fully view patient data & causes inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Periodic power supply checks Gemini Main App - System Message Verification Plan
4.7.5.4 Patient connectors become inoperable due to age/use & mechanical insertion/extraction allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid computed information shall either present as dashes or a warning message Gemini Main App - Numeric field Verification Plan
4.7.5.7 Fans become inoperable due to age/use leading to an internal temp above stated environmental limits allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	If fan stops and the internal device temp reaches a maximum threshold device will perform auto-shut off Gemini Main App - System Message Verification Plan

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SW Risk[5]	Control Measures / VeR Plan [6]
4.8.1.1 User does not have access to view provided electronic copy of DFU safety instructions, that allows for improper use of device & causes delay of treatment of patient	Ambient light detection message and alarm Gemini Main App - System Message Verification Plan
4.11.1.1 Disconnected, faulty Sensor, preamp or device causes the Medical Device to be inoperable resulting in a lack, delay or over treatment of patient	Periodic device hardware fault testing Fault conditions indicated & annunciated Always visible Alarm LED Gemini Main App - System Message Verification Plan Gemini Main App - Alarm Annunciation Verification Plan Gemini Main App - Alarm Silence Verification Plan
4.11.1.2 Lack of notification by Medical Device of the decrease in a patient's StO_2 values resulting in a lack, delay or over treatment of patient	Low Alarm limits available to alert user of decrease in StO_2 value Visual & audible annunciation of Low StO_2 Alarm Gemini Main App - Hi/Lo Alarm Limits Verification Plan Gemini Main App - Alarm Annunciation Verification Plan Gemini Main App - Alarm Silence Verification Plan
4.11.1.3 Lack of notification by Medical Device of the increase in a patient's StO_2 values resulting in a lack, delay or over treatment of patient	High Alarm limits available to alert user of increase in StO_2 value Visual & audible annunciation of High StO_2 Alarm Gemini Main App - Hi/Lo Alarm Limits Verification Plan Gemini Main App - Alarm Annunciation Verification Plan Gemini Main App - Alarm Silence Verification Plan
4.11.1.4 Annunciation of flashing visual Alarm conditions on screen may cause spasms and/or convulsions in people prone to seizures (e.g., epilepsy)	Visual Alarm Flashing conforms to IEC 60601-1-8 flash rates of alarm LEDs Gemini Main App - Alarm Annunciation Verification Plan Gemini Main App - Alarm Silence Verification Plan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SW Risk[5]	Control Measures / VeR Plan [6]
4.11.2.1 StO_2 High/Low Alarm Limit selection cannot be accurately tested against the actual Patient StO_2 value allowing a possible undetected change in physiological condition to exist resulting in circulatory injury	StO_2 computed value & StO_2 High & Low Alarm Limits have resolution of 1% High Alarm: StO_2 value > High StO_2 Limit Low Alarm: StO_2 value < Low StO_2 Limit Gemini Main App - Alarm Limit Layout Verification Plan Gemini Main App - Hi/Lo Alarm Limits Verification Plan

Software includes or uses SOUP[7]: ☐ Yes ☒ No

Description/Mfg: **N/A**

SOUP included in Risk Management review: ☐ Yes ☒ No

SOUP Risks: **N/A**

Control Measures: **N/A**

[7] SOUP = Software Of Unknown Provenance, refer to ANSI/AAMI/IEC 62304 Standard

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Author: M. Kenigsztein **Date:**[1] 05-Feb-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Project Leader	2/6/13 Date	Software Eng[2]	02/06/13 Date
Regulatory Affairs	2/6/13 Date		

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Form Revision History

00 – Initial release

Document Revision History

00 – Initial release
01 – Update Hazard/Risk Section numbers – Age/Weight feature/risks removed from RMF docs, Update list of Main Bootloader Verification plans

PURPOSE

The following Software Life Cycle Worksheet[3] shall be completed by the Project Leader early in Stage 4 with information obtained from Design Inputs (Product Specifications, Marketing Requirements or SPRs) and information gathered from Software Eng(s) involved in the design. A final review of this Software Life Cycle Worksheet shall be performed in Stage 7 prior to the Product Release.

1. Introduction – Describe the Project/Product

This document covers the Software Life Cycle of the Project Gemini's NSAM Application software. The NSAM Application will perform computation of the NIRS Algorithm based on Sensor Body locations and sensor types as well as allowing for upgrading of the NSAM Bootloader via serial code/file transfer from the Gemini Main Application

[1] Date: Refers to date the Information on this form was last fully updated and **not** the revision of the form itself (see footer)

[2] The Form may be altered to include approvals for additional Software Engs

[3] This form may be modified by the addition of other fields. Fields should **not** be removed, and unused fields should be indicated as Not Applicable (NA) along with a justification if necessary.

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Overall Software System Safety Class[4]:	☐ Class A: No injury or damage to health is possible
	☒ **Class B: Non-serious injury is possible**
	☐ Class C: Death or serious injury is possible

Rational: IFU: The prospective clinical value of data from the FORE-SIGHT Oximeter has not been demonstrated in disease states and these data should not be used as a sole basis for diagnosis or therapy. Warning in the User manual: The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. The calculations of the %StO2 values are performed (b)(4) [redacted]

Software items with lower Safely Class than Overall Software System (see above):

Software Item: **Boot loader update functionality** Class: A

Rationale: Does not affect safety / data collection, it is done offline by a biomed Documented in RM file: ☐

Software Item: **Auxiliary / Debug port functionality** Class: A

Rationale: Does not affect safety / data collection, it is used for debugging purposes only Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

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[4] Software System Safety Class is defined in ANSI/AAMI/IEC 62304 Standard

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Other Software Development processes used and not described in 21-07-0017 -

Software Style Guidelines: **None**

Design Input: Documents:		
	☒ Product Specifications:	**21-07-0302, Gemini Product Specifications**
	☐ Marketing Requirements:	
	☐ SPRs:	
	☐ Other:	

Design Outputs Software Documents:	
	21-07-0327, Gemini NSAM Application SW Requirements
	21-07-0331, Gemini NSAM Application SW Architecture
	Details the architecture and requirements of the NSAM Application to perform computation of the NIRS algorithm based on Sensor Body locations and allows for upgrading of the NSAM Bootloader

Verification Documents:	
	Gemini NSAM Application Power On Self-Test (POSTs) Verification Plan
	Gemini NSAM Application Algorithm Verification Plan
	VaP 120018, Gemini / FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan
	VaP 120019, Gemini / FORE-SIGHT ELITE Software PEMS Validation

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Config Management:

☒ **New Project & Files**

☐ Use Concurrent Versions System (CVS) files:

From Build _____ Rev: _____

☐ Use DocControl Archive files:

From Build Rev:

For each Software build, describe the Tools and Environment (Mfg, Name, Rev, etc.):

Software	Tools & Environment Used to Build Software
(b)(4) [redacted]	
(b)(4) [redacted]	

Complete the following if the Overall Software System is Class C ☐ or N/A ☒

Standards: **N/A**

Method: **N/A**

Other Problem Resolving processes not used or described in QSP4004 - System Performance Reports (SPR), Product Request (PR): **Yes -** (b)(4) [redacted] **Configuration and Management) solution, Software Version: 4.0, Database Version: 4.0**

Complete the following if the Overall Software Systems is Class B ☒, C☐ or N/A ☐

Integration Test Plans: 1) NSAM App: Main - Initialization & Task Creation Integration Plan

2) NSAM App: MQX Related/Common Drivers Integration Plan

3) NSAM App: 1-Wire Integration Plan

4) NSAM App: NIRS Algorithm Integration Plan

5) NSAM App: Shell and Debug Integration Plan

6) NSAM App: Utilities Integration Plan

7) NSAM App: Bootloader Upgrade Integration Plan

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Project Risk Management:	Risk Management Plan:	21-07-0303, Gemini Risk Management Plan
	Hazard Identification:	21-07-0304, Gemini Hazard Identification
	dFMEA Analysis:	21-07-0305, Gemini Monitor dFMEA Analysis
	Risk Analysis:	21-07-0306, Gemini Risk Analysis
	Risk Management Summary:	21-07-0307, Gemini Risk Management Summary
	Other:	N/A

SW Risks:[5]	Control Measures / VeR Plan:[6]
4.1.2.3 Sensor LED design, damaged monitor or Software issue that allows excessive current to drive LEDs causing localized tissue injury (burn)	Power to LEDs output is limited (current & duty cycle) (b)(4) [redacted] Gemini NSAM Application Algorithm Verification Plan
4.1.2.6 Applied Sensor raises the temperature under the Sensor to > 41.0℃ resulting in thermal tissue injury (heat) at Sensor site	(b)(4) [redacted] Gemini NSAM Application Algorithm Verification Plan
4.1.3.6 Patient moves/turns or loss of adhesion due to perspiration or inadequate placement causing Sensor to move from original position causing sensor to cover nose or mouth resulting in suffocation or injury	Ambient light detection to alert User Gemini NSAM Application Algorithm Verification Plan
4.3.1.1 Medical Device is inoperable due to susceptibility of electromagnetic fields (EMC) from other devices causing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Data filter attempts to eliminate noise signals Value captured & not updated during noisy periods Sustained noisy conditions will blank numeric & recover when noise is removed Gemini NSAM Application Algorithm Verification Plan
4.4.1.2 Sensor LEDs calibration values invalid allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	(b)(4) [redacted] Values need to inputted by NSAM, Checksum of Cal values must be correct in order for Sensors to be used and error message generated Gemini NSAM Application Algorithm Verification Plan
4.5.4.1 Medical Device used by unskilled/untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & values Gemini NSAM Application Algorithm Verification Plan
4.5.5.2 Medical Device used with an inappropriate Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display LEDs will not turn on if incorrect Sensor attached Gemini NSAM Application Algorithm Verification Plan
4.5.6.2 Medical Device used with an inappropriate size Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	LEDs will not turn on if incorrect Sensor attached Gemini NSAM Application Algorithm Verification Plan

[5] Refer to 21-07-0304 Gemini Hazard Identification & 21-07-0306 Gemini Risk Analysis for additional information

[6] All Control Measures are verified by specific Verification Plans as well as VaP 120018, Gemini / FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan

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SW Risks:[5]	Control Measures / VeR Plan:[6]
4.5.6.3 Software performance issue in Medical Device allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient Some examples of mitigating know SW issues:	Power On Self-Test (POST) & periodic system checks Software algorithm output verified against development SW (used to obtain clinical data) output for all Sensor sizes based on body locations Gemini NSAM Application Power On Self-Test (POSTs) Verification Plan Gemini NSAM Application Algorithm Verification Plan
Communication integrity between the NSAM and Host (SCB)	Checksum for every command Gemini NSAM Application Power On Self-Test (POSTs) Verification Plan Gemini NSAM Application Algorithm Verification Plan
Communication's port to Host not responding	Flag a critical system error on the host Gemini NSAM Application Algorithm Verification Plan
Un-normal input signals causing unpredicted calculations	Check signal levels to be appropriate, check for divide by zero and Log(0), avoid calculation and flag it to the host Gemini NSAM Application Algorithm Verification Plan
Memory fragmentation	Avoid excessive run time dynamic memory allocations Gemini NSAM Application Algorithm Verification Plan
Memory leaks	Code review, prolonged testing Gemini NSAM Application Algorithm Verification Plan
Data corruption while writing to a non-volatile memory	Use Checksums, redundant data storage, avoid /delay as possible power loss Gemini NSAM Application Algorithm Verification Plan
4.5.9.1 Continuous LED output to patient Sensor site causes increase of temperature at Sensor site resulting in tissue injury	Power to LED output is limited Gemini NSAM Application Algorithm Verification Plan
4.6.1.1 Medical Device presents information that are mistaken/ misinterpreted for actual values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & values Gemini NSAM Application Algorithm Verification Plan
4.6.3.1 Medical Device displays ambiguous or unclear states that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid information shall be presented as dashes & messages TPI displayed on main screen for each channel & values Gemini NSAM Application Algorithm Verification Plan
4.6.3.2 Wrong size Sensor used on an inappropriate type/size patient allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & value Gemini NSAM Application Algorithm Verification Plan
4.7.5.3 Medical Device calibration data incorrect that allows device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Sensor Flash R/W check Redundant checksum storage of critical calibration data Gemini NSAM Application Algorithm Verification Plan

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SW Risks:[5]	Control Measures / VeR Plan:[6]
4.7.5.6 Patient connectors become inoperable due to age/use and mechanical insertion/extraction allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid computed information shall either presented as dashes with warning message Gemini NSAM Application Algorithm Verification Plan
4.11.1.1 Disconnected, faulty Sensor, preamp or device causes the Medical Device to be inoperable resulting in a lack, delay or over treatment of patient	Sensing of Sensor & Preamp connect & disconnect Periodic Sensors & Preamp fault testing Periodic device hardware fault testing Fault conditions indicated & annunciated Gemini NSAM Application Algorithm Verification Plan

Software includes or uses SOUP[7]: ☐ Yes ☒ No

Description/Mfg: **N/A**

SOUP included in Risk Management review: ☐ Yes ☒ No

SOUP Risks: **N/A**

Control Measures: **N/A**

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[7] SOUP = Software Of Unknown Provenance, refer to ANSI/AAMI/IEC 62304 Standard

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Title: Gemini / FORE-SIGHT ELITE Software PEMS Validation Plan		

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals:

Validation Engineer	P. Tala	12.10.13 Date
Project Engineer	R. Bystrianyk	12/12/13 Date
Eng Project Leader	H. Triebel	11-Dec-13 Date
VP R & D	J. Gamelin	11-Dec-2013 Date
Mktg Product Manager	M. Aceves	12/11/13 Date
Quality Assurance Regulatory Affairs	R. Jeffrey	12/11/13 Date

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2.0	P. Tala	Update plan to include changes for Rev 0.3.3 Test Plan
3.0	P. Tala	Update plan to include changes for Rev 0.3.5 Test Plan
4.0	P. Tala	Update plan to include changes for Rev 0.3.6 Test Plan
5.0	P. Tala	Update plan to include changes for Rev 1.0.0 Test Plan
6.0	P. Tala	Update plan to include changes for Rev 1.0.1 Test Plan
7.0	P. Tala	Update plan to include changes for Rev 1.0.2 Test Plan
8.0	P. Tala	Update plan to include changes for Rev 1.1.0 Test Plan
9.0	P. Tala	Update plan to include changes for Rev 1.1.1 Test Plan

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Table of Contents

1 Introduction 7

2 Scope 7

3 Reference Documents 9

4 List of Equipment 10

5 Initial Setup 10

6 Regression Validation Justification 10

7 Data Sheets - Pass/Fail Criteria 11

8 Test Procedure 12

8.1 SCB & NSAM Software Code Upload & System Configuration 12
8.1.1 SCB & NSAM Package and Software Upload 12
8.1.2 System Configuration 13
8.1.3 Touch Screen Calibration 13

8.2 Oximeter Start Up 14
8.2.1 Standard Start Up 14
8.2.2 Start Up With Failed Power-On Self-Test 14

8.3 Visual & Display Indicators 15
8.3.1 Main Screen Display 15
8.3.1.1 Title Bar/Line Area 16
8.3.1.2 System Message Area 16
8.3.1.3 Trace Area 16
8.3.1.4 Numeric Field 17
8.3.1.5 1ST , 2nd Levels Touch button 18
8.3.1.6 Alarm Silence button 19

8.4 User Controls 20
8.4.1 Patient Menu 20
8.4.1.1 Patient Menu Selections 20
8.4.1.2 Body Location Settings 20
8.4.1.2.1 US Configuration 20
8.4.1.2.2 OUS Configuration 22
8.4.1.3 Alarm Limits Settings 23
8.4.1.4 Alarm Limit Range 24
8.4.1.5 Patient ID 25
8.4.1.6 New Patient 25
8.4.2 Event Marks 25
8.4.2.1 Events Menu Selection 25
8.4.2.2 Events from List Addition 26
8.4.2.3 Removing placed Events 28
8.4.2.4 Auto Events 29
8.4.3 Data Menu 30
8.4.3.1 Data Menu Selection 30
8.4.3.2 STS View Menu 31
8.4.3.3 STS Data Collection and Verification 32
8.4.3.4 Reference Value REF 35

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.4.4 Patient Data Management ... 36
8.4.4.1 Multiple Patients Storage ... 36
8.4.4.2 Saving Selected Files to the USB ... 37
8.4.4.3 Reviewing Data Saved to the USB ... 37
8.4.4.4 Deleting Selected Files to the USB ... 40
8.4.5 Setup Menu ... 40
8.4.5.1 Setup Menu Selection ... 40
8.4.5.2 View Settings ... 41
8.4.5.3 Volume Settings ... 41
8.4.5.4 Brightness Settings ... 42
8.4.5.5 Ports Settings ... 42
8.4.5.6 Time and Date Settings ... 43
8.4.5.7 Language Settings ... 45
8.4.5.8 Alarm Delay ... 46
8.4.5.9 Factory Defaults Settings ... 46
8.4.5.10 Help Menu ... 48

8.5 Connection Status & StO2 Data Collection ... 50
8.5.1 Patient & Monitor Cable Status ... 50
8.5.1.1 Connection Status at Power on ... 50
8.5.1.2 Disconnection Status after Power on ... 51
8.5.2 Sensor Connection and StO2 Data Acquisition ... 51
8.5.3 New /Continue Patient Timer & Prompting ... 52
8.5.4 TPI Status Indicator ... 53
8.5.5 Adult TOP Calibration Rule ... 55
8.5.6 NSAM Application Adult Cerebral Algorithm Verification ... 56
8.5.7 NSAM Application Adult Somatic Tissues Algorithm Verification ... 57

8.6 Data Communication ... 57
8.6.1 2-CH Comma Separated Value (CSV) ... 57
8.6.2 4-CH Comma Separated Value (CSV) ... 57
8.6.3 2-CH CAS Protocol (ATE) ... 58
8.6.4 4-CH CAS Protocol (ATE) ... 59
8.6.5 Philips VueLink and IntelliBridge Communication ... 61
8.6.6 Scientific Communication ... 61

8.7 Alarms Handling & Management ... 61
8.7.1 System LEDs ... 61
8.7.2 Parameter Alarms ... 61
8.7.2.1 2-Min Audio Disable Inactive ... 61
8.7.2.2 2-Min Audio Disable Active ... 62
8.7.3 Equipment Alarm ... 62
8.7.3.1 Ambient Light Condition ... 62
8.7.3.2 Sensor Temperature Monitoring ... 63
8.7.3.3 ESU Disturbance Condition ... 65
8.7.3.4 2-Min Audio Disable Inactive ... 65
8.7.3.5 2-Min Audio Disable Active ... 67
8.7.4 System Alarms ... 68
8.7.4.1 Battery Status ... 68
8.7.4.2 System Fan Status ... 68
8.7.4.3 System Temperature ... 69
8.7.4.4 2-Min Audio Disable Inactive ... 70
8.7.4.5 2-Min Audio Disable Active ... 71
8.7.5 Alarm Interference & Priority ... 72
8.7.5.1 Parameter and Equipment Alarms ... 72
8.7.5.2 Parameter and System Alarms ... 72

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.7.5.3 Equipment and System Alarms 73
8.7.5.4 Parameter, Equipment and System Alarms 74

9 Summary 75

FIGURES

Figure 1 – Initial Power On Screen (e.g. 2 Channels Mode) 15
Figure 2 – Numeric Field Organization 18
Figure 3 – Examples of button's Activation State 19
Figure 4 – Adult Cerebral (US) Body Location Menu 21
Figure 5 – Adult Tissue (OUS) Body Location Menu 22
Figure 6 – STS View Menu content 31
Figure 7 – Time & Date Menu 44
Figure 8 – Russian (Cyrillic) Alphabet keyboard 45
Figure 9 – About Help Menu 48
Figure 10 – Sensor Selection Help Screen 49
Figure 11 – Start Monitoring Help Screen 49
Figure 12 – Applying Sensors Help Screen 49
Figure 13 – Numeric Field Help Screen 50

TABLES

Table 1 – Alarm Silence Activation Access availability 20
Table 2 – Alarm Limit Range 24
Table 3 – OR Event Marks List 27
Table 4 – ICU Event Marks List 28
Table 5 – Vascular Event Marks List 28
Table 6 – NSAM Conditions Auto Events 30
Table 7 – STS View Data Record 33
Table 8 – STS DATA Calculation Data Sheet 34
Table 9 – Regional Oxygen Saturation Percentile Ranges Calculation 35
Table 10 – Calculated STS Data 35
Table 11 – Alarm Index Table 39
Table 12 – Password Protected Menu Screen 40
Table 13 – View Settings 41
Table 14 – Brightness Settings 42
Table 15 – Serial Protocols Baud Rates Selections 43
Table 16 – Simultaneous Serial Output Table 43
Table 17 – Time and Date setting 44
Table 18 – Alarm Delay 46
Table 19 - Factory Default Settings 48
Table 20 – Power On Connection Status 51
Table 21 – Connection Status during Monitoring. 51
Table 22 – Sensor Selection and StO2 Data Acquisition 52
Table 23 – TPI Symbol Status – Cerebral Monitoring 54
Table 24 – TPI Symbol Status – Somatic Tissues Monitoring 55
Table 25 – NSAM TOP Calculation Rule 56
Table 26 - ATE Serial Output Commands 60
Table 27 – Parameter Alarms Control (2-Min Audio Disable inactive) 62
Table 28 – Parameter Alarms Control (2-Min Audio Disable active) 62

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Table 29 – Equipment Alarms Control (2-Min Audio Disable inactive) 66
Table 30 – Equipment Alarms Control (2-Min Audio Disable active) 67
Table 31 – System Alarms Control (2-Min Audio Disable inactive) 71
Table 32 – System Alarms Control (2-Min Audio Disable active) 71
Table 33 – Parameter and Equipment Alarm condition Interference. 72
Table 34 – Parameter and System Alarm condition Interference. 73
Table 35 – Equipment and System Alarm condition Interference. 73
Table 36 – Parameter, Equipment and System Alarm condition Interference. 74

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1 Introduction

The purpose of this document is to detail the validation of the design requirements for the Gemini / FORE-SIGHT ELITE Oximeter Software. The Oximeter is a medical device comprised of a Color 10.4" display, user interface controls (Touchscreen) and hardware to support the acquisition of a patient's tissue oxygen concentration. The Validation Plan will validate that the performance output meets the design input requirements set out in Gemini Product Specification documents (refer to Section 0 below).

NOTE: The term Gemini refers to the Eng Project, while FORE-SIGHT ELITE refers to the product name. They may be used interchangeably.

2 Scope

The Oximeter Software shall include the following components:

1. Oximeter SCB Bootloader Software
2. Oximeter SCB Application Software
3. Oximeter NSAM Bootloader Software
4. Oximeter NSAM Application Software

The Software Package version to be verified is Rev 1.1.1

The plan shall include validation of the safety of PEMS of installed SW listed above and detailed in Section 4 List of Equipment.

Following are the Fixes (SPRs) to the SCB & NSAM Main Application and Boot Loader Software (15-06-0285, 15-06-0284, 15-06-0283 & 15-06-0282) to be validated within this Validation Plan. Refer to the appropriate sections in the Validation Plan:

Software	New Features, Improvements and Fixes
Main Boot 15-06-0284	• Touch screen calibration range check. (1026) • Adjust Ambient light upper threshold for NSAM test (1030)
Main App 15-06-0285	• Sensor Off Tissue and StO2 Value (928) • Addition of languages including Russian (multiple CRs) • Russian Cyrillic keyboard. (1029) • Implement adaptive fan speed based on internal temperatures. (1021, 1080) • Channel ATE and CSV (1008) • Ports no longer require a system reset (827) • Special file on the USB stick "eng1984.cas" automatically starts the network (1047) • Shell - 1-wire serial memory tests (command "serm") (1045) • Create secondary level of reporting NSAM issues to the user (1052, 1053) • Entering Biomed password will display Button bar with Language and defaults (1054) • Add confirm dialog to Stop STS data (1058) • Adjust priorities and error messages (1062) • Change Brightness settings scale (1064) • CAS/ATE Remap Unstable Signal status (1071) • Add Patient ID to USB File Name (1073) • Add one decimal digit to Cumulative Sat Below Thresh & Reg O2 % Ranges (1067) • Add scientific mode to all users. (1075) • Different body locations available in OUS (1077) • Add translation for Ports -> scientific (1081) • Add automatically generated events based on special NSAM conditions (1061) • Add languages to USB patient file (1095) • Add toggling bitmap Checkbox to Engineering settings dialog (1142)

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Software	New Features, Improvements and Fixes
	• Add klog tools to Engineering Dialog (1163) • Bug Fix - Correct redraw speed of numeric fields after display of events - Still may occur but is vastly improved (746) • Bug Fix - Rapid changes in Settings-View causes crash (1038) • Bug Fix - External Interference causes the Numeric field to go blank instead of dashes (1041) • Bug Fix - Monitor reset if Factory Defaults activated (1003, 827) • Bug Fix - Correct underlying alarm led and audio problems. (1057) • Bug Fix - Pressed Events, then OR then screen froze showing just bottom 3 options (949) • Bug Fix - Rapid switching between Event button and Undo button causes crash (965) • Bug Fix - Possibility to delete more than the last Event entered (1000) • Bug Fix - USB File - need to add a decimal digit precision to STS data (1094) • Bug Fix - ICU Event list "Reposition Patient" should be Green Event after "Prostaglandin" (1096) • Bug Fix - Caution - Investigational Device not displayed when engineering body locations are enabled (SPR 765)(1129) • Bug Fix - In Italian "View" 24 Hour selection is 1Ore, should be 24 Ore (SPR 762-2) (1136) • Bug Fix - In 4 CH CAS protocol, crash when baud rate is selected (SPR 761)(1145) • Bug Fix - Numeric Field "Current Value" sometimes blank after fast boot (SPR 764)(1147) • Bug Fix - Remove active case from USB save list (SPR 758 & 760) (1148) • Bug Fix - Change STS statistics to match CSV (SPR 756)(1149) • Bug Fix - Text for sensor over/under temperature not appearing in CSV event. (755)(1150) • Bug Fix - Clicking the Ref value does not toggle the Ref line on graph (757)(1151) • Bug Fix - Event Mark vertical dotted line (SPR 754) (1153) • Bug Fix - Dutch under STS & other string fixes(SPR 762-1 & 763) (1158)
NSAM App 15-06-0283	• (b)(4) [redacted] • Account for the 1 wire temperature NSAM offsets & Code Cleanup (1043) • Enable the Enhanced AGC, allow higher dynamic range for the gains (1044) • Adjust high Ambient Light Threshold (1048) • Enhance the Bovie Filter (1049) • (b)(4) [redacted] (b)(4) [redacted] • Add Adult Somatic IFU, adjust Adult Cerebral TPI Levels (1079) • Adjust Sensor Off Temp, Adjust Low Thb levels, High Ambient Light (1093) • Ignore Low brain 690nm values & do not include in spectral window calculation of "Sensor Off" (1140)

New Features, Improvements and Fixes	Section
SPR # 741 - Possibility to delete more than the last Event entered (CR 1000)	8.4.2.3
SPR # 747 - System Reset after Factory Defaults activation (CR 1003)	8.4.5.9
SPR # 754 - Event Mark vertical dotted line (CR 1153)	8.4.2.2
SPR # 755 - NSAM Auto Event Mark on USB (CR 1150 & 1154)	8.4.2.4
SPR # 756 - STS Data Calculation (SPR 1149 & 1155)	8.4.3.3
SPR # 757 - Reference Value: Horizontal dotted line not toggling (CR 1151 & 1156)	8.4.3.4
SPR # 758 - Active case total duration time. (CR 1148)	8.4.4.1
SPR # 760 - Active cases saved to the USB (CR 1148)	8.4.4.2
SPR # 761 - Ports Settings & Baud Rate (CR 1145)	8.4.5.5

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New Features, Improvements and Fixes	Section
SPR # 762 - Dutch & Italian Strings under STS & View Menus (CR 1136 & 1158)	8.4.5.7
SPR # 763 - GUI Strings Translation (CR 1158 & 1159)	8.4.5.7
SPR # 764 - System Reset & StO2 Numerics on Display (CR 1147)	8.3
SPR # 765 - OUS Configuration & Body Location (CR 1129 & 1160)	8.4.1.2.2

3 Reference Documents

- IEC 60601-1-8 Alarm Sounds
- CAS QSP1026, Risk Management
- CAS QSP4001, Product Design Procedure
- CAS QSP4002, Software Life Cycle Procedure
- CAS QSP4004, System Performance Report (SPR), Product Request (PR)
- CAS QSP4007, Design Verification and Validation
- 21-07-0302, Gemini Product Specification
- 21-07-0312, Gemini GUI Specifications
- 21-07-0322, Gemini Philips VueLink Translation Document
- 21-07-0323, Gemini Software Icons Specifications
- 21-07-0324, Gemini Main Bootloader Software Requirements
- 21-07-0325, Gemini Main Application Software Requirements
- 21-07-0326, Gemini NSAM Bootloader Software Requirements
- 21-07-0327, Gemini NSAM Application Software Requirements
- 21-07-0328, Gemini Main Bootloader Software Architecture & Specification
- 21-07-0329, Gemini Main Application Software Architecture & Specification
- 21-07-0330, Gemini NSAM Bootloader Software Architecture & Specification
- 21-07-0331, Gemini NSAM Application Software Architecture & Specification
- 21-07-0333, Gemini Main Bootloader Software Life Cycle Worksheet
- 21-07-0334, Gemini Main Application Software Life Cycle Worksheet
- 21-07-0335, Gemini NSAM Bootloader Software Life Cycle Worksheet
- 21-07-0336, Gemini NSAM Application Software Life Cycle Worksheet
- 21-07-0337, Gemini Software Level of Concern Document
- 21-07-0339, Gemini Software Revision History
- 21-07-0342, Gemini USB Patient Data File Storage Format
- 21-07-0343, Gemini Displayed Message Priority Assignment Document
- 21-07-0344, Gemini Help Screen Specifications
- 21-07-0345, Gemini Scientific Data Serial Output Protocol
- 21-07-0346, Gemini 4-Ch Comma Separated Value Serial Output Format
- 21-07-0355, Gemini/FORE-SIGHT ELITE GUI Text Translations (Fre, Spa, Dut, Ger, Ita, Rus)
- 21-07-0360, Gemini USB Patient Data File Storage Format - Scientific Debug Events
- FS ATE, FORE-SIGHT ATE SERIAL PROTOCOL
- IntelliVue Patient Monitor- Instructions For Use – Rev H.0
- VaP/VaR 120010 – FORE-SIGHT ELITE Philips IntelliBridge/VueLink Connectivity Validation
- VeP/VeR 130033 – FORE-SIGHT ELITE Main App Research Mode Verification

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4 List of Equipment

- Gemini Tissue Oximeter: SN 1315182 1315183 referred to as Unit Under Test (UUT)
  - NSAM Bootloader software 15-06-0282 Ver 1.0.0
  - NSAM Application software 15-06-0283 Ver 2.0.0a
  - Main Bootloader software 15-06-0284 Ver 1.1.0A
  - Main Application software 15-06-0285 Ver 1.1.1A
- 1 Hospital Grade AC Power Cord.
- Gemini Large & Medium Sensors w/ & w/o optical phantoms
- Gemini Dual Preamp Cables
- PC running XP or higher with an available USB, Ethernet, and serial port
- Windows Telnet program
- FS-Elite Large Sensor (03-05-0511)
- Gemini Large optical phantoms
- FORE-SIGHT Elite Dual Preamp Cable (01-06-3100)
- VueLink & IntelliBridge compatible Patient Monitor: INTELLIVUE MP50
  SW. Rev: J.10.26 SN: DE820A9121
- Philips VueLink® Interface Module Auxiliary Plus (M1032A, Type B)
- Philips VueLink® connection cable with D-SUB 9 connector (M1032A #K6C)
- DB9 M/M Null Modem Interconnect Cable
- Philips IntelliBridge EC10 Module: PN 865115 #A01 101
- Philips IntelliBridge EC5 Module: PN 865114 #104
- Max 10 m, CAT5, Straight wired Cable (to connect EC5 to EC10 modules)
- Assorted USB Sticks

5 Initial Setup

None required

6 Regression Validation Justification

None required. Full validation of the currently available features of the Oximeter Software shall be completed.

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7 Data Sheets - Pass/Fail Criteria

This Validation Plan will be considered completed when all Test Procedure steps referenced on the following pages have been completed. The following rules shall be followed for the Data Sheets:

- Checking and signing the Data Sheets results will be done in **blue** or **black** ink only.
- The word **PASS** in the associated _____ will be used to identify when a Data Sheet step was successfully been validated.
- The word **FAIL** in the associated _____ will be used to identify when a Data Sheet step was unsuccessfully been validated.
- All Data Sheet steps must be filled in w/ Pass or Fail.
- Data Sheet step failures shall be marked in red ink and shall be initialed and dated.
- Data Sheet step discrepancies shall be marked in red ink, be lined out with the correction inserted next to the error and shall be initialed and dated.
- All performance reports and Plan discrepancies will be reviewed and their resolution approved prior to releasing the product or accessory.

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8 Test Procedure

8.1 SCB & NSAM Software Code Upload & System Configuration

8.1.1 SCB & NSAM Package and Software Upload

a) Plug the power cord into a power outlet and in to the UUT and make sure the battery pack is installed

b) **Starting with a UUT that has the Software Package version 1.0.2 installed.**

c) Connect a USB that has the Software package folder "15-06-0339_FSElite_1.1.1" (**without new Bootloader Rev 1.1.0 included**) installed to the UUT.

d) Power on the UUT to validate the Bootloader automatically enters the **Package update** menu PASS

e) Validate the Bootloader application compares the Software update file on the USB to the currently installed on the UUT PASS

f) Validate files that needs to be upgraded are properly marked red. PASS

g) Wait for the "**Update System**" key to become available then start the package update.

h) Validate all software package are updated without any further user intervention. PASS

i) Exit the Bootloader menu once done with the package installation to enter the Main menu.

j) Connect appropriate Preamps, Sensors and optical simulators to validate the system starts to report valid StO2 data. PASS

k) Validate the UUT is operating properly. PASS (Note any encountered issues below)

l) Enter the Help\About menu to validate the Package version and date do match the Package version and installation date PASS

m) Cycle powers to the UUT and reenter the Bootloader menu.

n) Enter the "**About**" menu to validate the installed software versions do match the versions within the software package installed on the UUT. PASS

o) Cycle power to the UUT to reenter the Bootloader menu

p) Connect a USB that has the **Bootloader version 1.1.0** to the UUT and start to upload the Bootloader software into the UUT using the individual software download menu to validate the update is performed without any issues. PASS (Note any encountered difficulties below)

q) Enter the Engineering Menu and validate there is the possibility to either perform a Package or an individual Software Download.

   a. Engineering PASS
   b. Manufacturing PASS
   c. Service PASS
   d. Biomed PASS (Package Up date only)

r) Exit the Bootloader to enter Main menu.

s) Connect appropriate Preamps, Sensors and optical simulators to validate the system starts to report valid StO2 data. PASS

t) Validate the UUT is operating properly. PASS (Note any encountered issues below)

u) Enter the Help\About menu to validate the Package version and date do match the Package version and installation date PASS (An "*" appears next to the Package Version)

v) Turn off the UUT

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.

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FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.1.2 System Configuration

a) Turn On the UUT and apply the Three finger while the Monitor is displaying the splash screen to validate the UUT enters the Bootloader menu. PASS

b) Enter the special Menus below and validate there is the possibility to change the system **IP Address.** (same IP address reported on the Splash screen at system start)
   a. Engineering PASS
   b. Manufacturing PASS
   c. Service PASS

c) Enter the **Biomed** Menu to validate there is **no** possibility to Change the **IP Address** PASS

d) Enter the **View Logs\Audit Log** and **View Logs\Error Log** to validate all recently recorded events are accessible. PASS

e) Cycle power to the UUT and wait to enter the Main menu before entering the **Setup** menu.

f) Validate the same System **Serial-** & **Asset Number** reported in the Bootloader Menu are also reported in the Main **Help\About** menu and on the last line of the Splash screen. PASS

g) Enter the appropriate password to enter the Menus below and validate there is no possibility to change the Monitor type from **"US"** to **"OUS"**
   a. Engineering PASS
   b. Biomed PASS

h) Enter the **Manufacturing** Menu to validate there is the possibility to Change the Monitor Type from **"US"** to **"OUS"** PASS

i) Enter the About menu to validate the Monitor Model Number for **US** is **01-06-3000** PASS and **01-06-3005** for **OUS** PASS

j) Set the UUT for **US** before cycling powers to validate the Monitor configuration is kept PASS

k) Set the UUT for **OUS** before cycling powers to validate the Monitor configuration is kept PASS

l) Turn off the UUT

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.1.3 Touch Screen Calibration

a) Turn On the UUT and wait for the UUT to display the splash screen.

b) Press and hold the power key for at least 30 seconds while the UUT is still displaying the splash screen to validate the UUT turns off. PASS

c) Turn On the UUT and validate the UUT does not enter the usual splash screen but the touch screen Calibration menu. PASS

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d) Follow the indication up to the second touch but touch the opposite corners for the last two indications to validate the calibration menu is not exited and the user is redirected to beginning of the calibration procedure. PASS.

e) Cycle power to the UUT and wait to enter the Splash screen to validate the UUT does instead enter the touch screen calibration menu. PASS

f) Wait for at least three minutes to validate the screen is not exited and remains in the Calibration menu. PASS

g) Follow the indication on the calibration menu to validate that this time the calibration routine is completed and the menu exited. PASS

h) Cycle power to the UUT to validate the UUT enters the splash screen then the main menu. PASS

i) Turn off the UUT

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.2 Oximeter Start Up

8.2.1 Standard Start Up

a) Turn on the UUT

b) Validate UUT first enter the Bootloader screen PASS

c) Validate Bootloader displays a splash screen image after the LCD screen has been initialized PASS

d) Validate Bootloader generates 2 short duration "beeps"; one with the High Priority and the second with Medium Priority tone during the POST sequence PASS

e) Validate Bootloader turns on all the Yellow and then all the Red Alarm LEDs during the POST sequence PASS

f) Validate during the Diagnostics, the system displays the version of the SCB Bootloader Software PASS

g) Validate the UUT enter Main Screen PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.2.2 Start Up With Failed Power-On Self-Test

a) Turn off the UUT

b) Disconnect the NSAM Board from the UUT

c) Turn on the UUT

d) Validate the UUT enters the Bootloader Menu and starts the POSTs sequence PASS

e) Validate the UUT displays **"E009-1" Error message** PASS

f) Validate the UUT generates a High Priority Alarm tone sequence and the Alarm LEDs are flashing Red PASS

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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g) Validate the UUT does not enter the Main application menu and stays in the High Priority Alarm condition PASS (Red LEDs and High Priority alarm tone)

h) Turn off the UUT

i) Reinstall the NSAM Board into the UUT

j) Turn on the UUT

k) Validate the UUT completes the POSTs tests sequence and enters Main Screen PASS

l) Turn off the UUT

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.3 Visual & Display Indicators

8.3.1 Main Screen Display

a) Turn On the UUT and wait to enter Main Screen

b) Validate the General look of the Main Screen follows Figure 1 below PASS

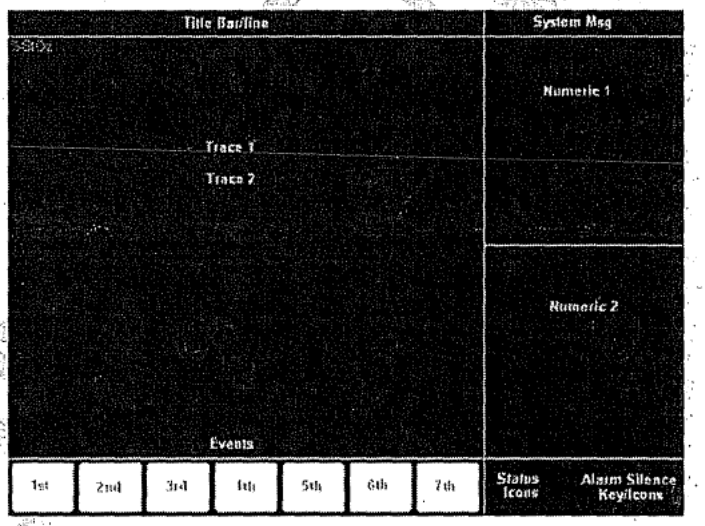

Figure 1 – Initial Power On Screen (e.g. 2 Channels Mode)

c) Validate the background color for normal operations is black PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

Test Performed By (signature): [signature] Date of Test: 12.12.13
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8.3.1.1 Title Bar/Line Area

a) Validate the current date and time do appear at the right corner of the Title Bar/Line area PASS

b) Validate the time is displayed in 24-hour format: 2-digit hours and 2 digit minutes (e.g., 11:34, leading zeros) PASS

c) Validate the date is displayed as a 2-digit day, 3-letter abbreviated month and 2-digit year (e.g., 02-Jun-11, leading zeros) PASS

d) Click on the Time/Date area of the Title Bar to validate the Data & Time entry menu opens up and any changes made there are readily implemented. PASS

e) Validate the Patient ID do appear at the left corner of the Title Bar. PASS

f) Click on the Patient ID area to validate the Patient ID entry menu opens up and any changes made there are readily implemented PASS

g) Validate the current View do appear in the middle section of the Title Bar. PASS

h) Click on the View area to validate the View entry menu opens up and any changes made there are readily implemented. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.3.1.2 System Message Area

a) Validate all system messages appear in the System message area PASS

b) Validate all System Alarm message texts are able to fit in the System message area PASS

c) Validate all translated System Alarm messages are able to fit in the System Message area. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.3.1.3 Trace Area

a) Validate the trace area has a black background PASS

b) Validate there is a maximum of four distinct sub areas for the traces PASS

c) Access any of the sub menus by selecting one of the available 1st then 2nd Level touch buttons to validate the trace area is covered/ replaced by the new menu PASS

d) Validate all trace areas have the same vertical scale with reference marks/values along the left side PASS (0-100%)

e) Validate all trace areas have the same view scale with reference time values along the top side PASS

f) Validate all active Channels are each represented by a trace. PASS

g) Validate user has the possibility to select:

All channels in one single trace area PASS

Two channels in one trace area 1&2 or 3&4. PASS

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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One channel per trace area. PASS

h) Validate traces have the same color as the matching Channel's Numeric PASS

i) Validate traces do not present any spike from bottom of graph to initial value. PASS

j) Cycle powers to the UUT to validate the traces are maintained across power cycles. PASS (If same patient and Off Time < 15 Minutes)

k) Connect Preamp and StO2 simulators to the UUT and wait for StO2 Numerics to be displayed

l) Enable the Ethernet connection and open a telnet session using the UUT's IP address.

m) Send the "Reset" command to the UUT at least 20 times to validate the UUT reset itself and return to the Main menu with all traces maintained PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.3.1.4 Numeric Field

a) Validate there are four numeric areas along the right side of the display (one for each channel: ①, ②, ③, ④) if the UUT is set for three to four valid Channels PASS

b) Validate there are only two numeric areas along the right side of the display (one for each channel: ①, ②, ③ or ④) if the UUT is set for one to two Channels (1&2, 1&3, 1&4, 2&3, 2&4 or 3&4) PASS

c) Open all menus and sub-menus from the selection below to validate the Numeric fields are always displayed:

- Patient/Case Selection P ☑ F ☐
- Patient Setup P ☑ F ☐
- Body Location Menu P ☑ F ☐
- High/Low Limits Menu P ☑ F ☐
- Setup Menu P ☑ F ☐
- Brightness Menu P ☑ F ☐
- Volume setting Menu P ☑ F ☐
- View Menu P ☑ F ☐
- Date & Time Menu P ☑ F ☐

d) Validate each of the following item below are represented in the numeric area at the indicated location per Figure 2 (If Channel active)

		4-Ch Mode	2-Ch Mode
• Channel ID	Area 1	P ☑ F ☐	P ☑ F ☐
• Numeric in associated color	Area 2	P ☑ F ☐	P ☑ F ☐
• Sensor location icons in associated color	Area 3	P ☑ F ☐	P ☑ F ☐
• Left/Right/Somatic indicator	Area 4	P ☑ F ☐	P ☑ F ☐
• TPI value Icon	Area 5	P ☑ F ☐	P ☑ F ☐
• Channel specific messages	Area 6	P ☑ F ☐	P ☑ F ☐

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• Reference saturation value	Area 7	P ☑ F ☐	P ☑ F ☐
• High and Low Alarm Limits	Area 8	P ☑ F ☐	P ☑ F ☐

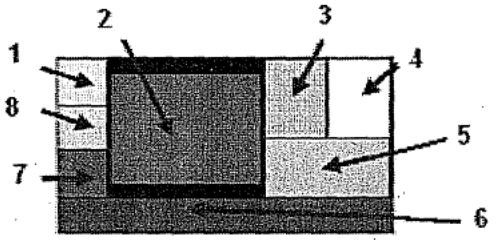

Figure 2 – Numeric Field Organization

e) Click in the area below to verify the Expected sub-menu appears as pop-up.

		4-Ch Mode	2-Ch Mode
• Sensor location icons	Patient Setup Menu	P ☑ F ☐	P ☑ F ☐
• Left/Right indicator	Patient Setup Menu	P ☑ F ☐	P ☑ F ☐
• High and Low Alarm Limits	Patient Setup Menu	P ☑ F ☐	P ☑ F ☐
• StO2 Numeric	Patient Setup Menu	P ☑ F ☐	P ☑ F ☐

a) Connect Preamp and StO2 simulators to the UUT and wait for StO2 Numerics to be displayed
b) Enable the Ethernet connection and open a telnet session using the UUT's IP address.
c) Send the "Reset" command to the UUT at least 20 times to validate the UUT reset itself and return to the Main menu with all traces maintained PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.3.1.5 1ST, 2nd Levels Touch button

a) Cycle power to the UUT.
b) Validate all 1st level touch button appear available PASS
c) Select any of the available touch button to validate they appear as touched PASS
d) Release the button to validate the intended action is performed PASS
e) Validate that only one button could be activated at the same time PASS
f) Validate that once any of the 1st level buttons is activated, the 1st Level buttons row is replaced by either a set of 2nd level buttons that is specific to the 1st Level button pressed or there will be a new menu, specific to the button pressed and rendering all other 1st level touch button unavailable until all secondary menus are exited PASS
g) Validate that once any of the 2nd level buttons is activated, there will be a new menu activated, specific to the button pressed and rendering all other 2nd level touch buttons unavailable until all menus are exited PASS

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h) Validate all 1st, 2nd or event 3rd level buttons are made out of both an Icon and a Text below the icon that properly match the function of the button. PASS

i) Validate there are no inactive buttons in any menu or submenu. PASS

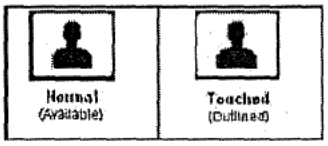

Figure 3 – Examples of button's Activation State

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.3.1.6 Alarm Silence button

a) Press on Alarm Silence button to disable Audio
b) Validate the disabled Audio remains on for 2 minutes PASS
c) The 2 Min-Audio Paused Icon & disabled Audio time is displayed PASS
d) Validate the 2 Min-Audio Paused Icon & disabled Audio time is removed after 2 minutes PASS
e) Press on Alarm Silence button to disable Audio
f) Turn the UUT off and back On
g) Validate the Alarm Silence defaults to off (Audio Enabled) after power on PASS
h) Enter the menu list in Table 1 below and validate the Alarm Silence button can always be pressed. (toggle from disabled to enabled for each menu)

Menu / Sub Menu	Validate
Patient	P ☑ F ☐
Patient Setup	P ☑ F ☐
Patient ID	P ☑ F ☐
High/Low Limits Menu	P ☑ F ☐
Events Menu	P ☑ F ☐
Data Menu	P ☑ F ☐
Files Menu	P ☑ F ☐
Files Manage Menu	P ☑ F ☐
Setup Menu	P ☑ F ☐
Brightness Menu	P ☑ F ☐
Language Menu	P ☑ F ☐
Volume setting Menu	P ☑ F ☐
View Menu	P ☑ F ☐
Date & Time Menu	P ☑ F ☐
Ports Menu	P ☑ F ☐

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Menu / Sub Menu	Validate
Alarm Delay Menu	P ☑ F ☐

Table 1 – Alarm Silence Activation Access availability

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4 User Controls

8.4.1 Patient Menu

8.4.1.1 Patient Menu Selections

a) Click on **Patient button** (1st level buttons row).

b) Validate the touch buttons **New Patient**, **Patient Setup**, and **Patient ID** buttons are all available PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.1.2 Body Location Settings

8.4.1.2.1 US Configuration

a) Turn On the UUT

b) Enter the Setup menu before entering the appropriated password for **Manufacturing.**

c) Make sure the current and **default** Monitor configuration is set to **US.** PASS

d) Cycle power to the UUT and proceed to the **Main** menu.

e) Select the Patient Menu from the 1st Level Target menu.

f) Click on the **Patient Setup** key to enter the Body Location and Alarm settings menu.

g) Validate the **Body Location** Menu is available once one of Ch1-Ch4 Body Location Icon within the **Patient Setup** Menu is selected PASS

h) Validate **only** the body Location **Left Brain**, **Right Brain** and **Unused** available and the Menu resembles **Figure 4** below. PASS

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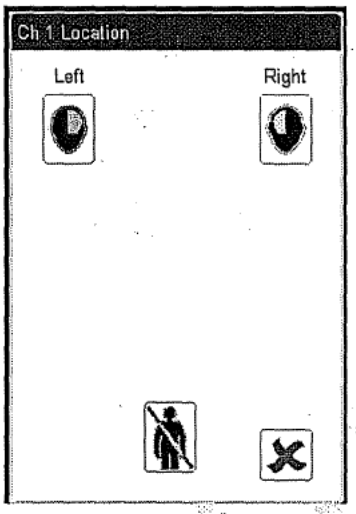

Figure 4 – Adult Cerebral (US) Body Location Menu

Select the "**Left Brain**" for the Ch1 area PASS

i) Validate "**Accept**" and "**Cancel**" buttons are available PASS

j) Validate the **Left Brain** Icon now appears in Ch1 area within the Patient Configuration Menu PASS

k) Select **Accept** from the **Patient Setup** Menu to validate the menu is closed

l) Validate there is a menu asking whether to start a new Patient. PASS

m) Select No to validate the change of Body Location is still performed. PASS

n) Validate the **Left Brain** Icon now appears in Ch1 area on the Right side of the Main menu area. PASS (Letter "**L**" next to Left Brain Icon)

o) Re-enter the Body location menu by pressing on the Body Location icon on Ch1 and set all body locations for CH2-CH4 to "**Unused**"

p) Validate it is not possible to set all Body Locations for CH1-CH4 to "**Unused**". PASS

q) Select **Accept** to validate channel CH2-CH4 body locations revert to **Unused** PASS

r) Return to Main menu to validate there are no Body Location Icons (Unused Icon) or any other Information in the Numeric area for CH3-CH4 PASS (See Figure 2)

s) Connect and disconnect Preamp and Sensor in Ch2 to Ch4 to validate there are no Preamp or Sensor disconnection Audio or Visual Alarms. PASS

t) Re-enter the **Patient** menu, make the entries for "**Right Brain**" for Ch3 before selecting **Accept** (Body Location Menu and new patient) to validate the User is redirected toward the Main Screen and the selected **Right Brain** Icon and letter "**R**" appear within the Numeric area for Ch3 PASS

u) Validate the UUT remains in a 2-Channels Mode with CH1 and CH3 activated while CH2 and CH4, set to Unused do not have any Numeric menu. PASS

v) Cycle power to the UUT and wait to enter the Main Screen. Accept to continue with the same patient.

w) Validate **Left Brain** Icon and letter "**L**" appear for CH1, **Right Brain** Icon and letter "**R**" appear for CH3 while Ch2 & Ch4 Numerics areas are not represented PASS

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PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.1.2.2 OUS Configuration

a) Turn On the UUT
b) Enter the **Setup** menu before entering the appropriated password for **Manufacturing.**
c) Make sure the current and **default** Monitor configuration is set to **OUS.** PASS
d) Exit the **Setup** menu and proceed to the **Main** menu.
e) Select the Patient Menu from the 1st Level Target menu.
f) Click on the **Patient Setup** key to enter the Body Location and Alarm settings menu.
g) Validate the **Body Location** Menu is available once one of Ch1-Ch4 Body Location Icon within the **Patient Setup** Menu is selected PASS
h) Validate the body Location **Left Brain**, **Left Arm**, **Left Flank**, **Left Leg**, **Right Brain**, **Right Arm**, **Right Flank**, **Right Leg** and **Unused** are available and the Menu resembles **Figure 5** below. PASS

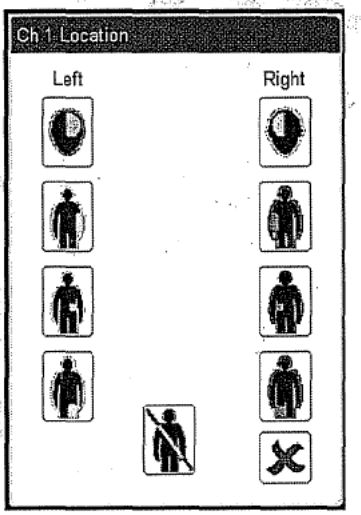

Figure 5 – Adult Tissue (OUS) Body Location Menu

i) Select the "**Left Flank**" for the Ch1 area PASS
j) Validate "**Accept**" and "**Cancel**" buttons are available PASS
k) Validate the **Left Flank** Icon now appears in Ch1 area within the Patient Configuration Menu PASS
l) Select **Accept** from the **Patient Setup** Menu to validate the menu is closed
m) Validate there is a menu asking whether to start a new Patient. PASS
n) Select **No** to validate the change of Body Location is still performed. PASS
o) Validate the **Left Flank** Icon now appears in Ch1 area on the Right side of the Main menu area. PASS (Letter "S" next to **Left Flank** Icon) L TT 12.13.13

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p) Re-enter the Body location menu by pressing on the Body Location icon on Ch1 and set all body locations for CH2-CH4 to "**Unused**"

q) Validate it is not possible to set all Body Locations for CH1-CH4 to "**Unused**". PASS

r) Select **Accept** to validate channel CH2-CH4 body locations revert to **Unused** PASS

s) Return to Main menu to validate there are no Body Location Icons (Unused Icon) or any other Information in the Numeric area for CH3-CH4 PASS (See Figure 2)

t) Connect and disconnect Preamp and Sensor in Ch2 to Ch4 to validate there are no Preamp or Sensor disconnection Audio or Visual Alarms. PASS

u) Re-enter the **Patient** menu, make the entries for "**Right Brain**" for Ch2, "**Right Leg**" for Ch3 and "**Left Arm**" for Ch4 before selecting **Accept** (Body Location Menu and new patient) to validate the User is redirected toward the Main Screen and the selected Icons and Letters do appear in the Numeric area

   i. **Left Flank** Icon and letter "**L**" for Ch1 PASS
   ii. **Right Brain** Icon and letter "**R**" for Ch2 PASS
   iii. **Right Leg** Icon and letter "**R**" for Ch3 PASS
   iv. **Left Arm** Icon and letter "**L**" for Ch4 PASS

v) Cycle power to the UUT and wait to enter the Main Screen. Accept to continue with the same patient.

w) Validate THE Numeric area configuration:

   i. **Left Flank** Icon and letter "**L**" for Ch1 PASS
   ii. **Right Brain** Icon and letter "**R**" for Ch2 PASS
   iii. **Right Leg** Icon and letter "**R**" for Ch3 PASS
   iv. **Left Arm** Icon and letter "**L**" for Ch4 PASS

x) Turn Off the UUT.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.1.3 Alarm Limits Settings

a) Turn On the UUT and wait to enter the Main menu.

b) Enter the **Patient Setup** Menu under Patient

c) Validate it is possible to set the alarm limits for each channel individually. PASS

d) Validate the current set of **High** and **Low** alarm limits are displayed in the numeric area on Main Menu as long as the channel is active. PASS

e) Reenter the Patient Configuration Menu then select to change the **High** or **Low** limits setting on any of the channels to validate the **Accept** key is only executed if a valid or no entry at all was made. PASS (Accept key within Numeric menu)

f) Make changes to the **High** and **Low** settings before hitting the **Accept** key within the **Numeric** entry menu.

g) Depress the **Cancel** key once in the **Patient Configuration** Menu to validate the changes made to the **High** and **Low** alarm limits were not implemented. PASS

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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h) Make changes to the **High** and **Low** settings before hitting the **Accept** key within the **Numeric** entry menu.

i) Depress the **Accept** key once in the **Patient Configuration** Menu to validate the changes made to the **High** and **Low** alarm limits were implemented. PASS

j) Validate **High** & **Low** alarm limit setting changes made from the **Patient Setup, Limit's** value **or Body Location** Icon are all implemented. PASS

k) Validate all steps above are valid for **US** and **OUS** Monitor Configuration. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.1.4 Alarm Limit Range

a) Enter the **Patient Setup** Menu

b) Set the **Low** Limit to the value in **Table 2** below then attempt to enter the recommended **High** Limit values to validate the expected test outcome

c) Set the **High** Limit to the value in **Table 2** below then attempt to enter the recommended **Low** Limit values to validate the expected test outcome

d) Validate all steps above are valid for **US** and **OUS** Monitor Configuration. PASS

Limit Low	Attempt High	Expected Outcome	Validate
3	0 to 7	Invalid	P ☑ F ☐
3	8 to 98	Valid	P ☑ F ☐
3	99	Invalid	P ☑ F ☐
93	0 to 97	Invalid	P ☑ F ☐
93	98	Valid	P ☑ F ☐
93	99	Invalid	P ☑ F ☐
Limit High	**Attempt Low**	**Expected Outcome**	**Validate**
8	4 to 99	Invalid	P ☑ F ☐
8	3	Valid	P ☑ F ☐
8	0 to 2	Invalid	P ☑ F ☐
98	94 to 99	Invalid	P ☑ F ☐
98	3 to 93	Valid	P ☑ F ☐
98	0 to 2	Invalid	P ☑ F ☐

Table 2 – Alarm Limit Range

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

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8.4.1.5 Patient ID

a) Enter the **Patient ID** Menu

b) Validate up to 20 Alphanumeric Characters could be entered for the Patient ID PASS

c) Validate the entered Patient ID is displayed at the Upper Left corner of the Display in the title bar. PASS

d) Validate the Patient ID could be entered and altered any time during the same case. PASS

e) Validate it is the last entered ID that is displayed on Main menu and as Case ID under Files\Manage for the active case. PASS

f) Enter a new Patient ID but press the Cancel ✗ to validate the newly entered but not accepted ID is not displayed on title bar while the previous one is still on the title bar. PASS

g) Validate all steps above are valid for **US** and **OUS** Monitor Configuration. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.1.6 New Patient

a) Power on the UUT then start to monitor a patient

b) Enter a Patient ID, Event Marks to the case

c) Enter the **Patient** Menu then select New Patient to validate there is a menu requester user's confirmation. PASS

d) Select ✗ to validate the same case continues. PASS

e). Select ✓ to validate:

- Current trace is removed from the display P ☑ F ☐
- Patient ID blanked P ☑ F ☐
- Events removed P ☑ F ☐
- Ref value blanked out P ☑ F ☐
- All other settings (Alarm limits, Body Location, View, time) remain P ☑ F ☐

f) Validate all steps above are valid for **US** and **OUS** Monitor Configuration. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.2 Event Marks

8.4.2.1 Events Menu Selection

a) Click on the **Events** key (1st level buttons row).

b) Validate the buttons **Home**, **OR**, **ICU**, **Vascular** & **Undo** (in that order) are all available PASS

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c) Validate each Event dialog/listing has the Listing Name on the Menu Title PASS
d) Validated only one listing is available at the same time. PASS
e) Validate the **NICU** listing is not available. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.2.2 Events from List Addition

a) Power on the UUT and start a new case "**OR EVENTS**"
b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data.
c) Connect the UUT to an IBM PC then use the Ports menu to set either one of the Ports for Scientific data output.
d) Start the appropriate LabView program that could store and display the UUT's scientific output data.
e) Select the Events from the List in **Table 3** below then proceed to add each Event to the data set. (Separately Note time of addition).
f) Validate the Event menu is always closed promptly after the event has been selected allowing for a fast redraw of the Numeric field area PASS (the event menu is closed at once)
g) Validate for every added Event there is a new dot, color matched to the Event Category that is added to the bottom right corner of the display. PASS
h) Click on the new dot to validate the Event mark represented by the dot appears with date stamp right next to the dot with a color matched to the Event category. PASS
i) Validate only one event mark at a time is displayed by the UUT. PASS
j) Validate the displayed time matches the time above the Graph area. PASS
g) Review the scientific data set saved to validate in **Table 3** that all Events (with matching data code) were properly incorporated and saved within the scientific data output. PASS
h) Save the case into a USB from the Files\Manage menu and review the file to validate all added Event Marks have been saved with the appropriate time stamp. PASS
i) Start a new Case ""**ICU EVENTS**" and start a new LabView data collection session.
k) Validate in Table below all steps **e)** to **h)** continue to pass using **Table 4**. PASS
l) Start a new Case ""**Vascular EVENTS**" and start a new LabView data collection session.
m) Validate in Table below all steps **e)** to **h)** continue to pass using **Table 5**. PASS
j) Select the **Home** key to return to the Main Menu.
k) Start a new Patient called "Mixed Events" an attempt to enter many events coming from different Lists and validate it is possible to add Event Marks out of different lists in the same case. PASS
l) Validate it is not possible to change the position (Vertical & Horizontal) of the Event Mark. PASS
m) Save the case into a USB from the Files\Manage menu and review the file to validate all added Event Marks have been saved with the appropriate time stamp. PASS

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EVENT	Code	Validate	EVENT	Code	Validate
Miscellaneous ✓	900	P ☑ F☐	Antegrade SCP ON ✓	172	P ☑ F☐
Cannulation ✓	100	P ☑ F☐	Blood Transfusion ✓	64	P ☑ F☐
Cardioplegia ✓	101	P ☑ F☐	Defib/Cardioversion ✓	160	P ☑ F☐
Closing Sternum ✓	102	P ☑ F☐	ECLS On ✓	71	P ☑ F☐
Cooling ✓	103	P ☑ F☐	Fluid/Volume Expander ✓	162	P ☑ F☐
CPB On/Off ✓	109	P ☑ F☐	Hemoconcentrate/MUF ✓	163	P ☑ F☐
Cross Clamp Off ✓	105	P ☑ F☐	Increase Anesthetic ✓	164	P ☑ F☐
Cross Clamp On ✓	106	P ☑ F☐	Increase CO2 ✓	165	P ☑ F☐
Extubation ✓	2	P ☑ F☐	Increase FiO2 ✓	267	P ☑ F☐
Induction of Anesth ✓	111	P ☑ F☐	Increase Pressure ✓	173	P ☑ F☐
Intubation ✓	3	P ☑ F☐	Increase Pump Flow ✓	166	P ☑ F☐
Sternotomy ✓	110	P ☑ F☐	Inotrope ✓	75	P ☑ F☐
Warming ✓	104	P ☑ F☐	Pacing: Atrial ✓	174	P ☑ F☐
Arrhythmia ✓	31	P ☑ F☐	Pacing: A-V ✓	175	P ☑ F☐
Circulatory Arrest ✓	130	P ☑ F☐	Pacing: Ventricular ✓	176	P ☑ F☐
Hypocapnia ✓	131	P ☑ F☐	Reposition Cannula ✓	168	P ☑ F☐
Hypotension ✓	132	P ☑ F☐	Reposition Clamp ✓	169	P ☑ F☐
Low SpO2 ✓	133	P ☑ F☐	Reposition Head/Heart ✓	170	P ☑ F☐
Pump Flow Down ✓	134	P ☑ F☐	Retrograde SCP ON ✓	177	P ☑ F☐
Venous Return Down ✓	135	P ☑ F☐	Vasopressor ✓	81	P ☑ F☐
Afterload Reduction ✓	60	P ☑ F☐			

Table 3 – OR Event Marks List

EVENT	Code	Validate	EVENT	Code	Validate
Miscellaneous ✓	900	P ☑ F☐	Defib/Cardioversion ✓	85 ~~160~~	P ☑ F☐ PT 12.13.13
Enteral Feeding ✓	1	P ☑ F☐	Dialysis/CRRT ✓	84	P ☑ F☐
Extubation ✓	2	P ☑ F☐	Diuretic ✓	68	P ☑ F☐
Intubation ✓	3	P ☑ F☐	ECLS Off ✓	70	P ☑ F☐
Apnea ✓	30	P ☑ F☐	ECLS On ✓	71	P ☑ F☐
Arrhythmia ✓	31	P ☑ F☐	ET Tube Suctioned ✓	72	P ☑ F☐
Bradycardia ✓	32	P ☑ F☐	Fluid Bolus ✓	73	P ☑ F☐
ICP Changes ✓	34	P ☑ F☐	High Frequency Vent ✓	83	P ☑ F☐
LOC Changes ✓	35	P ☑ F☐	Hypothermia ✓	74	P ☑ F☐
Painful Procedure ✓	36	P ☑ F☐	Inotrope ✓	75	P ☑ F☐
Seizure Activity ✓	37	P ☑ F☐	Nitric Oxide ✓	76	P ☑ F☐
Tamponade ✓	38	P ☑ F☐	Paralytic ✓	77	P ☑ F☐
Afterload Reduction ✓	60	P ☑ F☐	PDA Ligated ✓	78	P ☑ F☐

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EVENT	Code	Validate	EVENT	Code	Validate
Anti-Arrhythmic ✓	61	P ☑ F☐	Prostaglandin ✓	79	P ☑ F☐
Anti-Epileptic ✓	62	P ☑ F☐	Reposition Patient ✓	4	P ☑ F☐
Blood Transfusion ✓	64	P ☑ F☐	Sedation ✓	80	P ☑ F☐
Chest Closed ✓	65	P ☑ F☐	Vasopressor ✓	81	P ☑ F☐
			Ventilator Change ✓	82	P ☑ F☐

Table 4 – ICU Event Marks List

EVENT	Code	Validate	EVENT	Code	Validate
Miscellaneous ✓	900	P ☑ F☐	BiVAD On/Off ✓	274	P ☑ F☐
Cannulation ✓	100	P ☑ F☐	Blood Transfusion ✓	64	P ☑ F☐
Clamp Off Vessel ✓	200	P ☑ F☐	EPD Deployed ✓	262	P ☑ F☐
Clamp On Vessel ✓	201	P ☑ F☐	Fogarty Catheter In ✓	263	P ☑ F☐
Decannulation ✓	202	P ☑ F☐	IAB Catheter Off ✓	264	P ☑ F☐
Extubation ✓	3	P ☑ F☐	IAB Catheter On ✓	265	P ☑ F☐
Heparin Given ✓	203	P ☑ F☐	IAB Pump Off ✓	275	P ☑ F☐
Incision ✓	204	P ☑ F☐	IAB Pump On ✓	276	P ☑ F☐
Intubation ✓	2	P ☑ F☐	Increase Anesthetic ✓	164	P ☑ F☐
Arrhythmia ✓	31	P ☑ F☐	Increase ETCO2 ✓	266	P ☑ F☐
Blood Loss ✓	230	P ☑ F☐	Increase FiO2 ✓	267	P ☑ F☐
Contrast Dye Injected ✓	231	P ☑ F☐	LVAD On/Off ✓	277	P ☑ F☐
Dissection ✓	232	P ☑ F☐	RVAD On/Off ✓	278	P ☑ F☐
EEG Change ✓	233	P ☑ F☐	Shunt Flushed ✓	268	P ☑ F☐
Hypocapnia ✓	131	P ☑ F☐	Shunt Open ✓	269	P ☑ F☐
Hypotension ✓	132	P ☑ F☐	Shunt Reposition ✓	270	P ☑ F☐
Shunt Clamped ✓	234	P ☑ F☐	Stent Deployed ✓	271	P ☑ F☐
Thrombus Suspected ✓	235	P ☑ F☐	Thrombus Removed ✓	272	P ☑ F☐
Balloon Deflated ✓	260	P ☑ F☐	Vasodilator ✓	273	P ☑ F☐
Balloon Inflated ✓	261	P ☑ F☐	Vasopressor ✓	81	P ☑ F☐

Table 5 – Vascular Event Marks List

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.2.3 Removing placed Events

a) Power on the UUT and start a new case "**Remove EVENTS**"

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b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data.

c) Connect the UUT to an IBM PC then use the Ports menu to set either one of the Ports for Scientific data output.

d) Place two events on trace and validate they both appear on the Graph. PASS

e) Press on "Undo" to validate the last placed event is removed. PASS

f) Press on "Undo' a second time to remove the first placed event and validate the event is not being removed. PASS (Only the last placed event could be removed)

g) Cycle power to the UUT to validate as the UUT is entering Main menu that the first placed event is still available on the trace. PASS

h) Press on "Undo" to validate the event is not removed. PASS

i) End the Case, save the file into a USB to validate only the first placed event is available on the data set. PASS

j) Validate the both placed events are available in the saved Scientific serial output. PASS

k) Select an event from the menu below then quickly remove it by pressing "Undo" to validate the event is removed. Repeat the quick series of adding/removing at least 10 times to validate no adverse reaction of the system is observed (make note of any occurrence)

   i. OR List PASS
   ii. ICU List PASS
   iii. Vascular List PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.2.4 Auto Events

a) Power on the UUT and start a new case "**AUTO EVENTS**"

b) Set one of the Ports "A" or "B" to the "Scientific" serial Output mode.

c) Connect appropriate Preamps and sensors to the monitor and wait for the UUT to start collecting data.

d) Start to create the individual Conditions in **Table 6** below and wait for the appropriate messages to be displayed on the UUT before initiating a new one.

e) Make note on as separate piece of paper about the time, type & Chanel ID for each specific auto event.

f) Validate there are no Event dots placed on the Display for the Auto Events. PASS

g) Enter some of the Events from the Events lists and make note of the time and name of the event entered. PASS

h) Create some High and Low StO2 conditions for some of the Channels and make note of the time and type of Limit violation.

i) Disconnect then reconnect the sensors and wait for StO2 data to be displayed.

j) Disconnect then reconnect the Preamps and wait for the StO2 data to be displayed.

k) Close the case once all conditions have been created and save the case into a USB.

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l) Connect the USB and use "Notepad" to review the case.

m) Validate the header format and content of the Patient file do match the format defined in 21-07-0342 and 21-07-0360 specifications. PASS

n) Using the FORE-SIGHT ELITE Graphing Tool, open the Patient file and proceed to compare the events reported to those recorded in the Scientific data output.

o) Validate in **Table 6** that the Auto Events do match the incidents reported in the Scientific data output and as noted.

p) Validate all Limit violation alarms were properly captured and reported. PASS

q) Validate none of the sensor or Preamp disconnect events were captured or represented otherwise as Auto Events. PASS

Condition	SCB Message	CH1	CH2	CH3	CH4	Validate
Brain Signal Low Brain Signal High	**Signal Out Of range**	X	-	-	-	P ☑ F☐
Scalp Signal Low Scalp Signal High	**Signal Out Of range**	X	X	-	-	P ☑ F☐
Monitor Signal Low Monitor Signal High	**Signal Out Of range**	-	-	-	X	P ☑ F☐
(b)(4) [redacted]					-	P ☑ F☐
(b)(4) [redacted]		X	-	X	-	P ☑ F☐
Excessive Ambient light	**High Ambient Light**	X	X	X	X	P ☑ F☐
High Ambient light	**Ambient Light**	-	-	X	-	P ☑ F☐
Signal Out of Range (AGC)	**Signal Out Of range**	-	-	-	X	P ☑ F☐
sensor not secured	**Check under sensor**	-	X	-	-	P ☑ F☐
Low Total Hb		X	-	-	-	P ☑ F☐
Unstable StO2 (Bovie)	**External Interference**	-	-	X	-	P ☑ F☐
Sensor Off StO2 not in range	**Sensor off**	X	-	-	-	P ☑ F☐

Table 6 – NSAM Conditions Auto Events

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.3 Data Menu

8.4.3.1 Data Menu Selection

a) Click on the **Data** key (1st level buttons row).

b) Validate the buttons **Home**, **STS Starts/Stops**, **REF Reference** and **STS View** are all available PASS

c) Validate the **STS Starts/Stops** Key is displayed as **STS Start** if the Data collection has not started. PASS

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d) Validate the **STS Starts/Stops** Key is displayed as **STS Stop** if the Data collection is ongoing. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.3.2 STS View Menu

a) Enter the STS View Menu to validate all elements contained within **Figure** 6 below are available (Arrangement and Look of Menu may differ) PASS

b) Validate fields are constantly being updated during ongoing data collection while the menu remain open. PASS

c) Validate the data under "Cumulative Saturation Below…" and "Regional Oxygen …" are represented with one decimal digit as long as space permit. PASS

d) Starts a new Patient/Case session while STS DATA collection is ongoing on the previous case to validate the previously collected data have been cleared from the STS View menu. PASS

e) Validate unused Channel do not have any field filled out in the STS View. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

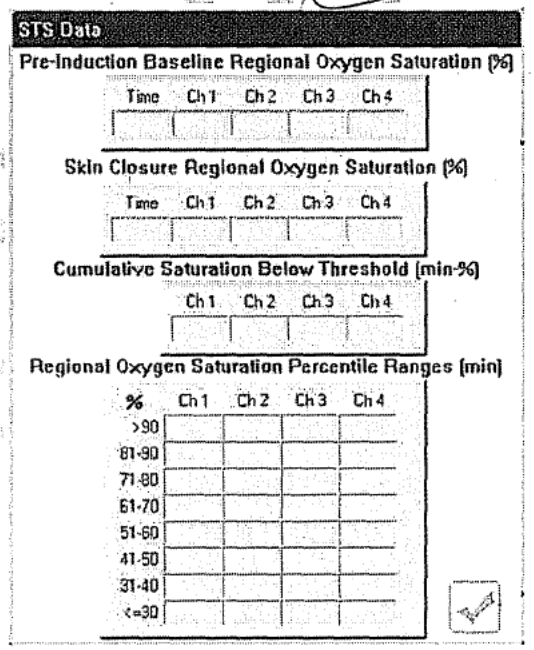

Figure 6 – STS View Menu content

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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8.4.3.3 STS Data Collection and Verification

a) Connect appropriate Preamps and sensors to the monitor.

b) Attempts to start the Data Collection while there are no StO2 data on either one of the Channels to validate there is a Pop Up alerting the user the Data Collection could not start until there are valid StO2 values on at least one channel. PASS

c) Wait for the UUT to display valid StO2 data.

d) Enter the **Data** menu and press on Click on **STS Start** to start the Data collection and validate the **STS Start** switches to **STS Stop.** PASS

e) Validate the wording **STS DATA** appears on top of the Graph area as soon as the Data collection has started. PASS

f) Click on **STS Stop** to stop the Data collection and validate there is a popup "Do you really want to..." appearing on the display. PASS

g) Press on "NO" to validate the popup is removed and the data collection not stopped. PASS

h) Click on **STS Stop** to stop the Data collection and confirm once ask to validate the popup is removed and the data collection stopped. PASS

i) Validate the **STS Stop** switches to **STS Start.** PASS

j) Restart an STS Data Collection session and validate the Data Collection could be stopped at any time whether there are valid data on the display or not. PASS

k) Starts a new Case "**STS DATA Verification**"

l) Set the UUT to monitor the Left Brain on CH1 & CH3 while monitoring the Right Brain on CH2 and CH4.

m) Start the Data Collection and note the StO2 values on the display for each channel

	Main Display	STS View	Threshold (75%)
➢ CH1	61	61	46
➢ CH2	59	59	44
➢ CH3	83	83	62
➢ CH4	65	65	49

n) Enter the STS View menu to verify the Pre-Induction Baseline Regional Oxygen Saturation values reported to match those recorded in the step above. PASS

o) Verify the Time reported under Pre-Induction Baseline Regional Oxygen Saturation do match the Time reported in the step above. PASS

p) Calculate the **Threshold** that will be used for the **Cumulative Saturation below Threshold** as 75% of the **first valid** %StO2 value displayed and recorded in the **STS Review** Menu as **Pre-Induction Baseline Regional Oxygen Saturation**

q) Click on STS/FS Stop to stop the Data collection and note the Time (18:00) and StO2 values on the four channels (CH1 61, CH2 59, CH3 58, CH4 64)

r) Disconnect both preamps from the Monitor to stop the data collection without restarting a new Patient.

s) Enter the STS View Menu to validate the values recorded as **last valid** %StO2 values do match with the values recorded as **Skin Closure** for the respective channels. PASS

t) Using the Table Below, records all values from the **STS Review** Menu

Test Performed By (signature): [signature] Date of Test: 12-13-13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	CH1	CH2	Ch3	Ch4
Pre-Induction Baseline Regional Oxygen Saturation (%)				
TIME	**CH1**	**CH2**	**Ch3**	**Ch4**
14:25	61	59	83	65
Skin Closure Regional Oxygen Saturation (%)				
TIME	**CH1**	**CH2**	**Ch3**	**Ch4**
15:00	61	59	58	64
Cumulative Saturation below Threshold (min %)				
	CH1	**CH2**	**Ch3**	**Ch4**
	–	57.5	106.4	119.6
Regional Oxygen Saturation Percentile Ranges (min)				
	CH1	**CH2**	**Ch3**	**Ch4**
> 90 %	0.0	0.0	0.0	0.0
81 – 90 %	0.0	0.0	2.3	0.0
71 – 80 %	6.0	0.0	1.3	0.0
61 – 70 %	29.4	0.0	10.9	18.7
51 – 60 %	0.0	28.8	20.8	2.6
41 – 50 %	0.0	0.3	0.0	3.8
	CH1	**CH2**	**Ch3**	**Ch4**
31 – 40 %	0.0	4.9	0.0	1.7
≤30 %	0.0	0.9	0.0	3.5

Table 7 – STS View Data Record

u) Enter the Files\Manage menu to save the file "**STS DATA Verification**" into a connected USB.

v) Using Excel, open the saved Patient Data to verify the values reported in the **STS Data** portions do match with the values reported in **Table 7** above. PASS

w) Using Excel, proceed to calculate the **Cumulative Saturations** and all **Percentile Ranges** values for all channels.

x) Using the sample in **Table 8** & **Table 9** below, enter the proper formulas in the Cells to calculate the values.

- **Cumulative Saturation below STS DATA Threshold: (CSBT)**

  Calculation Formulas to be entered into the cells.

  Chx Cuml. Cells = (IF (**CHx** > 0, (IF ((**T_{CHx}** - **CHx**) > 0, (**T_{CHx}** - **CHx**) * 2, 0)), 0)) = **C_{CHxi}**

  SUM: CHx CSBT = (Σ C_{CHxi})/60 Minute-%

- **Regional Oxygen Saturation Percentile Ranges Calculation**
  - **Formula to be entered into the cells for ≤ 30%:**

    Chx Linear Cells =(IF(**CHx** > 0, (IF((31 - **CHx**) > 0, 2, 0)), 0)) = **C_{CHxi}**

  - **Formula to be entered into the cells for 31- 40 %**

    Chx Linear Cells =(IF(**CHx** > 30, (IF((41 - **CHx**) > 0, 2, 0)), 0)) = **C_{CHxi}**

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- **Formula to be entered into the cells for 41-50%**

  Chx Linear Cells =(IF(**CHx** > 40, (IF((51 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for 51 - 60%**

  Chx Linear Cells =(IF(**CHx** > 50, (IF((61 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for 61 - 70%**

  Chx Linear Cells =(IF(**CHx** > 60, (IF((71 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for 71 - 80%**

  Chx Linear Cells =(IF(**CHx** > 70, (IF((81 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for 81 - 90%**

  Chx Linear Cells =(IF(**CHx** > 80, (IF((91 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for > 90%**

  Chx Linear Cells =(IF(**CHx** > 0, (IF((**CHx - 90**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

SUM (for each Range): Ch1 Linear Percentile Range = (Σ C_{CHxl})/60 Minutes

y) Enter the calculated values into **Table 10** below. Print and attach a copy of the calculated data.
z) Validate all calculated data in **Table 10** do match within ± 1.0 unit to those reported by the UUT's Display and as recorded in **Table 7**. PASS
aa) Power Down the UUT

USB Values						Cumulative Saturations			
Date	Time	Ch1	Ch2	Ch3	Ch4	Ch1	Ch2	Ch3	Ch4
7/7/2013									
	10:54:11	90	68	90	68	0	0	0	0
	10:54:13	42	44	42	44	52	14	52	14
	10:54:15	59	68	59	68	18	0	18	0
	10:54:17	86	56	86	56	0	0	0	0
					SUM	**1.17**	**0.23**	**1.17**	**0.23**

Table 8 – STS DATA Calculation Data Sheet

Date	Time	CHx	≤ 30%	31 - 40 %	41 – 50 %	51 – 60 %	61 – 70 %	71 – 80 %	81 – 90 %	> 90 %
7/7/2013										

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Date	Time	CHx	≤ 30%	31- 40 %	41 – 50 %	51 – 60 %	61 – 70 %	71 – 80 %	81 – 90 %	> 90 %
	10:54:11	90	0	0	0	0	0	0	2	0
	10:54:13	42	0	0	2	0	0	0	0	0
	10:54:15	59	0	0	0	2	0	0	0	0
	10:54:17	86	0	0	0	0	0	0	2	0
		SUM	**0.0**	**0.0**	**0.03**	**0.03**	**0.0**	**0.0**	**0.07**	**0.0**

Table 9 – Regional Oxygen Saturation Percentile Ranges Calculation

Cumulative Saturation below Threshold (Min %)			
Channel 1	**Channel 2**	**Channel 3**	**Channel 2**
0.0	57.5	106.6	119.7

Ranges	Regional Oxygen Saturation Percentile Ranges (Min)			
	Channel 1	**Channel 2**	**Channel 3**	**Channel ~~2~~ 4**
> 90 %	0.0	0.0	0.0	0.0
81 – 90 %	0.0	0.0	2.4	0.0
71 – 80 %	6.0	0.0	1.4	0.0
61 – 70 %	29.4	0.0	10.9	18.8
51 – 60 %	0.0	28.8	20.9	2.6
Ranges	**Channel 1**	**Channel 2**	**Channel 3**	**Channel 2**
41 – 50 %	0.0	0.3	0.0	3.8
31 – 40 %	0.0	4.9	0.0	1.7
≤30 %	0.0	1.0	0.0	3.5

JT 12.14.13

Table 10 – Calculated STS Data

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.3.4 Reference Value REF

a) Power up the UUT
b) Start a new Case "REFERENCE REF"
c) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data.
d) Validate the space reserved for the REF value is blank at the beginning of any new case. PASS

Test Performed By (signature): Proto Tola Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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e) Cycle power to the UUT and keep the same patient to validate the REF space continue to be blank. PASS

f) Enter the DATA menu then click on the **Ref** key to validate the current StO2 values now appears above **Ref** in the appropriate position (see **Figure 2**). PASS

g) Validate there is a dotted line now appearing on the Graph matching the displayed Ref value for that specific channel and matching the Body Location color. PASS

h) Press on the **Ref** value within the Numeric field the dotted line is removed. PASS

i) Press again on the **Ref** value to validate the dotted line reappears on the Graph. PASS

j) Disconnect one of the Sensor from the Preamp then click again on the Ref Key to validate the all reference values are updated and the channel with disconnected sensor is now displaying a blank as Reference value. PASS

k) Reconnect the sensor to the Preamp and wait for the UUT to display valid StO2 values for that channel.

l) Click on Ref again and verify all channels are updated with the current StO2 values. PASS

m) Cycle power to the UUT and **keep the same patient** to verify the UUT returns with the pre-shut down Ref values and dotted lines. N/A

n) Wait for the UUT to start reporting StO2 values then click on the **Ref** key to validate all Ref values are updated for all channels. PASS

o) Start a new case to verify the last **Ref** value and dotted line are removed from the display as soon as a new case is started. PASS

p) Activate a new Reference value for all active channels and validate they all get an updated "Ref" value assigned. PASS

q) Deactivate one channel by assigning them "Unused" as Body Location to validate the Ref value remains set to blank event after repeated attempts to reset it on all channels. PASS

r) Reactivate the channel (L or R Brain Body Location) then wait for the channel to restart displaying valid StO2 Data and validate there are no Ref values displayed for that channel until after the "Ref" key has been pressed again. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.4.4 Patient Data Management

8.4.4.1 Multiple Patients Storage

a) Power up the UUT

b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data. (create at least three new patient cases)

c) Click on the **Files** key (1st level buttons row) then on **Manage** to enter the Patient Data Management menu.

d) Validate multiple Patient Files are stored. PASS

e) Validate each Patient file is represented by an individual Button on the menu. PASS

f) Validate the patient ID (if entered) is included in the Patient file name with the format **"yyyy-mm-dd-hhxxss-ID.csv"** PASS

Test Performed By (signature): [signature] Date of Test: 12-13-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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g) Validate the current case is not available. PASS

h) Cycle power to the UUT and wait to enter the Files menu to validate the current case is still not being displayed. PASS

i) Click on any file to validate it now appears highlighted/outlined. PASS

j) Click on the file again to validate it now appears deselected. PASS

k) Validate the keys "**Save**" and "**Delete** only become available after a file has been selected. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.4.2 Saving Selected Files to the USB

a) Power up the UUT

b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data. (create at least three new patient cases)

c) Select a File then click on "**Save**" to validate there is a menu alerting the User a USB has to be connected before the file could be saved. PASS

d) Connected an appropriate USB to the UUT then attempt to save the file into the USB to validate the data transfer is effectively started. PASS

e) Validate there is a percentage File Progression update. PASS

f) Validate the word "**Done**" is displayed once the data saving is done. PASS

g) Validate saved files are still available in the menu once the file transfer done. PASS

h) Validate it is possible to stop the data saving at any time once started and the incomplete file is not available on the USB. PASS (Note any observed system crash, reset or frozen)

i) Validate a case cannot be saved while it is ongoing but only after it is closed. PASS

j) Validate it is not possible to select a second file for saving in the middle of an ongoing USB data saving. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.4.3 Reviewing Data Saved to the USB

a) Power up the UUT

b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data.

c) Create the four types of cases below

i. No STS Data Collection: Name "**Regular Test Case**" (No STS COLLECTION)

ii. STS Data Collection Done: Name "**STS Data Done**"

iii. Ongoing STS Data Collection: "**STS Data Ongoing**"

iv. Case without Name: " "

Test Performed By (signature): [signature] Date of Test: 12.18.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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d) Add Event Marks, High and Low Parameter Alarms on all channels and note the time and duration of each event and alarms on a separate piece of paper.

e) Note for each case the High & Low Parameter Alarm and Body Locations on all channels for each case on a separate sheet of paper.

f) Save the cases into a USB

g) Connect the USB to a free USB slot on the PC.

h) Validate the saved files have the file name format "**yyyy-mm-dd-hhmmss-ID**[1] e.g. "**2013-05-09-152649.csv**". PASS, PASS, PASS, PASS

i) Validate there are no two files with the same file name. PASS

j) Double click on the FORE-SIGHT files in the USB stick to open it using **Notepad**.

k) Validate for the three cases the **File Header Information** has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

l) Validate the **Patient/Case Information** section has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

m) Validate the **Gemini Created STS Information** section has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

n) Validate the **Viewer Created STS Information** section has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

o) Validate the **Case Info** section has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

p) Validate the case Info content does match the patient settings in the monitor at the end of the case for old cases or at the time of data saving for ongoing cases. PASS, PASS, PASS, PASS

q) Validate the **Patient Data Information** section has the Format defined in Doc 21-07-0360. PASS, PASS, PASS, PASS

r) Validate all events Marks entered in the cases are properly represented in the Patient Data Information section. PASS, PASS, PASS, PASS

s) Validate all Parameter Alarms enunciated during the cases are properly represented in the Patient Data Information section following the High/Low Alarm index in **Table 11** below: PASS, PASS, PASS, PASS

CH1 Low	CH1 High	CH2 Low	CH2 High	CH3 Low	CH3 High	CH4 Low	CH4 High	VALUE	CH1 Low	CH1 High	CH2 Low	CH2 High	CH3 Low	CH3 High	CH4 Low	CH4 High	VALUE
X		-	-	-	-	-	-	1	-	X	X	-	X	-	X	-	86
-	X	-	-	-	-	-	-	2	-	-	-	X	X	-	X	-	88
-	-	X	-	-	-	-	-	4	X	-	-	X	X	-	X	-	89
X	-	X	-	-	-	-	-	5	-	X	-	X	X	-	X	-	90
-	X	X	-	-	-	-	-	6	-	-	-	-	-	X	X	-	96
-	-	-	X	-	-	-	-	8	X	-	-	-	-	X	X	-	97
X	-	-	X	-	-	-	-	9	-	X	-	-	-	X	X	-	98
-	X	-	X	-	-	-	-	10	-	-	X	-	-	X	X	-	100
-	-	-	-	X	-	-	-	16	X	-	X	-	-	X	X	-	101
X	-	-	-	X	-	-	-	17	-	X	X	-	-	X	X	-	102

[1] **yyyy-mm-dd-hhmmss**: Date and Time of Case start; **ID**: Last Patient ID entered.

Test Performed By (signature): [signature] Date of Test: 12.13.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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CH1 Low	CH1 High	CH2 Low	CH2 High	CH3 Low	CH3 High	CH4 Low	CH4 High	VALUE	CH1 Low	CH1 High	CH2 Low	CH2 High	CH3 Low	CH3 High	CH4 Low	CH4 High	VALUE
-	X	-	-	X	-	-	-	18	-	-	-	X	-	X	X	-	104
-	-	X	-	X	-	-	-	20	X	-	-	X	-	X	X	-	105
X	-	X	-	X	-	-	-	21	-	X	-	X	-	X	X	-	106
-	X	X	-	X	-	-	-	22	-	-	-	-	-	-	-	X	128
-	-	-	X	X	-	-	-	24	X	-	-	-	-	-	-	X	129
X	-	-	X	X	-	-	-	25	-	X		-	-	-	-	X	130
-	X	-	X	X	-	-	-	26	-		X	-	-	-	-	X	132
-	-	-	-	-	X	-	-	32	X		X	-	-	-	-	X	133
X	-	-	-	-	X	-	-	33	-	X	X	-	-	-	-	X	134
-	X	-	-	-	X	-	-	34	-	-	-	X	-	-	-	X	136
-	-	X	-	-	X	-	-	36	X	-	-	X	-	-	-	X	137
X	-	X	-	-	X	-	-	37	-	X	-	X	-	-	-	X	138
-	X	X	-	-	X	-	-	38	-	-	-	-	X	-	-	X	144
-	-	-	X	-	X	-	-	40	X	-	-	-	X	-	-	X	145
X	-	-	X	-	X	-	-	41	-	X	-	-	X	-	-	X	146
-	X	-	X	-	X	-	-	42	-	-	X	-	X	-	-	X	148
-	-	-	-	-	-	X	-	64	X	-	X	-	X	-	-	X	149
X	-	-	-	-	-	X	-	65	-	X	X	-	X	-	-	X	150
-	X	-	-	-	-	X	-	66	-	-	-	X	X	-	-	X	152
-	-	X	-	-	-	X	-	68	X	-	-	X	X	-	-	X	153
X	-	X	-	-	-	X	-	69	-	X	-	X	X	-	-	X	154
-	X	X	-	-	-	X	-	70	-	-	-	-	-	X	-	X	160
-	-	-	X	-	-	X	-	72	X	-	-	-	-	X	-	X	161
X	-	-	X	-	-	X	-	73	-	X	-	-	-	X	-	X	162
-	X	-	X	-	-	X	-	74	-	-	X	-	-	X	-	X	164
-	-	-	-	X	-	X	-	80	X	-	X	-	-	X	-	X	165
X	-	-	-	X	-	X	-	81	-	X	X	-	-	X	-	X	166
-	X	-	-	X	-	X	-	82	-	-	-	X	-	X	-	X	168
-	-	X	-	X	-	X	-	84	X	-	-	X	-	X	-	X	169
X	-	X	-	X	-	X	-	85	-	X	-	X	-	X	-	X	170

Table 11 – Alarm Index Table

Note: X = Alarm present, - = Alarm not present

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

Test Performed By (signature): _____ Date of Test: 12.13.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.4.4.4 Deleting Selected Files

a) Select a File then click on "**Delete**" to validate there is a menu alerting the User and requiring a confirmation. PASS

b) Validate the Patient case is not removed if user decide not to delete. PASS

c) Validate the case is removed from the list if the user agrees to delete it. PASS

d) Validate only the selected case has been removed. PASS

e) Attempt to delete the current case to validate the current case could not be removed. PASS

f) Delete all cases from the UUT until there is just the current case left. Attempt to delete the last case to validate there is a warning that the current case could not be removed. PASS

g) Disconnect the Preamps from the Monitor to force a data collection stop without starting a new case.

h) Attempt to delete the last case to validate there is a warning that the current case could not be removed. PASS

i) Return to the Main menu and start a new Patient/Case.

j) Attempt to delete the previous case to validate the case could be removed. PASS

k) Attempt to delete the last case to validate there is a warning that the current case could not be removed. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5 Setup Menu

8.4.5.1 Setup Menu Selection

a) Click on the **Setup** key (1st level buttons row).

b) Validate the buttons **View, Brightness, Volume, Time/Date, Alarm Delay, Log** and **Home** buttons are all available PASS

c) Click on the **Log In** key to validate there is a Menu requiring the User to enter the appropriate Password PASS

d) Enter a wrong password to validate a Popup menu appears and alert about a wrong password being entered. PASS

e) Enter the appropriate Password to validate the selection in Table appears.

Selection / Password	Language	Ports	Defaults	Model Number	View FAT	TCP IP On	Core Dump	Eng Settings	Validate
BIOMED 2466	X	X	X	-	-	-	-	-	P ☑ F ☐
FSMANUF 3762	-	-	-	X	-	-	-	-	P ☑ F ☐
ACCESS1 2223771	-	-	-	-	X	X	X	X	P ☑ F ☐

Table 12 – Password Protected Menu Screen

Test Performed By (signature): Prof or Tda Date of Test: 12.13.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5.2 View Settings

a) Enter the **View** Menu from the **Setup** Menu selection.
b) Validate the current View setting is highlighted in the View menu PASS
c) Validate it is possible to select any of the other choices. PASS
d) Touch the **Cancel** button to validate the View menu is closed and the current selection maintained. PASS
e) Re-enter the View menu and select each of the settings per **Table 13**
f) Validate the time scale is adjusted to match the current view setting PASS
g) Cycle Power to the UUT to validate the view setting is maintained once back into Main menu.
h) Reenter the View menu to make rapid changes from one setting to the next to validate the system does not crash or otherwise becomes irresponsive and all new settings are executed accordingly. PASS

View	Validate	View	Validate
15 Min	P ☑ F ☐	4 Hr	P ☑ F ☐
30 Min	P ☑ F ☐	8 Hr	P ☑ F ☐
1 Hr	P ☑ F ☐	12 Hr	P ☑ F ☑
2 Hr	P ☑ F ☐	24 Hr	P ☑ F ☐

Table 13 – View Settings

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5.3 Volume Settings

a) Enter the **Volume** from the **Setup** Menu selection.
b) Validate the current **Volume** level is highlighted in the Volume menu PASS
c) Validate all allowed Volume level selections are available PASS (20%, 40%, 60%, 80% and 100%)
d) Press on **Cancel** button
e) Validate the **Volume** menu is exited and the UUT returned to the **Setup** menu. PASS
f) Re-enter the **Volume** menu to set the Volume to 100%..
g) Create a High Priority Alarm (e.g. High or Low Limit violation) to validate the Audio corresponds to the set Volume level PASS
h) Create a Medium Priority Alarm (e.g. Sensor or Cable disconnected) to validate the Audio corresponds to the 100% Volume level PASS

Test Performed By (signature): [signature] Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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i) Create a Low Priority Alarm (e.g. External Interference) to validate the Audio Volume corresponds to the 100% Volume level PASS

j) Set the Volume to the 20%.

k) Validate at this Volume the Audio is still noticeable PASS (above system own operating noise)

l) Cycle power to UUT and validate the tone initiated during Initialization are at 20% PASS

m) Set the Volume to 100%

n) Cycle power to UUT and validate the tones initiated during Initialization are at 100% PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.5.4 Brightness Settings

a) Enter the **Brightness** Menu from the **Setup** Menu selection.

b) Validate the current Brightness level is highlighted in the Brightness menu PASS

c) Validate it is possible to select any of the other choices. PASS

d) Touch the **Cancel** button to validate the Brightness menu is closed and the current setting maintained. PASS

e) Re-enter the Brightness menu and select each of the settings per **Table 14**

f) Validate the Brightness level is adjusted to match the current setting PASS

g) Cycle Power to the UUT to validate the Brightness level is maintained.

Brightness	Validate	Brightness	Validate
20 %	P ☑ F ☐	80 %	P ☑ F ☐
40 %	P ☑ F ☐	100 %	P ☑ F ☐
60 %	P ☑ F ☐		

Table 14 – Brightness Settings

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.5.5 Ports Settings

a) Enter the **Ports** from the **Setup** Menu selection.

b) Validate the current **Ports setup** and **Baud Rate** are displayed PASS

c) Validate following Serial Output mode **IntelliBridge, VueLink, 2 Ch CAS, 4 Ch CAS, 2 Ch CSV, 4 Ch CSV, Scientific** and **None** are available. PASS

d) Validate the Baud Rates could be selected separately from the Serial Output selection per **Table 15** below PASS

e) Validate each of the two Serial Output **Port A** or **Port B** could be setup individually. PASS

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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		Protocol						
		IntelliBridge	VueLink	2 Ch CAS	4 Ch CAS	2 Ch CSV	4 Ch CSV	Scientific
Baud	4800	-	X	X	X	X	X	-
	9600	X	X	X	X	X	X	-
	19200	X	X	X	X	X	X	-
	38400	-	-	X	X	X	X	-
	57600	-	-	X	X	X	X	X
	115200	-	-	X	X	X	X	X
	Validate	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐

Table 15 – Serial Protocols Baud Rates Selections

f) Set the UUT for simultaneous Serial Port Output per **Table 16** below to validate all ports are operating accordingly and all necessary data are serially and accurately outputted. PASS
g) Validate there is no need to restart the UUT following the Changes to the ports. PASS
h) Cycle power to the UUT to validate the Port configuration is kept. PASS
i) Validate the UUT could operate in each of the settings below without any system crash, reset or otherwise becoming unresponsive. PASS

Port A		Port B		Pass /Fail
Output	Baud Rate	Output	Baud Rate	
2 Ch CSV	4800	4 Ch CSV	115200	P ☑ F ☐
IntelliBridge	19200	2 Ch CAS	115200	P ☑ F ☐
IntelliBridge	19200	VueLink	4800	P ☑ F ☐
2 Ch CAS	115200	4 Ch CAS	19200	P ☑ F ☐
IntelliBridge	9600	CVS-2Ch	9600	P ☑ F ☐
2 Ch CAS	4800	4 Ch CSV	4800	P ☑ F ☐
Scientific	115200	VueLink	9600	P ☑ F ☐
Scientific	115200	Scientific	57200	P ☑ F ☐
Scientific	57200	4 Ch CAS	19200	P ☑ F ☐

Table 16 – Simultaneous Serial Output Table

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5.6 Time and Date Settings

a) Select the **Setup button.**
b) Validate the current Time and Date setting are individually displayed PASS
c) Validate there is a warning that the current case will be closed if the time is changed during a case. PASS **(Figure 7)**

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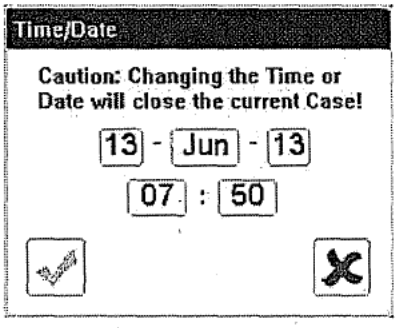

Figure 7 – Time & Date Menu

d) Touch the **Cancel** button to validate the menu is exited without any change to the time and the current case is not closed. PASS
e) Re-enter the **Time & Date** menu, make changes to the Time or Date
f) Touch the **Cancel** button to validate the menu is exited without any change to the time and the current case is not closed. PASS
g) Re-enter the **Time & Date** menu and make changes to the time and date per **Table 17** and validate only the indicated ranges are acceptable PASS
h) Validate the Leap and non-leap years exceptions are respected PASS
i) Click on the **Accept** button after entering the date and time
j) Validate the time and date on the Main Screen are updated accordingly and the current case is stopped while another case is restarted PASS
k) Turn off the UUT (Note Time & Date: PASS 12 Dec 13 15:50)
l) Disconnect the line cord and battery pack, wait 5 minute
m) Reconnect the battery pack to the UUT and power on the UUT
n) Validate appropriate date and time are displayed PASS (Note Time & Date: 12 Dec 13 15:57)

Setting	Range	Validate
Hour	0 to 23	P ☑ F ☐
Min	0 to 59	P ☑ F ☐
Day[2]	1 to 31	P ☑ F ☐
Month	Jan to Dec	P ☑ F ☐
Year	12 to 99	P ☑ F ☐

Table 17 – Time and Date setting

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

[2] Max Acceptable value for Days is 31, 30, 29 or 28 based on current Month whether Leap or Non-Leap Year

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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8.4.5.7 Language Settings

a) Select the **Biomed** Menu then enter the **Language** menu.

b) Validate the following Languages are available:

English PASS **Spanish** PASS **French** PASS
Italian PASS **German** PASS **Dutch** PASS **Russian** PASS

c) Validate each Language appears in the native language translation. PASS

d) Validate any of the language could be selected. PASS

e) Validate the change is applied and the menu closed as soon as a selection is made. PASS

f) Validate the QWERTY keyboard type is used for all Languages except Russian. PASS

g) Validate the Cyrillic keyboard is used for the Russian language selection. (See **Figure 8** below) PASS

h) Enter each one of the menu & submenu to verify all strings fit in the respective fields.

ENGLISH	FRENCH	SPANISH	GERMAN	DUTCH	ITALIAN	RUSSIAN
MAIN	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
PATIENT	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
EVENT	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
DATA	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
FILES	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
SETUP	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
HELP	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐

i) Save a Patient File to the **USB** while each of the language below is selected and review the file to validate the header section is are translated according to the language selected and that events entered while in that language are also available in the event section as translated. PASS (Use as Patient ID the name of the Language being used)

English PASS **Spanish** PASS **French** PASS
Italian PASS **German** PASS **Dutch** PASS **Russian** PASS

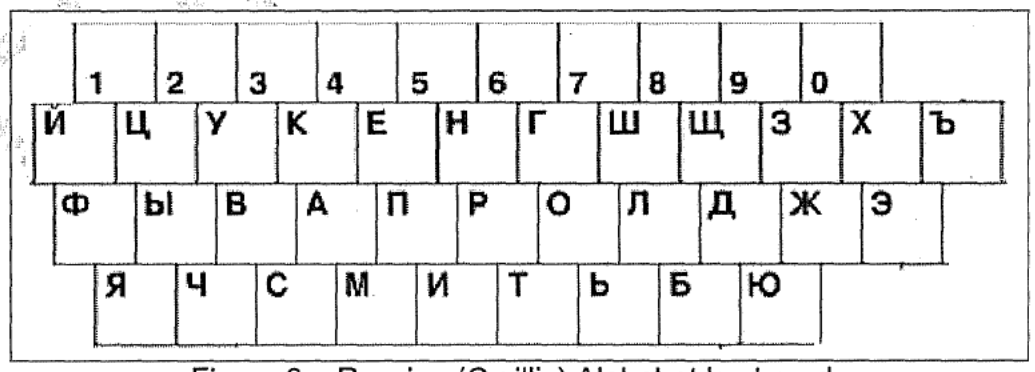

Figure 8 – Russian (Cyrillic) Alphabet keyboard

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PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.4.5.8 Alarm Delay

a) Select the **Setup button** then enter the **Alarm Delay** menu
b) Validate the selections **0**, **5**, **10** & **15** seconds are available PASS
c) Provoke a StO2 Limit violation Alarm. Validate the Parameter Alarms (High Priority Audio and Visuals) are initiated within the set delay PASS
d) While there is no Alarm present, click on the Audio Silence/Reset Key to activate the 2-Min Audio Disable.
e) Provoke a StO2 Limit violation Alarm. Validate the Parameter Alarms (Visuals) are initiated within the set delay PASS
f) Wait for the two minute Audio disable to be over and verify the High Priority Audio is started if the Parameter Alarm condition is still present. PASS

Alarm Delay	Audio Enabled	Audio Disabled
0 Sec	P☑ F☐	P☑ F☐
5 Sec	P☑ F☐	P☑ F☐
10 Sec	P☑ F☐	P☑ F☐
15 Sec	P☑ F☐	P☑ F☐

Table 18 – Alarm Delay

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.4.5.9 Factory Defaults Settings

a) Select the **Biomed** Menu then select the **Defaults** key.
b) Validate the user is warned "**This will cause all settings to change to Factory Defaults**" PASS
c) Select Cancel ✖ to validate the currents settings are kept. PASS
d) Set the UUT for the values in **Table 19** below under "**Settings**"
e) Cycle Powers to the UUT to validate upon returning to main menu all new settings are still available. PASS

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f) Reenter the "**Factory Defaults**" menu to set all settings and validate all settings are effectively returned to the Defaults per **Table 19** below. PASS (Only the group "**Altered by pressing Restore Factory Defaults**")

g) Cycle Powers to the UUT to validate upon returning to main menu all Default settings are still available. PASS

h) Validate the entered settings under "**Should not be Altered by pressing Restore Factory Defaults**" have not been changed/affected by the factory defaults settings restoration and numerous system power cycles. PASS

FEATURE	SETTINGS	DEFAULT	Validate
Altered by pressing Restore Factory Defaults			
Ch 1 High	**75 %**	**90 %**	P☑ F☐
Ch 1 Low	**15 %**	**50 %**	P☑ F☐
Ch 2 High	**80 %**	**90 %**	P☑ F☐
Ch 2 Low	**20 %**	**50 %**	P☑ F☐
Ch 3 High	**85 %**	**90 %**	P☑ F☐
Ch 3 Low	**25 %**	**50 %**	P☑ F☐
Ch 4 High	**98 %**	**90 %**	P☑ F☐
Ch 4 Low	**3 %**	**50 %**	P☑ F☐
Trace View	**2 Hours**	**30 Min**	P☑ F☐
Volume	**20 %**	**100 %**	P☑ F☐
Brightness	**80 %**	**100 %**	P☑ F☐
Port A Protocol	**2 Ch CSV**	**None**	P☑ F☐
Port A Baud	**57600**	**115200**	P☑ F☐
Port B Protocol	**VueLink**	**None**	P☑ F☐
Port B Baud	**19600**	**115200**	P☑ F☐
Language	**French**	**English**	P☑ F☐
Alarm Limit Delay	**15 Sec**	**0 Sec**	P☑ F☐
Should not be Altered by pressing Restore Factory Defaults			
Ch 1 Body Location	R-Brain	L-Brain	P☑ F☐
Ch 2 Body Location	L-Arm	R-Brain	P☑ F☐
Ch 3 Body Location	L-Leg	Unused	P☑ F☐
Ch 4 Body Location	R-Flank	Unused	P☑ F☐
Patient ID	John Doe	Blank	P☑ F☐
References	X	Blank/Invalid	P☑ F☐
STS Data Collection	Ongoing	Disabled & Stopped	P☑ F☐
Eng. Audio Settings	Disabled	Enabled	P☑ F☐
Eng. LED Alarm	Disabled	Enabled	P☑ F☐
US/OUS	OUS	US	P☑ F☐

Test Performed By (signature): Jonathan Tolc Date of Test: 12.14.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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FEATURE	SETTINGS	DEFAULT	Validate
Serial Number	1234567	000000	P☑ F☐
Asset Number	101010	000000	P☑ F☐
Time/Date	Current	1 Jan 2013 / 00:00	P☑ F☐
Stored Patient Data	Data	No data	P☑ F☐
Ethernet IP Address	Current	192.168.10.90	P☑ F☐
TCP	Enabled	Disabled (each Power cycle)	P☑ F☐

Table 19 - Factory Default Settings

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5.10 Help Menu

a) Select the **Setup button** then enter the **Help** menu. (US Monitors PT 12.14.13)

b) Validate following Help menu Selections are available
Sensor Selection PASS ; **Start Monitoring** PASS
Applying the Sensor PASS ; **Numeric Field** PASS ; **About** PASS

c) Select About to validate the menu reassembles **Figure 9** below. PASS

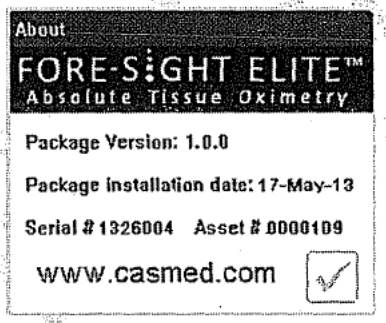

Figure 9 – About Help Menu

d) Validate the displayed **Package** version is the same under the **Bootloader\About** Menu PASS

e) Validate the displayed **Serial Number** and **Asset #** are the same under **Bootloader\About** Menu PASS

f) Validate the **Package Installation date** does match the last Package upgrade installation for that specific unit PASS

g) Validate the Outlook and content of the **Sensor Selection Help** menu resembles **Figure 10** below. PASS

h) Validate all sensor allowed on the System are represented. PASS

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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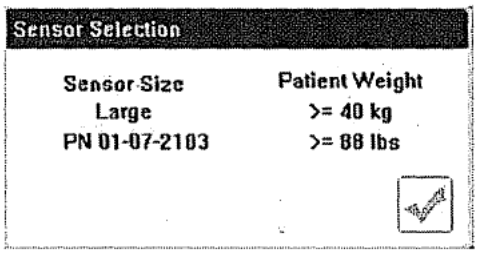

Figure 10 – Sensor Selection Help Screen

i) Validate the Outlook and content of the **Start Monitoring Help** menu resembles **Figure 11** below. _____

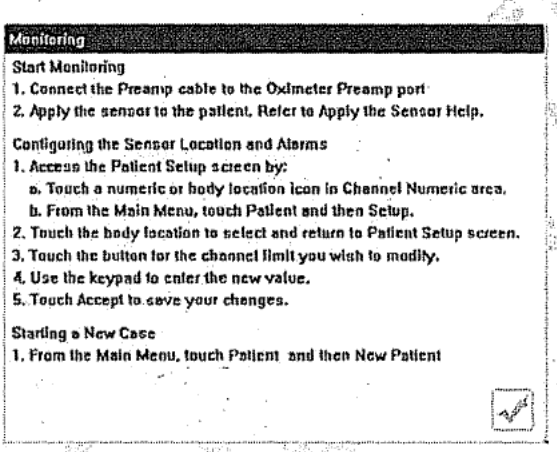

Figure 11 – Start Monitoring Help Screen

j) Validate the Outlook and content of the **Applying the Sensor Help** menu resembles **Figure 12** _____

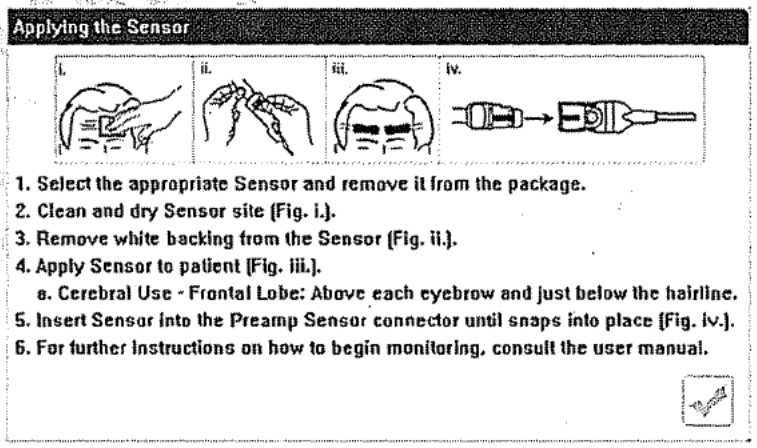

Figure 12 – Applying Sensors Help Screen

Test Performed By (signature): _____ Date of Test: 12.13.6

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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k) Validate the Outlook and content of the **Numeric Field Help** menu resembles **Figure 13.** PASS

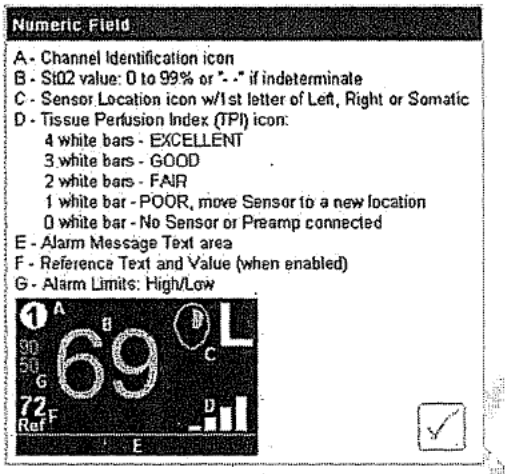

Figure 13 – Numeric Field Help Screen

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.5 Connection Status & StO2 Data Collection

8.5.1 Patient & Monitor Cable Status

8.5.1.1 Connection Status at Power on

a) Enter the **Patient Configuration** menu, select Left brain (Ch1 & Ch3) or Right (Ch2 & Ch4) brain

b) Power down the UUT

c) Connect Preamps and Sensor to the UUT following **Table 20** below

d) Power on the UUT

e) Validate the expected message per **Table 20** is displayed in the individual Numeric field and the appropriate Audio Alarm[3] is initiated. PASS

f) Performs the recommended action and validate the expected outcome (message, Alarm or Data) after a maximum of 30 seconds

g) Validate the Sensor connection Status LED on the preamp does match the Channel ID
- Ch1 or Ch3 on Preamp Left Side. PASS
- Ch2 or Ch4 on Preamp Right Side. PASS

h) Validate there was no occurrence of "Incorrect Sensor Size" errors after valid and calibrated sensors (Large & Medium) were connected to the Preamp. PASS

[3] See 21-07-0243 for accompanying Alarm Audio type (High, Medium, Low and No Audio)

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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Initial State	Preamp LED Status	Message[4]	Action[5]	Preamp LED Status	New Message[6]	Validate
No Preamp	OFF	Connect Preamp	Nothing	OFF	Connect Preamp	P ☑ F☐
No Preamp	OFF	Connect Preamp	Connect Preamp	White	Connect Sensor	P ☑ F☐
Preamp, No Sensor	White	Connect Sensor	Nothing	White	Connect Sensor	P ☑ F☐
Preamp, No Sensor	White	Connect Sensor	Connect Sensor	Green	Acquiring Data	P ☑ F☐
Preamp & Sensor	Green	Acquiring Data	Nothing	Green	"No Message"	P ☑ F☐

Table 20 – Power On Connection Status

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.5.1.2 Disconnection Status after Power on

a) Connect Preamps and Sensors to the UUT.
b) Validate valid StO2 values are displayed in the Numeric area of each channel PASS
c) Disconnect Preamps and/or Sensor from the UUT following **Table 21** below.
d) Performs the recommended action to validate the expected outcome (message, Alarm or Data) after a maximum of 30 seconds

Action	Message[7]	Preamp LED Status	Validate
Disconnect Preamp	Preamp Disconnected	OFF	P ☑ F☐
Disconnect Sensor	Sensor Disconnected	White	P ☑ F☐

Table 21 – Connection Status during Monitoring.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.5.2 Sensor Connection and StO2 Data Acquisition

a) Connect Preamps on each channel on the UUT, no sensor attached
b) Enter the Patient Menu and select the appropriate Body Location or Unused per **Table 22**

[4] See 21-07-0243 for accompanying Alarm Audio type (High, Medium, Low and No Audio)
[5] Monitor will issue a special "Preamp connected" Audio once Preamp connected or a special "Sensor connected" Audio tone once a sensor is newly connected.
[6] UUT is displaying dashes "- -" as a numeric value for case without "Acquiring Data" status.
[7] UUT is displaying dashes "- -" as a numeric value for case without "Acquiring Data" status.

Test Performed By (signature): [signature] Date of Test: 12.14.13
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c) Connect the suggested sensor to validate the UUT does start acquiring data or the expected message is displayed

d) Validate the displayed trace is smoothed. PASS

e) Disconnect Preamp and Sensors before powering down the UUT.

Body Location	Suggested Sensor	Expected Outcome[8]	Validate
Left Brain	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Right Brain	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Left Arm	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Right Arm	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Left Flank	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Right Flank	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Left Leg	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Right Leg	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Unused	Large	No Data, Messages or Audio Alarm	P ☑ F☐
	None	No Data, Messages or Audio Alarm	P ☑ F☐

Table 22 – Sensor Selection and StO2 Data Acquisition

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.5.3 New /Continue Patient Timer & Prompting

a) Power up the UUT and select to monitor the Left Brain on CH1 and the Right Brain on CH2.

b) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE 1**" and some Event Marks.

c) Validate the Event Marks and the Patient ID are properly reported on the display in the appropriate position. PASS

d) Let UUT undisturbed and collecting data for at least 40 minutes before powering down the Unit.

e) Wait for maximum 10 minutes before powering the UUT back on to validate there is menu asking the user whether or not to continue with the current case. PASS

f) Validate the previous case is continued (Patient ID, trace, Event Marks) if the User accept to continue the case PASS

[8] UUT is displaying dashes "- -" as a numeric value for case without "Acquiring Data" status. See 21-07-0243 for accompanying Alarm Audio type (High, Medium, Low and No Audio).

Test Performed By (signature): [signature] Date of Test: 12-14-13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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g) Let UUT undisturbed and collecting data for at least 40 minutes before powering down the Unit.

h) Wait for a minimum of 31 minutes before powering the UUT back on to validate the previous case is discontinued (previous Patient ID, trace, Event Marks removed) without any warning or menu PASS

i) Do enter the Patient ID "**CASE 2**" and some Event Marks. Let UUT undisturbed and collecting data for at least 40 minutes before powering down the Unit.

j) Disconnect the Sensor from the Preamp cables.

k) Wait for maximum 10 minutes before powering the UUT back on. Agree to keep the same case.

l) Validate the UUT is automatically switching to a new patient 30 minutes after power up. PASS

m) Enter the Patient ID "**CASE 3**" then wait 10 minutes before starting the data collection (connect the sensors/Phantom back to the Preamp). Let UUT undisturbed and collecting data for at least 40 minutes.

n) Disconnect the sensors from the Preamp and press the silence Key in order to dismiss the equipment alarm.

o) Validate after 30 minutes the case is closed and a new case is automatically started. PASS

p) Reconnect the sensors /Phantom to the Preamp then enter the Patient ID "**CASE 4**". Let UUT undisturbed and collecting data for at least 40 minutes.

q) Change the body location from Left to Right Brain for Channel 1 and from Right to Left Brain for Channel 2.

r) Validate that once exiting the Patient settings menu there is a menu asking whether the user will like to start a new case. PASS

s) Select **No** to validate the current case is continued. PASS

t) Let UUT undisturbed and collecting data for at least 5 minutes.

u) Change the body location from Left to Right Brain for Channel 2 and from Right to Left Brain for Channel 1.

v) Validate that once exiting the Patient settings menu there is a menu asking whether the user will like to start a new case. PASS

w) Select **Yes** to validate the current case is discontinued. PASS

x) Validate the Patient cases "**CASE 1**", "**CASE 2**", "**CASE 3**" & "**CASE 4**" were saved and are available under "Files\Manage" menu. PASS

y) Repeat above tests steps with **Left Arm** on **Ch3** and **Right Leg** on **Ch3** to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.5.4 TPI Status Indicator

a) Turn on the UUT.

b) Set the UUT to monitor the Left Brain on Ch1, Right Brain on Ch2, Left Brain on Ch3 and leaving Ch4 as unused channel.

c) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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d) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**Scientific**"

e) Start the appropriate LabView program that could store and display the UUT's scientific output data. (Using the **21-07-0345** Gemini Scientific Data Serial Output Protocol)

f) Record in **Table 23** & **Table 24** below the TotalHb values

g) Connect Preamps and sensor according to **Table 23** & **Table 24** below to validate the TPI value remains blank or is adjusted to the signal level.

Preamp & Sensor Status	TPI Status	TotalHb Range	Recorded TotalHb	TPI Symbol	Validate
Preamp & Sensor	TPI symbol adjusted to signal	> 50	63		P ☑ F☐
		42 to 49.99	43		P ☑ F☐
		35 to 41.99	40		P ☑ F☐
		< 35	29		P ☑ F☐
Preamp, No Sensor	TPI symbol set to "Blank"	0	—		P ☑ F☐
No Preamp	TPI symbol set to "Blank"	0	—		P ☑ F☐
Unused, Preamp & Sensor	No TPI symbol	--	--	--	P ☑ F☐

Table 23 – TPI Symbol Status – Cerebral Monitoring

Preamp & Sensor Status	TPI Status	TotalHb Range	Recorded TotalHb	TPI Symbol	Validate
Preamp & Sensor	TPI symbol adjusted to signal	> 30	30.6		P ☑ F☐
		20 to 29.99	25		P ☑ F☐
		10 to ~~11.99~~ 19.99 PT 12.14.13	11		P ☑ F☐

Test Performed By (signature): [signature] Date of Test: 12.14.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Preamp & Sensor Status	TPI Status	TotalHb Range	Recorded TotalHb	TPI Symbol	Validate
		< 10	9.9		P ☑ F ☐
Preamp, No Sensor	TPI symbol set to "Blank"	0	✓		P ☑ F ☐
No Preamp	TPI symbol set to "Blank"	0	✓		P ☑ F ☐
Unused, Preamp & Sensor	No TPI symbol	--	--	--	P ☑ F ☐

Table 24 – TPI Symbol Status – Somatic Tissues Monitoring

h) Allow the Sensor to be properly applied to optical simulator to validate the maximum TPI level is reached. PASS

i) Start to gradually lift off the cable end of the sensor from the simulator while avoiding any Ambient Light disturbance to validate the TPI level is reduced from 4 to 3, 3 to 2 or even to level 1. PASS

j) Validate the displayed TPI matches the TotalHb value. PASS

k) Validate the UUT is reporting a **"Check under Sensor"** Alarm as soon as the TPI level reaches **"level 1"** as an indication of a poorly perfused area. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.5.5 Adult TOP Calibration Rule

a) Power up the UUT.

b) Set the UUT to monitor the Left Brain on Ch1, Right Brain on Ch2, Left Brain on Ch3 and leaving Ch3 as unused channel.

c) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.

d) Enter the **"Ports"** Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as **"Scientific"**

e) Start the appropriate LabView program that could store and display the UUT's scientific output data. (Using the **21-07-0345** Gemini Scientific Data Serial Output Protocol)

f) Verify following steps to calculate a new TOP value: PASS

   i) Sensor is connected to Preamp
   ii) Monitor is displaying "**Acquiring Data**" during the Top calculation
   iii) Monitor is displaying an StO2 value ca 20 seconds after start of "**Acquiring data**" status
   iv) Top value on the LabView Application is fluctuating and is updated during the calculation period.

Test Performed By (signature): [signature] Date of Test: 12-14-13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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v) Once Top is calculate, the message "**Acquiring Data**" is no longer displayed on the UUT and the Top value is locked

g) Let the lasers turned on for the indicated time in **Table 25**

h) Perform the recommended actions and validate the outcome. PASS

i) Repeat above tests steps with **Left Arm** on **Ch3** and **Right Leg** on **Ch3** to validate all tests continue to pass. PASS

j) Power down the UUT.

Sensor Connection	Event	Action		Expected Outcome	Validate Cerebral	Validate Somatic
T > 15 Minutes	Disconnect Sensor	Reconnect < 3 Min		Same TOP	P ☑ F ☐	P ☑ F ☐
		Reconnect > 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		Reconnect New Sensor < 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		New Body Location	Reconnect same sensor < 3 Min	New TOP	P ☑ F ☐	P ☑ F ☐
		New Patient	Reconnect same sensor <3 Min	Same TOP	P ☑ F ☐	P ☑ F ☐
		New Patient	Reconnect Diff sensor <3 Min	New TOP	P ☑ F ☐	P ☑ F ☐
	Excessive Ambient Light	T > 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		T < 3 Min		Same TOP	P ☑ F ☐	P ☑ F ☐
T < 15 Minutes	Disconnect Sensor	Reconnect < 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		Reconnect > 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		Reconnect New Sensor < 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		New Body Location	Reconnect same sensor < 3 Min	New TOP	P ☑ F ☐	P ☑ F ☐
		New Patient	Reconnect same sensor <3 Min	New TOP	P ☑ F ☐	P ☑ F ☐
	Excessive Ambient Light	T < 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐

Table 25 – NSAM TOP Calculation Rule

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.5.6 NSAM Application Adult Cerebral Algorithm Verification

a) Validate a verification plan for the implementation of the Adult Cerebral Algorithm into The NSAM Application Software has been drafted and executed. PASS (Record Doc # VeIN-App-001)

b) Validate all tests passed. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

Test Performed By (signature): [signature] Date of Test: 12-14-13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.5.7 NSAM Application Adult Somatic Tissues Algorithm Verification

a) Validate a verification Plan for the implementation of the Adult Somatic Tissues Algorithm into The NSAM Application Software has been drafted and executed. PASS (Record Doc # VaPN-App-000 V2.10

b) Validate all tests passed. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.6 Data Communication

8.6.1 2-CH Comma Separated Value (CSV)

a) Power the Oximeter with full monitor/patient cables connected.
b) Select to monitor the Left Brain on CH1 and the Right Brain on CH2. (2 Channels only)
c) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.
d) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**2-CH CSV**"
e) Click on the "**Setup**" Box right next to the Port and set the Baud.
f) Verify the port settings now appears next to the Port in the form e.g. "**57600**" PASS
g) Set the Baud rate in HyperTerminal to the one currently being displayed on the port being tested, set the Data Bits to "**8**", Parity to "**None**", Stop Bits to "**1**" and the Flow Control to "**None**"
h) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE CSV1**" and some Event Marks
i) Verify the matching StO2 values are continuously displayed and updated on Hyper Terminal PASS
j) Verify the output format of the SCT do match with the description in document **21-07-0202** "**FORE-SIGHT Simple Comma Text Serial Output Format**" for two Channels PASS
k) Validate the Alarm Index values follows **Table 11** and are updated with a maximum 2 seconds delay. PASS
l) Validate entered events are not represented on the serial stream. PASS
m) Validate NSAM Auto Events are not represented on the serial stream. PASS
n) Cycle power to the UUT to validate the **2-CH CSV** data output is restarted as soon as the UUT is back in Main Menu. PASS
o) Pull the SRS232 cable to validate the UUT continue to run without any issues or Alarms. PASS
p) Repeat all Test steps above this time with Left Brain on Ch1, Right Brain on CH2, Left Flank on Ch3 and Right Arm on Ch4. (4 Channels only) to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.6.2 4-CH Comma Separated Value (CSV)

a) Select to monitor the Left Brain on CH1 and the Right Brain on CH2. (2 Channels only)
b) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.

Test Performed By (signature): [signature] Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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c) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**4-CH CSV**"
d) Click on the "**Setup**" Box right next to the Port and set the Baud.
e) Verify the port settings now appears next to the Port in the form e.g. "**57600**" PASS
f) Set the Baud rate in HyperTerminal to the one currently being displayed on the port being tested, set the Data Bits to "**8**", Parity to "**None**", Stop Bits to "**1**" and the Flow Control to "**None**"
g) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE CSV2**" and some Event Marks
h) Verify the matching StO2 values are continuously displayed and updated on Hyper Terminal PASS
i) Verify the output format of the SCT do match with the description in document **21-07-0346** "**Gemini 4-Ch Comma Separated Value Serial Output Format**" for two Channels PASS
j) Validate the Alarm Index values follows **Table 11** and are updated with a maximum 2 seconds delay. PASS
k) Validate entered events are not represented on the serial stream. PASS
l) Validate NSAM Auto Events are not represented on the serial stream. PASS
m) Cycle power to the UUT to validate the **4-CH CSV** data output is restarted as soon as the UUT is back in Main Menu. PASS
n) Pull the SRS232 cable to validate the UUT continue to run without any issues or Alarms. PASS
o) Repeat all Test steps above this time with Left Brain on Ch1, Right Brain on CH2, Left Flank on Ch3 and Right Arm on Ch4. (4 Channels only) to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.6.3 2-CH CAS Protocol (ATE)

a) Select to monitor the Left Brain on CH1 and the Right Brain on CH2. (2 Channels only)
b) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.
c) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**2- CH CAS**"
d) Click on the "**Setup**" Box right next to the Port and set the Baud.
e) Verify the port settings now appears next to the Port in the form e.g. "**57600**" PASS
f) Set the Baud rate in HyperTerminal to the one currently being displayed on the port being tested, set the Data Bits to "**8**", Parity to "**None**", Stop Bits to "**1**" and the Flow Control to "**None**"
g) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE CAS ATE 1**" and some Event Marks
h) Attempts to send the following command in **Table 26** per **FORE-SIGHT ATE Serial Protocol** to verify all commands are being executed accordingly.
i) Set the UUT for ATE Streaming Measurement Values output. (Command "72")
j) Verify the output format of the UUT do match the description in document "**FORE-SIGHT ATE Serial Protocol**" for **CH1** & **CH2** PASS
k) Validate the Alarm Index values follows **Table 11** for the **CH1** & **CH2.** PASS
l) Validate entered events are not represented on the serial stream. PASS
m) Validate NSAM Auto Events are not represented on the serial stream. PASS
n) Pull the SRS232 cable to validate the UUT continue to run without any issues or Alarms. PASS
o) Let the UUT in Streaming data output mode for at least 12 Hours (Overnight) nonstop to verify the UUT is still outputting the required set of data and is still operating without interruption. PASS

Test Performed By (signature): [signature] Date of Test: 12.13.12
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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p) Repeat all Test steps above this time with Left Brain on Ch1, Right Brain on CH2, Left Flank on Ch3 and Right Arm on Ch4. (4 Channels only) to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.6.4 4-CH CAS Protocol (ATE)

a) Select to monitor the Left Brain on CH1 and the Right Brain on CH2. (2 Channels only)
b) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.
c) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**4- CH CAS**"
d) Click on the "**Setup**" Box right next to the Port and set the Baud.
e) Verify the port settings now appears next to the Port in the form e.g. "**57600**" PASS
f) Set the Baud rate in HyperTerminal to the one currently being displayed on the port being tested, set the Data Bits to "**8**", Parity to "**None**", Stop Bits to "**1**" and the Flow Control to "**None**"
g) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE CAS ATE 2**" and some Event Marks
h) Attempts to send the following commands in **Table 26** per **FORE-SIGHT ATE Serial Protocol** to verify all commands are being executed accordingly.
i) Verify the output format of the serial output from the UUT do match the description in document **21-07-0204** "**FORE-SIGHT CAS Serial Command Protocol Specifications**" PASS
j) Set the UUT for ATE Streaming Measurement Values output. (Command "72")
k) Validate the Alarm Index values follows **Table 11.** PASS
l) Validate entered events are not represented on the serial stream. PASS
m) Validate NSAM Auto Events are not represented on the serial stream. PASS
n) Pull the RS232 cable to validate the UUT continue to run without any issues or Alarms. PASS
o) Reconnect the RS232 cable to validate the streaming data output is restarted immediately. PASS
p) Let the UUT in Streaming data output mode for at least 12 Hours (Overnight) nonstop to verify the UUT is still outputting the required set of data and is still operating without interruption. PASS
q) Repeat all Test steps above this time with Left Brain on Ch1, Right Brain on CH2, Left Flank on Ch3 and Right Arm on Ch4. (4 Channels only) to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

Command	Validate 2-CH CAS	Validate 4-CH CAS
'50' Model Number	P ☑ F ☐	P ☑ F ☐
'51' Device Serial Number		P ☑ F ☐
'52' Software Versions		P ☑ F ☐
'53' Communication Version	P ☑ F ☐	P ☑ F ☐
'54' Channel Capacity of Device	P ☑ F ☐	P ☑ F ☐
'55' Time/Date		P ☑ F ☐

Test Performed By (signature): Prot Tola Date of Test: 12-13-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Command		Validate 2-CH CAS	Validate 4-CH CAS
'56' Patient ID			P ☑ F ☐
'57' Patient Age Range			~~P ☐ F ☐~~ N/A
'59' Channel Numeric/Trace values		P ☑ F ☐	P ☑ F ☐
'60' Channel Low Alarm Limit values			P ☑ F ☐
'61' Channel High Alarm Limit values			P ☑ F ☐
'63' Channel Body Location values			P ☑ F ☐
'64' Channel Sensor Sizes			P ☑ F ☐
'65' Channel TPI Calculations			P ☑ F ☐
'66' Patient Alarms	No Alarm	P ☑ F ☐	P ☑ F ☐
	Low StO_2	P ☑ F ☐	P ☑ F ☐
	High StO_2	P ☑ F ☐	P ☑ F ☐
	Ambient Light	P ☑ F ☐	P ☑ F ☐
	Check under Sensor	P ☑ F ☐	P ☑ F ☐
	High Ambient Light	P ☑ F ☐	P ☑ F ☐
	No Signal/ Sensor Off	P ☑ F ☐	P ☑ F ☐
	Signal out of Range	P ☑ F ☐	P ☑ F ☐
	Preamp Disconnected	P ☑ F ☐	P ☑ F ☐
	Sensor Disconnected	P ☑ F ☐	P ☑ F ☐
	Faulty Sensor/Faulty Preamp N/A	~~P ☐ F ☐~~	~~P ☐ F ☐~~
	Unstable Signal repeat K	P ☑ F ☐	P ☑ F ☐
'68' Equipment Alarms	No error	P ☑ F ☐	P ☑ F ☐
	(b)(4) [redacted]	P ☑ F ☐	P ☑ F ☐
		P ☑ F ☐	P ☑ F ☐
	Dead Battery/ Depleted Battery	P ☑ F ☐	P ☑ F ☐
	Low Battery	P ☑ F ☐	P ☑ F ☐
	Connect to AC	P ☑ F ☐	P ☑ F ☐
	Set Clock/ Set Time/Date	P ☑ F ☐	P ☑ F ☐
	Faulty Clock Battery	P ☑ F ☐	P ☑ F ☐
	2-Min Audio Disable is Off – Audio is Enabled	P ☑ F ☐	P ☑ F ☐
	2-Min Audio Disable is On – Audio is Disabled	P ☑ F ☐	P ☑ F ☐
'69' Specific Channel FORE-SIGHT (FS) Data Values N/A			~~P ☐ F ☐~~
'70' Specific Channel Time Under Threshold (TUT) Values N/A			~~P ☐ F ☐~~
'71' Specific Channel STS Data Calculations Values			P ☑ F ☐
'72' Request Enable/Disable Streaming Measurement Values Output	'80' Without Checksum	P ☑ F ☐	P ☑ F ☐
	'80' With Checksum	P ☑ F ☐	P ☑ F ☐

Table 26 - ATE Serial Output Commands

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

Test Performed By (signature): Smita Tale Date of Test: 12.12.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.6.5 Philips VueLink and IntelliBridge Communication

a) Review the **VaP/VR120010** to validate all tests were executed. PASS
b) Validate all tests passed. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.6.6 Scientific Communication

a) Review the **VeP/VeR130033** to validate all tests were executed. PASS
b) Validate all tests for the Scientific Serial output passed. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7 Alarms Handling & Management

8.7.1 System LEDs

a) Connect Preamps and Sensors to the UUT.
b) Validate the UUT starts to display valid StO_2 values in the Numeric Area
c) Create a **High** priority Alarm while there is no other ongoing Alarm and validate the **Red** Alarm LEDs are **flashing** PASS
d) Remove the High limit condition and validate all LEDs are now off PASS
e) Create a **Medium** priority Alarm while there is no other ongoing Alarm and validate the **Yellow** Alarm LEDs are **flashing** PASS
f) Reconnect the Preamp and validate all LEDs are now off PASS
g) Create a **Low** priority Alarm (e.g. External Interference) while there is no other ongoing Alarm and validate the **Yellow** Alarm LEDs are **on** but **not flashing** PASS
h) Clear the Low Priority Alarm to validate all LEDs are now off PASS
i) Create an **Information signal** (AC disconnected) while there is no other ongoing Alarm and validate the **All** LEDs are **off** PASS
j) Reconnect the AC and validate all LEDs remain off PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.2 Parameter Alarms

8.7.2.1 2-Min Audio Disable Inactive

a) Create the High or Low Parameter Alarm as indicated in **Table 27**
b) Press the **Silence button** to validate the Audio is muted for 2 minutes PASS
c) Validate visual Alarms continue (red flashing LEDs & message) PASS

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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d) Validate the Audio is restarted at the end of the 2 minutes PASS

e) Clear the parameter alarm

Alarm	Message[9]	LED	Audio[10]	Silence button Pressed	Validate
Low %StO_2		Red Flashing	YES	Audio silenced, Visual remains	P ☑ F☐
High %StO_2					P ☑ F☐

Table 27 – Parameter Alarms Control (2-Min Audio Disable inactive)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.2.2 2-Min Audio Disable Active

a) Press the Alarm Silence button while there are no other Alarms present

b) Validate the Audio disabled Icon is displayed and the Audio disable timer is running PASS

c) Create the High or Low Parameter Alarm as indicated in **Table 28** below

d) Validate there is no Alarm Audio initiated while Audio disable icon is displayed PASS

e) Remove the limits violation

f) Validate the Alarms are removed.

Alarm	Message[11]	LED	Audio	CH1
Low %StO_2		Red Flashing	No	P ☑ F☐
High %StO_2				P ☑ F☐

Table 28 – Parameter Alarms Control (2-Min Audio Disable active)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.3 Equipment Alarm

Whenever possible, many subsections could be run in parallel

8.7.3.1 Ambient Light Condition

a) Enter the **"Ports"** Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as **"Scientific"**

b) Start the appropriate LabView program that could store and display the UUT's scientific output data. (Using the **21-07-0345** Gemini Scientific Data Serial Output Protocol)

c) Connect Preamps and Sensors to the UUT.

d) Place the sensor on the tester forehead

[9] Message color is white over Red Background
[10] The audio associated with these alarms are always High priority.
[11] Message color is white over Red Background

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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e) Enter the Patient Configuration menu to enter a Cerebral Body location e.g. Left Brain.

f) Covers the sensors in such a ways that they will be protected from any Ambient light disturbances

g) Validate the UUT start to report valid StO2 values PASS

h) Validate the Ambient Light levels are displayed for each Channel on the LabView application. PASS

i) Gradually lift off the sensor from the subject skin to Create a minor Ambient Light disturbance

j) Validate the UUT displays "**Ambient Light**" message and an Informational Alarm is generated in the numeric area for that channel as soon as the Ambient Light is above **4.5V** PASS

k) Validate the StO2 values continue to be displayed PASS

l) Continue to lift off the sensor so they are more exposed to ambient light.

m) Validate the "**High Ambient Light"** Medium Priority Alarm is generated in the numeric area for that channel as soon as the Ambient Light for that Threshold is above **6.5V**. PASS

n) Validate StO2 are no longer reported by that channel (- -) PASS

o) Continue to lift off the sensor until they are completely exposed to ambient light to validate the alarm is not removed, the ambient light level continue to increase (until max value of **10V**) and the StO2 value remain dashed. PASS

p) Gradually and slowly start to lower/replace the sensor to reduce the ambient light level and validate the UUT restart to display valid StO2 data as soon as the Ambient Light level drops below **6.5V**. PASS

q) Validate the alarm switches from Medium back to informational Priority and the message display switches from **High Ambient Light** to **Ambient Light** while the level is between **6.5** and **4.5V**. PASS

r) Validate the UUT restarts to display valid StO2 values for that channel PASS

s) Continue to reduce the Ambient light exposure until the level is below **4.5V**. PASS

t) Validate all Alarms are removed PASS

u) Validate the UUT continues to display valid StO2 values for that channel PASS

v) Set the UUT to monitor a Non-Cerebral Body Location e.g. Right Arm.

w) Repeat above tests steps to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.7.3.2 Sensor Temperature Monitoring

a) Enter the "**Ports"** Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**Scientific**"

b) Start the appropriate LabView program that could store and display the UUT's scientific output data. (Using the **21-07-0345** Gemini Scientific Data Serial Output Protocol)

c) Connect Preamps and Sensors to the UUT.

d) Place the sensor on an optical simulator.

e) Enter the Patient Configuration menu to enter a Cerebral (e.g. Left Brain) Body location

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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f) Covers the sensors in such a ways that they will be protected from any Ambient light disturbances

g) Validate the Sensor Temperature levels are displayed for each Channel on the LabView application. PASS (as soon as UUT is reporting "**Acquiring Data**")

h) Validate the UUT is displaying a **Sensor Off** message and is not reporting any StO2 value if after 10 Minutes the Temperature reported by the sensor is still below 28.2ºC. PASS

i) Validate the UUT start to acquire and report valid StO2 values once the Temperature is higher than 28.2ºC. PASS (with sensor placed on Forehead)

j) Place the Sensor on optical simulator once UUT has been reporting valid StO2 for at least 10 minutes.

k) Place a warm fluid or medium on top of the sensor and validate there is a gradual (no sudden jump) increase of Temperature on that specific channel. PASS

l) Validate the UUT is reporting a Medium Priority alarm with the message "**Sensor Over Temp**" as soon as the Temperature reported by the sensor for that channel is above **43.0ºC.** PASS

m) Validate the UUT is no longer reporting StO2 data for that channel until the Temperature drops below **41.0ºC.** PASS (Remove fluid or medium)

n) Place a cold fluid or medium on top of the sensor and validate there is a gradual (no sudden jump) decrease of Temperature on that specific channel. PASS

o) Validate the UUT continues to report valid StO2 data while the Temperature is gradually decreasing. PASS

p) Validate the UUT is reporting an Informational Priority alarm with the message "**Sensor Under Temp**" as soon as the Temperature reported by the sensor for that channel is below **8.0ºC.** PASS

q) Validate the UUT continues to report StO2 data. PASS

r) Disconnect the sensor then reconnect a different one.

s) Set the UUT to monitor a Non-Cerebral Body Location e.g. Right Arm.

t) Covers the sensors in such a ways that they will be protected from any Ambient light disturbances

u) Validate the Sensor Temperature levels are displayed for each Channel on the LabView application. PASS (as soon as UUT is reporting "**Acquiring Data**")

v) Validate the UUT is displaying a **Sensor Off** message and is not reporting any StO2 value if after 10 Minute the Temperature reported by the sensor is still below 27.0ºC. PASS

w) Validate the UUT start to acquire and report valid StO2 values once the Temperature is higher than 27.0ºC. PASS (Sensor placed on Arm)

x) Place the Sensor on optical simulator once UUT has been reporting valid StO2 for at least 10 minutes.

y) Place a warm fluid or medium on top of the sensor and validate there is a gradual (no sudden jump) increase of Temperature on that specific channel. PASS

z) Validate the UUT is reporting a Medium Priority alarm with the message "**Sensor Over Temp**" as soon as the Temperature reported by the sensor for that channel is above **43.0ºC.** PASS

aa) Validate the UUT is no longer reporting StO2 data for that channel until the Temperature drops below **41.0ºC.** PASS (Remove fluid or medium)

bb) Place a cold fluid or medium on top of the sensor and validate there is a gradual (no sudden jump) decrease of Temperature on that specific channel. PASS

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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cc) Validate the UUT continues to report valid StO2 data while the Temperature is gradually decreasing. PASS

dd) Validate the UUT is reporting an Informational Priority alarm with the message "**Sensor Under Temp**" as soon as the Temperature reported by the sensor for that channel is below **8.0°C**. PASS

ee) Validate the UUT continues to report StO2 data. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.3.3 ESU Disturbance Condition

a) Properly attach a sensor to an Optical Simulator

b) Connect the ESU Test fixture to the UUT and connect it to a power source without turning it on.

c) Wait at least 60 seconds for the UUT to display valid StO2 values (StO2 = 62)

d) Turn On the ESU test Fixture in order to induce the ESU disturbance

e) Validate the StO2 value is dashed "- -" with possible showing of "**Unstable Signal**" or "**Signal out of Range**" messages and appropriate Low or Medium Priority Alarm Audio and LEDs activation PASS

f) Maintain the ESU fixture in a cycle of maximum 10 seconds On, Maximum 5 seconds Off before turning back On for another 10 seconds.

g) Validate the StO2 values remain dashed as long as the ESU interference is present PASS (Stop the interference after a minimum of 60 seconds)

h) Validate the StO2 values are displayed again after a maximum of 20 seconds once the interferences are no longer generated PASS

i) Validate the values displayed are within the simulator tolerances as recorded before the noise injection PASS **c)** above (Records StO2 = 63)

j) Let the UUT continue to run for at least 3 minutes to validate the displayed StO2 values continue to be within the Simulator's tolerances PASS

k) Cycle power to the UUT.

l) Restart the interference injection before any StO2 values are displayed.

m) Validate the StO2 value are dashed with possible showing of "**Unstable Signal**" or "**Signal out of Range**" messages and appropriate Low or Medium Alarm Audio and LEDs activation PASS

n) Validate the StO2 values are displayed after a maximum of 30 seconds once the interferences are no longer generated PASS

PASS/FAIL CRITERIA:
PASS: All validate statements are filled with Pass.
FAIL: Any of the validate statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.3.4 2-Min Audio Disable Inactive

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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a) Simulate the conditions in **Table 29** below.
b) Validate in **Table 29** the appropriate High, Medium, Low or Informational Alarm Priority (LEDs and Audio) are initiated by the UUT.
c) Press the **Silence button** for each condition
d) Validate the Audio is disabled
e) Re-enable the Audio after generating each alarm

Error/Condition	Message	Numeric	Priority	Silence Pressed	Validate	
Faulty Preamp connected	Faulty Preamp	Blank	Medium	Audio & Visual Removed[12]	~~P ☐ F ☐~~	N/A
Preamp unplugged after monitoring started	Preamp Disconnected				P ☑ F ☐	
Sensor faulty	Faulty Sensor	Dashed			~~P ☐ F ☐~~	N/A
Sensor unplugged after monitoring started	Sensor Disconnected	Blank			P ☑ F ☐	
Computed StO_2 not in valid range Hb value < 0 & HbO_2 value < 0 Low input Brain Signal **or** Wavelength ratios out of Spec	Sensor Off	Dashed			P ☑ F ☐	
(b)(4) [redacted]				Audio removed, Visual remains	P ☑ F ☐	
Sensor on inappropriate object, or data not consistent with tissue measurements	Signal out of Range				P ☑ F ☐	
Tissue under Sensor is too little perfused. May have fluid accumulation/edema	Check under Sensor				P ☑ F ☐	
Sensor is not in correct contact with patient or excessive light interference	High Ambient Light				P ☑ F ☐	
Wrong size Sensor connected	Incorrect Sensor Size	Dashed	Low		P ☑ F ☐	
Expired Sensor connected	Sensor Use Ended				~~P ☐ F ☐~~	N/A
StO2 Values cannot be computed	Unstable Signal				P ☑ F ☐	
Sensor is not in contact with patient or excessive light interference	Ambient Light	Valid	Info	Visual remains, 2-min Silence start	P ☑ F ☐	
(b)(4) [redacted]					PASS	
Sensor connected; Body Location set to Unused	Set Body Location	Blank			~~P ☐ F ☐~~	N/A
No Preamp connected	Connect Preamp				P ☑ F ☐	
No Sensor connected; Valid Body Location	Connect Sensor				P ☑ F ☑	
Initial StO2 values being computed	Acquiring Data	Dashed			P ☑ F ☐	

Table 29 – Equipment Alarms Control (2-Min Audio Disable inactive)

PASS/FAIL CRITERIA:

[12] After pressing on the Silence key the message is switched from "**Preamp Disconnected**" to "**Connect Preamp**" and from "**Sensor Disconnected**" to "**Connect Sensor**"

Test Performed By (signature): _____ Date of Test: 12.14.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.7.3.5 2-Min Audio Disable Active

a) Press on the Silence button to disable Audio
b) Create the Alarm as indicated in **Table 30** below
c) Validate the appropriate Priority Alarm is initiated (LED status and message)
d) Validate there is no Alarm Audio initiated
e) Clear the alarm condition
f) Validate the Alarm indicators are removed

Error/Condition	Message	Numeric	LEDs	Validate
Faulty Preamp connected	Faulty Preamp	Blank	Yellow & Flashing	P ☐ F ☐
Preamp unplugged after monitoring started	Preamp Disconnected[13]			P ☑ F ☐
Sensor faulty	Faulty Sensor	Dashed		P ☐ F ☐
Sensor unplugged after monitoring started	Sensor Disconnected[14]	Blank		P ☑ F ☐
Computed StO_2 not in valid range Hb value < 0 & HbO_2 value < 0 Low input Brain Signal **or** Wavelength ratios out of Spec	Sensor Off	Dashed		P ☑ F ☐
(b)(4) [redacted]				P ☑ F ☐
Sensor on inappropriate object, or data not consistent with tissue measurements	Signal out of Range			P ☑ F ☐
Tissue under Sensor is too little perfused. May have fluid accumulation/edema	Check under Sensor			P ☑ F ☐
Sensor is not in correct contact with patient or excessive light interference	High Ambient Light			P ☑ F ☐
Wrong size Sensor connected	Incorrect Sensor Size	Dashed	Yellow	P ☑ F ☐
Expired Sensor connected	Sensor Use Ended			P ☐ F ☐
StO2 Values cannot be computed	Unstable Signal			P ☑ F ☐
Sensor is not in contact with patient or excessive light interference	Ambient Light	Valid	Off	P ☑ F ☐
(b)(4) [redacted]		Valid		PASS
Sensor connected; Body Location set to Unused	Set Body Location	Blank		P ☐ F ☐
No Preamp connected	Connect Preamp			P ☑ F ☐
No Sensor connected; Valid Body Location	Connect Sensor			P ☑ F ☐
Initial StO2 values being computed	Acquiring Data	Dashed		P ☑ F ☐

Table 30 – Equipment Alarms Control (2-Min Audio Disable active)

[13] Press on the Silence key to validate all visual alarms are removed and the message is switched from "**Preamp Disconnected**" to "**Connect Preamp**"
[14] Press on the Silence key to validate all visual alarms are removed and the message is switched from "**Sensor Disconnected**" to "**Connect Sensor**"

Test Performed By (signature): _____ Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.7.4 System Alarms

8.7.4.1 Battery Status

a) Make sure UUT has power cord connected to an AC outlet and a battery pack is installed
b) Turn on the UUT and wait for the Unit to enter Main menu.
c) Validate the Battery status resembles while the UUT is on AC. PASS
d) Connect Preamps and Sensors to the Unit then place the Sensor on an optical Simulator.
e) Validate the UUT starts to acquire and display valid StO2 data. PASS
f) Wait for the Battery to be sufficiently charged before disconnecting the AC.
g) Validate the Battery status icon resembles . PASS
h) Validate the UUT does not shut down and continue to acquire and display valid StO2 data PASS
a) Validate the UUT is displaying the message "**Connect to AC**", there are no Audio Alarm and the Alarm LEDs are off PASS
i) Cycle power to the UUT
j) Validate the UUT continues to display the message "**Connect to AC**", no Audio and the Alarm LEDs are off PASS
k) Validate the Battery status icon resembles . PASS
l) Allow the UUT to run undisturbed until occurrence of a low Battery condition occurs to validate the UUT is reporting a **Low** Priority "**Low Battery**" condition PASS (ca 1 Hour)
m) Validate the Battery status icon resembles . PASS
n) Allow the UUT to continue to run on Battery while acquiring and displaying StO2 data. PASS
o) Validate the UUT will report a "**Depleted Battery**" alarm condition and a **Medium** priority Alarm is generated PASS
p) Validate the Battery status icon resembles . PASS
q) Validate the UUT will shut down after 2 minutes PASS
r) Connect the UUT to AC and allow the battery pack to be fully recharged (ca 4 Hours)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.7.4.2 System Fan Status

b) Connect the UUT to the AC power cord and make sure the internal battery is securely mounted.

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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c) Validate the Green LED in front of the UUT is lit up (green) PASS
d) Validate the System Fan is not running PASS
e) Power up the UUT
f) Validate the System Fan is operating PASS
g) Connect the proper set of Preamps and sensor to start the monitoring of the Left or Right brain on all Channels PASS
h) Validate all channels soon start to report valid StO2 values. PASS
i) Carefully jam the System Fan to validate the UUT continue to run PASS
j) Validate the UUT is displaying the message "**Faulty System Fan**", there are no Audio Alarm and the LEDs are all off PASS
k) Let the UUT undisturbed for another 30 minutes to validate the displayed StO2 values are still within tolerances PASS
l) Remove the Jam to validate the message is no longer displayed and the UUT continue to run PASS
m) Power down the UUT.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.7.4.3 System Temperature

a) Power off the UUT
b) Disconnect the Fan Connector from the SCB and install a "Fan-Installed" jumper in its place
c) Power on the UUT and connect appropriate Sensors and optical simulators to monitor either a Cerebral or Non-Cerebral Body Location.
d) Validate the System is not reporting a Fan error and the UUT is reporting valid StO2 data PASS
e) Place the UUT in an elevated Temperature environment (starting at 38 ºC); A Lamp with high heat radiation could also be placed in a way that it is radiating into the UUT. (**UUT should never be left alone during the test**)
f) The UUT should be connected to the TELNET program running on a PC in order to monitor the internal Temperature sensors.
g) Validate the Telnet application reports temperatures measurement values from all internal sensors PASS (Temperature and Fan speed using Telnet's "**systemtemperatures**" command)
h) Validate the Fan speed is gradually adjusted to match the internal temperatures reported. PASS
i) Validate the UUT starts to report an internal temperature error "**High Internal Temp**" as soon as any of the reported Temperature rises above the **Warning threshold** set for the specific internal sensor PASS (see attached **FSE Thermal Thresholds Rev01** document)
j) Validate the appropriate **Low Priority** Alarm Audio and LEDs are initiated. PASS
k) Continue to watch the system as the temperature continue to rise to validate the Fan speed is adjusted accordingly. PASS
l) Validate the reported StO2 values are still within the simulator tolerances if displayed or dashed PASS

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m) Validate the UUT starts to report an internal temperature error **"Max Internal Temp"** as soon as any of the reported Temperature rises above the **Maximum threshold** set for the specific internal sensor PASS (see attached **FSE Thermal Thresholds Rev01** document)

n) Validate the appropriate **Medium Priority** Alarm Audio and LEDs are initiated. PASS

o) Validate the UUT shuts off **2 minutes** after the internal Temperature error condition PASS

p) Remove "Fan-Installed" jumper and reconnecting the Fan Connector to the SCB

q) Power On the UUT and allow UUT to cool down.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.7.4.4 2-Min Audio Disable Inactive

a) Power On the UUT.

b) Enter the New Patient menu and enter the Proper Age/Weight and Body location in order to use the connected Sensors.

c) Properly attach the sensors to the Optical Simulators.

d) Make sure the Audio is in the enabled state. PASS

e) Simulate following System Error conditions in **Table 31** below

f) Press the **Silence Key** and validate the appropriate Audio and/or Visual are removed as expected.

g) Continue with the same case and sensors into the next section.

h) Press on the On /Standby key to power On the UUT.

i) Continue with the same case and sensor into the next section.

Error/Condition	Message	Numeric	Priority	Silence Key Pressed	Validate	
System Error	System Error Exx	Dashed	Medium	Audio removed, Visual remains	~~P ☐ F ☐~~	
Depleted Battery	Depleted Battery	Blank			P ☑ F ☐	
Internal Temp > Max	Max Internal Temp				P ☑ F ☐	
Low Battery	Low Battery	Valid or Dashed	Low	Audio removed, Visual remains	P ☑ F ☐	
Monitor Internal Temp > normal limit	High Internal Temp				P ☑ F ☐	
No AC, Unit operating on Battery	Connect to AC	Valid or Dashed	Informal	Visual remains, 2-min Silence start	P ☑ F ☐	
Communications with external Wired device problem	Port X Comm Lost				P ☑ F ☐	
Faulty/Inoperative Fan	Faulty System Fan				P ☑ F ☐	
Battery problem	Faulty Battery				N/A	
Battery 1-wire Memory or Temp device problem	Unknown Battery				~~P ☐ F ☐~~	N/A
RTC Time/Date not set	Set Time/Date				~~P ☐ F ☐~~	N/A
USB & VGA power problem	Faulty USB/VGA				N/A	
Serial port problem	Faulty Serial Port				~~P ☐ F ☐~~	N/A
Front USB Power Problem	Faulty Front USB				~~P ☐ F ☐~~	N/A
Rear USB Power Problem	Faulty Rear USB				~~P ☐ F ☐~~	N/A
RTC Battery low or not present	Faulty Clock Battery				P ☑ F ☐	

Test Performed By (signature): [signature] Date of Test: 12-14-13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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Table 31 – System Alarms Control (2-Min Audio Disable inactive)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.4.5 2-Min Audio Disable Active

a) Continuing with the previous case
b) Press on the Silence Key.
c) Validate the Audio disabled Icon is displayed. PASS
d) Provoke the System Alarms as indicated in **Table 32** below to validate the appropriate Priority Alarm is initiated (LED status and message). PASS
e) Validate there is no Alarm Audio initiated. PASS
f) Clear the equipment alarm condition and validate the **Alarm visual indicators** are removed (messages) or turned off (LEDs) while the Audio is still turned off. PASS
g) Power down the UUT.

Error/Condition	Message	Numeric	LEDs	Validate	
System Error	System Error Exx	**Dashed**	**Yellow & Flashing**	P ☐ F ☐	N/A
Depleted Battery	Depleted Battery	**Blank**		P ☑ F ☐	
Internal Temp > Max	Max Internal Temp			P ☑ F ☐	
Low Battery	Low Battery	**Valid or Dashed**	**Yellow**	P ☑ F ☐	
Monitor Internal Temp > normal limit	High Internal Temp			P ☑ F ☐	
No AC, Unit operating on Battery	Connect to AC	**Valid or Dashed**	**Off**	P ☑ F ☐	
Communications with external Wired device problem	Port X Comm Lost			P ☑ F ☐	
Faulty/Inoperative Fan	Faulty System Fan			P ☑ F ☐	
Battery problem	Faulty Battery			N/A	
Battery 1-wire Memory or Temp device problem	Unknown Battery			P ☐ F ☐	N/A
RTC Time/Date not set	Set Time/Date			P ☐ F ☐	N/A
USB & VGA power problem	Faulty USB/VGA			N/A	
Serial port problem	Faulty Serial Port			P ☐ F ☐	N/A
Front USB Power Problem	Faulty Front USB			P ☐ F ☐	N/A
Rear USB Power Problem	Faulty Rear USB			P ☐ F ☐	N/A
RTC Battery low or not present	Faulty Clock Battery			P ☑ F ☐	

Table 32 – System Alarms Control (2-Min Audio Disable active)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

Test Performed By (signature): [signature] Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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8.7.5 Alarm Interference & Priority

8.7.5.1 Parameter and Equipment Alarms

a) Power On the UUT.
b) Enter the New Patient menu and enter the Proper Body location in order to use the connected Sensors.
c) Properly attach the sensors to the Optical Simulators.
d) Make sure the Audio is in the enabled state. PASS
e) Simulate following Error conditions in **Table 33** below
f) Validate the expected messages; Audio Alarm level and LEDs status are initiated by the UUT PASS
a) Press the **Silence Key** and validate the Audio is silenced but the Visuals remain PASS
b) Power down the UUT.

CASES	Error/Condition	Channel Message (s)	LED	Audio	Validate
1	Ch1 StO2 Low Ch1 Ambient Light	Ch1 Low StO2 & Ch1 Ambient Light	Red & Flashing	High Priority	P ☑ F☐
2	Ch1 StO2 High Ch2 Ambient Light Ch3 StO2 High	Ch1 High StO2 Ch2 Ambient Light Ch3 High StO2			P ☑ F☐
3	Ch1 Sensor Disconnected Ch2 StO2 High Ch2 Sensor Under Temp Ch3 Sensor Disconnected Ch4 Incorrect Sensor size	Ch1 Sensor Disconnected Ch2 High StO2 & Ch2 Sensor Under Temp Ch3 Sensor Disconnected Ch3 Incorrect Sensor size			P ☑ F☐

Table 33 – Parameter and Equipment Alarm condition Interference.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.7.5.2 Parameter and System Alarms

a) Power On the UUT.
b) Enter the New Patient menu and enter the Proper Body location in order to use the connected Sensors.
c) Properly attach the sensors to the Optical Simulators.
d) Make sure the Audio is in the enabled state. PASS
e) Simulate following Error conditions in **Table 34** below
f) Validate the expected messages; Audio Alarm level and LEDs status are initiated by the UUT PASS
g) Press the **Silence Key** and validate the Audio is silenced but the Visuals remain PASS
h) Power down the UUT.

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CASES	Error/Condition	System Message	Channel Message	LED	Audio	Validate
1	Ch1 StO2 Low Battery Depleted	Battery Depleted	Ch1 Low StO2	Red & Flashing	High Priority	P ☑ F ☐
2	Ch2 StO2 High Connect to AC	Connect to AC	Ch2 High StO2			P ☑ F ☐
3	Ch3 StO2 High High Internal Temp Connect to AC	High Internal Temp	Ch3 High StO2			P ☑ F ☐

Table 34 – Parameter and System Alarm condition Interference.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.5.3 Equipment and System Alarms

a) Power On the UUT.
b) Enter the New Patient menu and enter the Proper Age/Weight and Body location in order to use the connected Sensors.
c) Properly attach the sensors to the Optical Simulators.
d) Make sure the Audio is in the enabled state. PASS
e) Simulate following Error conditions in **Table 35** below
f) Validate the expected messages; Audio Alarm and LEDs status are initiated by the UUT PASS
c) Press the **Silence Key** and validate the Audio is silenced but the Visuals remain PASS
d) Power down the UUT.

CASES	Error/Condition	System Messages	Channel Message	LED	Audio	Validate
1	Depleted Battery Ambient Light	Depleted Battery	Ambient Light	Yellow Flashing	Medium Priority	P ☑ F ☐
2	High Internal Temp Ch1 High Ambient Light Faulty System Fan Ch4 Sensor Disconnected	High Internal Temp	Ch1 High Ambient Light Ch4 Sensor Disconnected			P ☑ F ☐
3	Ch1 Ambient Light Connect to AC Ch2 Connect Sensor Ch3 Incorrect Sensor Size	Connect to AC	Ch1 Ambient Light Ch2 Connect Sensor Ch3 Incorrect Sensor Size	Yellow	OFF	P ☑ F ☐
4	Ch1 Ambient Light Connect to AC Ch2 Connect Sensor	Connect to AC	Ch1 Ambient Light Ch2 Connect Sensor	OFF	OFF	P ☑ F ☐

Table 35 – Equipment and System Alarm condition Interference.

PASS/FAIL CRITERIA:

Test Performed By (signature): [signature] Date of Test: 12.16.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.5.4 Parameter, Equipment and System Alarms

a) Power On the UUT.
b) Enter the New Patient menu and enter the Proper Age/Weight and Body location in order to use the connected Sensors.
c) Properly attach the sensors to the Optical Simulators.
d) Make sure the Audio is in the enabled state. PASS
e) Simulate following Error conditions in **Table 36** below
f) Validate the expected messages; Audio Alarm level and LEDs status are initiated by the UUT PASS
e) Press the **Silence Key** and validate the Audio is silenced but the Visuals remain PASS
f) Power down the UUT.

CASES	Error/Condition	System Messages	Channel Message	LED	Audio	Validate
1	Depleted Battery Ch1 Ambient Light Ch1 High StO2	Depleted Battery	Ch1 High StO2	Red Flashing	High Priority	P ☑ F☐
2	Ch3 Low StO2 High Internal Temp Ch4 High Ambient Light Faulty System Fan	High Internal Temp	Ch3 Low StO2 Ch4 High Ambient Light			P ☑ F☐
3	Ch1 High Ambient Light Connect to AC Ch4 Sensor Disconnected Ch 3 Low StO2	Connect to AC	Ch1 High Ambient Light Ch4 Sensor Disconnected Ch3 Low StO2			P ☑ F☐

Table 36 – Parameter, Equipment and System Alarm condition Interference.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

Test Performed By (signature): [signature] Date of Test: 12.16.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9 Summary

All Applicable Tests were performed
All performed Tests passed

Performed by: [illegible] Date: 12-16-13

Attachments:

21-07-0204
21-07-0343
21-07-0346
FS-ATE Serial Protocol
STS Verification
6x USB Header (Translation)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CASMED®	Document Number VaR 120019	Rev 9.0
TITLE: Gemini / FORE-SIGHT ELITE Software PEMS Validation Report		

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals:

Validation Engineer	P. Tala	12-16-13 Date
Project Engineer	R. Bystrianyk	12-16-13 Date
Eng Project Leader	H. Triebel	12/16/13 Date
VP R & D	J. Gamelin	12/16/2013 Date
Mktg Product Manager	M. Aceves	12/17/2013 Date
Quality Assurance Regulatory Affairs	R. Jeffrey	12/17/13 Date

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FOR WHAT'S VITAL

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Rev	Author(s)	Description
1.0	P. Tala	Initial release, FORE-SIGHT ELITE Software Rev 0.2.0 Test Report
2.0	P. Tala	Update Test Report for Software Rev 0.3.3 build Package
3.0	P. Tala	Update Test Report for Software Rev 0.3.5 build Package
4.0	P. Tala	Update Test Report for Software Rev 0.3.6 build Package
5.0	P. Tala	Update Test Report for Software Rev 1.0.0 build Package
6.0	P. Tala	Update Test Report for Software Rev 1.0.1 build Package
7.0	P. Tala	Update Test Report for Software Rev 1.0.2 build Package
8.0	P. Tala	Update Test Report for Software Rev 1.1.0C build Package
9.0	P. Tala	Update Test Report for Software Rev 1.1.1A build Package

Table of Contents

1. INTRODUCTION 3
1.1 PURPOSE 3
1.2 SCOPE 3
1.3 REFERENCE DOCUMENTS 3
1.4 ACRONYMS 3
2. SUMMARY OF TESTING PERFORMED 3
3. DEFECTS, VARIANCES AND INCIDENTS 5
4. COMPREHENSIVE ASSESSMENT 5
5. EVALUATION 5

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1. INTRODUCTION

1.1 PURPOSE

This Validation Report summarizes the testing performed on the Gemini / FORE-SIGHT ELITE Software PEMS per VaP 120019 Rev9_0. For information on VaP 120019 Rev9_0 refers to the attached Validation plan (**Appendix A).**

1.2 SCOPE

Refer to VaP 120019 Rev9_0 for details on the scope of this testing.

Sample Size Rationale – 2 Fore-Sight Monitors were used as Unit Under Test (UUT) to execute VaP 120019 Rev9_0. 2 UUTs demonstrates sufficient consistency of performance in the Validation of the software features.

1.3 REFERENCE DOCUMENTS

- VaP 120019 Rev9_0 – Gemini / FORE-SIGHT ELITE Software PEMS Validation Plan

1.4 ACRONYMS

- VaP Validation Plan
- VaR Validation Report

2. SUMMARY OF TESTING PERFORMED

The following tests were conducted per VaP 120019 Rev9_0:

Section #	Test Description	Comments	Results
8.1	SCB & NSAM Software Code Upload & System Configuration		
8.1.1	***SCB & NSAM Package and Software Upload***		**PASS**
8.1.2	System Configuration		**PASS**
8.1.3	Touch Screen Calibration		**PASS**
8.2	Oximeter Start Up		
8.2.1	Standard Start Up		**PASS**
8.2.2	Start Up With Failed Power-On Self-Test		**PASS**
8.3	Visual & Display Indicators		
8.3.1	Main Screen Display		**PASS**
8.3.1.1	Title Bar/Line Area		**PASS**
8.3.1.2	System Message Area		**PASS**
8.3.1.3	Trace Area		**PASS**
8.3.1.4	Numeric Field		**PASS**
8.3.1.5	1st, 2nd Levels Touch button		**PASS**
8.3.1.6	Alarm Silence button		**PASS**
8.4	User Controls		
8.4.1	Patient Menu		**PASS**
8.4.1.1	Patient Menu Selections		**PASS**
8.4.1.2	Body Location Settings		**PASS**
8.4.1.2.1	US Configuration		**PASS**
8.4.1.2.2	OUS Configuration		**PASS**
8.4.1.3	Alarm Limits Settings		**PASS**
8.4.1.4	Alarm Limit Range		**PASS**

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Section #	Test Description	Comments	Results
8.4.1.5	Patient ID		PASS
8.4.1.6	New Patient		PASS
8.4.2	Event Marks		PASS
8.4.2.1	Events Menu Selection		PASS
8.4.2.2	Events from List Addition		PASS
8.4.2.3	Removing placed Events		PASS
8.4.2.4	Auto Events		PASS
8.4.3	Data Menu		PASS
8.4.3.1	Data Menu Selection		PASS
8.4.3.2	STS View Menu		PASS
8.4.3.3	STS Data Collection and Verification		PASS
8.4.3.4	Reference Value REF		PASS
8.4.4	Patient Data Management		
8.4.4.1	Multiple Patients Storage		PASS
8.4.4.2	Saving Selected Files to the USB		PASS
8.4.4.3	Reviewing Data Saved to the USB		PASS
8.4.4.4	Deleting Selected Files to the USB		PASS
8.4.5	Setup Menu		PASS
8.4.5.1	Setup Menu Selection		PASS
8.4.5.2	View Settings		PASS
8.4.5.3	Volume Settings		PASS
8.4.5.4	Brightness Settings		PASS
8.4.5.5	Ports Settings		PASS
8.4.5.6	Time and Date Settings		PASS
8.4.5.7	Language Settings		PASS
8.4.5.8	Alarm Delay		PASS
8.4.5.9	Factory Defaults Settings		PASS
8.4.5.10	Help Menu		PASS
8.5	Connection Status & StO2 Data Collection		
8.5.1	Patient & Monitor Cable Status		PASS
8.5.1.1	Connection Status at Power on		PASS
8.5.1.2	Disconnection Status after Power on		PASS
8.5.2	Sensor Connection and StO2 Data Acquisition		PASS
8.5.3	New /Continue Patient Timer & Prompting		PASS
8.5.4	TPI Status Indicator		PASS
8.5.5	Adult TOP Calibration Rule		PASS
8.5.6	NSAM Application Adult Cerebral Algorithm Verification		PASS
8.5.7	NSAM Application Adult Somatic Tissues Algorithm Verification		PASS
8.6	Data Communication		
8.6.1	2-CH Comma Separated Value (CSV)		PASS
8.6.2	4-CH Comma Separated Value (CSV)		PASS
8.6.3	2-CH CAS Protocol (ATE)		PASS
8.6.4	4-CH CAS Protocol (ATE)		PASS
8.6.5	Philips VueLink and IntelliBridge Communication		PASS
8.6.6	Scientific Communication		PASS
8.7	Alarms Handling & Management		
8.7.1	System LEDs		PASS
8.7.2	Parameter Alarms		PASS

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Section #	Test Description	Comments	Results
8.7.2.1	2-Min Audio Disable Inactive		PASS
8.7.2.2	2-Min Audio Disable Active		PASS
8.7.3	Equipment Alarm		PASS
8.7.3.1	Ambient Light Condition		PASS
8.7.3.2	(b)(4) [redacted]		PASS
8.7.3.3	ESU Disturbance Condition		PASS
8.7.3.4	2-Min Audio Disable Inactive		PASS
8.7.3.5	2-Min Audio Disable Active		PASS
8.7.4	System Alarms		PASS
8.7.4.1	Battery Status		PASS
8.7.4.2	System Fan Status		PASS
8.7.4.3	System Temperature		PASS
8.7.4.4	2-Min Audio Disable Inactive		PASS
8.7.4.5	2-Min Audio Disable Active		PASS
8.7.5	Alarm Interference & Priority		PASS
8.7.5.1	Parameter and Equipment Alarms		PASS
8.7.5.2	Parameter and System Alarms		PASS
8.7.5.3	Equipment and System Alarms		PASS
8.7.5.4	Parameter, Equipment and System Alarms		PASS

All data sheets (Printout) corresponding to each test have been completed and are included in **Appendix A** of this report.

3. DEFECTS, VARIANCES AND INCIDENTS

No defects, variances or incidents were noted in any of tests.

4. COMPREHENSIVE ASSESSMENT

The testing performed fully exercised the Operational Capabilities of the Gemini / FORE-SIGHT ELITE Software PEMS Rev 1.1.1 software Package.
No additional hazards or concerns were identified in the testing.

5. EVALUATION

All applicable Tests were executed.

All performed tests passed

The following SPRs were verified as resolved:

New Features, Improvements and Fixes
SPR # 741 - Possibility to delete more than the last Event entered (CR 1000)
SPR # 747 - System Reset after Factory Defaults activation (CR 1003)
SPR # 754 - Event Mark vertical dotted line (CR 1153)
SPR # 755 - NSAM Auto Event Mark on USB (CR 1150 & 1154)
SPR # 756 - STS Data Calculation (SPR 1149 & 1155)

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New Features, Improvements and Fixes
SPR # 757 - Reference Value: Horizontal dotted line not toggling (CR 1151 & 1156)
SPR # 758 - Active case total duration time. (CR 1148)
SPR # 760 - Active cases saved to the USB (CR 1148)
SPR # 762 - Dutch & Italian Strings under STS & View Menus (CR 1136 & 1158)
SPR # 763 - GUI Strings Translation (CR 1158 & 1159)
SPR # 764 - System Reset & StO2 Numerics on Display (CR 1147)
SPR # 765 - OUS Configuration & Body Location (CR 1129 & 1160)

The FS-ELITE US/OUS Software Update Package V1.1.1, consisting of the following SW parts, has not been determined to be safe and available for release:

- 15-06-0282 Rev1.0.0 FS-ELITE NSAM Bootloader Software
- 15-06-0283 Rev2.0.0g FS-ELITE NSAM Application Software
- 15-06-0284 Rev1.1.0A FS-ELITE MAIN Bootloader Software
- 15-06-0285 Rev1.1.1A FS-ELITE MAIN Application Software, US

APPENDIX A

VaP 120019 Rev9_0 (attached)

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18. Electromagnetic Compatibility and Electrical Safety

PERFORMANCE COMPLIANCE INFORMATION

Standard, Guidance, Validation, or Requirement	Document Title or Test Requirement	Report / Results NOTE – A listing here indicates full testing and compliance with the standard
AAMI ES60601-1: 2005	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance	100742469BOX Complies with the requirements of the standards. Pass
CSA C22.2 No. 60601-1:2008	Ed: 3.0 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance	100742469BOX Complies with the requirements of the standards. Pass
IEC60601-1:2005	ED 3.0 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance.	100742469BOX Complies with the requirements of the standards. Pass
IEC60601-1-2:2007	Ed 3.0 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Electromagnetic Compatibility	100742469BOX-008 Complies with the requirements of the standards. Pass
IEC60601-1-6: 2010	Ed 3 Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard : Usability	100742469BOX Complies with the requirements of the standards. Pass
IEC 62366: 2007	Medical devices – application of Usability Engineering to Medical Devices	100742469BOX Complies with the requirements of the standards. Pass
IEC60601-1-8: 2006	Ed 2.0 Part 1-8: General Requirements for Basic Safety and Essential Performance – General Requirements, Test and Guidance for Alarm Systems in Medical Electrical Equipment and Systems.	100742469BOX Complies with the requirements of the standards. Pass

See Attachment F for Safety and EMC reports.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EMC TEST REPORT

Report Number: 100742469BOX-008a
Project Number: G100742469

Report Issue Date: 11/13/2013

Product Designation: FORE-SIGHT Elite Absolute Tissue Oximeter Part # 01-06-3000

Standards: IEC 60601-1-2 ed3.0 (2007-03)

Tested by:
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, MA 01719 USA

Client:
CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405 USA

Report prepared by

Rick Duval / Associate Engineer

Report reviewed by

Kouma Sinn / Senior Project Engineer

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1 Introduction and Conclusion

The tests indicated in section 2.0 were performed on the product constructed as described in section 4.0. The remaining test sections are the verbatim text from the actual data sheets used during the investigation. These test sections include the test name, the specified test Method, a list of the actual Test Equipment Used, documentation Photos, Results and raw Data. No additions, deviations, or exclusions have been made from the standard(s) unless specifically noted.

Based on the results of our investigation, we have concluded the product tested **complies** with the requirements of the standard(s) indicated. The results obtained in this test report pertain only to the item(s) tested.

2 Test Summary

Section	Test full name	Result
3	Client Information	--
4	Description of Equipment Under Test	--
5	System Setup and Method	--
6	Radiated Emissions CISPR11 ed5.0 (with A1:2010)	Pass
7	AC Mains Conducted Emissions CISPR11 ed5.0 (with A1:2010)	Pass
8	Harmonics IEC 61000-3-2 ed3.0 (with A1:2008+A2:2009)	Pass
9	Flicker IEC 61000-3-3 ed2.0 (2008-06)	Pass
10	Electro-Static Discharge Immunity Test IEC 61000-4-2 ed2.0 (2008-12)	Pass
11	Radiated, Radio-Frequency, Electromagnetic Immunity IEC 61000-4-3 ed3.0 (with A1:2007+A2:2010)	Pass
12	Electrical Fast Transient/Burst Immunity Test IEC 61000-4-4 ed3.0 (2012-04)	Pass
13	Immunity to Surges IEC 61000-4-5 ed2.0 (2005-11)	Pass
14	Conducted, Radio-Frequency, Electromagnetic Immunity Test IEC 61000-4-6 ed2.0 (with A1:2004+A2:2006)	Pass
15	Power Frequency Magnetic Field Immunity Test IEC 61000-4-8 ed2.0 (2009-09)	Pass
16	Voltage Dips/Interruptions Immunity Test IEC 61000-4-11 ed2.0 (2004-03)	Pass
17	Section 5 User Information and Guidance Tables	--
18	Revision History	--

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 Client Information

This EUT was tested at the request of:

Company: CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405 USA
Contact: Mr. Ron Jeffrey
Telephone: (203) 488-6056
Fax: (203) 315-6344
Email: rjeffrey@casmed.com

4 Description of Equipment Under Test

Equipment Under Test			
Description	Manufacturer	Model Number	Serial Number
Absolute Tissue Oximetry	CAS Medical	FORE-SIGHT Elite Absolute Tissue Oximeter Part # 01-06-3000	ENG-15
*Absolute Tissue Oximetry	CAS Medical	FORE-SIGHT Elite Absolute Tissue Oximeter Part # 01-06-3000	1345005

Receive Date:	08/01/2012 & 11/11/2013
Received Condition:	Good
Type:	Production

Description of Equipment Under Test (provided by client)
Absolute Tissue Oximetry to measure oxygen saturation levels.

Equipment Under Test Power Configuration			
Rated Voltage	Rated Current	Rated Frequency	Number of Phases
100-240 VAC	1.5 A	50/60 Hz	1

Operating modes of the EUT:

No.	Descriptions of EUT Exercising
1	Measuring a signal through a medium simulating human tissue.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 System Setup and Method

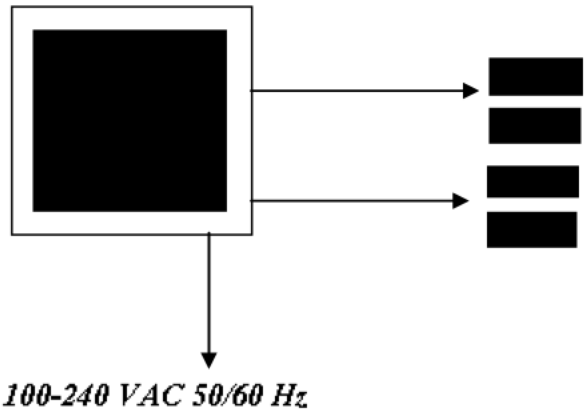
Cables					
ID	Description	Length (m)	Shielding	Ferrites	Termination
1	AC Cable	3.0	None	Yes	AC
2	Patient Leads	2.9	Yes	No	Simulator

Support Equipment			
Description	Manufacturer	Model Number	Serial Number
None			

5.1 Method:

Configuration as required by IEC 60601-1-2.

5.2 EUT Block Diagram:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.3 EUT Performance Criteria and Monitoring:

Performance as required by IEC 60601-1-2. Basic Safety and Essential Performance must be maintained throughout testing.

Product Essential Functions:

No.	Description
1	Absolute Tissue Oximetry to measure oxygen saturation levels of tissue.

Product Specific Performance:

No.	Description
1	Continuous operation with +/- 15% deviation during all testing.
2	Under the test conditions specified in 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide the BASIC SAFETY and ESSENTIAL PERFORMANCE. The following DEGRADATIONS, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, shall not be allowed: – component failures; – changes in programmable parameters; – reset to factory defaults (MANUFACTURER'S presets); – change of operating mode; – false alarms; – cessation or interruption of any intended operation, even if accompanied by an alarm; – initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm; – error of a displayed numerical value sufficiently large to affect diagnosis or treatment; – noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring; – artifact or distortion in an image in which the artifact would interfere with diagnosis, treatment or monitoring; – failure of automatic diagnosis or treatment ME EQUIPMENT and ME SYSTEMS to diagnose or treat, even if accompanied by an alarm. For ME EQUIPMENT and ME SYSTEMS with multiple FUNCTIONS, the criteria apply to each FUNCTION, parameter and channel. The ME EQUIPMENT or ME SYSTEM may exhibit DEGRADATION of performance (e.g. deviation from MANUFACTURER'S specifications) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE

Description of how performance was observed during testing:

No.	Description
1	The EUT was monitored ensuring the following artifact readings did not deviate by greater that 15%: The 4 readings monitored were 66, 65, 67, and 67
2	The EUT was monitored ensuring no alarm was present

General notes: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 Radiated Emissions

6.1 Method

Tests are performed in accordance with CISPR 11.

TEST SITE: 10m ALSE

The 10m ALSE is 13m (Length) x 21m (Depth) x 10m (Height) with the effective size in terms of space from the tips of the absorber is 12m (Length) x 20m (Depth) x 8.5m (Height). This chamber achieves broadband performance using a unique arrangement of hybrid and ferrite tile absorber. This chamber has a built in 3m diameter turntable (Embedded type). The metal structure of the table makes electrical connection around the entire circumference of the turntable to the ground plane with a metal brush type connection. The turntable is located on one end of the chamber and the antennas are mounted 3 and 10 meters away at the other end of the chamber on the adjustable an Antenna Mast. The antenna mast is a non-conductive bore sighted type with remote control of antenna height and polarization. The Antenna Mast and the turntable can be remotely controlled through the controller located in the adjacent Control room. A wooden table 80 cm high is used for table-top equipment.

Measurement Uncertainty

For radiated emissions, U_{lab} (3.5 dB at 3m and 3.5 dB at 10m below 1 GHz, and 4.2 dB at 3m above 1 GHz) < U_{CISPR} (5.2 dB), which is the reference value in CISPR 16-4-2 Table 1, hence the compliance of the product is only based on the measured value, and no measurement uncertainty correction is required, based on CISPR 22 and CISPR 11 (for 2006 and later revisions) Clause 11.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sample Calculation

The field strength is calculated by adding the Antenna Factor and Cable Factor, and subtracting the Amplifier Gain (if any) from the measured reading. The basic equation with a sample calculation is as follows:

FS = RA + AF + CF - AG

Where FS = Field Strength in dBμV/m
RA = Receiver Amplitude (including preamplifier) in dBμV
CF = Cable Attenuation Factor in dB
AF = Antenna Factor in dB
AG = Amplifier Gain in dB

In the following table(s), the reading shown on the data table reflects the preamplifier gain. An example for the calculations in the following table is as follows.

Assume a receiver reading of 52.0 dBμV is obtained. The antenna factor of 7.4 dB and cable factor of 1.6 dB is added. The amplifier gain of 29 dB is subtracted, giving a field strength of 32 dBμV/m. This value in dBμV/m was converted to its corresponding level in μV/m.

RA = 52.0 dBμV
AF = 7.4 dB/m
CF = 1.6 dB
AG = 29.0 dB
FS = 32 dBμV/m

To convert from dBμV to μV or mV the following was used:

$UF = 10^{(NF / 20)}$ where UF = Net Reading in μV
NF = Net Reading in dBμV

Example:

FS = RA + AF + CF – AG = 52.0 + 7.4 + 1.6 – 29.0 = 32.0
$UF = 10^{(32\ dB\mu V / 20)}$ = 39.8 μV/m

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
145 106	Bilog Antenna (30MHz - 5GHz)	Sunol Sciences	JB5	A111003	08/15/2011	08/15/2012
145 003	Preamplifier (150 KHz to 1 3 GHz)	Hewlett Packard	8447D	2443A04077	10/04/2011	10/04/2012
145 128	EMI Receiver 40 GHz (20 Hz - 40 Ghz)	Rohde & Schwarz	ESI	8392831001	08/23/2011	08/23/2012
145 410	Cables 145-400 145-403 145-405 145-406 145-407	Huber + Suhner	10m Track A Cables	multiple	09/04/2011	09/04/2012
Dav 001	Weather Station	Davis Instruments	7400	PE80519A61	08/17/2011	08/17/2012

Test equipment used on 11/13/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
145-410'	Cables 145-400 145-403 145-405 145-406 145-407	Huber + Suhner	10m Track A Cables	multiple	10/04/2013	10/04/2014
145003'	Preamplifier (150 KHz to 1.3 GHz)	Hewlett Packard	8447D	2443A04077	10/07/2013	10/07/2014
145128'	EMI Receiver 40 GHz (20 Hz - 40 Ghz)	Rohde & Schwarz	ESI	8392831001	10/01/2013	10/01/2014
Ant2a'	BROADBAND ANTENNA	Compliance Design	B100	1852	03/26/2013	03/26/2014
Ant2b'	BROADBAND ANTENNA	Compliance Design	B200	1850	03/26/2013	03/26/2014
Ant2c'	BROADBAND ANTENNA	Compliance Design	B300	00674	03/26/2013	03/26/2014
Dav004'	Weather Station	Davis Instruments	7400	PE80529A61A	09/25/2012	09/25/2014

Software Utilized:

Name	Manufacturer	Version
C5	Teseq	5.26.46.46

6.3 Results:

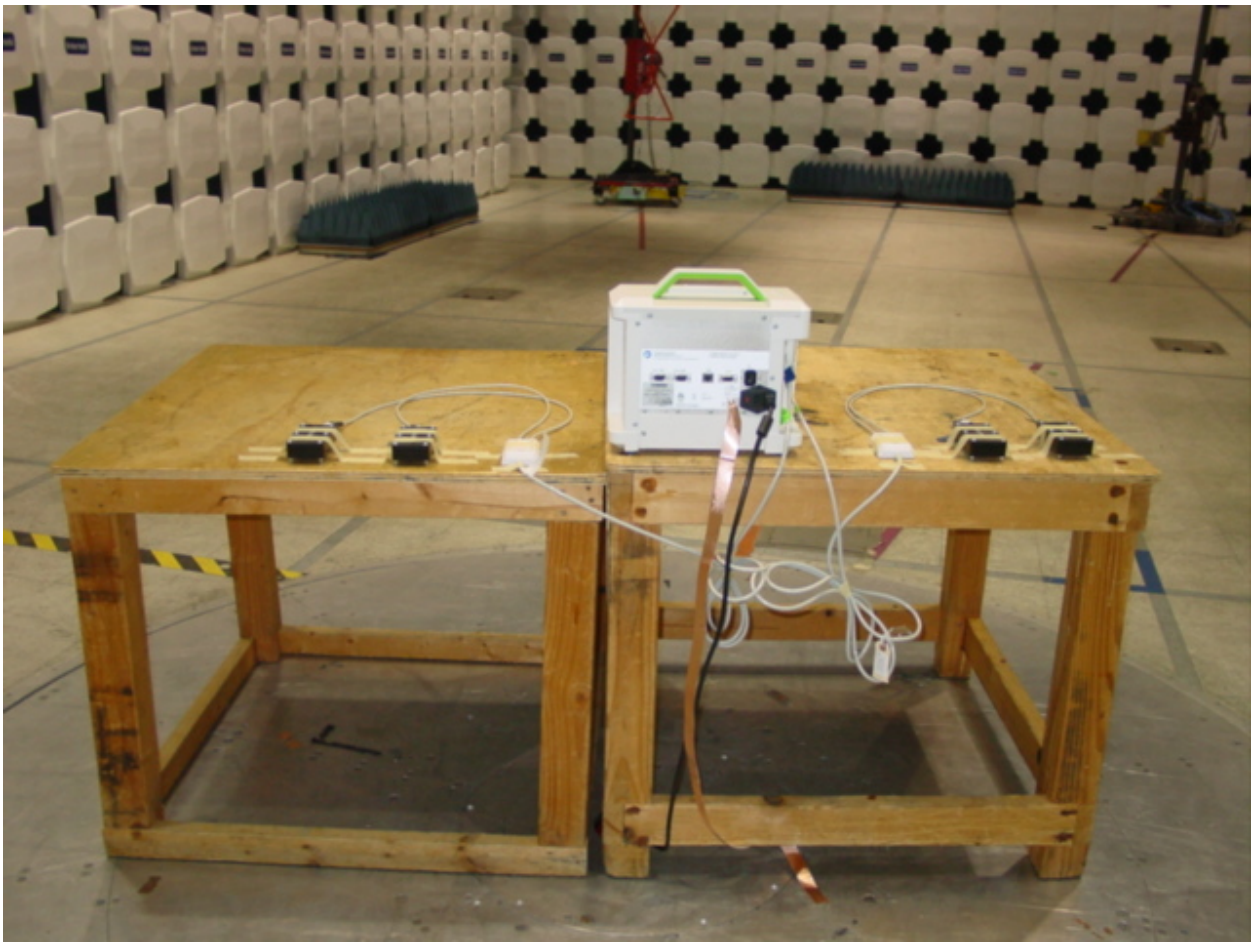
The sample tested was found to Comply.

Note: On 11/13/2013 testing, the unit was scanned at 100VAC 50 and 60Hz and was determined that 60Hz was the worst case. The final testing was performed at 100V/60Hz.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

6.4 Setup Photographs:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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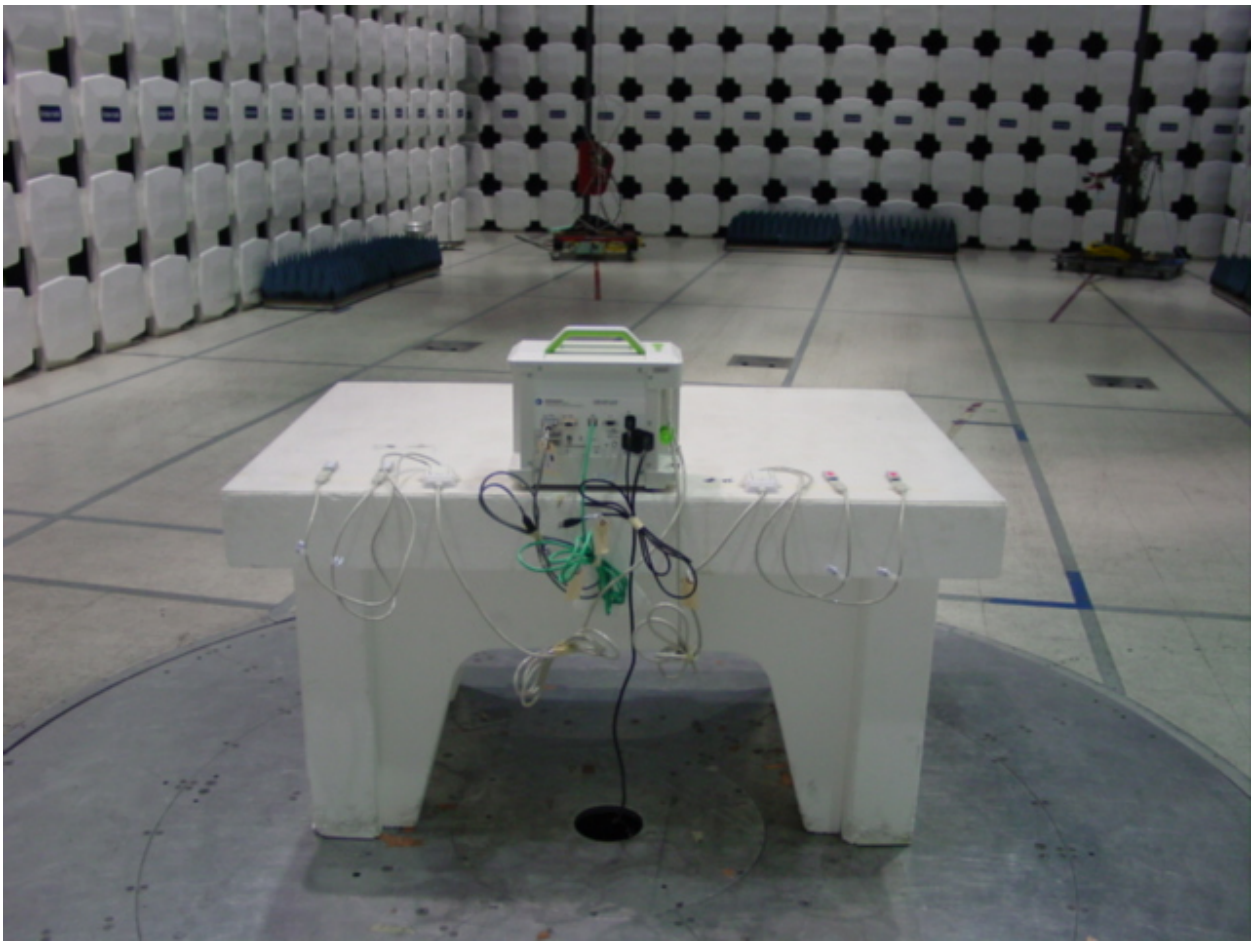
11-13-2013 100V 60Hz



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

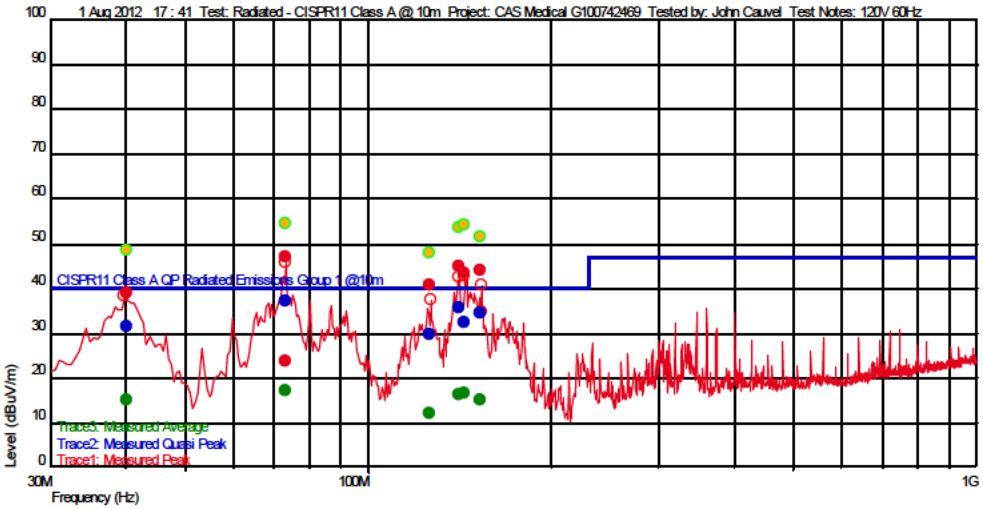
6.5 Plots/Data:

120V 60Hz

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	120V 60Hz	
Tested by:	John Cauvel	
Test Started:	1 Aug 2012 17 : 41	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

__ Swept Peak Data
__ Swept Quasi Peak Data
__ Swept Average Data

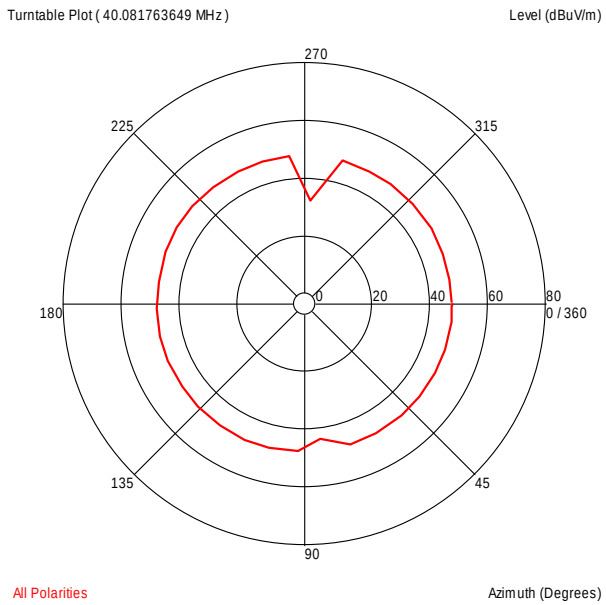
Emissions Test Data
Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	Hor (–), Ver (|)	Azimuth (deg)(Deg)	Mast Height(m)	RBW(Hz)
126.495 M	29.68	14.000	-25.014	40.000	-10.32	|	272	1.78	120 k
40 081 M	31.60	14.135	-26.078	40.000	-8.40	|	253	1.04	120 k
143.936 M	32.48	13.200	-24.792	40.000	-7.52	|	342	1.35	120 k
153.255 M	34.34	12.500	-24.689	40.000	-5.66	|	261	1.15	120 k
141.239 M	35.64	13.300	-24.826	40.000	-4.36	|	280	1.46	120 k
73.199 M	37.13	8.100	-25.765	40.000	-2.87	|	0	1.55	120 k

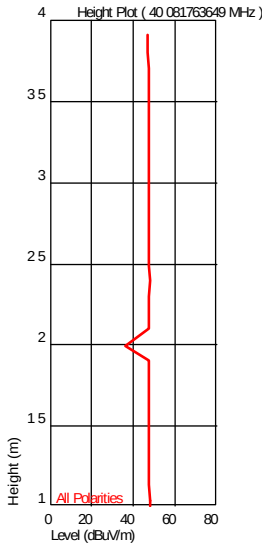
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

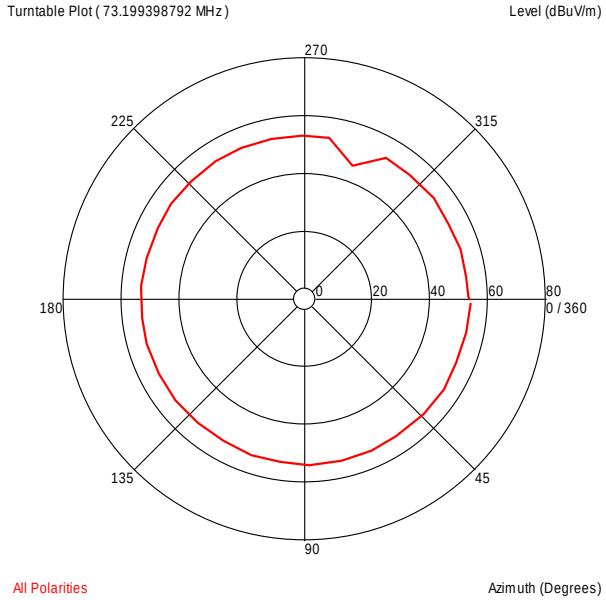
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

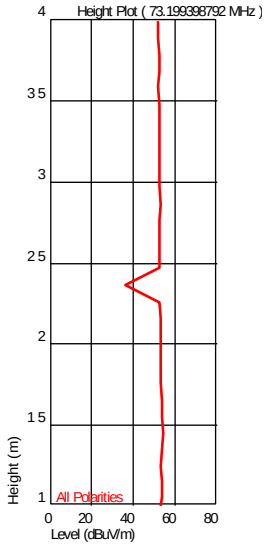
Azimuth Plots



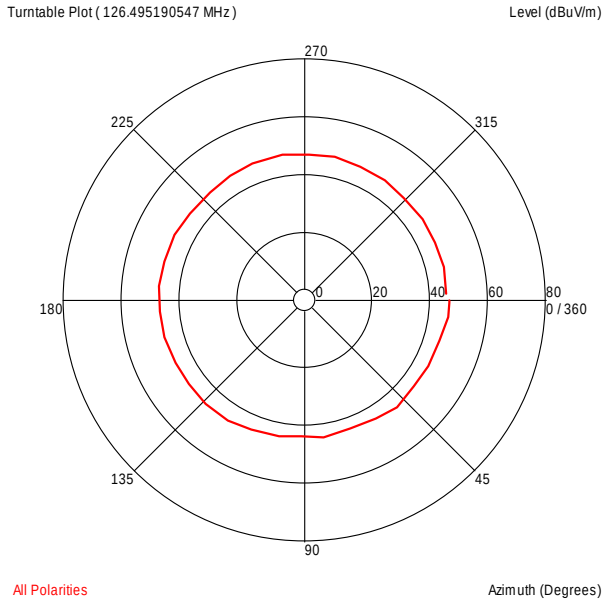
Turntable Plots

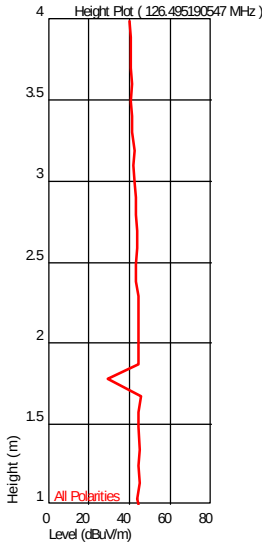


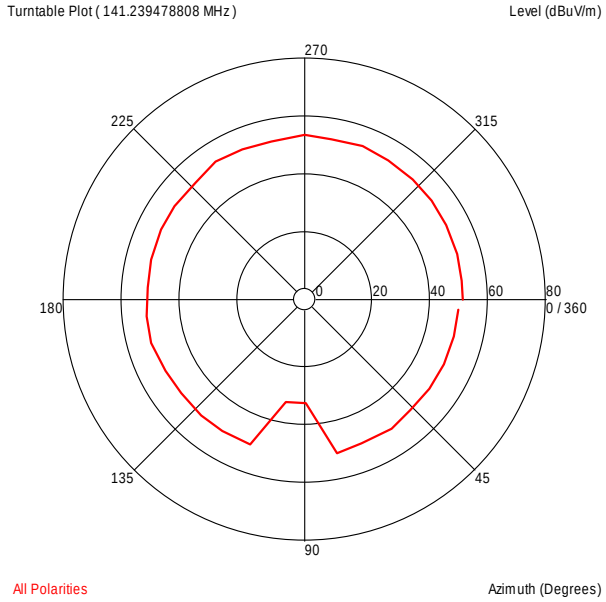


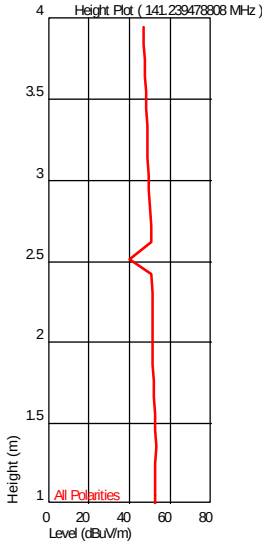


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

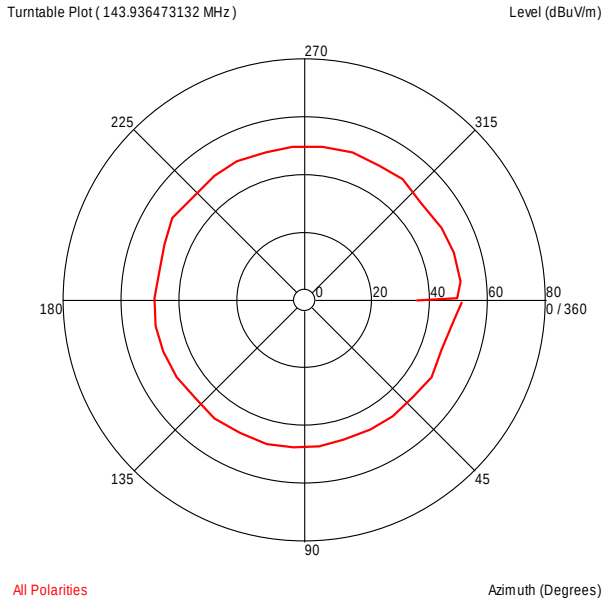


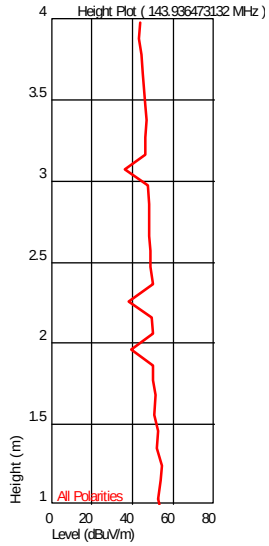


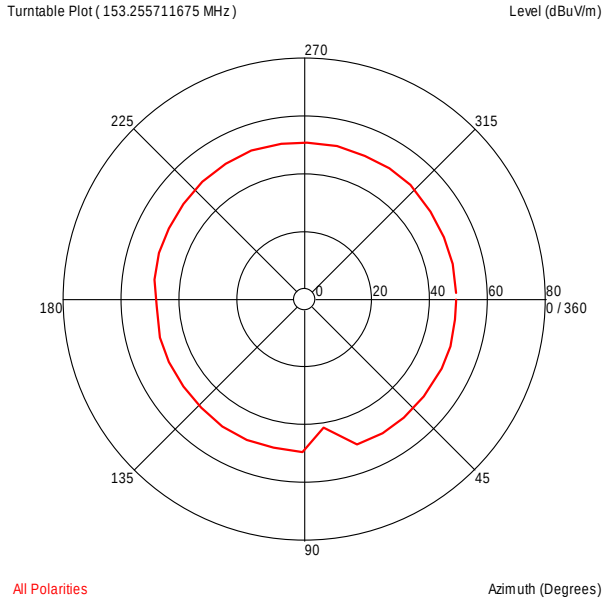


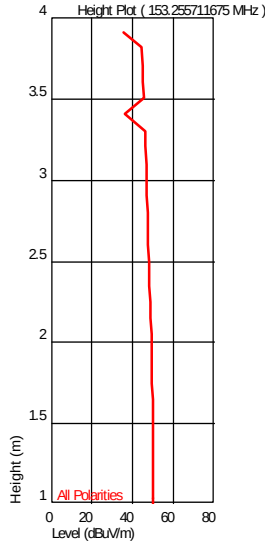


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

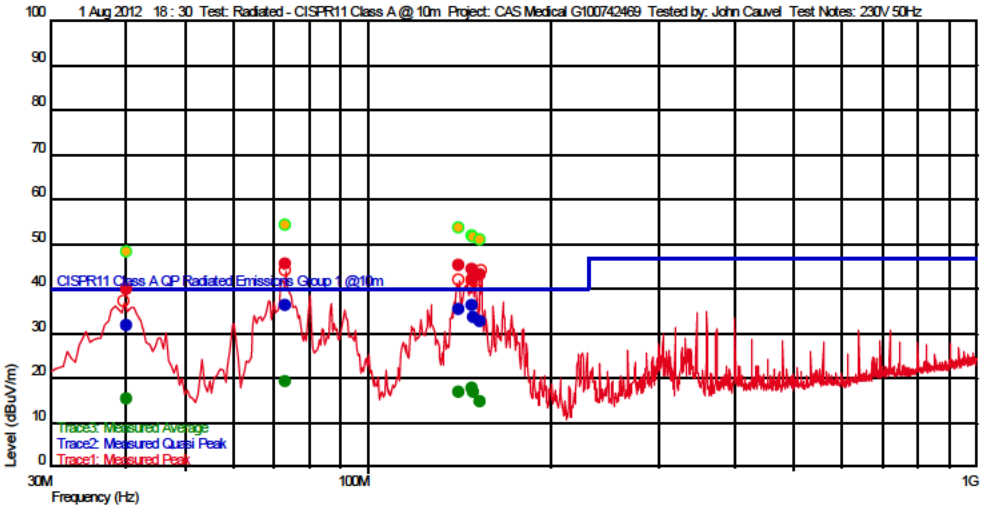
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

230V 50Hz

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	230V 50Hz	
Tested by:	John Cauvel	
Test Started:	1 Aug 2012 18 : 30	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

__ Swept Peak Data
__ Swept Quasi Peak Data
__ Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

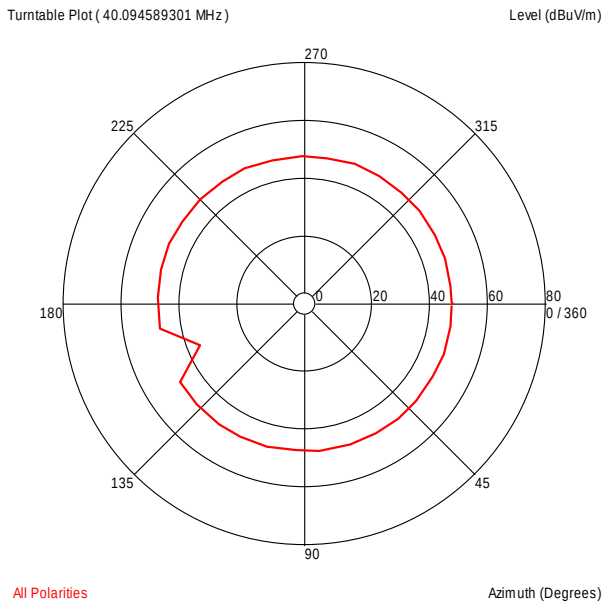
Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	Hor (–), Ver (|)	Azimuth (deg)(Deg)	Mast Height(m)	RBW(Hz)
40 094 M	31.90	14.124	-26.078	40.000	-8.10	|	279	2.56	120 k
153.407 M	32.76	12.500	-24.688	40.000	-7.24	|	258	1.45	120 k
149.544 M	33.44	12.746	-24.721	40.000	-6.56	|	226	1.34	120 k
141.192 M	35.29	13.300	-24.827	40.000	-4.71	|	240	1.45	120 k
73 365 M	36.24	8.100	-25.763	40.000	-3.76	|	28	1.55	120 k
148.303 M	36.40	12.870	-24.737	40.000	-3.60	|	300	1.25	120 k

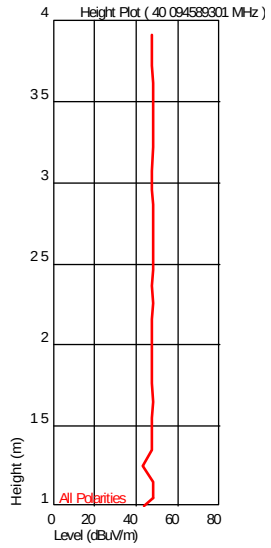
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

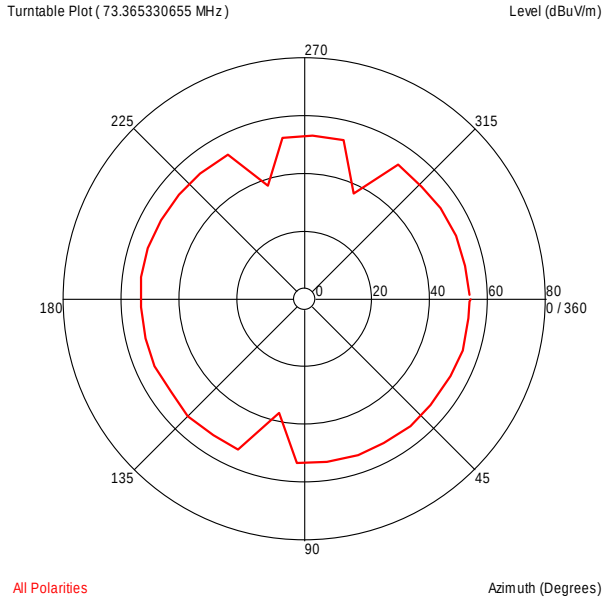
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

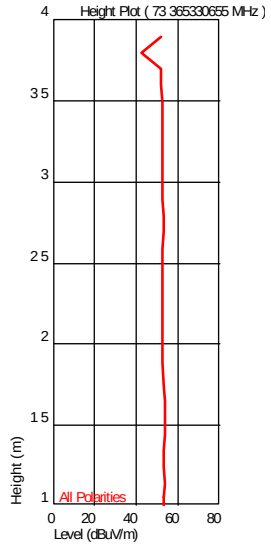
Azimuth Plots

Turntable Plots





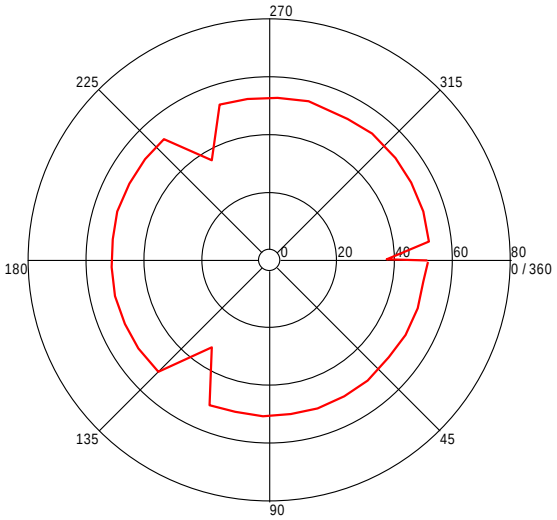




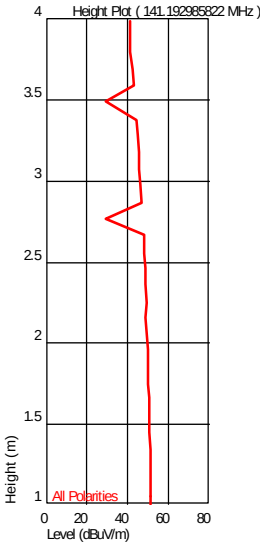
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

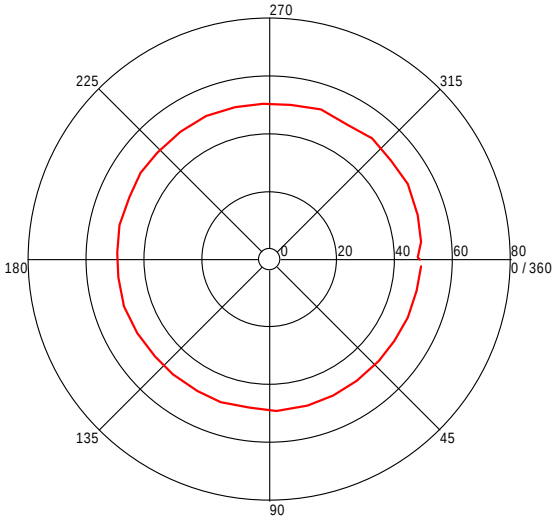
Turntable Plot (141.192985822 MHz) Level (dBuV/m)



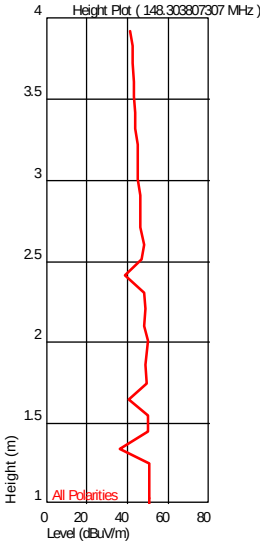
All Polarities Azimuth (Degrees)



Turntable Plot (148.303807307 MHz) Level (dBuV/m)



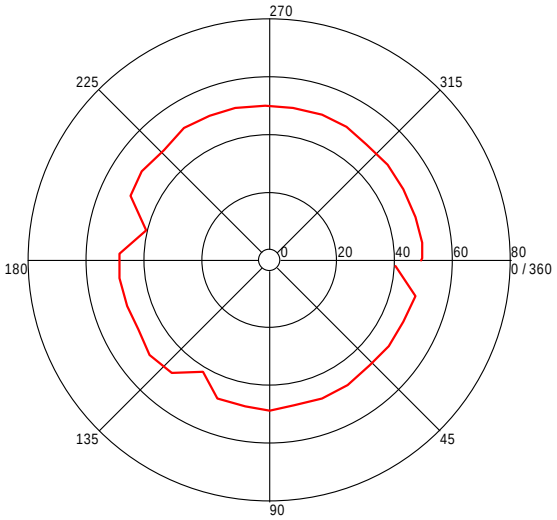
All Polarities Azimuth (Degrees)



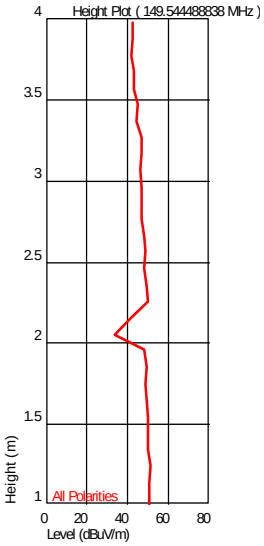
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

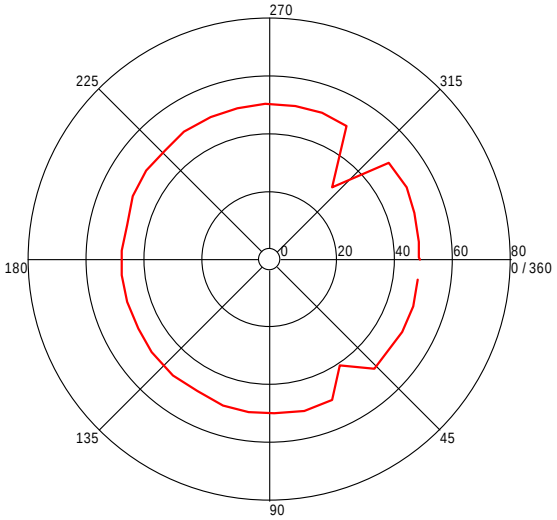
Turntable Plot (149.544488838 MHz) Level (dBuV/m)



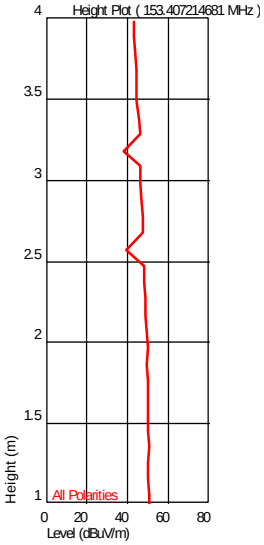
All Polarities Azimuth (Degrees)



Turntable Plot (153.407214681 MHz) Level (dBuV/m)



All Polarities Azimuth (Degrees)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

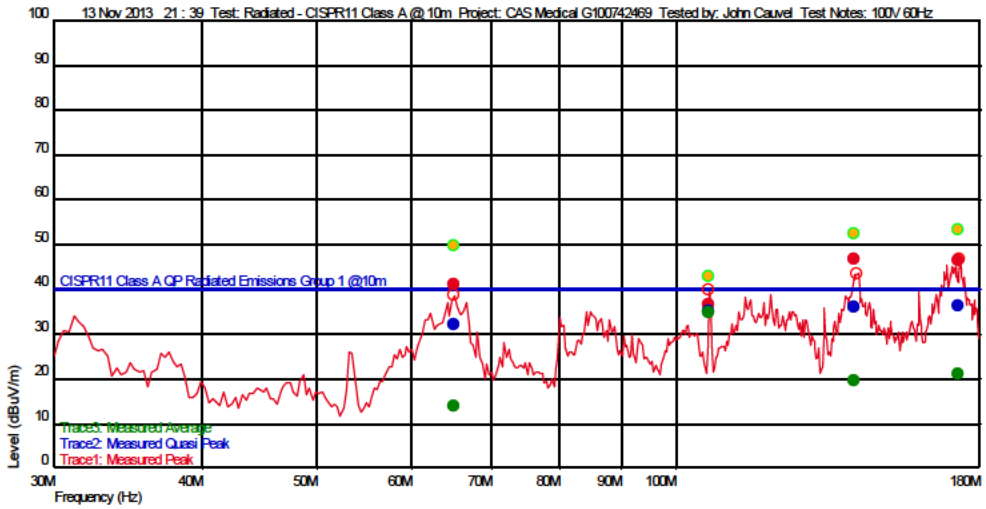
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz (30-180 MHz)

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	100V 60Hz	
Tested by:	John Cauvel	
Test Started:	13 Nov 2013 21 : 39	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

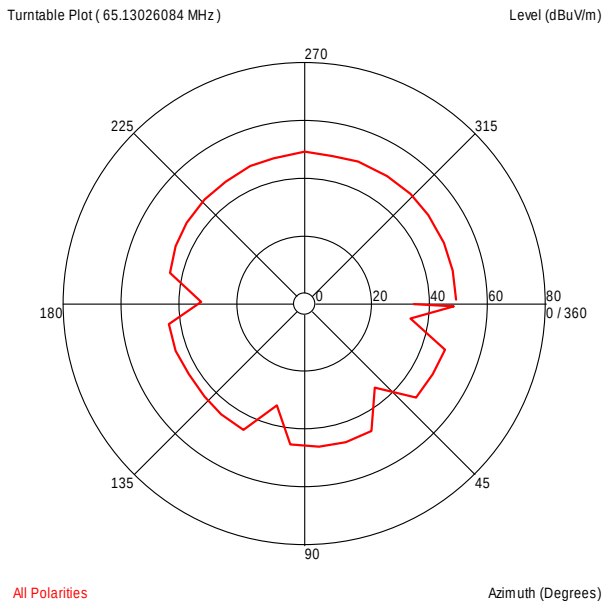
Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dB)	Hor (–), Ver (|)	Azimuth (Deg)	Mast Height(m)	RBW(Hz)
65.130 M	32 06	7.974	-25 959	40 000	-7.94	|	324	1.74	120 k
106.674 M	35 09	11.867	-25.449	40 000	-4.91	|	29	3.70	120 k
141.450 M	35 93	11.145	-25.289	40 000	-4.07	|	242	1.25	120 k
172.976 M	36 35	16.398	-24.625	40 000	-3.65	|	38	1.54	120 k

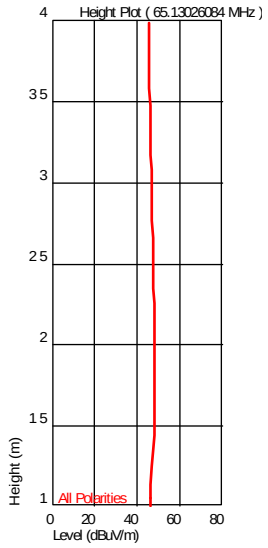
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

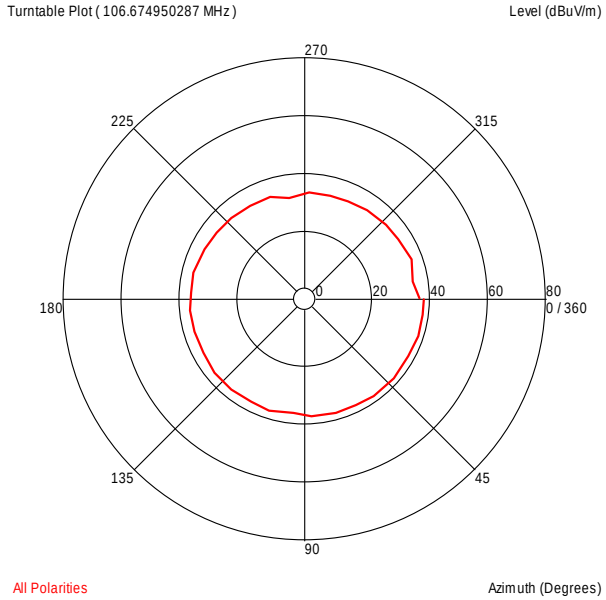
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

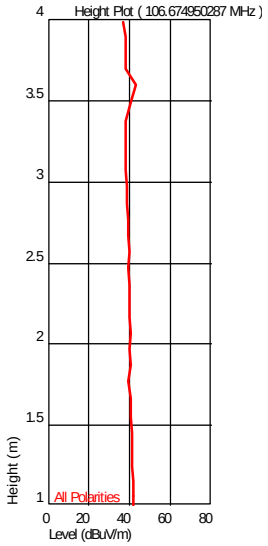
Azimuth Plots

Turntable Plots





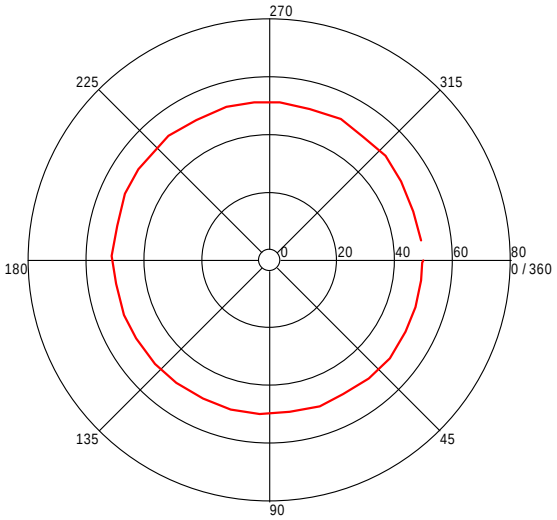




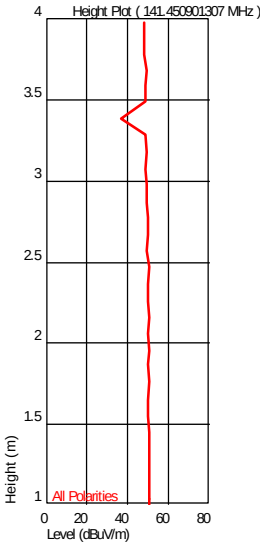
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

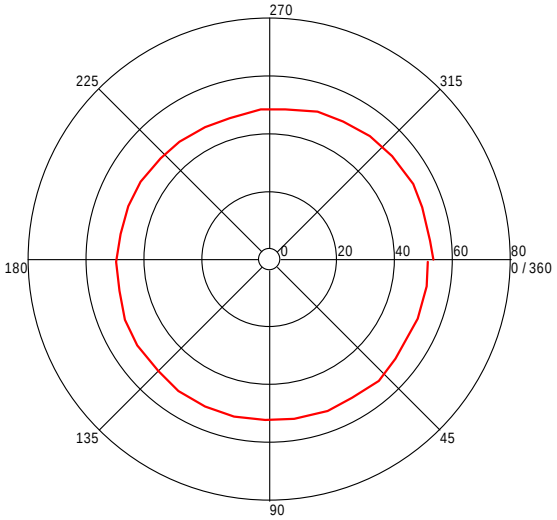
Turntable Plot (141.450901307 MHz) Level (dBuV/m)



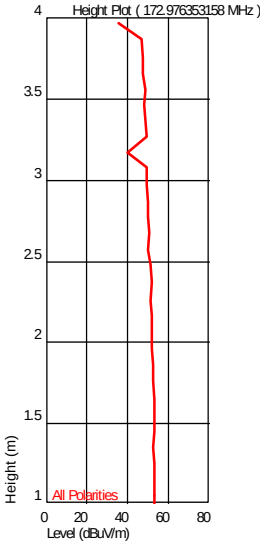
All Polarities Azimuth (Degrees)



Turntable Plot (172.976353158 MHz) Level (dBuV/m)



All Polarities Azimuth (Degrees)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

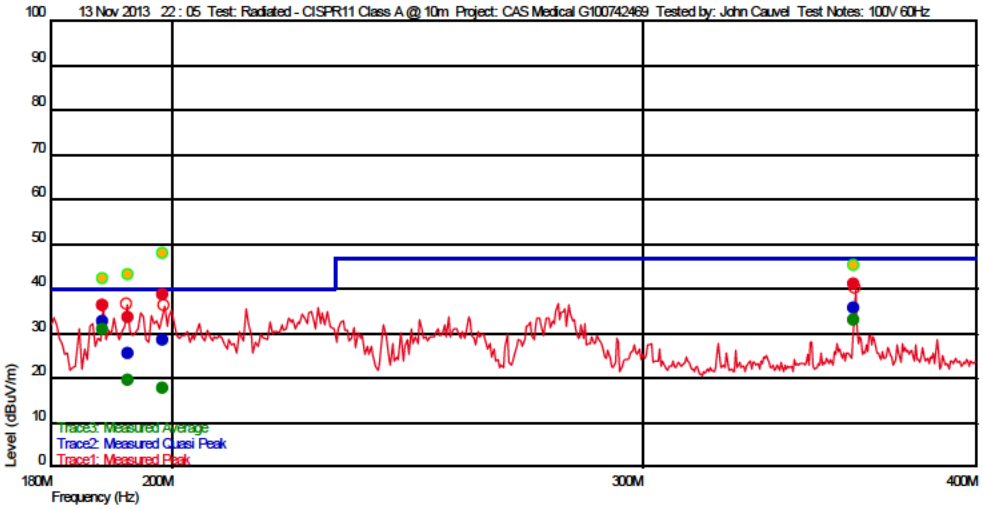
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz (180-400 MHz)

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	100V 60Hz	
Tested by:	John Cauvel	
Test Started:	13 Nov 2013 22 : 05	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

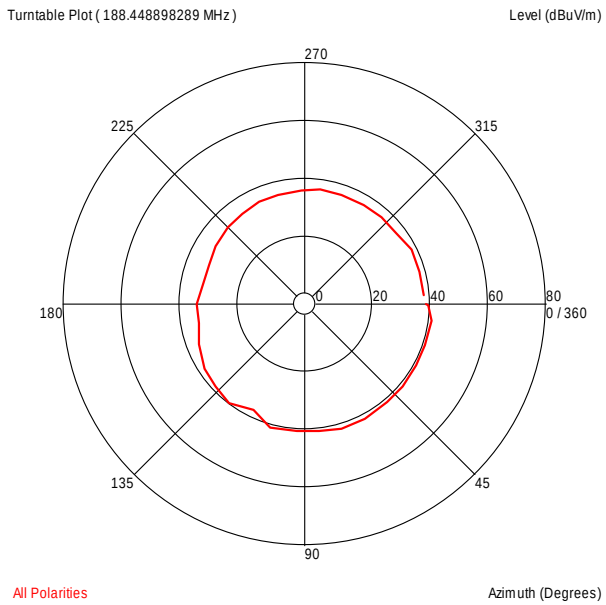
Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dB)	Hor (–), Ver (|)	Azimuth (Deg)	Mast Height(m)	RBW(Hz)
192.602 M	25.48	15.200	-24.091	40 000	-14 52	|	96	1.34	120 k
198.349 M	28.38	15.334	-23.935	40 000	-11 62	|	299	1.04	120 k
360.119 M	35.66	22.090	-23.292	47 000	-11 34	|	1	1.16	120 k
188.448 M	32.66	15.138	-24.204	40 000	-7.34	|	73	1.05	120 k

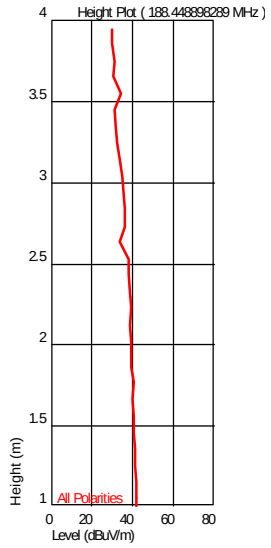
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

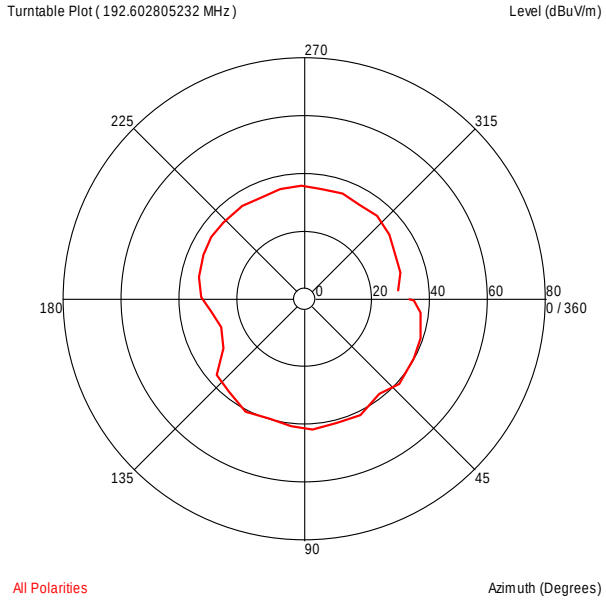
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

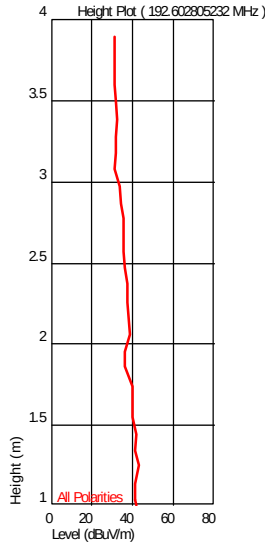
Azimuth Plots

Turntable Plots

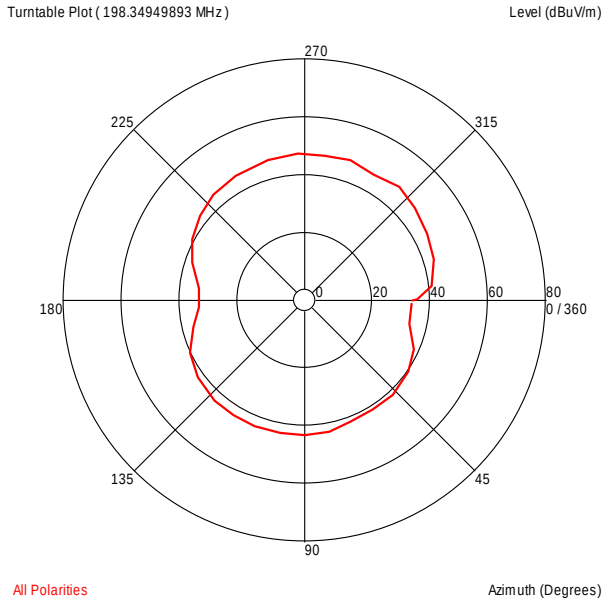


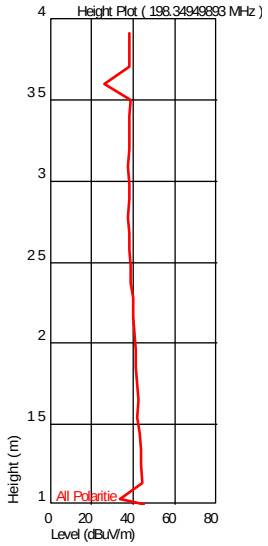


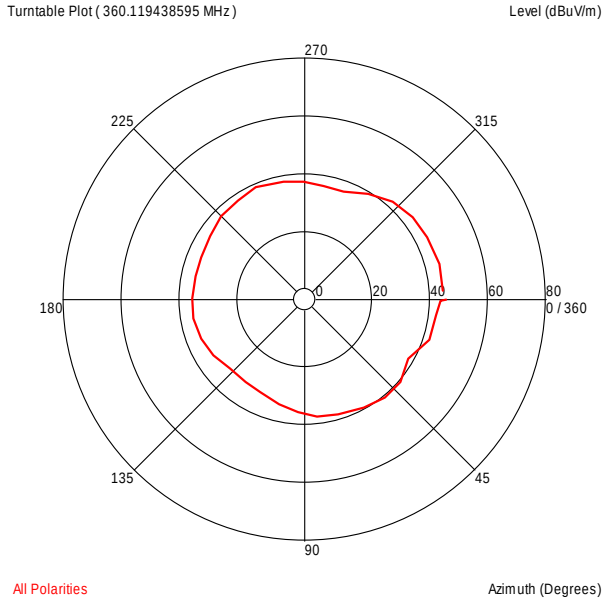


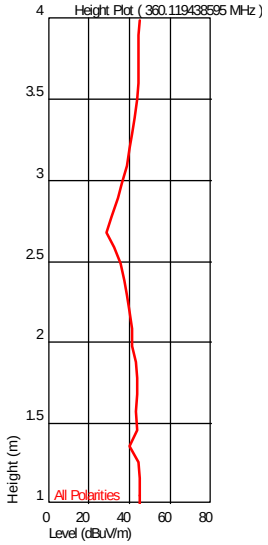


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

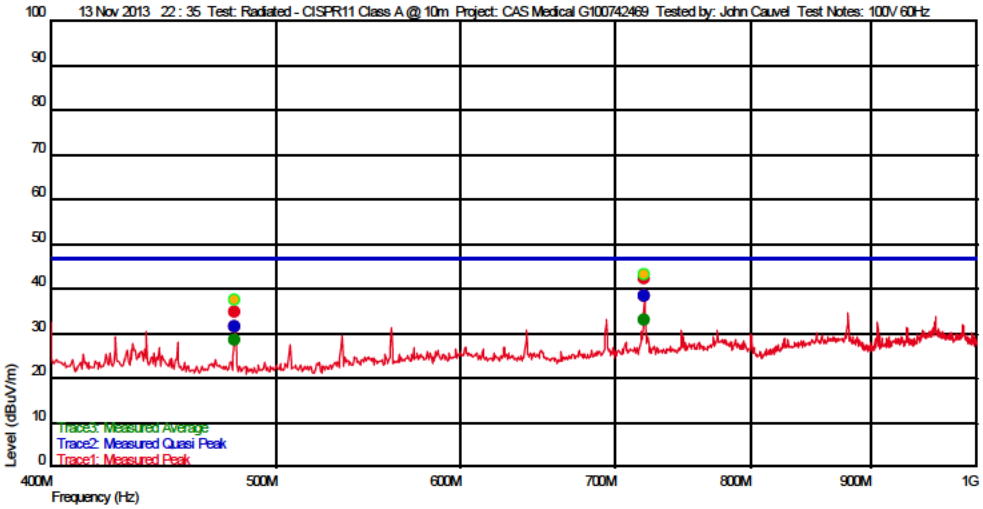
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz (400-1000 MHz)

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	100V 60Hz	
Tested by:	John Cauvel	
Test Started:	13 Nov 2013 22 : 35	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

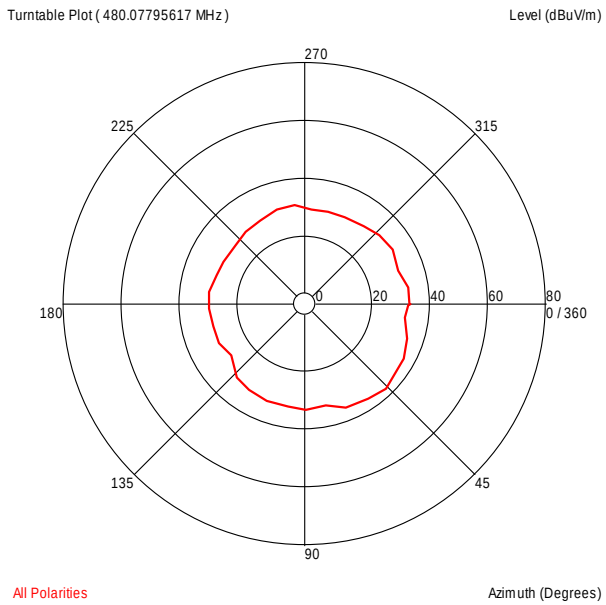
Trace2: Measured Quasi Peak

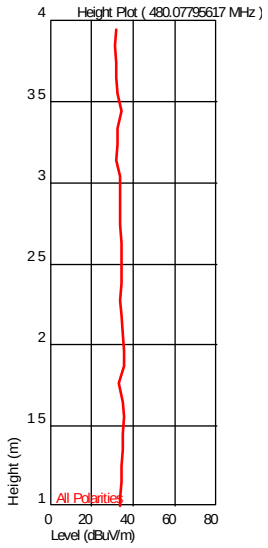
Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dB)	Hor (–), Ver (|)	Azimuth (Deg)	Mast Height(m)	RBW(Hz)
480.077 M	31 50	22.497	-24 561	47 000	-15 50	–	56	2.07	120 k
720.136 M	38.42	25.600	-23 611	47 000	-8.58	–	210	1.05	120 k

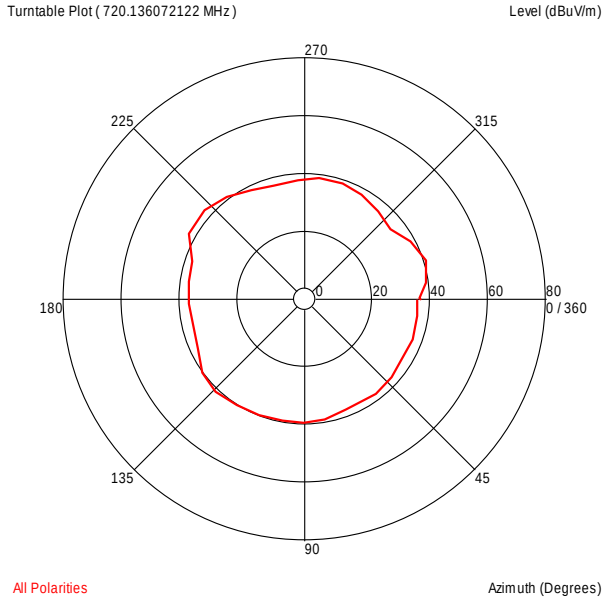
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

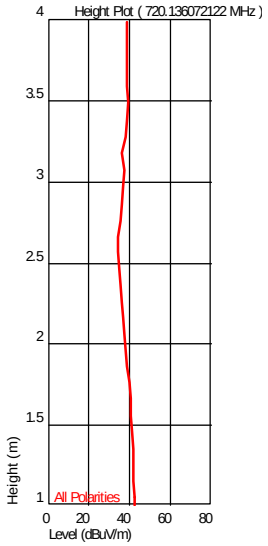
Azimuth Plots

Turntable Plots









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Personnel:	John R. Cauvel J.R.C	Test Date:	8/1/2012
	John R. Cauvel J.R.C		11-13-2013
Supervising/Reviewing Engineer: (Where Applicable)	Vathana Ven VJV		
Product Standard:	IEC 60601-1-2	Test Levels:	CISPR 11 Group 1 Class A
Input Voltage:	120V/60Hz, 230V/50Hz, 100V/60Hz (Worst Case)		
Pretest Verification w/ Ambient Signals or BB Source:	Yes, Ambient Signals	Ambient Temperature:	21,20 ºC
		Relative Humidity:	64,17 %
		Atmospheric Pressure:	1000,1012 mbars

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

7 AC Mains Conducted Emissions

7.1 Method

Tests are performed in accordance with CISPR 11.

TEST SITE: BUMP OUT (AMAP) and EMC Lab

The AMAP Building and Lab includes general lab space that can be used for testing where a shielded/enclosed environment is not required.

Measurement Uncertainty

For conducted emissions, U_{lab} (3.2 dB in worst case) < U_{CISPR} (3.6 dB), which is the reference value in CISPR 16-4-2 Table 1, hence the compliance of the product is only based on the measured value, and no measurement uncertainty correction is required, based on CISPR 22 and CISPR 11 (for 2006 and later revisions) Clause 11.

Sample Calculations

The following is how net line-conducted readings were determined:

NF = RF + LF + CF + AF
Where NF = Net Reading in dBμV
RF = Reading from receiver in dBμV
LF = LISN Correction Factor in dB
CF = Cable Correction Factor in dB
AF = Attenuator Loss Factor in dB

To convert from dBμV to μV or mV the following was used:

$UF = 10^{(NF / 20)}$ where UF = Net Reading in μV
NF = Net Reading in dBμV

Example:

NF = RF + LF + CF + AF = 28.5 + 0.2 + 0.4 + 20.0 = 49.1 dBμV
$UF = 10^{(49.1\ dB\mu V / 20)}$ = 285.1 μV/m

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

7.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Ros 002	9kHz to 3GHz EMI Test Receiver	Rohde & Schwartz	ESCI 1166.5950K03	100067	06/13/2012	06/13/2013
Cblbnc 51'	50 ohm Coaxial Cable	Pomona	RG58C/U	CBLBNC51	09/08/2011	09/08/2012
Ds 26a	Attenuator, 20dB	Mini Circuits	20dB, 50 ohm	DS26A	10/04/2011	10/04/2012
145 015	LISN: 50 Ohm/50 microHenry	Solar Electronics	9252-50-R-24-BNC	971617	02/06/2012	02/06/2013
Dav 001	Weather Station	Davis Instruments	7400	PE80519A61	08/17/2011	08/17/2012

Test equipment used on 11/13/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 001	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
ROS 002	9kHz to 3GHz EMI Test Receiver	Rohde & Schwartz	ESCI 1166.5950K03	100067	06/18/2013	06/18/2014
CBLBNC 2012-7	50 Ohm Coaxial Cable	Pomona	RG58C/U	CBLBNC2012-7	11/13/2012	11/13/2013
DS 26A	Attenuator, 20dB	Mini Circuits	20dB, 50 ohm	DS26A	10/04/2013	10/04/2014
145 015	LISN: 50 Ohm/50 microHenry	Solar Electronics	9252-50-R-24-BNC	971617	03/07/2013	03/07/2014

Software Utilized:

Name	Manufacturer	Version
C5	Teseq	5.26.46.46

7.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

7.4 Setup Photographs:

120V 50 & 60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

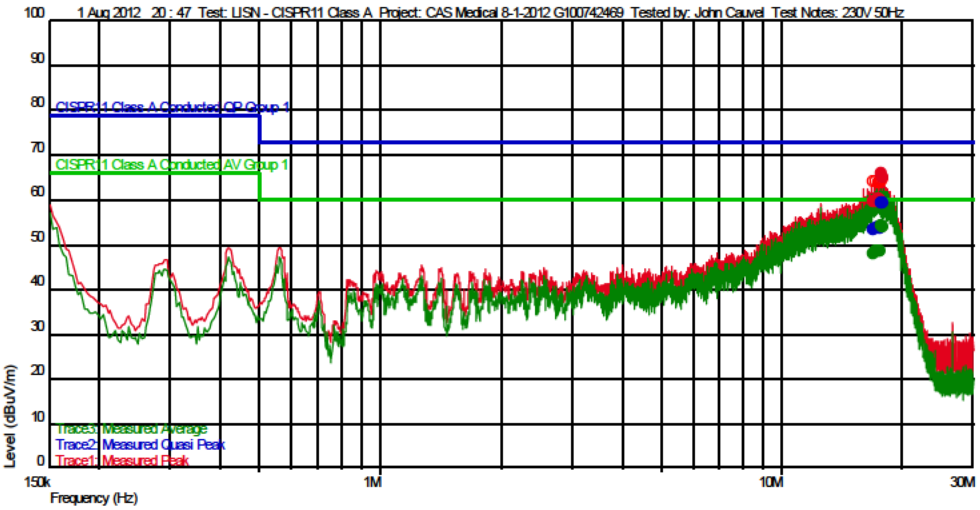
7.5 Plots/Data:

230V 50Hz

Test Information

Test Details	User Entry	Additional Information
Test:	LISN - CISPR11 Class A	
Project:	CAS Medical 8-1-2012 G100742469	
Test Notes:	230V 50Hz	
Tested by:	John Cauvel	
Test Started:	1 Aug 2012 20 : 47	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV/m)	TF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	RBW(Hz)	Comment	LINE
16 944 M	53.18	0.475	21.029	73 000	-19.82	9 k		L1
17.196 M	53.58	0.485	21.032	73 000	-19.42	9 k		L1
17 643 M	53.60	0.503	21.036	73 000	-19.40	9 k		L1
17.466 M	53.81	0.496	21.035	73 000	-19.19	9 k		L1
17 97 M	59 25	0.517	21.040	73 000	-13.75	9 k		N
17 823 M	59 37	0.511	21.038	73 000	-13.63	9 k		N

Trace3: Measured Average

Frequency(Hz)	Level(dBuV/m)	TF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	RBW(Hz)	Comment	LINE
16 944 M	48.03	0.475	21.029	60 000	-11.97	9 k		L1
17 643 M	48.37	0.503	21.036	60 000	-11.63	9 k		L1
17.196 M	48.48	0.485	21.032	60 000	-11.52	9 k		L1
17.466 M	48.63	0.496	21.035	60 000	-11.37	9 k		L1
17 97 M	54 02	0.517	21.040	60 000	-5 98	9 k		N
17 823 M	54.11	0.511	21.038	60 000	-5 89	9 k		N

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

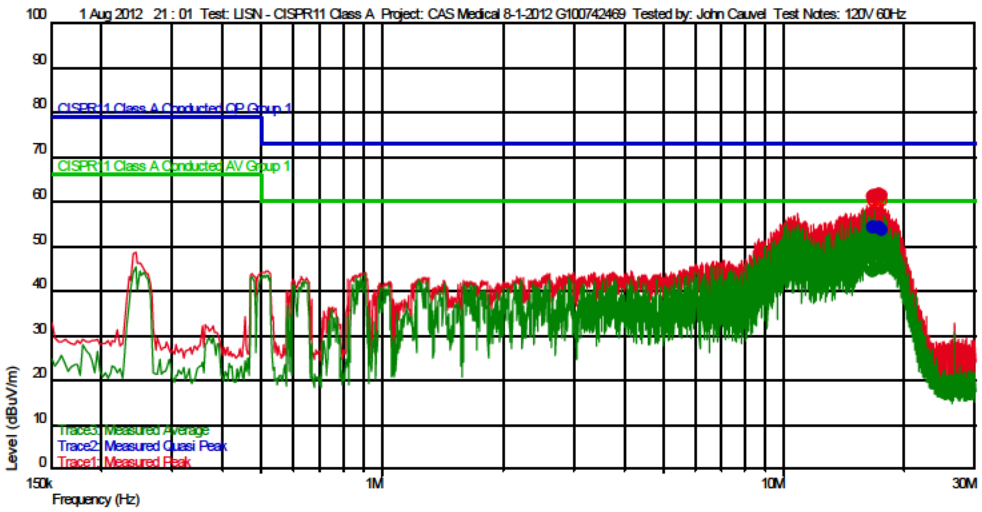
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

120V 60Hz

Test Information

Test Details	User Entry	Additional Information
Test:	LISN - CISPR11 Class A	
Project:	CAS Medical 8-1-2012 G100742469	
Test Notes:	120V 60Hz	
Tested by:	John Cauvel	
Test Started:	1 Aug 2012 21 : 01	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV/m)	TF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	RBW(Hz)	L NE
17 61 M	53.49	0.502	21.036	73 000	-19.51	9 k	L1
16.758 M	54.05	0.467	21.028	73 000	-18.95	9 k	L1
16 899 M	54.10	0.473	21.029	73 000	-18.90	9 k	L1
17.445 M	54.11	0.495	21.034	73 000	-18.89	9 k	L1
16 854 M	54.12	0.471	21.029	73 000	-18.88	9 k	L1
16 914 M	54.16	0.473	21.029	73 000	-18.84	9 k	L1

Trace3: Measured Average

Frequency(Hz)	Level(dBuV/m)	TF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	RBW(Hz)	L NE
16.758 M	44.47	0.467	21.028	60 000	-15.53	9 k	L1
16 854 M	44.60	0.471	21.029	60 000	-15.40	9 k	L1
16 899 M	44.68	0.473	21.029	60 000	-15.32	9 k	L1
16 914 M	44.77	0.473	21.029	60 000	-15.23	9 k	L1
17 61 M	44.92	0.502	21.036	60 000	-15.08	9 k	L1
17.445 M	45.16	0.495	21.034	60 000	-14.84	9 k	L1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

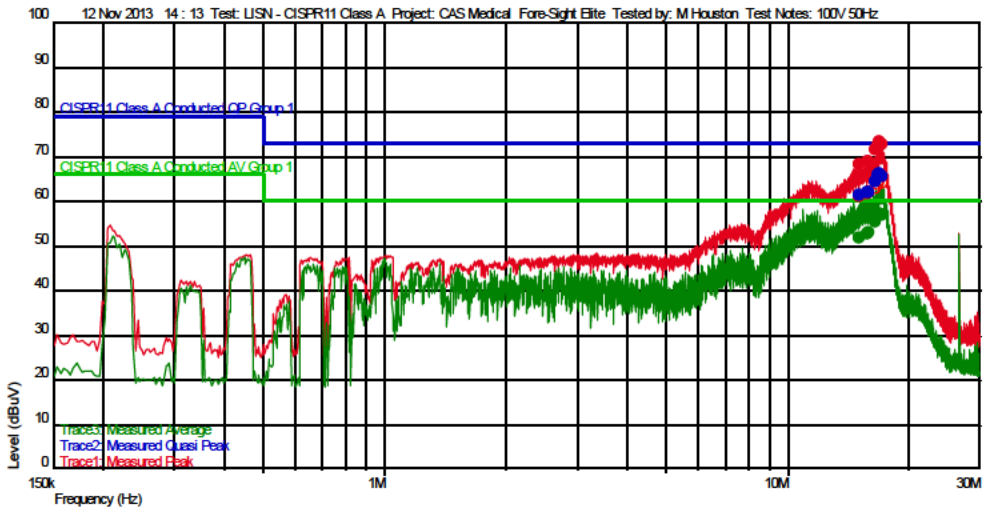
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 50Hz

Test Information

Test Details	User Entry	Additional Information
Test:	LISN - CISPR11 Class A	
Project:	CAS Medical Fore-Sight Elite	
Test Notes:	100V 50Hz	
Tested by:	M.Houston	
Test Started:	12 Nov 2013 14 : 13	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV)	TF	Losses	Gains	Limit(dBuV)	Margin(dBuV)	L NE
15.159 M	61.30	0.460	0.000	0 000	73.000	-11.70	L1
15 912 M	62.02	0.488	0.000	0 000	73.000	-10 98	L1
15 969 M	62.02	0.490	0.000	0 000	73.000	-10 98	L1
16 647 M	64.31	0.514	0.000	0 000	73.000	-8.69	N
17 229 M	65.65	0.534	0.000	0 000	73.000	-7.35	N
16 857 M	65.81	0.521	0.000	0 000	73.000	-7.19	L1
16 926 M	65.90	0.524	0.000	0 000	73.000	-7.10	L1
16 962 M	66.15	0.525	0.000	0 000	73.000	-6.85	L1

Trace3: Measured Average

Frequency(Hz)	Level(dBuV)	TF	Losses	Gains	Limit(dBuV)	Margin(dBuV)	L NE
15.159 M	51.82	0.460	0.000	0 000	60.000	-8.18	L1
15 912 M	52.79	0.488	0.000	0 000	60.000	-7.21	L1
15 969 M	52.85	0.490	0.000	0 000	60.000	-7.15	L1
16 647 M	55.26	0.514	0.000	0 000	60.000	-4.74	N
17 229 M	56.75	0.534	0.000	0 000	60.000	-3.25	N
16 857 M	56.77	0.521	0.000	0 000	60.000	-3.23	L1
16 926 M	57.06	0.524	0.000	0 000	60.000	-2.94	L1
16 962 M	57.20	0.525	0.000	0 000	60.000	-2.80	L1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

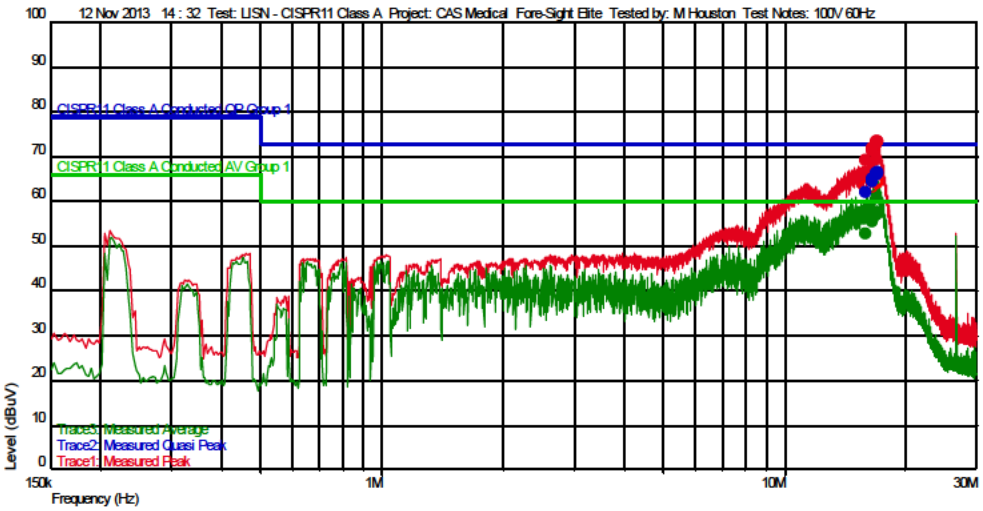
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz

Test Information

Test Details	User Entry	Additional Information
Test:	LISN - CISPR11 Class A	
Project:	CAS Medical Fore-Sight Elite	
Test Notes:	100V 60Hz	
Tested by:	M.Houston	
Test Started:	12 Nov 2013 14 : 32	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV)	TF	Losses	Gains	Limit(dBuV)	Margin(dBuV)	L NE
15 972 M	62.06	0.490	0.000	0 000	73.000	-10 94	L1
16 59 M	64.45	0.512	0.000	0 000	73.000	-8.55	L1
16 632 M	64.81	0.514	0.000	0 000	73.000	-8.19	L1
16 971 M	65.81	0.525	0.000	0 000	73.000	-7.19	N
17 04 M	66.07	0.528	0.000	0 000	73.000	-6.93	N
17 031 M	66.16	0.527	0.000	0 000	73.000	-6.84	L1
17.136 M	66.26	0.531	0.000	0 000	73.000	-6.74	L1
17 058 M	66.48	0.528	0.000	0 000	73.000	-6.52	L1

Trace3: Measured Average

Frequency(Hz)	Level(dBuV)	TF	Losses	Gains	Limit(dBuV)	Margin(dBuV)	L NE
15 972 M	52.79	0.490	0.000	0 000	60.000	-7.21	L1
16 59 M	55.37	0.512	0.000	0 000	60.000	-4.63	L1
16 632 M	55.64	0.514	0.000	0 000	60.000	-4.36	L1
16 971 M	56.79	0.525	0.000	0 000	60.000	-3.21	N
17 04 M	56.99	0.528	0.000	0 000	60.000	-3.01	N
17 031 M	57.30	0.527	0.000	0 000	60.000	-2.70	L1
17 058 M	57.31	0.528	0.000	0 000	60.000	-2.69	L1
17.136 M	57.35	0.531	0.000	0 000	60.000	-2.65	L1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Personnel:	John R. Cauvel J.R.C	Test Date:	8-1-2012
	Michael Houston MH		11/12/2013
Supervising/Reviewing Engineer: (Where Applicable)	Vathana Ven VJV		
Product Standard:	IEC 60601-1-2	Test Levels:	CISPR 11 Group 1 Class A
Input Voltage:	120V 60Hz, 230V 50Hz 100V 50 & 60Hz	Ambient Temperature:	21, 23 ºC
Pretest Verification w/ Ambient Signals or BB Source:	Yes, Ambient Signals	Relative Humidity:	64, 40 %
		Atmospheric Pressure:	1000, 1008 mbars

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8 Harmonics

8.1 Method

Tests are performed in accordance with IEC 61000-3-2.

TEST SITE: EMC

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

The AMAP Building and Lab includes general lab space that can be used for testing where a shielded/enclosed environment is not required.

8.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
SCH 8	EMC Test System consisting of: NSG-1007-45 (SN 55512), CCN 1000-3 (SN 72203), INA 2197 (SN 72200), INA 2196 (SN 72198), INA 2145 (SN 72199), INA 2171 (SN 8006), NA 2141 (SN 6012)	Schaffner	MX45-3PI-CTSHL-SCH	43964	03/21/2012	03/21/2014

Test equipment used on 11/12/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV001'	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
145-141A'	Power Supply NSG 1007-5-208	California Instr. Co	5kVa	56119	03/22/2012	03/22/2014
145-141B'	Power Supply NSG 1007-5-208	California Instr. Co	5kVa	56120	03/22/2012	03/22/2014
145-141C'	Power Supply NSG 1007-5-208	California Instr. Co	5kVa	56121	03/22/2012	03/22/2014
145-141D'	3 Phase Profline AC Switching Unit	Schaffner	NSG 2200-3	200239-003EK	03/13/2010	Verified
145-141E'	Signal Conditioning Unit	Schaffner	CCN1000-3	72319	03/22/2012	03/22/2014
145-141F'	3 Phase Impedance Network	Schaffner	INA 2154	72320	03/22/2012	03/22/2014

Software Utilized:

Name	Manufacturer	Version
Win2100V3	California Instruments Corp.	3.2.0.28

8.3 Results:

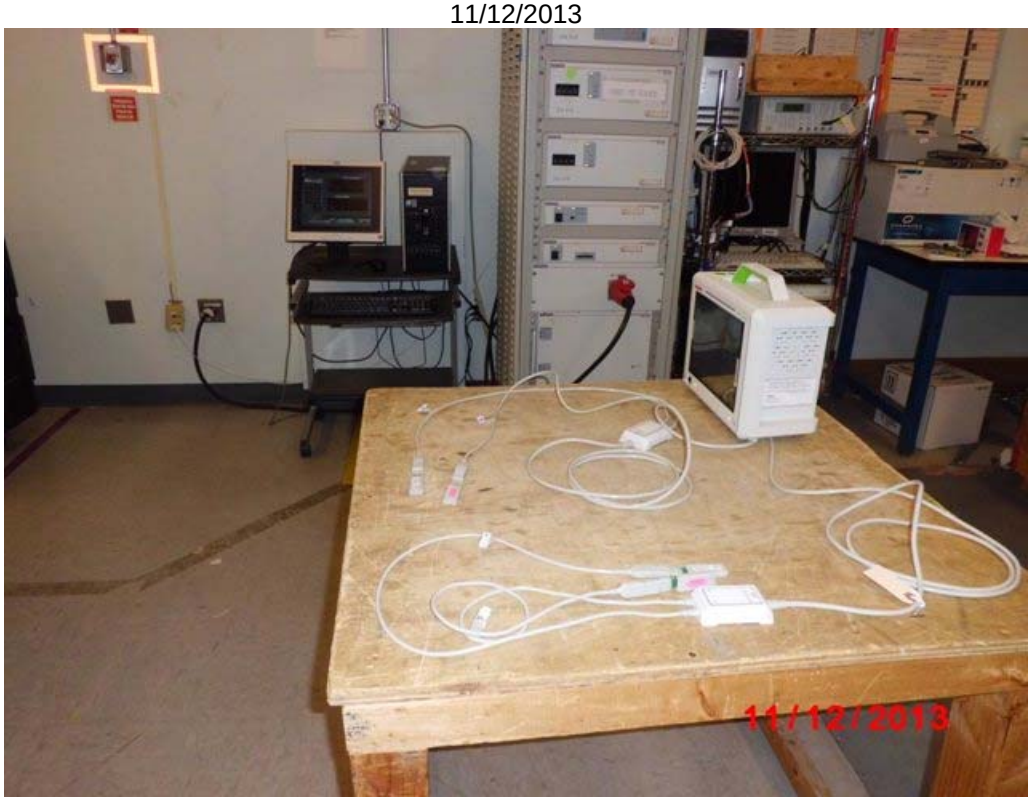
The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.4 Setup Photographs:

11/12/2013



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.5 Plots/Data:

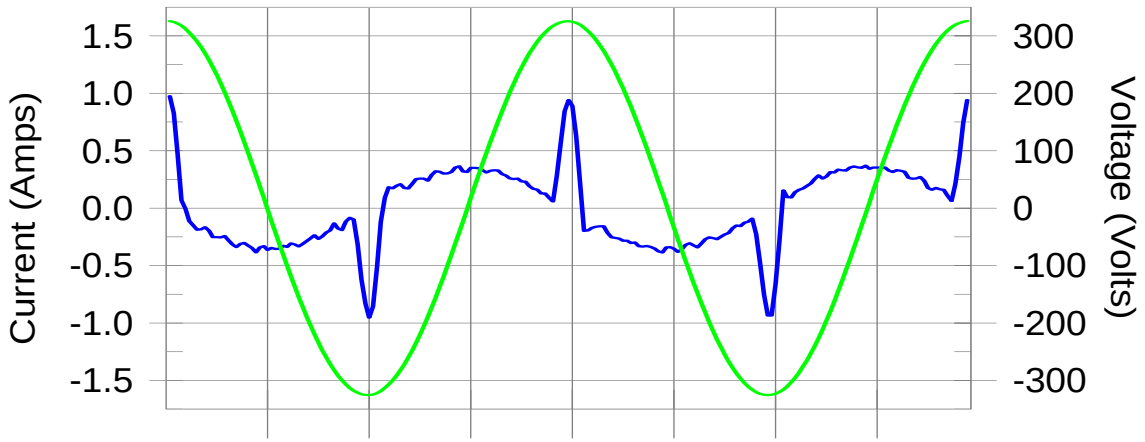
230V 50Hz

Harmonics – Class-A per Ed. 3.0 (2006) (Run time)

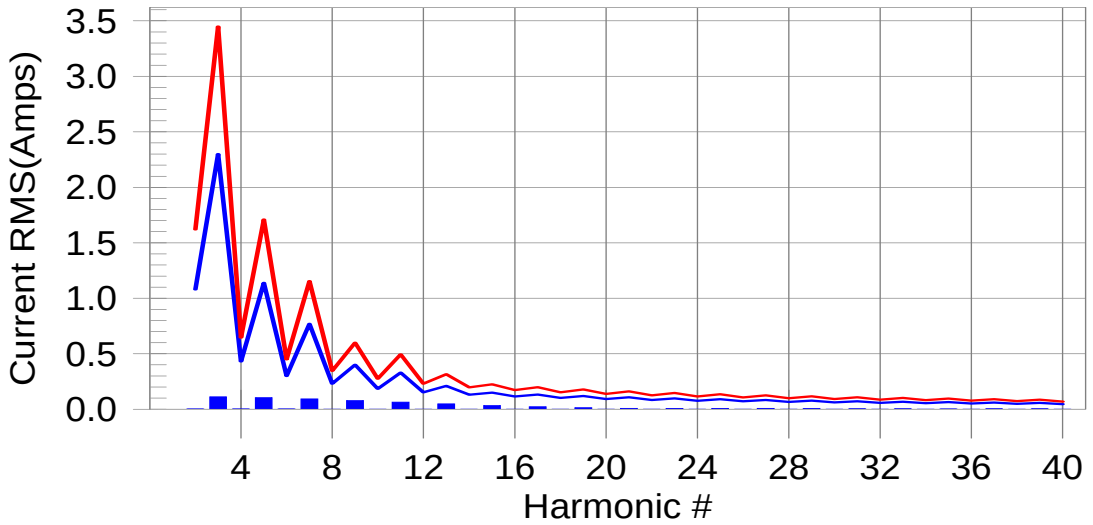
EUT: Model 3000 Oximetry **Tested by: Gary Ball**
Test category: Class-A per Ed. 3.0 (2006) (European limits) **Test Margin: 100**
Test date: 8/1/2012 **Start time: 9:32:36 AM** **End time: 9:42:57 AM**
Test duration (min): 10 **Data file name: H-000644.cts_data**
Comment: Comment
Customer: CAS Medical

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **European Limits**



<u>Test result: Pass Worst harmonic was #15 with 23.12% of the limit.</u>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Current Test Result Summary (Run time)

EUT: Model 3000 Oximetry **Tested by: Gary Ball**
Test category: Class-A per Ed. 3.0 (2006) (European limits) **Test Margin: 100**
Test date: 8/1/2012 **Start time: 9:32:36 AM** **End time: 9:42:57 AM**
Test duration (min): 10 **Data file name: H-000644.cts_data**
Comment: Comment
Customer: CAS Medical

Test Result: Pass **Source qualification: Normal**
THC(A): 0.21 **I-THD(%): 77.28** **POHC(A): 0.015** **POHC Limit(A): 0.277**
Highest parameter values during test:

V_RMS (Volts):	230.26	Frequency(Hz):	50.00
I_Peak (Amps):	1.038	I_RMS (Amps):	0.355
I_Fund (Amps):	0.274	Crest Factor:	2.949
Power (Watts):	27.2	Power Factor:	0.341

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.002	1.080	0.0	0.003	1.620	0.16	Pass
3	0.109	2.300	4.7	0.113	3.450	3.27	Pass
4	0.002	0.430	0.0	0.002	0.645	0.38	Pass
5	0.101	1.140	8.8	0.104	1.710	6.10	Pass
6	0.002	0.300	0.0	0.002	0.450	0.52	Pass
7	0.090	0.770	11.7	0.093	1.155	8.07	Pass
8	0.002	0.230	0.0	0.002	0.345	0.49	Pass
9	0.077	0.400	19.3	0.080	0.600	13.25	Pass
10	0.001	0.184	0.0	0.001	0.276	0.48	Pass
11	0.063	0.330	19.0	0.064	0.495	13.01	Pass
12	0.001	0.153	0.0	0.001	0.230	0.49	Pass
13	0.049	0.210	23.1	0.050	0.315	15.76	Pass
14	0.000	0.131	0.0	0.001	0.197	0.32	Pass
15	0.035	0.150	23.1	0.035	0.225	15.67	Pass
16	0.000	0.115	0.0	0.001	0.173	0.32	Pass
17	0.023	0.132	17.4	0.023	0.199	11.72	Pass
18	0.001	0.102	0.0	0.001	0.153	0.67	Pass
19	0.013	0.118	11.4	0.014	0.178	7.81	Pass
20	0.001	0.092	0.0	0.001	0.138	0.68	Pass
21	0.008	0.107	7.1	0.008	0.161	4.85	Pass
22	0.000	0.084	0.0	0.001	0.125	0.47	Pass
23	0.007	0.098	6.9	0.007	0.147	4.82	Pass
24	0.000	0.077	0.0	0.001	0.115	0.54	Pass
25	0.007	0.090	7.6	0.007	0.135	5.36	Pass
26	0.000	0.071	0.0	0.000	0.106	0.44	Pass
27	0.007	0.083	8.6	0.007	0.125	5.84	Pass
28	0.000	0.066	0.0	0.000	0.099	0.23	Pass
29	0.006	0.078	7.6	0.006	0.116	5.16	Pass
30	0.000	0.061	0.0	0.000	0.092	0.30	Pass
31	0.004	0.073	0.0	0.004	0.109	3.89	Pass
32	0.000	0.058	0.0	0.000	0.086	0.37	Pass
33	0.003	0.068	0.0	0.003	0.102	3.17	Pass
34	0.000	0.054	0.0	0.000	0.081	0.45	Pass
35	0.002	0.064	0.0	0.003	0.096	2.69	Pass
36	0.000	0.051	0.0	0.000	0.077	0.65	Pass
37	0.003	0.061	0.0	0.003	0.091	3.70	Pass
38	0.000	0.048	0.0	0.000	0.073	0.67	Pass
39	0.004	0.058	0.0	0.004	0.087	4.52	Pass
40	0.000	0.046	0.0	0.000	0.069	0.65	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Voltage Source Verification Data (Run time)

EUT: Model 3000 Oximetry **Tested by: Gary Ball**
Test category: Class-A per Ed. 3.0 (2006) (European limits) **Test Margin: 100**
Test date: 8/1/2012 **Start time: 9:32:36 AM** **End time: 9:42:57 AM**
Test duration (min): 10 **Data file name: H-000644.cts_data**
Comment: Comment
Customer: CAS Medical

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	230.26	Frequency(Hz):	50.00
I_Peak (Amps):	1.038	I_RMS (Amps):	0.355
I_Fund (Amps):	0.274	Crest Factor:	2.949
Power (Watts):	27.2	Power Factor:	0.341

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.046	0.460	9.94	OK
3	0.043	2.072	2.08	OK
4	0.012	0.460	2.53	OK
5	0.023	0.921	2.47	OK
6	0.016	0.460	3.49	OK
7	0.056	0.691	8.09	OK
8	0.006	0.460	1.27	OK
9	0.059	0.460	12.77	OK
10	0.006	0.460	1.35	OK
11	0.045	0.230	19.39	OK
12	0.012	0.230	5.02	OK
13	0.053	0.230	23.04	OK
14	0.005	0.230	2.08	OK
15	0.044	0.230	19.18	OK
16	0.003	0.230	1.24	OK
17	0.032	0.230	13.87	OK
18	0.008	0.230	3.63	OK
19	0.027	0.230	11.82	OK
20	0.010	0.230	4.15	OK
21	0.015	0.230	6.55	OK
22	0.003	0.230	1.28	OK
23	0.020	0.230	8.89	OK
24	0.005	0.230	2.01	OK
25	0.011	0.230	4.73	OK
26	0.004	0.230	1.80	OK
27	0.017	0.230	7.47	OK
28	0.003	0.230	1.38	OK
29	0.015	0.230	6.66	OK
30	0.005	0.230	2.19	OK
31	0.003	0.230	1.16	OK
32	0.003	0.230	1.21	OK
33	0.014	0.230	6.25	OK
34	0.004	0.230	1.80	OK
35	0.007	0.230	2.98	OK
36	0.005	0.230	2.09	OK
37	0.008	0.230	3.66	OK
38	0.004	0.230	1.67	OK
39	0.012	0.230	5.08	OK
40	0.008	0.230	3.39	OK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

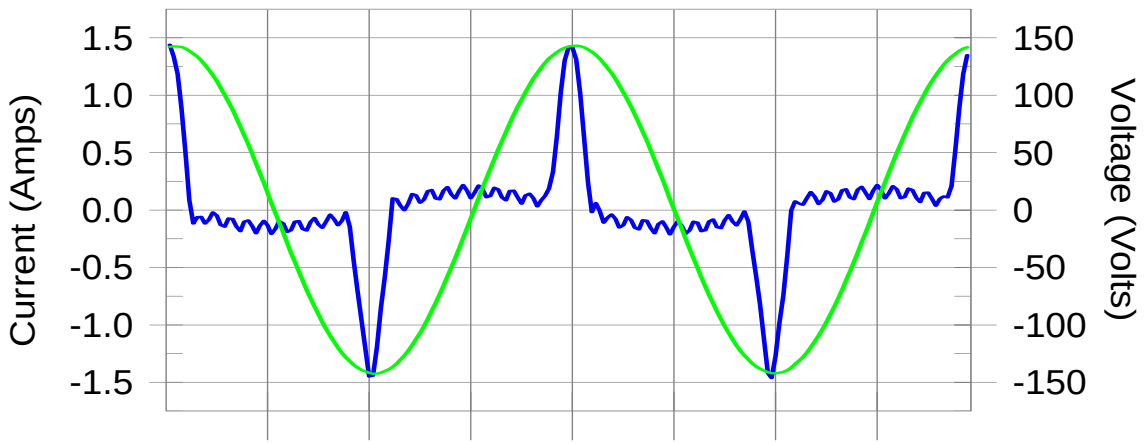
100V 50Hz

Harmonics – Class-A per Ed. 3.2 (2009) (Run time)

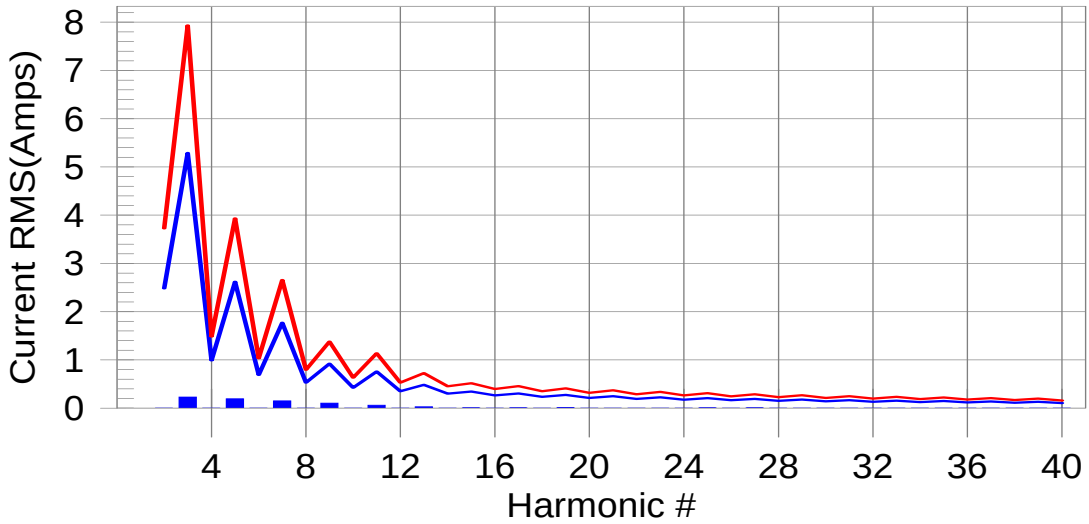
EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:39:40 AM** **End time: 11:50:02 AM**
Test duration (min): 10 **Data file name: H-000300.cts_data**
Comment: G100742469 PCOR 500488596 - 100V 50Hz
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **Japanese Limits**



Test result: Pass **Worst harmonic was #9 with 11.21% of the limit.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Current Test Result Summary (Run time)

EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:39:40 AM** **End time: 11:50:02 AM**
Test duration (min): 10 **Data file name: H-000300.cts_data**
Comment: G100742469 PCOR 500488596 - 100V 50Hz
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**
THC(A): 0.36 **I-THD(%): 129.00** **POHC(A): 0.006** **POHC Limit(A): 0.578**
Highest parameter values during test:

V_RMS (Volts):	100.81	Frequency(Hz):	50.00
I_Peak (Amps):	1.527	I_RMS (Amps):	0.459
I_Fund (Amps):	0.280	Crest Factor:	3.335
Power (Watts):	25.3	Power Factor:	0.548

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.000	2.484	0.0	0.001	3.726	0.01	Pass
3	0.231	5.290	4.4	0.231	7.935	2.91	Pass
4	0.001	0.989	0.1	0.001	1.484	0.05	Pass
5	0.196	2.622	7.5	0.196	3.933	4.98	Pass
6	0.001	0.690	0.1	0.001	1.035	0.13	Pass
7	0.151	1.771	8.5	0.151	2.657	5.67	Pass
8	0.001	0.529	0.1	0.001	0.794	0.11	Pass
9	0.103	0.920	11.2	0.103	1.380	7.48	Pass
10	0.001	0.423	0.2	0.001	0.635	0.13	Pass
11	0.060	0.759	7.9	0.060	1.139	5.31	Pass
12	0.001	0.352	0.2	0.001	0.529	0.17	Pass
13	0.027	0.483	5.6	0.027	0.725	3.75	Pass
14	0.000	0.301	0.1	0.000	0.453	0.09	Pass
15	0.006	0.345	1.9	0.007	0.518	1.26	Pass
16	0.000	0.265	0.1	0.000	0.398	0.07	Pass
17	0.006	0.304	2.0	0.006	0.458	1.36	Pass
18	0.000	0.235	0.1	0.000	0.352	0.08	Pass
19	0.007	0.272	2.7	0.007	0.409	1.81	Pass
20	0.000	0.212	0.0	0.000	0.317	0.04	Pass
21	0.005	0.246	1.9	0.005	0.370	1.25	Pass
22	0.000	0.192	0.1	0.000	0.288	0.06	Pass
23	0.003	0.225	1.3	0.003	0.338	0.90	Pass
24	0.000	0.176	0.1	0.000	0.265	0.07	Pass
25	0.005	0.207	2.4	0.005	0.311	1.58	Pass
26	0.000	0.163	0.1	0.000	0.244	0.10	Pass
27	0.006	0.192	2.9	0.006	0.288	1.95	Pass
28	0.000	0.152	0.1	0.000	0.228	0.05	Pass
29	0.004	0.178	2.3	0.004	0.267	1.57	Pass
30	0.000	0.141	0.1	0.000	0.212	0.13	Pass
31	0.003	0.167	1.5	0.003	0.251	1.04	Pass
32	0.000	0.132	0.1	0.000	0.198	0.07	Pass
33	0.003	0.157	1.7	0.003	0.235	1.15	Pass
34	0.000	0.124	0.1	0.000	0.186	0.08	Pass
35	0.003	0.148	2.2	0.003	0.221	1.46	Pass
36	0.000	0.118	0.1	0.000	0.177	0.09	Pass
37	0.003	0.140	2.0	0.003	0.209	1.35	Pass
38	0.000	0.111	0.1	0.000	0.168	0.07	Pass
39	0.002	0.133	1.3	0.002	0.200	0.88	Pass
40	0.000	0.106	0.1	0.000	0.159	0.13	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Voltage Source Verification Data (Run time)

EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:39:40 AM** **End time: 11:50:02 AM**
Test duration (min): 10 **Data file name: H-000300.cts_data**
Comment: G100742469 PCOR 500488596 - 100V 50Hz
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	100.81	Frequency(Hz):	50.00
I_Peak (Amps):	1.527	I_RMS (Amps):	0.459
I_Fund (Amps):	0.280	Crest Factor:	3.335
Power (Watts):	25.3	Power Factor:	0.548

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.017	0.202	8.64	OK
3	0.063	0.907	6.99	OK
4	0.009	0.202	4.26	OK
5	0.047	0.403	11.78	OK
6	0.044	0.202	22.02	OK
7	0.040	0.302	13.25	OK
8	0.020	0.202	9.71	OK
9	0.034	0.202	16.94	OK
10	0.009	0.202	4.60	OK
11	0.025	0.101	25.20	OK
12	0.019	0.101	18.84	OK
13	0.013	0.101	12.48	OK
14	0.004	0.101	4.04	OK
15	0.004	0.101	4.37	OK
16	0.005	0.101	4.60	OK
17	0.007	0.101	7.07	OK
18	0.010	0.101	10.22	OK
19	0.006	0.101	5.56	OK
20	0.005	0.101	4.92	OK
21	0.006	0.101	5.70	OK
22	0.004	0.101	3.74	OK
23	0.004	0.101	3.64	OK
24	0.006	0.101	6.15	OK
25	0.003	0.101	2.65	OK
26	0.004	0.101	4.28	OK
27	0.008	0.101	7.67	OK
28	0.003	0.101	3.32	OK
29	0.003	0.101	3.43	OK
30	0.007	0.101	6.94	OK
31	0.004	0.101	4.09	OK
32	0.003	0.101	3.22	OK
33	0.006	0.101	6.05	OK
34	0.002	0.101	1.73	OK
35	0.005	0.101	5.14	OK
36	0.004	0.101	4.08	OK
37	0.005	0.101	4.64	OK
38	0.002	0.101	1.52	OK
39	0.002	0.101	2.29	OK
40	0.005	0.101	4.50	OK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

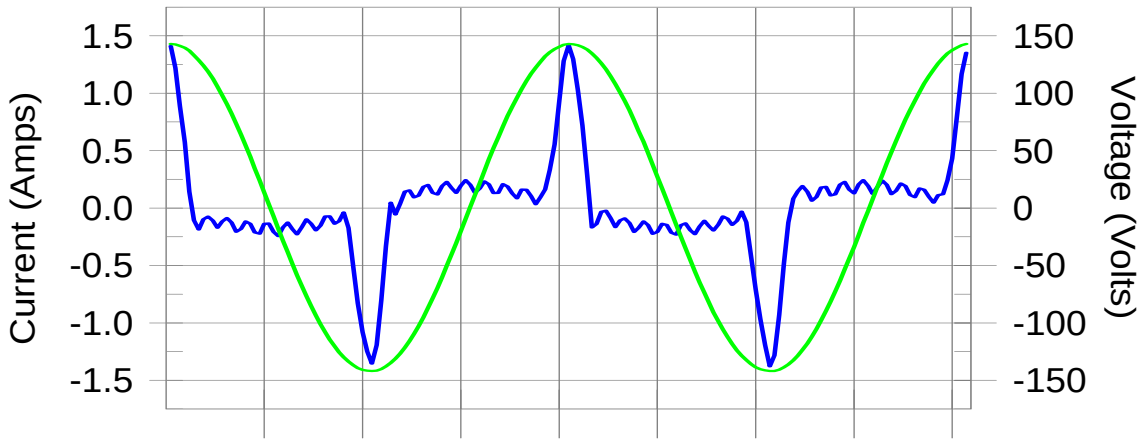
100V 60Hz

Harmonics – Class-A per Ed. 3.2 (2009)(Run time)

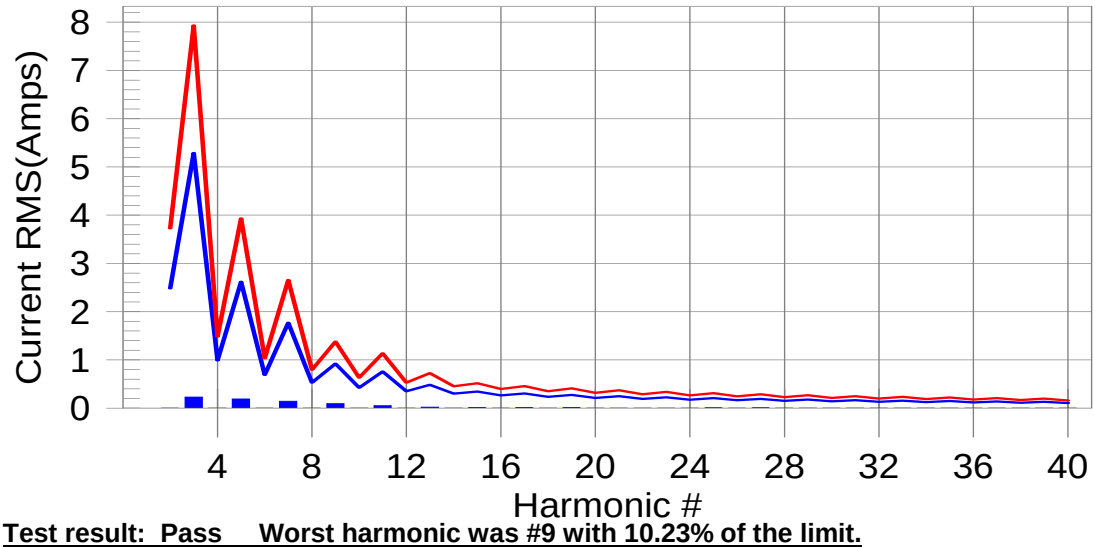
EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:27:12 AM** **End time: 11:37:34 AM**
Test duration (min): 10 **Data file name: H-000298.cts_data**
Comment: G100742469 PCOR 500488596 – 100V 60Hz
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **Japanese Limits**



Test result: Pass **Worst harmonic was #9 with 10.23% of the limit.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Current Test Result Summary (Run time)

EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:27:12 AM** **End time: 11:37:34 AM**
Test duration (min): 10 **Data file name: H-000298.cts_data**
Comment: G100742469 PCOR 500488596
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**
THC(A): 0.35 **I-THD(%): 123.03** **POHC(A): 0.008** **POHC Limit(A): 0.578**
Highest parameter values during test:

V_RMS (Volts):	100.82	Frequency(Hz):	60.00
I_Peak (Amps):	1.451	I_RMS (Amps):	0.454
I_Fund (Amps):	0.285	Crest Factor:	3.219
Power (Watts):	25.3	Power Factor:	0.555

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.002	2.484	0.1	0.003	3.726	0.07	Pass
3	0.229	5.290	4.3	0.230	7.935	2.90	Pass
4	0.001	0.989	0.1	0.002	1.484	0.13	Pass
5	0.191	2.622	7.3	0.191	3.933	4.87	Pass
6	0.001	0.690	0.1	0.001	1.035	0.09	Pass
7	0.143	1.771	8.1	0.144	2.657	5.41	Pass
8	0.001	0.529	0.2	0.001	0.794	0.17	Pass
9	0.094	0.920	10.2	0.094	1.380	6.84	Pass
10	0.001	0.423	0.2	0.001	0.635	0.18	Pass
11	0.052	0.759	6.8	0.052	1.139	4.55	Pass
12	0.001	0.352	0.2	0.001	0.529	0.15	Pass
13	0.021	0.483	4.4	0.022	0.725	2.98	Pass
14	0.000	0.301	0.1	0.000	0.453	0.11	Pass
15	0.009	0.345	2.6	0.009	0.518	1.80	Pass
16	0.000	0.265	0.1	0.000	0.398	0.11	Pass
17	0.010	0.304	3.4	0.011	0.458	2.31	Pass
18	0.000	0.235	0.1	0.000	0.352	0.06	Pass
19	0.008	0.272	3.0	0.008	0.409	2.05	Pass
20	0.000	0.212	0.1	0.000	0.317	0.08	Pass
21	0.004	0.246	1.7	0.004	0.370	1.16	Pass
22	0.000	0.192	0.1	0.000	0.288	0.08	Pass
23	0.004	0.225	2.0	0.005	0.338	1.34	Pass
24	0.000	0.176	0.1	0.000	0.265	0.08	Pass
25	0.006	0.207	2.9	0.006	0.311	1.97	Pass
26	0.000	0.163	0.1	0.000	0.244	0.13	Pass
27	0.005	0.192	2.9	0.006	0.288	1.94	Pass
28	0.000	0.152	0.1	0.000	0.228	0.10	Pass
29	0.004	0.178	2.0	0.004	0.267	1.37	Pass
30	0.000	0.141	0.1	0.000	0.212	0.08	Pass
31	0.003	0.167	1.9	0.003	0.251	1.29	Pass
32	0.000	0.132	0.1	0.000	0.198	0.13	Pass
33	0.004	0.157	2.6	0.004	0.235	1.76	Pass
34	0.000	0.124	0.1	0.000	0.186	0.08	Pass
35	0.004	0.148	2.6	0.004	0.221	1.75	Pass
36	0.000	0.118	0.1	0.000	0.177	0.16	Pass
37	0.003	0.140	2.1	0.003	0.209	1.41	Pass
38	0.000	0.111	0.1	0.000	0.168	0.12	Pass
39	0.002	0.133	1.7	0.002	0.200	1.16	Pass
40	0.000	0.106	0.2	0.000	0.159	0.19	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Voltage Source Verification Data (Run time)

EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:27:12 AM** **End time: 11:37:34 AM**
Test duration (min): 10 **Data file name: H-000298.cts_data**
Comment: G100742469 PCOR 500488596
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	100.82	Frequency(Hz):	60.00
I_Peak (Amps):	1.451	I_RMS (Amps):	0.454
I_Fund (Amps):	0.285	Crest Factor:	3.219
Power (Watts):	25.3	Power Factor:	0.555

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.119	0.202	58.97	OK
3	0.146	0.907	16.15	OK
4	0.064	0.202	31.93	OK
5	0.082	0.403	20.37	OK
6	0.036	0.202	17.94	OK
7	0.066	0.302	21.94	OK
8	0.040	0.202	19.85	OK
9	0.047	0.202	23.46	OK
10	0.024	0.202	12.07	OK
11	0.035	0.101	34.87	OK
12	0.008	0.101	8.25	OK
13	0.025	0.101	25.11	OK
14	0.013	0.101	12.95	OK
15	0.013	0.101	13.11	OK
16	0.009	0.101	9.01	OK
17	0.016	0.101	16.30	OK
18	0.006	0.101	6.23	OK
19	0.013	0.101	12.77	OK
20	0.007	0.101	7.10	OK
21	0.008	0.101	8.28	OK
22	0.005	0.101	5.37	OK
23	0.010	0.101	10.02	OK
24	0.004	0.101	4.10	OK
25	0.012	0.101	11.41	OK
26	0.006	0.101	5.76	OK
27	0.010	0.101	9.77	OK
28	0.004	0.101	3.95	OK
29	0.006	0.101	6.39	OK
30	0.004	0.101	3.92	OK
31	0.006	0.101	6.40	OK
32	0.004	0.101	3.69	OK
33	0.010	0.101	9.84	OK
34	0.003	0.101	2.49	OK
35	0.007	0.101	7.36	OK
36	0.004	0.101	3.77	OK
37	0.009	0.101	8.82	OK
38	0.002	0.101	2.17	OK
39	0.007	0.101	7.31	OK
40	0.003	0.101	2.75	OK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Personnel:	Gary Ball GB	Test Date:	08/01/2012
	Michael Houston MH		11/12/2013
Supervising/Reviewing Engineer: (Where Applicable)	N/A		
Product Standard:	IEC 60601-1-2	Test Levels:	See Data
Input Voltage:	230VAC/50 Hz, 100VAC/60 Hz	Ambient Temperature:	22, 23 ºC
Pretest Verification w/ Artifact:	Yes	Relative Humidity:	59, 40 %
		Atmospheric Pressure:	1001,1008 mbars

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

9 Flicker

9.1 Method

Tests are performed in accordance with IEC 61000-3-3.

TEST SITE: EMC

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

The AMAP Building and Lab includes general lab space that can be used for testing where a shielded/enclosed environment is not required.

9.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
SCH 8	EMC Test	Schaffner	MX45-3PI-CTSHL-SCH	43964	03/21/2012	03/21/2014

Software Utilized:

Name	Manufacturer	Version
Win2100V3	California Instruments Corp.	3.2.0.28

9.3 Results:

The sample tested was found to Comply.

9.4 Setup Photograph:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

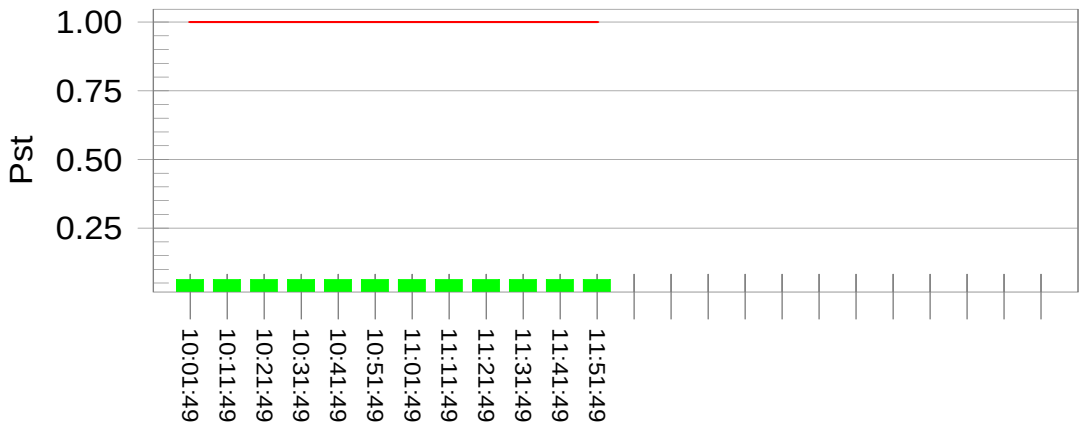
9.5 Plots/Data:

Flicker Test Summary per EN/IEC61000-3-3 (Run time)

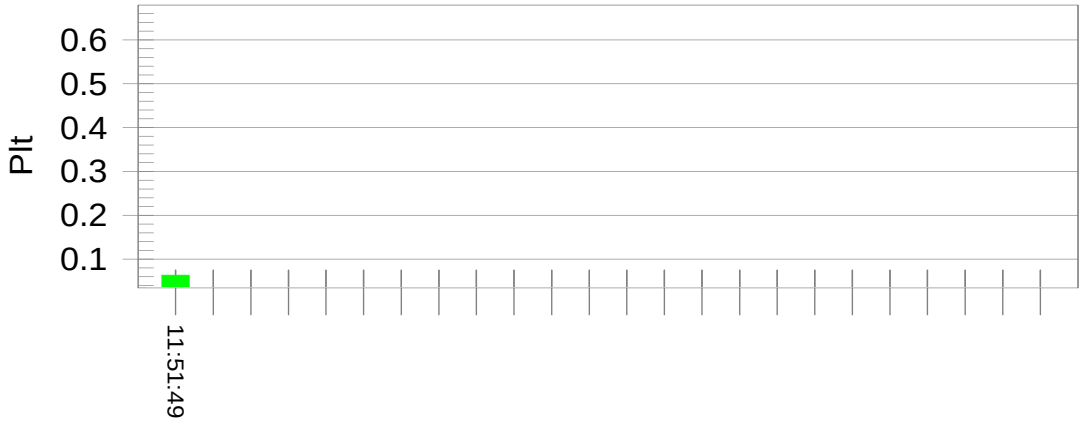
EUT: Model 3000 Oximetry **Tested by: Gary Ball**
Test category: All parameters (European limits) **Test Margin: 100**
Test date: 8/1/2012 **Start time: 9:51:29 AM** **End time: 11:51:50 AM**
Test duration (min): 120 **Data file name: F-000645.cts_data**
Comment: 230VAC 50Hz
Customer: CAS Medical

Test Result: Pass **Status: Test Completed**

Pst_i and limit line **European Limits**



Plt and limit line



Parameter values recorded during the test:

Vrms at the end of test (Volt):	**230.25**			
Highest dt (%):	**0.00**	**Test limit (%):**	**3.30**	**Pass**
Time(mS) > dt:	**0.0**	**Test limit (mS):**	**500.0**	**Pass**
Highest dc (%):	**0.00**	**Test limit (%):**	**3.30**	**Pass**
Highest dmax (%):	**0.00**	**Test limit (%):**	**4.00**	**Pass**
Highest Pst (10 min. period):	**0.064**	**Test limit:**	**1.000**	**Pass**
Highest Plt (2 hr. period):	**0.064**	**Test limit:**	**0.650**	**Pass**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Personnel:	Gary Ball GB	Test Date:	08/01/2012
Supervising/Reviewing Engineer: (Where Applicable)	N/A		
Product Standard:	IEC 60601-1-2	Test Levels:	See Data
Input Voltage:	230 VAC/50 Hz	Ambient Temperature:	22 ºC
Pretest Verification w/ Artifact:	Yes	Relative Humidity:	59 %
		Atmospheric Pressure:	1001 mbars

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

10 Electrostatic Discharge Immunity Test

10.1 Method

Tests are performed in accordance with IEC 61000-4-2.

TEST SITE: EMC LAB

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

The AMAP Building and Lab includes general lab space that can be used for testing where a shielded/enclosed environment is not required.

10.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Sch 12	ESD Test Set	Schaffner	NSG 438	588	02/20/2012	02/20/2013
Sen 01	Electrostatic Voltmeter	Sensitive Research	ESH	U24187	03/07/2011	03/07/2013
Dav 001	Weather Station	Davis Instruments	7400	PE80519A61	08/17/2011	08/17/2012

Testing performed on 11/13/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV001	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
147273	ESD Simulator	NoiseKen	ESS-2000	ESS0382050	10/15/2013	10/15/2014
Emc 82	1000X High Voltage Probe	Tektronix	P6015A	B055113	03/13/2013	03/13/2014
Agl002	1GHz 4CH O'Scope	Agilent Technologies	DSO6104A	MY44008115	08/02/2013	08/02/2014

Software Utilized:

Name	Manufacturer	Version
None		

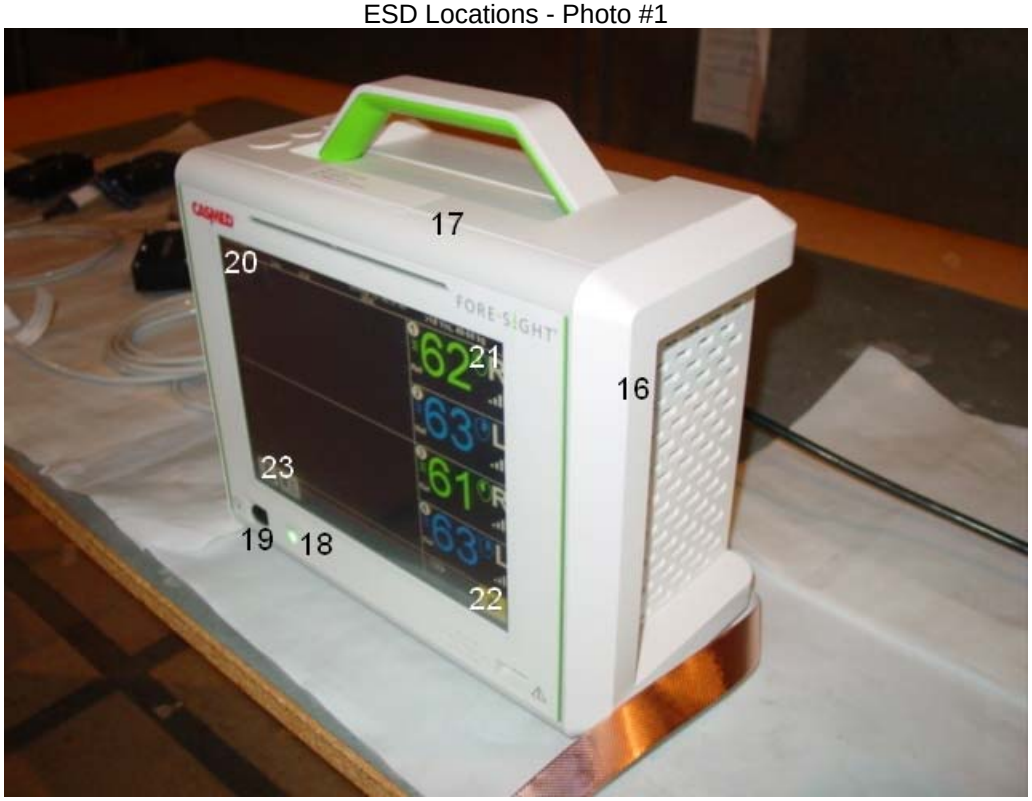
10.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

ESD Locations - Photo #1

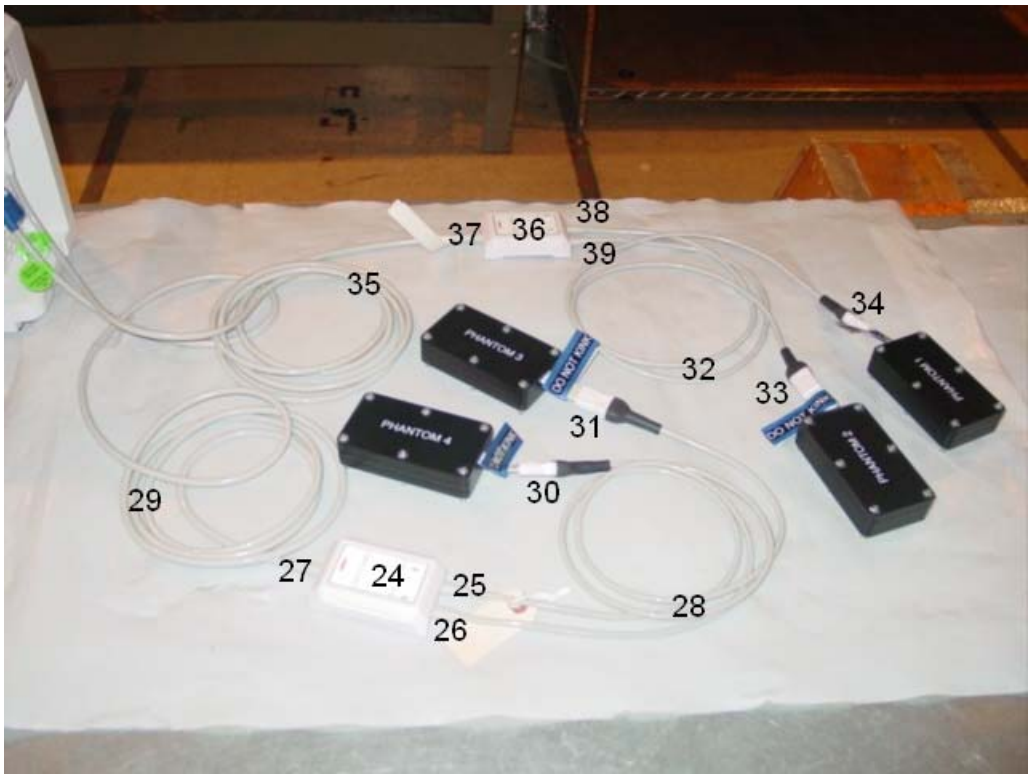


ESD Locations - Photo #2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

ESD Locations - Photo #3



ESD Locations - Photo #4 100VAC 60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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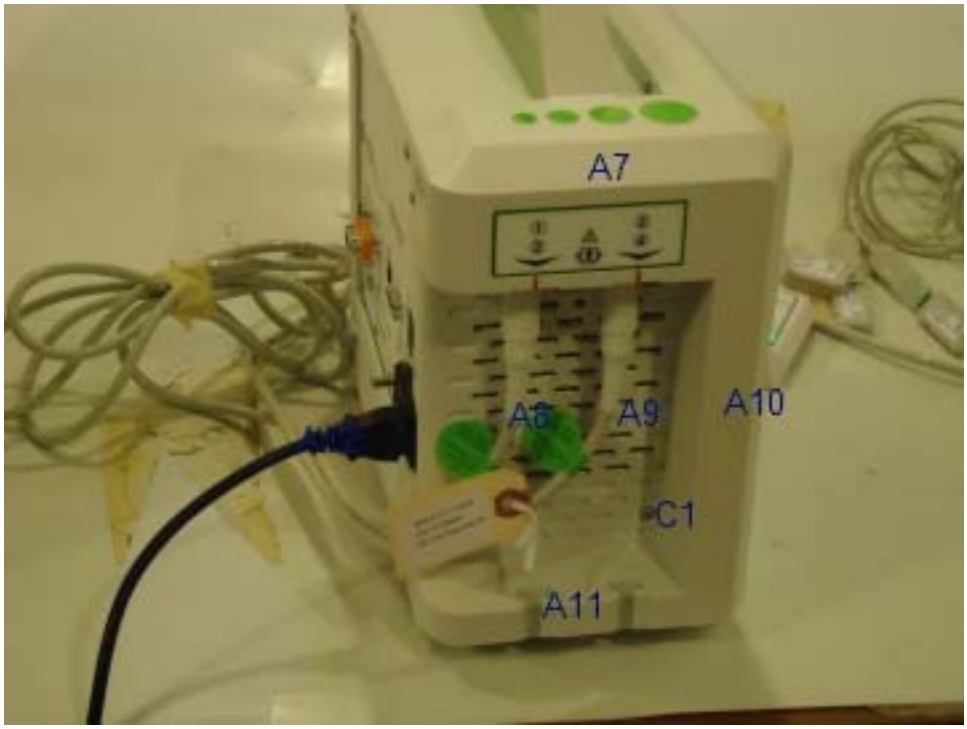
ESD Locations - Photo #5 100VAC 60Hz

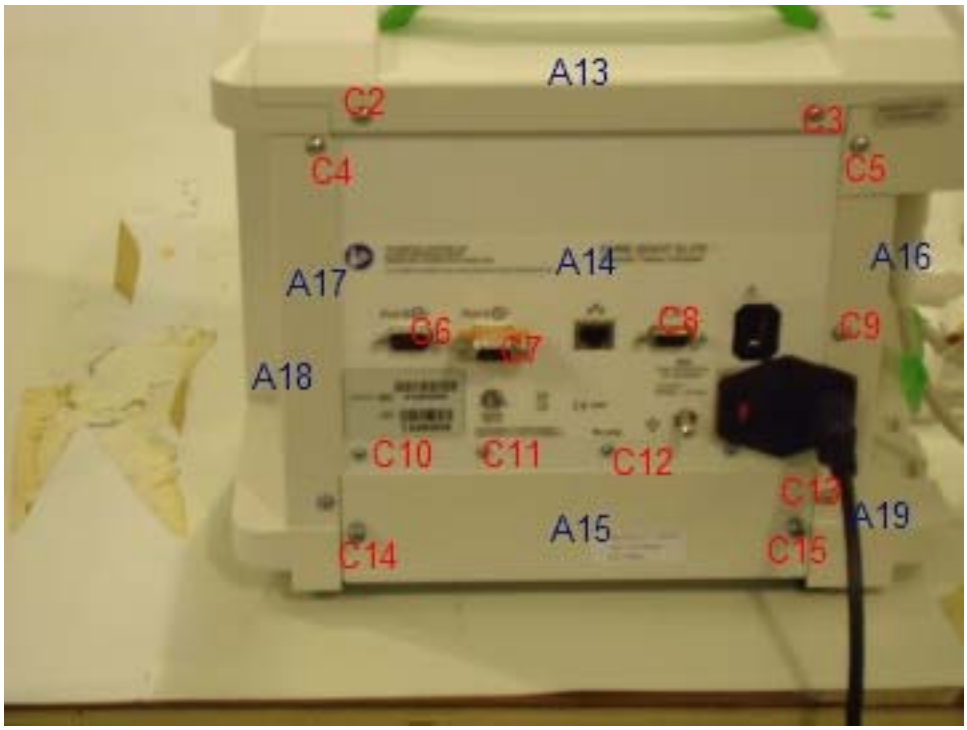
ESD Locations - Photo #6 100VAC 60Hz



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

ESD Locations - Photo #7 100VAC 60Hz



ESD Locations - Photo #8 100VAC 60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

10.4 Test Data:

230V 50Hz

Test Point	Discharge Voltage Type	Test Voltages, Polarities and Result Classification													
		2 kV		4 kV		6 kV		8 kV			15 kV		__ kV	
		Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg		Pos	Neg	Pos	Neg
HCP	Contact	(1)	(1)	(1)	(1)	(1)	(1)			Air Discharges only above 8 kV				
Edge	Contact	(2)	(2)	(2)	(2)	(2)	(2)							
VCP	Contact	(3)	(3)	(3)	(3)	(3)	(3)							
1	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
2	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
3	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
4	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
5	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
6	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
7	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
8	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
9	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
10	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
11	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
12	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
13	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
14	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
15	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
16	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
17	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
18	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
19	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
20	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
21	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
22	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
23	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
24	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
25	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
26	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
27	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
28	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
29	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
30	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
31	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
32	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
33	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
34	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
35	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
36	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
37	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
38	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
39	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz

Test Point	Discharge Voltage Type	Test Voltages, Polarities and Result Classification											
		2 kV		4 kV		6 kV		8 kV		15 kV		kV	
		Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
HCP	Contact	(6)	(6)	(6)	(6)	(6)	(6)						
VCP	Contact	(6)	(6)	(6)	(6)	(6)	(6)						
C1-C15	Contact	(6)	(6)	(6)	(6)	(6)	(6)						
A1-A28	Air	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)				

Air Discharges only above 8 kV

Test Personnel: John R. Cauvel J.R.C

Rick Duval RD

Supervising/Reviewing Engineer: (Where Applicable) Tony L. TL

Product Standard: IEC 60601-1-2

Input Voltage: 230V 50Hz & 100V 60Hz

Verified on ESD Voltmeter: YES

470k x 2 Strap(s) Verified: YES

Test Date: 8-3-2012

11/13/2013

Test Levels: ±2kV, ±4kV, ±6kV, Contact
±2kV, ±4kV, ±8kV, Air

Performance Criteria: See Report Section 5.3

Ambient Temperature: 24, 23 ºC

Relative Humidity: 49, 40 %

Atmospheric Pressure: 1003, 1008 mbars

Notes:
(1) Discharged to Horizontal Coupling Plane, 4 locations.
(2) Discharged to front edge of Horizontal Coupling Plane
(3) Discharged to Vertical Coupling Plane, 4 locations
(4) No degradation of performance observed.
(5) Entire surface swept, No discharges observed, no change in operation.
(6) The EUT met the requirements without any degradation of performance.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

11 Radiated, radio-frequency, electromagnetic field immunity test

11.1 Method

Tests are performed in accordance with IEC 61000-4-3.

TEST SITE: Large Enclosure EMC

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

11.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
AMP 32	Antenna, Log Periodic, 80 - 1000MHz	Amplifier Research	AT1080	19465	VBU	Verified
EMC 03	ANTENNA, RIDGED GUIDE, 1-18 GHZ	EMCO	3115	2878	VBU	Verified
KAL 02	AMPLIF ER; 1kW; 10kHz-200MHz	Kalmus	137C/1-60-105-002	8044-1	VBU	Verified
OPH 001	RF Amplifier	Ophir RF	5227FE	1001	VBU	Verified
HEW 46	METER, POWER	Hewlett Packard	436A/022	2604A23768	04/05/2012	04/05/2013
HEW 63	Generator, Signal	Hewlett Packard	8648C	3847A05291	01/23/2012	01/23/2013
AMP 12	Isotropic Field Monitor	Amplifier Research	FM2000	14937	VBU	Verified
AMP 37	AMPLIF ER 50W .8 - 4.2GHz	Amplifier Research	50S1G4A	29183	11/2/2000	Verified
WER 3	COUPLER, BI-DIRECTIONAL	Werlatone inc.	C3910	5283	01/29/2012	01/29/2013
AMP 36	Dual Directional Coupler	Amplifier Research	DC7144, .8 - 4 2GHz	28765	01/24/2012	01/24/2013
AMP 12	Isotropic Field Monitor	Amplifier Research	FM2000	14937	VBU	Verified

Test equipment used on 11/14/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Dav001'	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
Oph001'	RF Amplifier	Ophir RF	5227FE	1001	VBU	Verified
Hew46'	METER, POWER	Hewlett Packard	436A/022	2604A23768	04/11/2013	04/11/2014
Hew63'	Generator, Signal	Hewlett Packard	8648C	3847A05291	01/25/2013	01/25/2014
Amp37"	AMPLIF ER, 50W, .8 - 4.2GHz	Amplifier Research	50S1G4A	29183	11/2/2000	Verified
Amp9'	Isotropic Field Monitor	Amplifier Research	FM2000	16839	VBU	Verified
Wer4'	COUPLER, BI-DIRECTIONAL	Werlatone inc.	C3910	5284	04/27/2013	04/27/2014
Amp36'	Dual Directional Coupler	Amplifier Research	DC7144, .8 - 4 2GHz	28765	01/28/2013	01/28/2014
Hew48'	SENSOR, POWER	Hewlett Packard	8481A	1928A17048	04/11/2013	04/11/2014
147085'	Antenna , BiLog	Schaffner	CBL 6140A	1201	11/18/2003	Verified
Emc03'	ANTENNA, RIDGED GUIDE, 1-18 GHZ	EMCO	3115	2878	VBU	Verified
TEL154'	Function Generator, .002 Hz to 2 MHz	Leader Electronics C	LFG-1300S	1040413	04/12/2013	04/12/2014

Software Utilized:

Name	Manufacturer	Version
TILE	Quantum Change	3.4.J.2

11.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

11.4 Setup Photographs:

100V 60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

11.5 Test Data:

230V 50Hz

Field Level (V/m)	Frequency Range MHz	Antenna Polarity, Azimuths and Result Classification							
		Vertical				Horizontal			
		0	90	180	270	0	90	180	270
3	80-2500	A(1)	A(1)	A(1)	A(1)	A(1)	A(1)	A(1)	A(1)

100V 50Hz

Field Level (V/m)	Frequency Range MHz	Antenna Polarity, Azimuths and Result Classification							
		Vertical				Horizontal			
		0	90	180	270	0	90	180	270
3	80-2500	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)

Test Personnel:	Gary Ball GB	Test Date:	08/03/2012
	Rick Duval RD		11/14/2013
Supervising/Reviewing Engineer: (Where Applicable)	N/A		
Product Standard:	IEC 60601-1-2	Test Levels:	3 V/m, 80% AM @ 1 kHz
Input Voltage:	230 V/50 Hz, 100 V/60 Hz	Performance Criteria:	See Report Section 5.3
		Ambient Temperature:	21,20 ºC
Field Level Monitored:	Yes	Relative Humidity:	62,12 %
		Atmospheric Pressure:	1004,1009 mbars

Notes:

(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

12 Electrical Fast Transient/Burst Immunity Test

12.1 Method

Tests are performed in accordance with IEC 61000-4-4.

TEST SITE: EMC Lab

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

12.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
SAF 774	Digital Storage Oscilloscope	Agilent	DSO6104A	MY50340108	01/11/2012	01/11/2013
Emc 82	1000X High Voltage Probe	Tektronix	P6015A	B055113	03/09/2012	03/09/2013
The 001	EMC Immunity Test System	Thermo Fisher	EMCPro Plus	0809207	02/10/2012	02/10/2013
Dav 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012

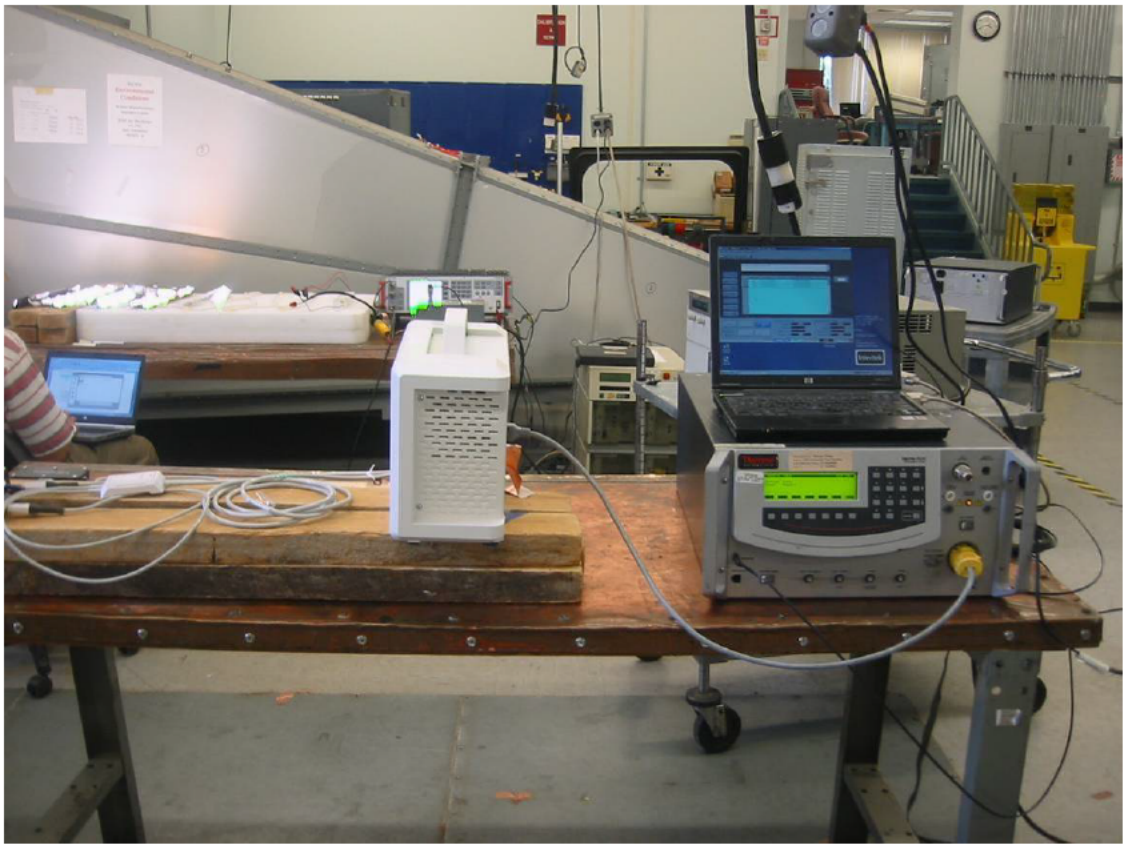
Software Utilized:

Name	Manufacturer	Version
CEWare32	Thermo Electron Corporation	4.00

12.3 Results:

The sample tested was found to Comply.

12.4 Setup Photographs:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

12.5 Test Data:

Test Point	Coupling Method	Test Voltages, Polarities, and Result Classification									
		0.25kV		0.5kV		1 kV		2 kV		4 kV	
		pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
Power L1	Direct			(1)	(1)	(1)	(1)	(1)	(1)		
Power L2	Direct			(1)	(1)	(1)	(1)	(1)	(1)		
Power PE	Direct			(1)	(1)	(1)	(1)	(1)	(1)		

Test Personnel: Gary Ball GB
Supervising/Reviewing Engineer: (Where Applicable) N/A
Product Standard: IEC 60601-1-2
Input Voltage: 100 VAC/60 Hz, 240 VAC/50 Hz
Waveform verified on Oscilloscope: Yes

Test Date: 08/01-02/2012
Test Levels: 500V 1 & 2kV
Performance Criteria: See Report Section 5.3
Ambient Temperature: 22, 21 ºC
Relative Humidity: 50, 64 %
Atmospheric Pressure: 1001, 1000 mbars

Notes:
(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

13 Immunity to Surge

13.1 Method

Tests are performed in accordance with IEC 61000-4-5.

TEST SITE: EMC Lab

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

13.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
SAF 774	Digital Storage Oscilloscope	Agilent	DSO6104A	MY50340108	01/11/2012	01/11/2013
Emc 82	1000X High Voltage Probe	Tektronix	P6015A	B055113	03/09/2012	03/09/2013
The 001	EMC Immunity Test System	Thermo Fisher	EMCPro Plus	0809207	02/10/2012	02/10/2013
Dav 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012

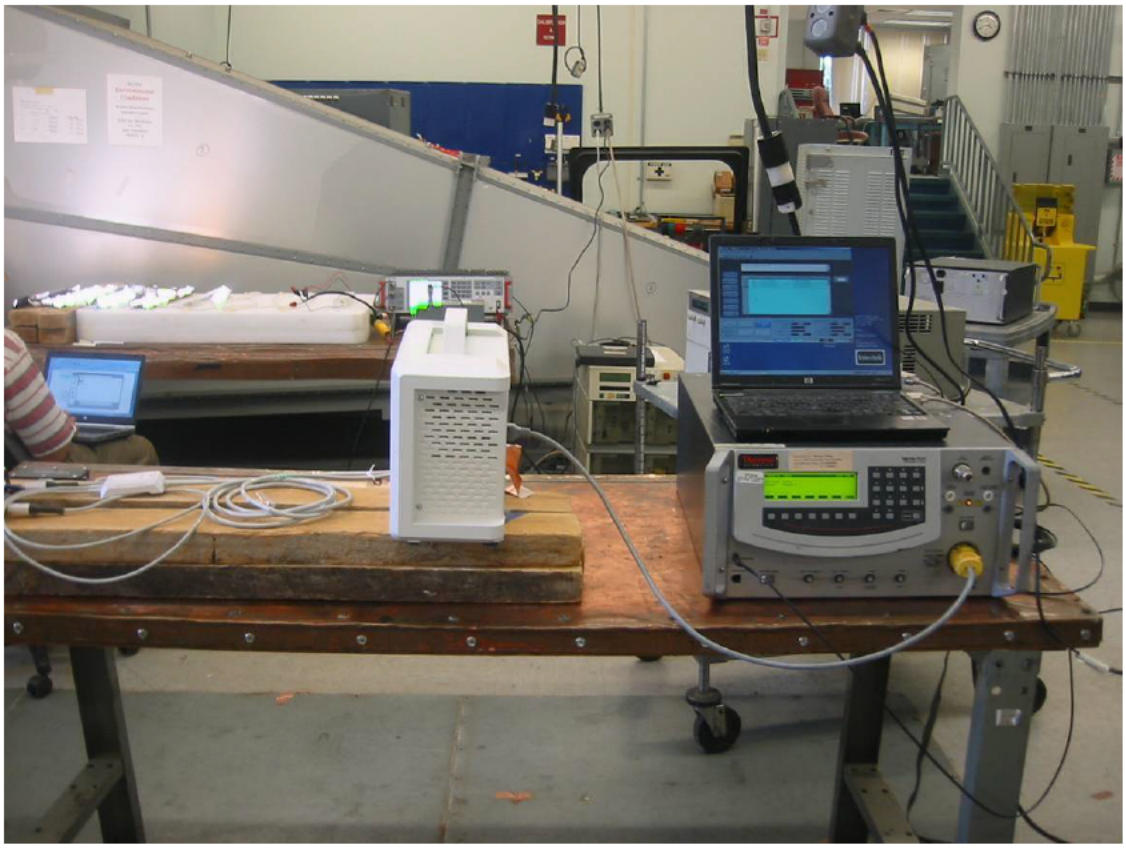
Software Utilized:

Name	Manufacturer	Version
CEWare32	Thermo Electron Corporation	4.00

13.3 Results:

The sample tested was found to Comply.

13.4 Setup Photograph:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

13.5 Test Data:

Test	Test Voltages, Polarities, and Result Classification							
	0.5kV		1kV		2kV		4kV	
	pos	neg	pos	neg	pos	neg	pos	neg
L1-PE, at 0 deg	(1)	(1)	(1)	(1)	(1)	(1)		
L1-PE, at 90 deg	(1)	(1)	(1)	(1)	(1)	(1)		
L1-PE, at 180 deg	(1)	(1)	(1)	(1)	(1)	(1)		
L1-PE, at 270 deg	(1)	(1)	(1)	(1)	(1)	(1)		
N-PE, at 0 deg	(1)	(1)	(1)	(1)	(1)	(1)		
N-PE, at 90 deg	(1)	(1)	(1)	(1)	(1)	(1)		
N-PE, at 180 deg	(1)	(1)	(1)	(1)	(1)	(1)		
N-PE, at 270 deg	(1)	(1)	(1)	(1)	(1)	(1)		
L1-N, at 0 deg	(1)	(1)	(1)	(1)				
L1-N, at 90 deg	(1)	(1)	(1)	(1)				
L1-N, at 180 deg	(1)	(1)	(1)	(1)				
L1-N, at 270 deg	(1)	(1)	(1)	(1)				

Gary Ball GB

Test Personnel: John R. Cauvel J.R.C

Supervising/Reviewing Engineer: (Where Applicable) Gary Ball GB

Product Standard: IEC 60601-1-2

Input Voltage: 100 VAC/60 240 VAC/50

Waveform verified on Oscilloscope: Yes

Test Date: 08/02/2012

Test Levels: 500V 1 & 2kV

Performance Criteria: See Report Section 5.3

Ambient Temperature: 21 ºC

Relative Humidity: 64 %

Atmospheric Pressure: 1000 mbars

Test Matrix	Line to Physical Earth (ground)	Line to Line (or Neutral)
AC:	2kV	500V & 1kV
DC:	N/A	N/A
Indoor Signal:	N/A	N/A
Outdoor Signal:	N/A	N/A

Notes:
(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

14 Conducted, radio-frequency, electromagnetic field immunity test

14.1 Method

Tests are performed in accordance with IEC 61000-4-6.

TEST SITE: EMC

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

14.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
FCC 16	Coupling, Decoupling Network	Fischer Custom Commu	FCC-801-M3-25	157	02/15/2011	02/15/2013
FCC 15	Kit, Calibration	Fischer Custom Commu	FCC-801-150-50-CDN	744 & 745	03/05/2012	03/05/2013
TES 002	Conducted RF Immunity Test Set	Teseq Ltd	NSG 4070	25826	04/23/2012	04/23/2013

Test equipment used on 13/11/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV001'	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
EMC 63'	50-150 Ohm Adapter Set	Fischer Custom Comm.	FCC-150-50	310 and 311	09/02/2012	09/02/2013
TES002'	Conducted RF Immunity Test Set	Teseq Ltd	NSG 4070	25826	10/02/2013	10/02/2014
TEG8'	CAL BRATION JIG	Tegam	95241-1	12542	VBU	Verified
TEG10'	PROBE, CURRENT INJECTION	Tegam	95236-1	12499	VBU	Verified

Software Utilized:

Name	Manufacturer	Version
None		

14.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

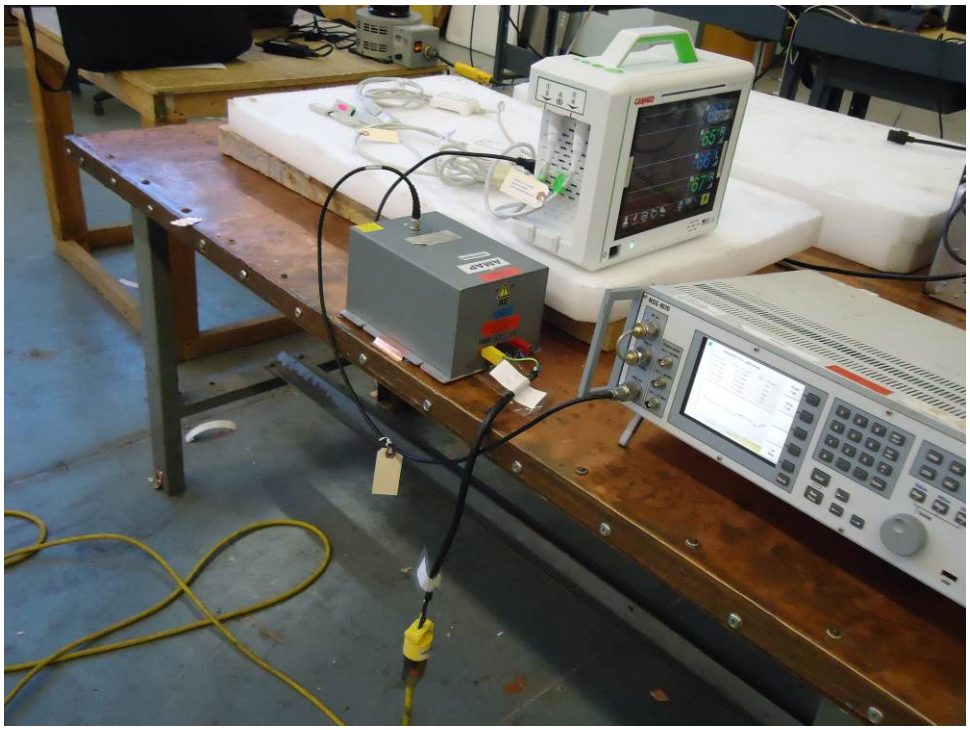
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

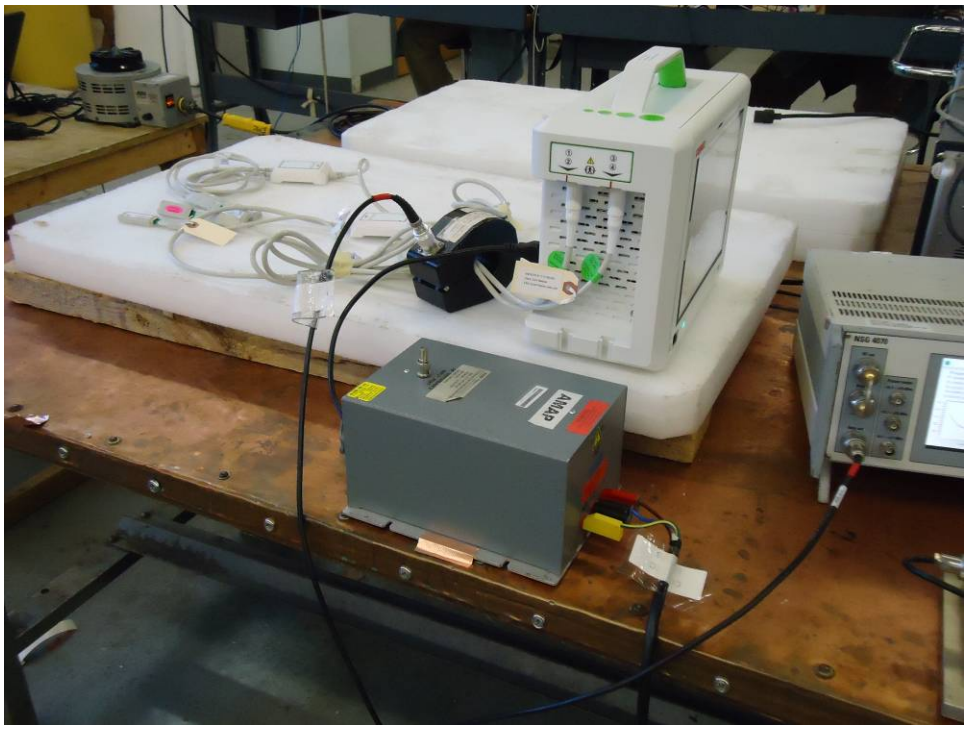
14.4 Setup Photographs:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

14.5 Test Data:

Injection Device Type	Port Description	Test Level (Vrms)	Result Classification
CDN	AC	3	(1)
Clamp	I/O Patient Leads	3	(1)

Testing Conducted on 11/13/2013

Injection Device Type	Port Description	Test Level (Vrms)	Result Classification
CDN	AC	3	(1)
Clamp	I/O Patient Leads	3	(1)

Test Personnel: Gary Ball GB
Rick Duval RD
Supervising/Reviewing Engineer: (Where Applicable) N/A
Product Standard: IEC 60601-1-2
Input Voltage: 230VAC/50Hz,100VAC/60Hz
Test Level Verification Performed: Yes

Test Date: 08/01/2012
11/13/2013
Test Levels: 3Vrms, 80% AM @ 1 kHz
Performance Criteria: See Report Section 5.3
Ambient Temperature: 22, 23 ºC
Relative Humidity: 59, 40 %
Atmospheric Pressure: 1001,1008 mbars

Notes:
(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

15 Power Frequency Magnetic Field Immunity Test

15.1 Method

Tests are performed in accordance with IEC 61000-4-8.

TEST SITE: EMC LAB

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

15.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Nar 011	Exposure Level Tester ELT-400	NARDA	2304/04	N-0024	11/21/2011	11/21/2012
Nar 012	B-Field Probe 100 cm2	NARDA	2300/90.10	M-0466	11/21/2011	11/21/2012
Dav 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
Emc 34	Magnetic Field Test Generator	Fischer Custom Commu	F-1000-4-8-G	28	VBU	Verified
Hew 42	HARMONIC/FLICKER TEST SYSTEM	Hewlett Packard	6843A	3531A00114	05/02/2012	05/02/2014

Software Utilized:

Name	Manufacturer	Version
None		

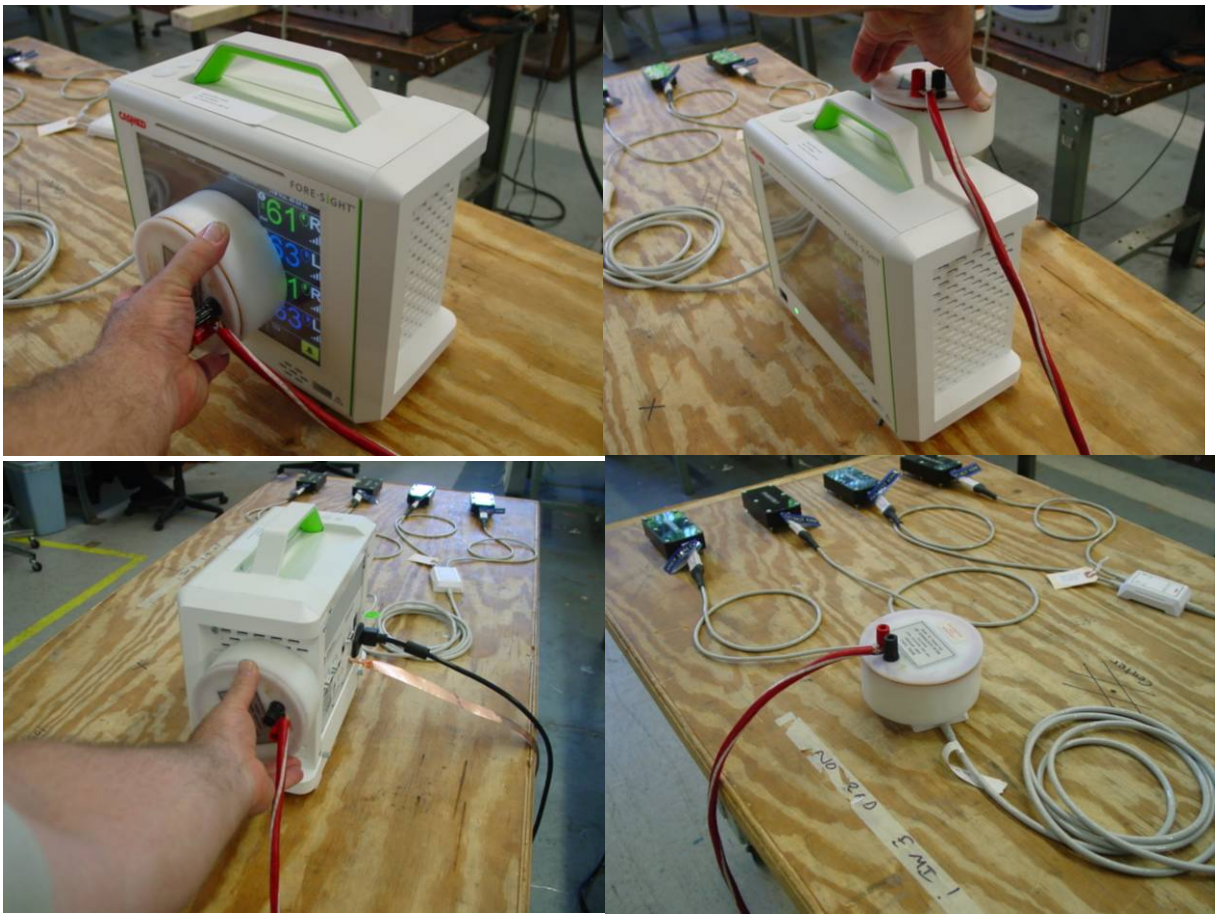
15.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

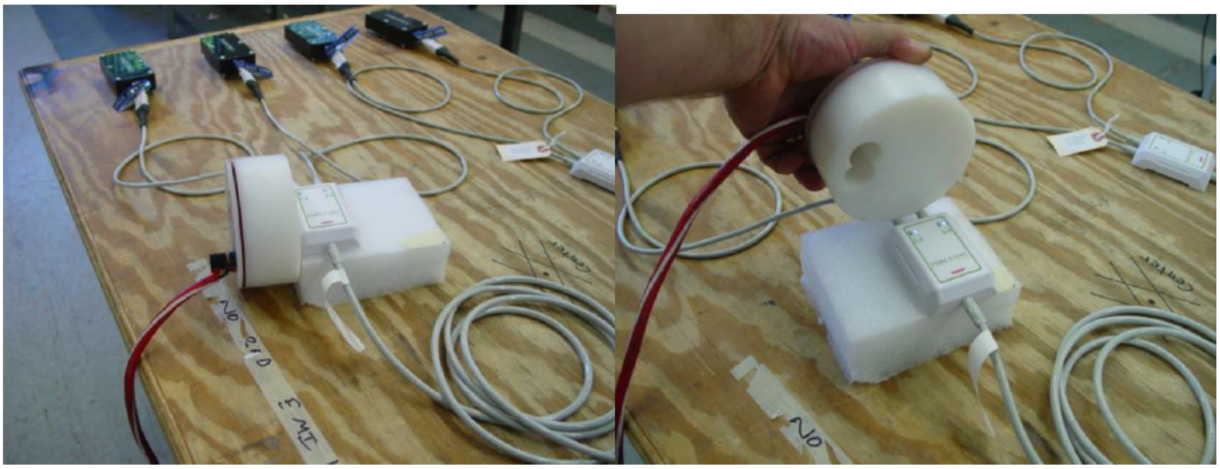
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

15.4 Setup Photographs:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015



15.5 Test Data:

Test Location/ Mode/ EUT AC Input	Test Level (A/m)	Frequency (Hz)	Result Classification		
			X – Axis	Y – Axis	Z – Axis
Enclosure/ Operating/ 100V 50 Hz	3	50	(1)	(1)	(1)
Enclosure/ Operating/ 100V 60 Hz	3	60	(1)	(1)	(1)

Test Personnel: Gary Ball GB
Supervising/Reviewing Engineer: (Where Applicable) N/A
Product Standard: IEC 60601-1-2
Input Voltage: 100V 50/60Hz
Ambient Field Level: 0.048 microTesla
Test Field Level Verified: YES

Test Date: 8-3-2012
Test Levels: 3A/m
Performance Criteria: See Report Section 5.3
Ambient Temperature: 21 ºC
Relative Humidity: 60 %
Atmospheric Pressure: 1007 mbars

Notes:
(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

16 Voltage Dips / Interruptions Immunity Tests

16.1 Method

Tests are performed in accordance with IEC 61000-4-11.

TEST SITE: EMC Lab

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

16.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
The 002	EMC Immunity Test System	Thermo Fisher	EMCPro Plus	0809208	01/10/2012	01/10/2013
Tek 3	OSCILLOSCOPE	Tektronix	2440	B010178	08/24/2011	08/24/2012
Emc 82	1000X High Voltage Probe	Tektronix	P6015A	B055113	03/09/2012	03/09/2013
Dav 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012

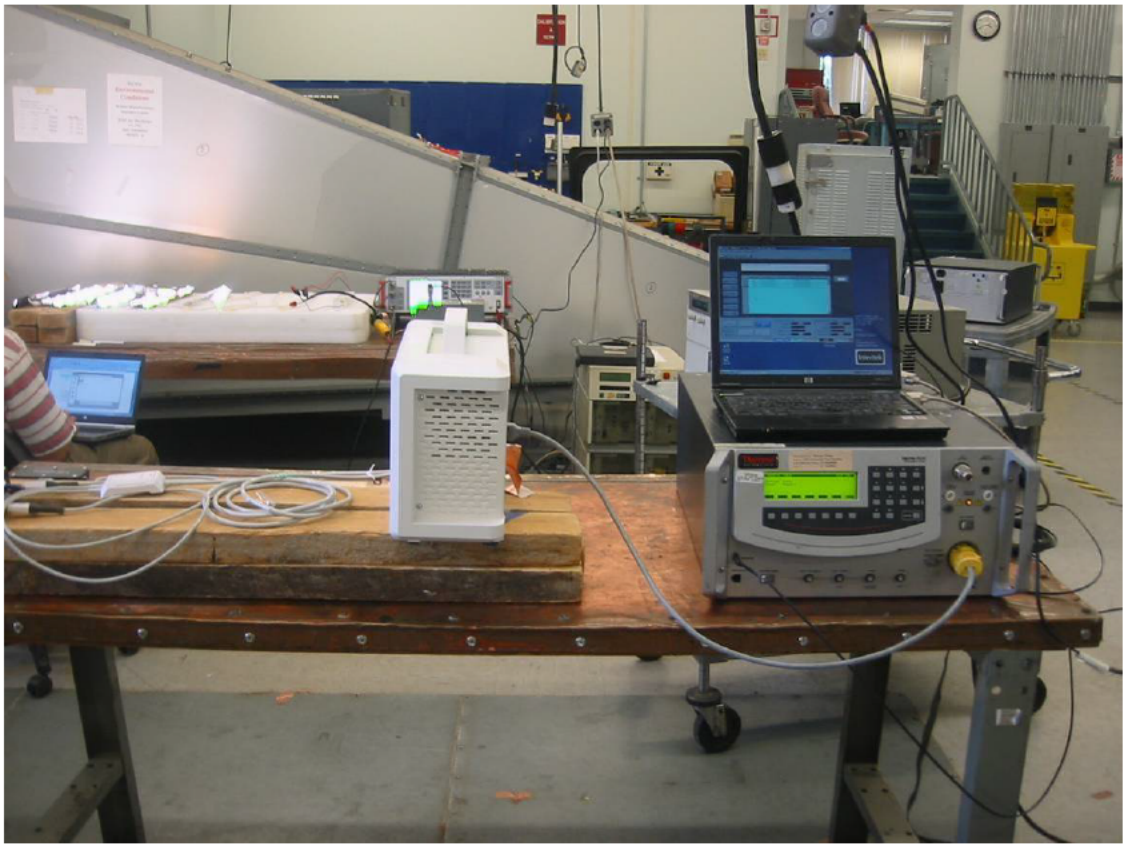
Software Utilized:

Name	Manufacturer	Version
CEWare32	Thermo Electron Corporation	4.00

16.3 Results:

The sample tested was found to Comply.

16.4 Setup Photograph:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

16.5 Test Data:

Specification	Rated Voltage (Vac)	Frequency (Hz)	Voltage Test Level (%)	Voltage Dip (%)	Test Voltage (Vac)	Duration (Periods)	Result Classification	
							0 deg	180 deg
Test Specification #1	100	50	0	100	0	.5	1	1
Test Specification #2	100	50	40	60	40	5	1	N/A
Test Specification #3	100	50	70	30	70	25	1	N/A
Test Specification #4	100	50	0	100	0	250	2	N/A
Test Specification #1	240	50	0	100	0	.5	1	1
Test Specification #2	240	50	40	60	96	5	1	N/A
Test Specification #3	240	50	70	30	168	25	1	N/A
Test Specification #4	240	50	0	100	0	250	2	N/A

Test Personnel: John R. Cauvel J.R.C
Supervising/Reviewing Engineer: (Where Applicable) Vathana Ven VJV
Product Standard: IEC 60601-1-2
Input Voltage: 100V/50Hz, 240V/50Hz
Waveform Verified on Oscilloscope: YES

Test Date: 8-2-2012
Test Levels: See Data Table
Performance Criteria: See Report Section 5.3
Ambient Temperature: 21 ºC
Relative Humidity: 60 %
Atmospheric Pressure: 1002 mbars

Notes:
(1) No degradation of performance was observed.
(2) AC Indicator light extinguished for the 5 second dropout, then lit when power was restored, no alarm was triggered, no change in operation.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

17 Section 5 User Information and Guidance Tables

5.2.1 Instructions for Use

The following statements need to be included in the user's manual for all equipment and systems:

1) "Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents."
2) "Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment."

5.2.2.1 Technical Description

The following information must be included in the Accompanying Documents provided to the end user for all equipment and systems:

a) A list of all cables and maximum lengths of cables (if applicable), transducers and other accessories with which the manufacturer claims compliance with the requirements of IEC60601-1-2 ed3.0 (2007-03) Sections 6.1 and 6.2.
b) A warning: "The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system."
c) Guidance Table 1 must be provided to the end user.
d) A warning: "The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used."
e) A justification must be provided for each reduced compliance level that is lower than the published levels for immunity tests in IEC 60601. The justifications must be based on physical, technological or physiological limitations that prevent compliance with the published test levels.
f) Guidance Table 2 must be provided to the end user.

5.2.2.2 Technical Description

The following information must be included in the Accompanying Documents provided to the end user for all equipment and systems:

Guidance Tables 4 and 6 must be provided to the end user for equipment and systems that are not Life-Supporting.

5.2.2.4 Guidelines to Include

For Equipment and Systems that intentionally apply RF energy for diagnosis or treatment, the accompanying documents shall include guidelines for avoiding or identifying and resolving adverse electromagnetic effects on other equipment that may result from operation of the Equipment or System.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

5.2.2.5 Accompanying Documents to Include

For Equipment that intentionally receive RF electromagnetic energy for the purpose of their operation, the accompanying documents shall include each frequency or frequency band of reception; the preferred frequency or frequency band, if applicable, and the bandwidth of the receiving section in those bands. A warning that ME Equipment/Systems may be interfered with by other equipment, even if that other equipment complies with CISPR Emissions requirements, must also be included.

5.2.2.6 Accompanying Documents to Include

For Equipment that include RF Transmitters, the accompanying documents shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the Effective Radiated Power (ERP).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Table 1 – Guidance and Manufacturer's Declaration – Emissions
All ME Equipment and ME Systems

Guidance and Manufacturer's Declaration - Emissions
The is intended for use in the electromagnetic environment specified below. The customer or user of the FORE-SIGHT Elite Absolute Tissue Oximeter should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The FORE-SIGHT Elite Absolute Tissue Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The FORE-SIGHT Elite Absolute Tissue Oximeter is suitable for use in all establishments, **other than** domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Table 2 – Guidance and Manufacturer's Declaration – Immunity
All ME Equipment and ME Systems

Guidance and Manufacturer's Declaration – Immunity
The FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use in the electromagnetic environment specified below. The customer or user of the FORE-SIGHT Elite Absolute Tissue Oximeter should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	Level 3 +/-6kV Contact +/- 8kV Air	Level 3 +/-6kV Contact +/- 8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FORE-SIGHT Elite Absolute Tissue Oximeter requires continued operation during power mains interruptions, it is recommended that the FORE-SIGHT Elite Absolute Tissue Oximeter be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Table 4 – Guidance and Manufacturer's Declaration – Immunity
ME Equipment and ME Systems that are NOT Life-supporting

Guidance and Manufacturer's Declaration – Immunity
The FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use in the electromagnetic environment specified below. The customer or user of the FORE-SIGHT Elite Absolute Tissue Oximeter should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	(V1)=3Vrms (E1)=3V/m	Portable and mobile communications equipment should be separated from the FORE-SIGHT Elite Absolute Tissue Oximeter by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150kHz to 80MHz D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 6 – Recommended Separation Distances between portable and mobile RF Communications equipment and the FORE-SIGHT Elite Absolute Tissue Oximeter
ME Equipment and ME Systems that are NOT Life-supporting

Recommended Separations Distances for the FORE-SIGHT Elite Absolute Tissue Oximeter
The FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the FORE-SIGHT Elite Absolute Tissue Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the FORE-SIGHT Elite Absolute Tissue Oximeter as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800MHz to 2.5GHz D=(7/E1)(Sqrt P)
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

18 Revision History

Revision Level	Date	Report Number	Prepared By	Reviewed By	Notes
0	11/13/2013	10742469BOX-008a	rd RD	KPS KPS	Original Issue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Report issued under the responsibility of:

Intertek

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	100742469BOX-001
Date of issue.....:	2012, November 15, M2: 2013-11-05
Total number of pages.....:	22 .....
CB Testing Laboratory.....:	Intertek Testing Services NA Inc.
Address.....:	70 Codman Hill Road Boxborough, MA 01719 USA
Applicant's name .....:	CAS Medical Systems Inc.
Address.....:	44 East Industrial Road Branford, CT 06405, USA
Test specification:	
Standard .....:	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
Test procedure.....:	CB Scheme
Non-standard test method……..:	
Test Report Form No.....:	IEC60601_1G
Test Report Form Originator.....:	Underwriters Laboratories Inc.
Master TRF.....:	Dated 2010-11

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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo shall be removed

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description.....:	Absolute Tissue Oximeter
Trade Mark .....:	CASMED®
Manufacturer.....:	Same as Applicant
Model/Type reference.....:	FORE-SIGHT Elite 01-06-3000 (US) and 01-06-3005 (OUS)
Ratings.....:	100-240 V~, 50/60 Hz, 1.5 A Max

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Testing procedure and testing location:	
☒ CB Testing Laboratory:	Intertek Testing Services NA Inc.
Testing location/ address ..... :	70 Codman Hill Road Boxborough, MA 01719 USA
☐ Associated CB Test Laboratory:	
Testing location/ address ..... :	
Tested by (name + signature)..... :	Brett Gagnon
Approved by (+ signature) ..... :	Tell Bailey
☐ Testing procedure: TMP	
Tested by (name + signature)..... :	
Approved by (+ signature) ..... :	
Testing location/ address ..... :	
☐ Testing procedure: WMT	
Tested by (name + signature)..... :	
Witnessed by (+ signature) ..... :	
Approved by (+ signature) ..... :	
Testing location/ address ..... :	
☐ Testing procedure: SMT	
Tested by (name + signature)..... :	
Approved by (+ signature) ..... :	
Supervised by (+ signature)..... :	
Testing location/ address ..... :	
☐ Testing procedure: RMT	
Tested by (name + signature)..... :	
Approved by (+ signature) ..... :	
Supervised by (+ signature)..... :	
Testing location/ address ..... :	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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List of Attachments (including a total number of pages in each attachment):

N/A		

Summary of testing:

Tests performed (name of test and test clause):

Clause	Test
8.7.4.5	Earth Leakage Current
8.7.4.6	Touch Leakage Current
8.7.4.7a	Patient Leakage Current
8.7.4.7b	Patient Leakage Current
8.7.4.7h	Total Patient Leakage
8.7.4.8	Patient Auxiliary Current
8.8.3	Dielectric Strength
11.1	Temperatures

Testing location:

Intertek Testing Services NA Inc.

70 Codman Hill Road

Boxborough, MA 01719 USA

Summary of compliance with National Differences

List of countries addressed: US, CA, CH, EN, JP

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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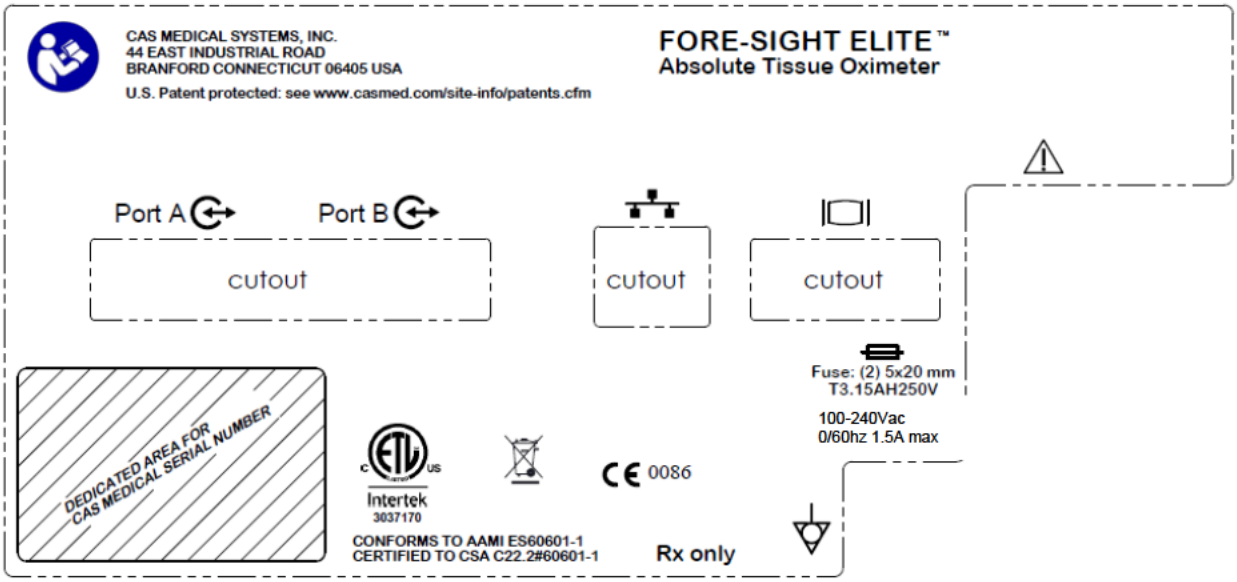
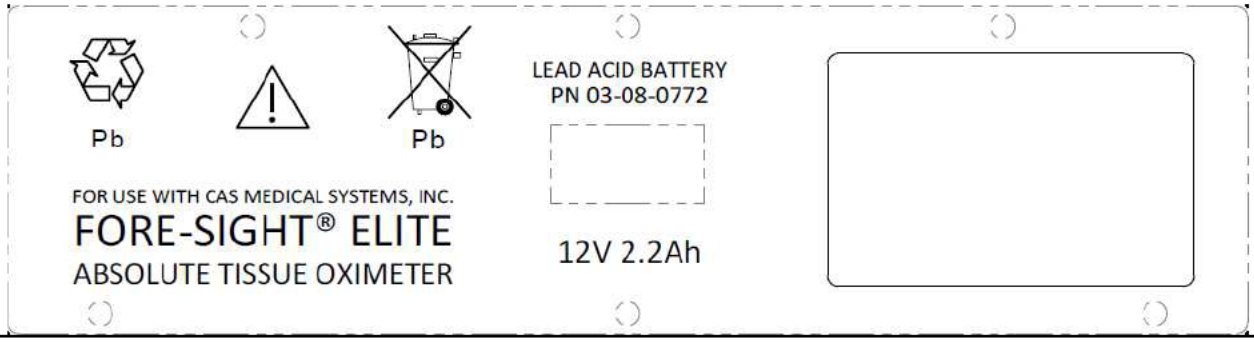
Copy of marking plate





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FORE-SIGHT
Absolute Tissue Oximetry ELITE™

x20

LARGE SENSORS
(includes alcohol prep pad)
REF 01-07-2103

SP: Sensor Grande **IT:** Sensore Grande **RU:** Большой Сенсор **FI:** Suuri Anturi
FR: Capteur Grand **NL:** Grote Sensor **DA:** Stor Sensor **NO:** Stor Sensor
PT: Sensor Grande **DE:** Großer Sensor **PL:** Duży Czujnik **CS:** Velký snímač

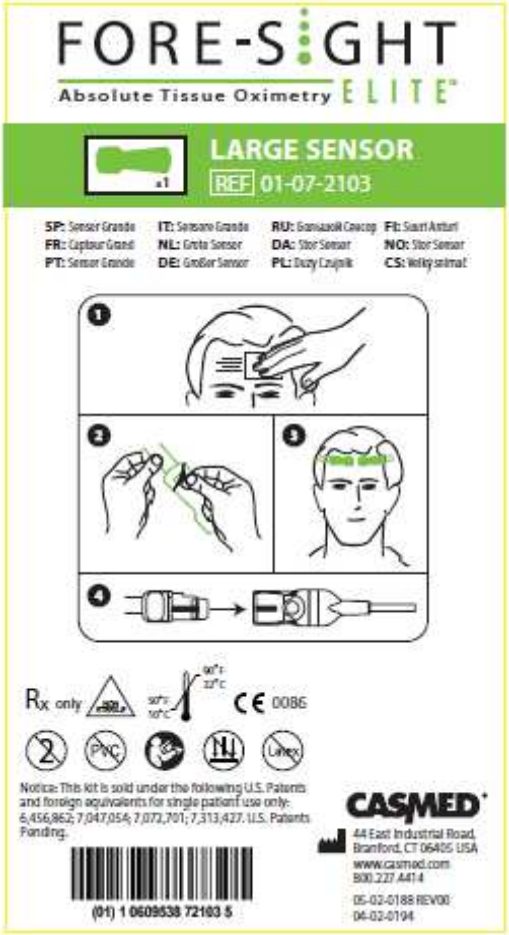
90°F 32°C
50°F 10°C
Rx only
CE 0086

05-02-0188 REV00
04-02-0194

CASMED®
44 East Industrial Road,
Branford, CT 06405 USA
www.casmed.com
800.227.4414

EC REP
MediMark® Europe.
11 rue E. Zola 38100
Grenoble. France

(01) 1 0609538 72103 5



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	portable
Device type (component/sub-assembly/ equipment/ system). :	Equipment
Intended use (Including type of patient, application location) . :	continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle
Mode of operation ..... :	Continuous
Supply connection ..... :	internally powered / appliance coupler
Accessories and detachable parts included ..... :	Preamp cables, Sensors
Other options include..... :	N/A
Testing	
Date of receipt of test item(s) ..... :	2013/10/31
Dates tests performed ..... :	2013/11/1 – 2013/11/05
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement.....:	N/E
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition .....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection .....: MOPP

General remarks:
"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Manufacturer's Declaration per sub-clause 6.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ Yes ☒ Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) ..... :	CAS Medical Systems 44 East Industrial Road Branford, CT 06405
General product information: The product covered in this report is a 110-240 VAC, Single Phase, ABSOLUTE TISSUE OXIMETER, intended to be installed indoors The Model FORE-SIGHT ELITE™ 01-06-3000 Series Monitor is a pre-configured monitor that can include the following measurement functions • Absolute tissue oxygen saturation (StO2) The FORE-SIGHT ELITE Oximeter is indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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M2: G100742469 2013-11-05

Modification 2 was created to add Japanese deviations along with the additional tests results for 10% above the nominal 100Vac at both 50Hz and 60Hz

Note: 110Vac inputs were not needed due to the fact that they were completed in the original evaluation

- New leakages added (before and after humidity)
- New dielectrics added (before and after humidity)
- New temps added
- Japanese country deviations added
- Ratings changed from 110Vac to 100Vac (label updated to match)

M1: G100742469 2013-10-28

03-05-0511 03+ Oximeter sensor construction had following changes

- Use alternate 5 mil (0.127 mm) thick FEP film into sensor bottom foam laminate construction for insulation;
- flexible circuit assembly increased sealed edge perimeter to 1 mm and insulating cover lay thickness to 25 µm; also the stiffener behind the photodiodes on flexible circuit changed to non-conductive FR4

Also the report updates are listed in the following pages

- Added test list on page 3
- Added M1 information in product general information on page 7
- Added alternate Teflon FEP in critical component list on page 9
- Added oximeter sensor in critical components list on page 10
- Add test data due to the modification on page 10 to 14
- Pictures for modified new Oximeter sensor on page 15
- Added test equipment list page 16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TEST EQUIPMENT LIST					
Item	**Equipment Type**	**Make**	**Model No.**	**Serial No.**	**Next Cal. Due**
1	Weather condition Station*	Davis Instruments	Vue / 6351	G120802D005	01/29/2014
2	A/C Power Source	Chroma	6415	641500000506	09/23/2014
3	Medical/ITS/Industrial switch and leakage box	Intertek	JP2	SAF771	01/07/2014
4	Hipot Tester	QuadTech	Sentry Plus	S00300001097	10/04/2014
5	Data Acquisition Switch Unit	Agilent Technolgies	34907A	MY44071449	09/23/2014
6	20 Channel Armature Multiplexer	Agilent Technolgies	34901A	MY41156028	09/24/2014
7	Large Temperature/Humidity Chamber (Walk In)	Bryant Manufacturing	WR-197	2177	02/19/2014
8	Chart Recorder (Walk-in)	Honeywell	DR45AT	0028Y0471539000	02/19/2014
9	True RMS Multimeter	Fluke	87 V	19020110	05/02/2014

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.7	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks	
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
B, NC, S5-1,S12-1	110	60	125		
B, NC, S5-1, S12-0	110	60	126		
B, NC, S5-0, S12-1	110	60	125		
B, NC, S5-0, S12-0	110	60	125		
A, NC, S5-1,S12-1	110	60	93.7		
A, NC, S5-1, S12-0	110	60	94.2		
A, NC, S5-0, S12-1	110	60	92.3		
A, NC, S5-0, S12-0	110	60	92.8		
B, SFC, S5-1,S12-1	110	60	234		
B, SFC, S5-1, S12-0	110	60	230		
B, SFC, S5-0, S12-1	110	60	231		
B, SFC, S5-0, S12-0	110	60	230		
A, SFC, S5-1,S12-1	110	60	174.2		
A, SFC, S5-1, S12-0	110	60	175.0		
A, SFC, S5-0, S12-1	110	60	174		
A, SFC, S5-0, S12-0	110	60	175		
B, NC, S5-1,S12-1	110	50	124		
B, NC, S5-1, S12-0	110	50	124		
B, NC, S5-0, S12-1	110	50	124		
B, NC, S5-0, S12-0	110	50	124		
A, NC, S5-1,S12-1	110	50	90.1		
A, NC, S5-1, S12-0	110	50	96.7		
A, NC, S5-0, S12-1	110	50	94.8		
A, NC, S5-0, S12-0	110	50	91.9		
B, SFC, S5-1,S12-1	110	50	235		
B, SFC, S5-1, S12-0	110	50	231		
B, SFC, S5-0, S12-1	110	50	232		
B, SFC, S5-0, S12-0	110	50	231		
A, SFC, S5-1,S12-1	110	50	170		
A, SFC, S5-1, S12-0	110	50	171		
A, SFC, S5-0, S12-1	110	50	172		
A, SFC, S5-0, S12-0	110	50	173		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
B, S1-1, S5-1, S7-1, S12-1	110	60	4.1	
B, S1-1, S5-1, S7-1, S12-0	110	60	3.6	
B, S1-1, S5-1, S7-0, S12-1	110	60	9.5	
B, S1-1, S5-1, S7-0, S12-0	110	60	9.6	
B, S1-1, S5-0, S7-1, S12-1	110	60	3.9	
B, S1-1, S5-0, S7-1, S12-0	110	60	3.6	
B, S1-1, S5-0, S7-0, S12-1	110	60	9.6	
B, S1-1, S5-0, S7-0, S12-0	110	60	9.0	
B, S1-0, S5-1, S7-1, S12-1	110	60	6.1	
B, S1-0, S5-1, S7-1, S12-0	110	60	4.9	
B, S1-0, S5-0, S7-1, S12-1	110	60	6.1	
B, S1-0, S5-0, S7-1, S12-0	110	60	6.0	
A, S1-1, S5-1, S7-1, S12-1	110	60	1.4	
A, S1-1, S5-1, S7-1, S12-0	110	60	1.0	
A, S1-1, S5-1, S7-0, S12-1	110	60	2.1	
A, S1-1, S5-1, S7-0, S12-0	110	60	3.0	
A, S1-1, S5-0, S7-1, S12-1	110	60	2.1	
A, S1-1, S5-0, S7-1, S12-0	110	60	1.0	
A, S1-1, S5-0, S7-0, S12-1	110	60	1.6	
A, S1-1, S5-0, S7-0, S12-0	110	60	2.9	
A, S1-0, S5-1, S7-1, S12-1	110	60	1.8	
A, S1-0, S5-1, S7-1, S12-0	110	60	1.1	
A, S1-0, S5-0, S7-1, S12-1	110	60	1.5	
A, S1-0, S5-0, S7-1, S12-0	110	60	0.9	
B, S1-1, S5-1, S7-1, S12-1	110	50	4.0	
B, S1-1, S5-1, S7-1, S12-0	110	50	3.6	
B, S1-1, S5-1, S7-0, S12-1	110	50	9.4	
B, S1-1, S5-1, S7-0, S12-0	110	50	9.5	
B, S1-1, S5-0, S7-1, S12-1	110	50	3.8	
B, S1-1, S5-0, S7-1, S12-0	110	50	3.5	
B, S1-1, S5-0, S7-0, S12-1	110	50	9.5	
B, S1-1, S5-0, S7-0, S12-0	110	50	9.0	
B, S1-0, S5-1, S7-1, S12-1	110	50	6.0	
B, S1-0, S5-1, S7-1, S12-0	110	50	4.8	
B, S1-0, S5-0, S7-1, S12-1	110	50	6.0	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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B, S1-0, S5-0, S7-1, S12-0	110	50	6.0	
A, S1-1, S5-1, S7-1, S12-1	110	50	1.3	
A, S1-1, S5-1, S7-1, S12-0	110	50	1.1	
A, S1-1, S5-1, S7-0, S12-1	110	50	2.1	
A, S1-1, S5-1, S7-0, S12-0	110	50	3.1	
A, S1-1, S5-0, S7-1, S12-1	110	50	2.4	
A, S1-1, S5-0, S7-1, S12-0	110	50	1.5	
A, S1-1, S5-0, S7-0, S12-1	110	50	1.3	
A, S1-1, S5-0, S7-0, S12-0	110	50	2.5	
A, S1-0, S5-1, S7-1, S12-1	110	50	1.2	
A, S1-0, S5-1, S7-1, S12-0	110	50	1.2	
A, S1-0, S5-0, S7-1, S12-1	110	50	1.5	
A, S1-0, S5-0, S7-1, S12-0	110	50	1.0	
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)
Sensor one				
B, S1-1, S5-1, S7-1, S13-1	110	60	0.9	
B, S1-1, S5-1, S7-1, S13-0	110	60	0.8	
B, S1-1, S5-1, S7-0, S13-1	110	60	1.1	
B, S1-1, S5-1, S7-0, S13-0	110	60	1.3	
B, S1-1, S5-0, S7-1, S13-1	110	60	0.9	
B, S1-1, S5-0, S7-1, S13-0	110	60	0.6	
B, S1-1, S5-0, S7-0, S13-1	110	60	1.3	
B, S1-1, S5-0, S7-0, S13-0	110	60	1.2	
B, S1-0, S5-1, S7-1, S13-1	110	60	1.0	
B, S1-0, S5-1, S7-1, S13-0	110	60	1.1	
B, S1-0, S5-0, S7-1, S13-1	110	60	1.1	
B, S1-0, S5-0, S7-1, S13-0	110	60	1.0	
A, S1-1, S5-1, S7-1, S13-1	110	60	0.5	
A, S1-1, S5-1, S7-1, S13-0	110	60	0.5	
A, S1-1, S5-1, S7-0, S13-1	110	60	0.6	
A, S1-1, S5-1, S7-0, S13-0	110	60	0.7	
A, S1-1, S5-0, S7-1, S13-1	110	60	0.6	
A, S1-1, S5-0, S7-1, S13-0	110	60	0.5	
A, S1-1, S5-0, S7-0, S13-1	110	60	0.5	

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A, S1-1, S5-0, S7-0, S13-0	110	60	0.8	
A, S1-0, S5-1, S7-1, S13-1	110	60	0.8	
A, S1-0, S5-1, S7-1, S13-0	110	60	0.7	
A, S1-0, S5-0, S7-1, S13-1	110	60	0.6	
A, S1-0, S5-0, S7-1, S13-0	110	60	0.6	
B, S1-1, S5-1, S7-1, S13-1	110	50	0.8	
B, S1-1, S5-1, S7-1, S13-0	110	50	0.7	
B, S1-1, S5-1, S7-0, S13-1	110	50	1.0	
B, S1-1, S5-1, S7-0, S13-0	110	50	1.3	
B, S1-1, S5-0, S7-1, S13-1	110	50	0.8	
B, S1-1, S5-0, S7-1, S13-0	110	50	0.7	
B, S1-1, S5-0, S7-0, S13-1	110	50	1.2	
B, S1-1, S5-0, S7-0, S13-0	110	50	1.1	
B, S1-0, S5-1, S7-1, S13-1	110	50	1.0	
B, S1-0, S5-1, S7-1, S13-0	110	50	1.0	
B, S1-0, S5-0, S7-1, S13-1	110	50	1.0	
B, S1-0, S5-0, S7-1, S13-0	110	50	0.7	
A, S1-1, S5-1, S7-1, S13-1	110	50	0.8	
A, S1-1, S5-1, S7-1, S13-0	110	50	0.6	
A, S1-1, S5-1, S7-0, S13-1	110	50	0.6	
A, S1-1, S5-1, S7-0, S13-0	110	50	0.7	
A, S1-1, S5-0, S7-1, S13-1	110	50	0.8	
A, S1-1, S5-0, S7-1, S13-0	110	50	0.8	
A, S1-1, S5-0, S7-0, S13-1	110	50	0.7	
A, S1-1, S5-0, S7-0, S13-0	110	50	0.7	
A, S1-0, S5-1, S7-1, S13-1	110	50	0.6	
A, S1-0, S5-1, S7-1, S13-0	110	50	0.6	
A, S1-0, S5-0, S7-1, S13-1	110	50	0.7	
A, S1-0, S5-0, S7-1, S13-0	110	50	0.6	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 uA Type CF AP: 50 uA
Sensor one				
B, S5-1, S9-1, S13-1	110	60	30.1	
B, S5-1, S9-1, S13-0	110	60	32.3	
B, S5-1, S9-0, S13-1	110	60	34.1	
B, S5-1, S9-0, S13-0	110	60	32.2	

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

B, S5-0, S9-1, S13-1	110	60	31.1	
B, S5-0, S9-1, S13-0	110	60	31.1	
B, S5-0, S9-0, S13-1	110	60	30.2	
B, S5-0, S9-0, S13-0	110	60	32.2	
A, S5-1, S9-1, S13-1	110	60	34.5	
A, S5-1, S9-1, S13-0	110	60	34.8	
A, S5-1, S9-0, S13-1	110	60	36.4	
A, S5-1, S9-0, S13-0	110	60	35.2	
A, S5-0, S9-1, S13-1	110	60	34.6	
A, S5-0, S9-1, S13-0	110	60	36.4	
A, S5-0, S9-0, S13-1	110	60	36.2	
A, S5-0, S9-0, S13-0	110	60	34.5	-
B, S5-1, S9-1, S13-1	110	50	30.1	
B, S5-1, S9-1, S13-0	110	50	32.3	
B, S5-1, S9-0, S13-1	110	50	34.1	
B, S5-1, S9-0, S13-0	110	50	32.2	
B, S5-0, S9-1, S13-1	110	50	31.1	
B, S5-0, S9-1, S13-0	110	50	31.1	
B, S5-0, S9-0, S13-1	110	50	30.2	
B, S5-0, S9-0, S13-0	110	50	32.2	
A, S5-1, S9-1, S13-1	110	50	38.2	
A, S5-1, S9-1, S13-0	110	50	36.8	
A, S5-1, S9-0, S13-1	110	50	35.4	
A, S5-1, S9-0, S13-0	110	50	36.6	
A, S5-0, S9-1, S13-1	110	50	38.2	
A, S5-0, S9-1, S13-0	110	50	34.7	
A, S5-0, S9-0, S13-1	110	50	36.2	
A, S5-0, S9-0, S13-0	110	50	37.5	
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC(d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)
N/A	-	-	-	-
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 uA Type CF: N/A
N/A	-	-	-	-
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values:

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				Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC;50 uA SFC (d.c. or a.c. current)
Sensor one				
B, S7-1, S1-1, S5-1	110	60	0.9	
B, S7-1, S1-1, S5-0	110	60	0.8	
B, S7-1, S1-0, S5-1	110	60	1.1	
B, S7-1, S1-0, S5-0	110	60	1.0	
B, S7-0, S1-1, S5-1	110	60	1.9	
B, S7-0, S1-1, S5-0	110	60	1.9	
A, S7-1, S1-1, S5-1	110	60	1.2	
A, S7-1, S1-1, S5-0	110	60	1.3	
A, S7-1, S1-0, S5-1	110	60	2.0	
A, S7-1, S1-0, S5-0	110	60	2.1	
A, S7-0, S1-1, S5-1	110	60	3.1	
A, S7-0, S1-1, S5-0	110	60	2.9	
B, S7-1, S1-1, S5-1	110	50	0.9	
B, S7-1, S1-1, S5-0	110	50	0.8	
B, S7-1, S1-0, S5-1	110	50	1.1	
B, S7-1, S1-0, S5-0	110	50	1.0	
B, S7-0, S1-1, S5-1	110	50	0.3	
B, S7-0, S1-1, S5-0	110	50	0.3	
A, S7-1, S1-1, S5-1	110	50	1.1	
A, S7-1, S1-1, S5-0	110	50	1.3	
A, S7-1, S1-0, S5-1	110	50	1.9	
A, S7-1, S1-0, S5-0	110	50	1.8	
A, S7-0, S1-1, S5-1	110	50	2.0	
A, S7-0, S1-1, S5-0	110	50	3.1	
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
B, S1-1, S5-1, S7-1, S12-1	110	60	0.1	
B, S1-1, S5-1, S7-1, S12-0	110	60	0.1	
B, S1-1, S5-1, S7-0, S12-1	110	60	0.1	
B, S1-1, S5-1, S7-0, S12-0	110	60	0.1	

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

B, S1-1, S5-0, S7-1, S12-1	110	60	0.1	
B, S1-1, S5-0, S7-1, S12-0	110	60	0.1	
B, S1-1, S5-0, S7-0, S12-1	110	60	0.1	
B, S1-1, S5-0, S7-0, S12-0	110	60	0.1	
B, S1-0, S5-1, S7-1, S12-1	110	60	0.1	
B, S1-0, S5-1, S7-1, S12-0	110	60	0.1	
B, S1-0, S5-0, S7-1, S12-1	110	60	0.1	
B, S1-0, S5-0, S7-1, S12-0	110	60	0.1	
A, S1-1, S5-1, S7-1, S12-1	110	60	0.9	
A, S1-1, S5-1, S7-1, S12-0	110	60	0.5	
A, S1-1, S5-1, S7-0, S12-1	110	60	0.4	
A, S1-1, S5-1, S7-0, S12-0	110	60	1.0	
A, S1-1, S5-0, S7-1, S12-1	110	60	0.8	
A, S1-1, S5-0, S7-1, S12-0	110	60	0.4	
A, S1-1, S5-0, S7-0, S12-1	110	60	0.3	
A, S1-1, S5-0, S7-0, S12-0	110	60	0.2	
A, S1-0, S5-1, S7-1, S12-1	110	60	0.2	
A, S1-0, S5-1, S7-1, S12-0	110	60	0.2	
A, S1-0, S5-0, S7-1, S12-1	110	60	0.2	
A, S1-0, S5-0, S7-1, S12-0	110	60	0.2	
B, S1-1, S5-1, S7-1, S12-1	110	50	0.1	
B, S1-1, S5-1, S7-1, S12-0	110	50	0.1	
B, S1-1, S5-1, S7-0, S12-1	110	50	0.1	
B, S1-1, S5-1, S7-0, S12-0	110	50	0.1	
B, S1-1, S5-0, S7-1, S12-1	110	50	0.1	
B, S1-1, S5-0, S7-1, S12-0	110	50	0.1	
B, S1-1, S5-0, S7-0, S12-1	110	50	0.1	
B, S1-1, S5-0, S7-0, S12-0	110	50	0.1	
B, S1-0, S5-1, S7-1, S12-1	110	50	0.1	
B, S1-0, S5-1, S7-1, S12-0	110	50	0.1	
B, S1-0, S5-0, S7-1, S12-1	110	50	0.1	
B, S1-0, S5-0, S7-1, S12-0	110	50	0.1	
A, S1-1, S5-1, S7-1, S12-1	110	50	0.7	
A, S1-1, S5-1, S7-1, S12-0	110	50	0.6	
A, S1-1, S5-1, S7-0, S12-1	110	50	0.7	
A, S1-1, S5-1, S7-0, S12-0	110	50	0.7	

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

A, S1-1, S5-0, S7-1, S12-1	110	50	0.5	
A, S1-1, S5-0, S7-1, S12-0	110	50	0.8	
A, S1-1, S5-0, S7-0, S12-1	110	50	0.4	
A, S1-1, S5-0, S7-0, S12-0	110	50	0.5	
A, S1-0, S5-1, S7-1, S12-1	110	5	0.5	
A, S1-0, S5-1, S7-1, S12-0	110	50	0.6	
A, S1-0, S5-0, S7-1, S12-1	110	50	0.4	
A, S1-0, S5-0, S7-1, S12-0	110	50	0.7	
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC;1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
N/A	-	-	-	-
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000uA Type CF: 100 uA
N/A	-	-	-	-
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 uA Type CF: N/A
N/A	-	-	-	-

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PAT ENT LEAKAGE CURRENT values are only relative to equipment with multiple APPL ED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PAT ENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQU PMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER - Earth leakage current
TC – Touch current
P - Patient leakage current
PA – Patient auxiliary current
TP – Total Patient current
PM - Patient leakage current with mains on the applied parts
MD - Measuring device

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

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8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				Pass
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
Primary to Metal Enclosure	BI	110	-	1500	No
Secondary to Metal Enclosure	BI	110	-	1500	No
Preamp connector to preamp enclosure	BI	110	-	1500	No
Sensor connection to Preamp enclosure	BI	110	-	1500	No
Sensor to Sensor connector	BI	110	-	1500	No
Sensor connection to Metal Enclosure	BI	110	-	1500	No
Primary to Plastic Enclosure	RI	110	-	4000	No
Sensor Connection to Primary	BI	110	-	1500	No

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.
[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

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11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No. .....:		FORE-SIGHT Elite			
Test ambient (°C) .....:		23.8			
Test supply voltage/frequency (V/Hz)[4] .....:		110VAC/60HZ			
Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
	1	Ambient	-	23.8	
	2	Power Supply Board	105	47.2	
	3	PE Cable	105	24.7	
	4	Internal cables	105	26.5	
	5	PCB	105	28.8	
	6	Screen	70	25.5	
Model No. .....:			FORE-SIGHT Elite		
Test ambient (°C) .....:			23.8		
Test supply voltage/frequency (V/Hz)[4] .....:			110VAC/50HZ		
	1	Ambient	-	22.6	
	2	Power Supply Board	105	48.1	
	3	PE Cable	105	24.9	
	4	Internal cables	105	26.8	
	5	PCB	105	29.0	
	6	Screen	70	25.9	

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT TO TEST REPORT IEC 60601-1 JP- JAPAN NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Differences according to ..... :	National standard JIS T0601-1:2012		
Attachment Form No. ..... :	JP_ND_IEC60601_1A		
Attachment Originator..... :	TÜV Rheinland Japan Ltd.		
Master Attachment..... :	2009-08		
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—	Throughout the report, HAZARD shall be referred to as HAZARDOUS SITUATION	Informative	P
7	ME Equipment Identification, Marking, and Documents		—
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to JIS Z8202 (ISO 31 (IDT)) except the base quantities listed in Table 1 expressed in the indicated units		P
7.7.4	Addition: If polyvinyl chloride (JIS C3306) or rubber (JIS C3301) insulated flexible cord is used, the conductor may be colored “white”	Informative	P
7.7.5	Addition: If polyvinyl chloride (JIS C3306) or rubber (JIS C3301) insulated flexible cord is used, conductors may be the color specified in cited standards	Informative	P
8	Protection Against Electrical Hazards from ME Equipment		—
8.4.2	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V or more (VA or J) ..... :		P
8.8.2	For a), add the following NOTE: NOTE – Generally, “distance through insulation” means the thickness of insulation. However, for example, if a transformer installed into a metal case is insulated by filler, the thickness is always not uniformly. Therefore, such expression was used.	Note added	P
8.8.3	During the test of this clause, the state of the power switch shall be kept with closed circuit		P
8.9	Creepage Distances and Air Clearances		P
8.9.1.2	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.3	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.4	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.5	Creepage distances and air clearances of this clause shall be applied to MOOP and MOPP		P
8.9.1.6	Creepage distances and air clearances of this clause shall be applied to MOOP and MOPP		P
8.9.1.7	Creepage distances and air clearances of this		P

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

	clause shall be applied to MOOP		
8.9.1.8	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.9	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.10	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.11	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.12	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.13	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.14	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.11.3.2	POWER SUPPLY CORDS are no less robust than rubber (JIS C3301), polyvinyl chloride (JIS C3306), or cords of which the robustness is equal to or more than those are usable.	Supply cords to be provided by end user	N/A
	Cords of JIS C 3306 shall not use:		N/A
	- for polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 60 °C		N/A
	- for grade heat-resistant polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 75 °C		N/A
9.2.2.2	In the bottom column of Table 20, replace the existing text with the following: [a] The values in this table are taken from JIS B9711 (ISO 13854 (IDT)).	Replaced	P
9.7.5	In the last paragraph, delete “unmarked”.	Deleted	P
9.8.4.1	Replace the existing NOTE with the following: NOTE The upper carriage of the human body test mass apparatus is formed of wood or a similar material. The bottom portion is foam. The resiliency or spring factor of the foam (ILD or IFD ratings) has not been specified. The foam is cylindrical, rather than spherical.	Replaced	P
10	Protection Against Unwanted and Excessive Radiation Hazards		—
10.1.1	X-radiation dose-rate was ≤ 36 pA/kg (5 μSv/h) (0.5 mR/h ≈ 5 μGy/h) 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation :	No radiation hazards	N/A
11.1.1	To the existing text of a in the Table 22, add the following: (For example, the maximum temperature limit of a transformer with three insulating materials of Class A, Class B and Class E shall be 105 °C of Class A		N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	of the lowest limit.)		
13.2.10	In Table 26, replace the existing NOTE with the following: NOTE The temperature limits in this table were derived from Table B.1 of IEC 60950-1:2001 (in the corresponding international standard, IEC 61010-1:2001 [22]).	Replaced	P
16	ME Systems		—
16.1	Non-ME equipment used in the ME system shall be in compliance with applicable JIS standards or Technical Requirements of the Electrical Appliance and Material Safety Act	Not an ME system	N/A
	Equipment relying only on basic insulation for protection against electric shock not used in ME system.		N/A
	For measures for ensuring safety, e.g. the case combined with a separating transformer with double insulation or reinforced insulation, equipment only with basic insulation may be used		N/A
16.9.2.1	c) Multiple socket-outlet complied with IEC 60884-1 or JIS C82821		N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Report issued under the responsibility of:

Intertek

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	100742469BOX-001
Date of issue.....:	2012, November 15, M1: 2013-10-28
Total number of pages.....:	16 .....
CB Testing Laboratory.....:	Intertek Testing Services NA Inc.
Address.....:	70 Codman Hill Road Boxborough, MA 01719 USA
Applicant's name .....:	CAS Medical Systems Inc.
Address.....:	44 East Industrial Road Branford, CT 06405, USA
Test specification:	
Standard .....:	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
Test procedure.....:	CB Scheme
Non-standard test method……..:	
Test Report Form No.....:	IEC60601_1G
Test Report Form Originator.....:	Underwriters Laboratories Inc.
Master TRF.....:	Dated 2010-11

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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo shall be removed

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description.....:	Absolute Tissue Oximeter
Trade Mark .....:	CASMED®
Manufacturer.....:	Same as Applicant
Model/Type reference.....:	FORE-SIGHT Elite 01-06-3000 (US) and 01-06-3005 (OUS)
Ratings.....:	110-240 V~, 50/60 Hz, 1.5 A Max

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Testing procedure and testing location:		
☒ CB Testing Laboratory:	Intertek Testing Services NA Inc.	
Testing location/ address ..... :	70 Codman Hill Road Boxborough, MA 01719 USA	
☐ Associated CB Test Laboratory:		
Testing location/ address ..... :		
Tested by (name + signature)..... :	Yaqing Liu	*Signature on file*
Approved by (+ signature) ..... :	Tell Bailey	*Signature on file*
☐ Testing procedure: TMP		
Tested by (name + signature)..... :		
Approved by (+ signature) ..... :		
Testing location/ address ..... :		
☐ Testing procedure: WMT		
Tested by (name + signature)..... :		
Witnessed by (+ signature) ..... :		
Approved by (+ signature) ..... :		
Testing location/ address ..... :		
☐ Testing procedure: SMT		
Tested by (name + signature)..... :		
Approved by (+ signature) ..... :		
Supervised by (+ signature)..... :		
Testing location/ address ..... :		
☐ Testing procedure: RMT		
Tested by (name + signature)..... :		
Approved by (+ signature) ..... :		
Supervised by (+ signature)..... :		
Testing location/ address ..... :		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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List of Attachments (including a total number of pages in each attachment):

N/A		

Summary of testing:

Tests performed (name of test and test clause):

Clause	Test
8.5.5.1a	Defibrillation-Proof Applied Parts
8.5.5.1b	Defibrillation-Proof Recovery Time
8.5.5.2	Energy Reduction
8.7	Leakage Current
8.8.3	Dielectric Strength

Testing location:

Intertek Testing Services NA Inc.

70 Codman Hill Road

Boxborough, MA 01719 USA

Summary of compliance with National Differences

List of countries addressed: US, CA, CH, EN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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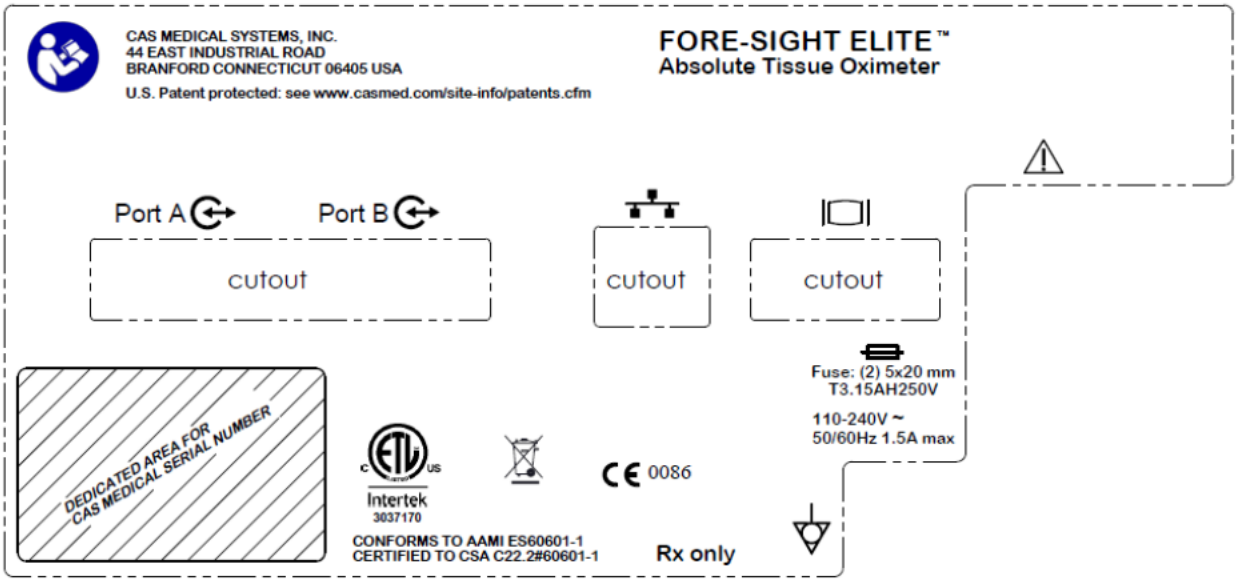
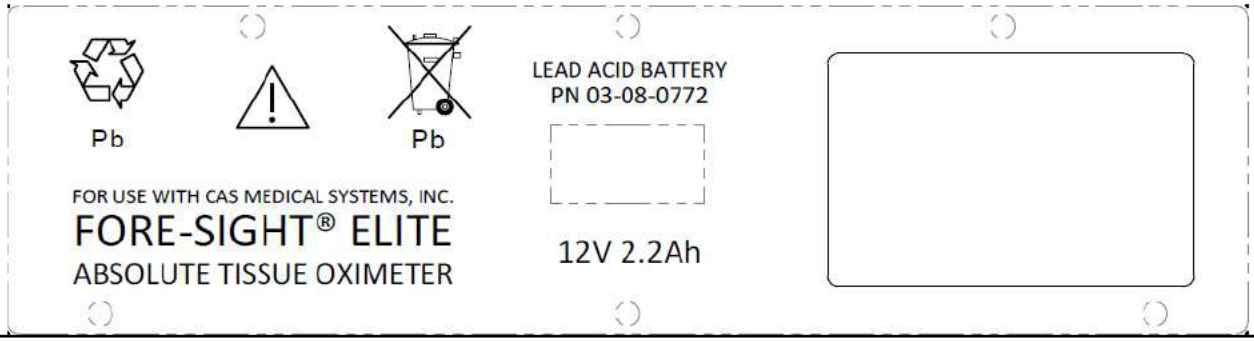
Copy of marking plate





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FORE-SIGHT
Absolute Tissue Oximetry ELITE™

x20

LARGE SENSORS
(includes alcohol prep pad)
REF 01-07-2103

SP: Sensor Grande **IT:** Sensore Grande **RU:** Большой Сенсор **FI:** Suuri Anturi
FR: Capteur Grand **NL:** Grote Sensor **DA:** Stor Sensor **NO:** Stor Sensor
PT: Sensor Grande **DE:** Großer Sensor **PL:** Duży Czujnik **CS:** Velký snímač

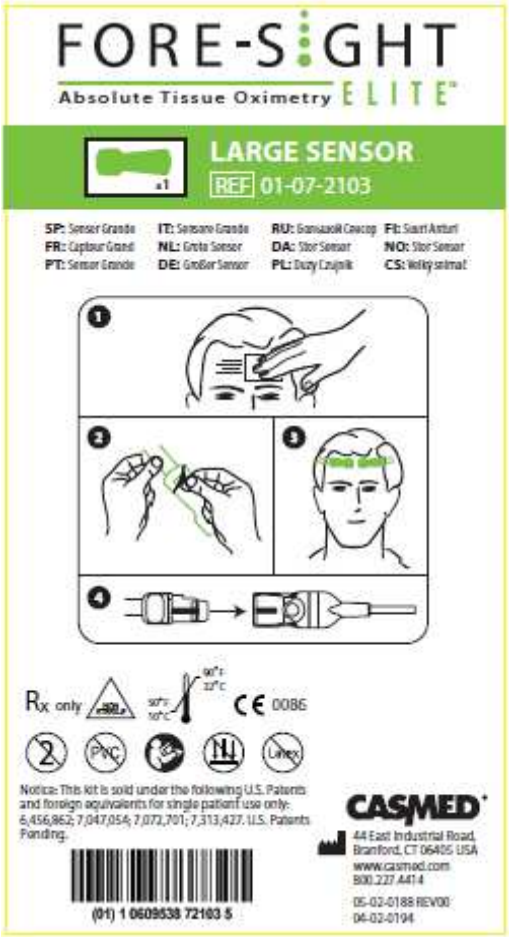
90°F 32°C
50°F 10°C
Rx only
CE 0086

05-02-0188 REV00
04-02-0194

CASMED®
44 East Industrial Road,
Branford, CT 06405 USA
www.casmed.com
800.227.4414

EC REP
MediMark® Europe.
11 rue E. Zola 38100
Grenoble. France

(01) 1 0609538 72103 5



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	portable
Device type (component/sub-assembly/ equipment/ system). :	Equipment
Intended use (Including type of patient, application location) . :	continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle
Mode of operation ..... :	Continuous
Supply connection ..... :	internally powered / appliance coupler
Accessories and detachable parts included ..... :	Preamp cables, Sensors
Other options include..... :	N/A
Testing	
Date of receipt of test item(s) ..... :	2013/09/16
Dates tests performed ..... :	2013/09/09/ – 2013/09/20
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement.....:	N/E
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition .....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection .....: MOPP

General remarks:
"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Manufacturer's Declaration per sub-clause 6.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :

☐ Yes
☒ Not applicable

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) ..... : CAS Medical Systems
44 East Industrial Road
Branford, CT 06405

General product information:

The product covered in this report is a 110-240 VAC, Single Phase, ABSOLUTE TISSUE OXIMETER, intended to be installed indoors

The Model FORE-SIGHT ELITE™ 01-06-3000 Series Monitor is a pre-configured monitor that can include the following measurement functions

- Absolute tissue oxygen saturation (StO2)

The FORE-SIGHT ELITE Oximeter is indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states.

M1: G100742469 2013-10-28

03-05-0511 03+ Oximeter sensor construction had following changes

- Use alternate 5 mil (0.127 mm) thick FEP film into sensor bottom foam laminate construction for insulation;
- flexible circuit assembly increased sealed edge perimeter to 1 mm and insulating cover lay thickness to 25 µm; also the stiffener behind the photodiodes on flexible circuit changed to non-conductive FR4

Also the report updates are listed in the following pages

- Added test list on page 3
- Added M1 information in product general information on page 7
- Added alternate Teflon FEP in critical component list on page 9
- Added oximeter sensor in critical components list on page 10
- Add test data due to the modification on page 10 to 14
- Pictures for modified new Oximeter sensor on page 15
- Added test equipment list page 16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.10	TABLE: List of critical components				Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity [1]
CAS Medical Hospital Grade Power Cord with Ferrite Bead	Feller Power Cords CCA-WESCO	Part No. 6922 CBL-PWR-SP30-FB-UK	SJT 3x 18AWG, rated 125VAC, 10A H05VV-F 32/0.2 BAx3C 250Vac,13A	UL62	UL, CSA VDE
AC Power Entry Module, Filtered	Tyco / Corcom	PE000DL6C	250VAC, 6A	UL 544, IEC 60601-1	UL, CSA, TUV
Primary Fuses (2 Provided)	Littelfuse	02153.15P	5x20mm type, T3.15AH250V, rated 250V, 3.15A slow-blow	IEC 60127	UL, CSA, TUV
Power Supply	Emerson / Astec	NPS-44M	100/250 VAC, 50/60Hz 2.5A	UL 60601-1/A2:1995	UL, CSA, TUV
Battery	Panasonic	LC-R122R2P	12V, 2.2aH, 0.33A Trickle Charge Current	UL 1989	UL
92x22mm Tube Axial Cooling Fan	NIDEC	U92T12MUA7-58 T92T12MUA7-58	12VDC, 0.25A, 3.0W, 3100RPM, 52CFM	UL 507	UL, CSA, TUV
Power Line Filter	Tyco / Corcom	3EHQ3	250VAC, 3A Medical Grade	UL60601-1	UL, CSA, TUV
F1	Littlefuse	0154002.DR	FUSEBLOCK W/2.0A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
F2,F4	Littlefuse	154.250DR	FUSEBLOCK W/.250A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
F3,F5	Littlefuse	154.125DR	FUSEBLOCK W/.125A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
T1	HALO	TGS110-S055NCRL	ETHERNET ISOLATION TRANSFORMER, UL, 1500V, 4MM CREEPAGE	UL 60601-1/A2:1995	UL
U44,U46	Linear Technology	LTM2882CY-3#PBF	IC, Transceiver, RS232, Isolated Isolated 2500 VRMS	UL 60950,RoHS	UR
U63	RECOM	RSO-1205S/H3 RS-1205S/H3	DC-DC Converter, 9-18V in, 5V out, Isolated 3kV	Tested in end system	-

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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C280 on PCB Assy # 03-59-0402	TDK	CD85-E2GA102MYNS	Cap, Cer, 1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	IEC/EN 60384-14 IEC/EN 60065 UL 1414 CSA C22.2 No.0 & No.1	UL, VDE, CSA, BSI, SEMKO, SEV, FIMKO, DEMKO, NEMKO, IMQ
C1 on PCB assy # 03-59-0403	TDK	CD85-E2GA102MYNS	Cap, Cer, 1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	IEC/EN 60384-14 IEC/EN 60065 UL 1414 CSA C22.2 No.0 & No.1	UL, VDE, CSA, BSI, SEMKO, SEV, FIMKO, DEMKO, NEMKO, IMQ
Coin cell battery on PCB assy 03-59-0402	Panasonic	BR1225	Battery, Coin Cell, Lithium, 48 mAh, 12.5 mm	UL 1642	UL
U64,U65,U66, U67	Silicon Laboratories	Si8640ED-B-IS Si8640BD-B-IS	IC, Digital Isolator, Quad channel, Wide Body SOIC-16, RoHS	IEC 60950-1, 61010-1, 60601-1 (reinforced insulation)	UL, CSA, VDE
Teflon FEP Fluorocarbon Film Tape	CS Hyde DuPont High Performance Films	23-FEP	FEP (Teflon®) film w/ Silicone Adhesive, 0.0035” Thick	Tested by Intertek met 5000VAC dielectric withstand	-
Alternate Teflon FEP Fluorocarbon Film Tape	DuPont High Performance Films	C-20	FEP (Teflon®) film w/ Silicone Adhesive, 0.005” Thick, 6500 V/mil	Tested by Intertek met 5000VAC dielectric withstand	-
Poron Foam	Rogers Corp.	4701-30-25035-34	Urethane foam 0.0035” thick	Tested by Intertek met 2500VAC dielectric withstand	-
Plastic enclosure	Plastic Design International	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene	UL 94	UR
Metal enclosure	Metalmen	Aluminum 5052-H32	Aluminum 5052-H32	Tested in end system	-
Sensors	CASMEDICAL	03-05-0511 03+	Disposable oximeter sensor	Tested in end system	-
Mylar Tape	3M™	Polyimide Film Tape 5413	Kapton® Polyimide Film Silicone Dielectric Strength: 7000 volts	UL 94 Tested by Intertek met 4000 VAC dielectric withstand	UL
Supplementary information: 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies				Pass
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
9	Foil underneath equipment	All 03-05-0511 03+ sensors tied together	+	490 mV	Pass
9	Foil underneath equipment		-	400 mV	Pass
9	Foil on enclosure		+	490 mV	Pass
9	Foil on enclosure		-	400 mV	Pass
9	Monitor SIP SOP		+	450 mV	Pass
9	Monitor SIP SOP		-	470 mV	Pass
9	Ethernet		+	450 mV	Pass
9	Ethernet		-	470 mV	Pass
9	Port A		+	840 mV	Pass
9	Port A		-	580 mV	Pass
9	Port B		+	450 mV	Pass
9	Port B		-	470 mV	Pass
9	USB		+	450 mV	Pass
9	USB		-	470 mV	Pass
9	USB front		+	840 mV	Pass
9	USB front		-	580 mV	Pass
10	Foil underneath equipment	One 03-05-0511 03+ sensor, rest tied to ground	+	760 mV	Pass
10	Foil underneath equipment		-	580 mV	Pass
10	Foil on enclosure		+	0.0 mV	Pass
10	Foil on enclosure		-	0.0 mV	Pass
10	Monitor SIP SOP		+	820 mV	Pass
10	Monitor SIP SOP		-	760 mV	Pass
10	Ethernet		+	820 mV	Pass
10	Ethernet		-	760 mV	Pass
10	Port A		+	0.0 mV	Pass
10	Port A		-	600 mV	Pass
10	Port B		+	820 mV	Pass
10	Port B		-	760 mV	Pass
10	USB		+	820 mV	Pass
10	USB		-	760 mV	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10	USB front	+	0.0 mV	Pass
10	USB front	-	600 mV	Pass
Supplementary information:				

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time			Pass
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
All 03-05-0511 03+ sensor tied together	+/-	20	0.0	Remained 0 at all measurements made above
Supplementary information:				

8.5.5.2	TABLE: defibrillation-proof applied parts or patient connections of defibrillation-proof applied parts - Energy reduction test –measurement of Energy delivered to a 100 Ω load		Pass
Test Voltage applied to	Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy E1 as % of E2 (%)
one 03-05-0511 03+ sensor with the rest of 3 same type sensors connected to earth	375.7	375.4	100%
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 Ω with ME Equipment connected; E2= Measured energy delivered to 100 Ω without ME equipment connected.			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.7	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks	
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
Only Oximeter sensor structure changed. No earth leakage re-test required					
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC	
Only Oximeter sensor structure changed. No touch current re-test required					
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)	
B, NC (S1=0, S5=1, S7=1, S13=1)	264	60	0.8	03-05-0511 03+	
B, SFC (S1=0, S5=0, S7=0, S13=0)	264	60	2.1	03-05-0511 03+	
A, NC (S1=0, S5=1, S7=1, S13=1)	264	60	1.5	03-05-0511 03+	
A, SFC (S1=0, S5=0, S7=0, S13=0)	264	60	4.0	03-05-0511 03+	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 uA Type CF AP: 50 uA	
B, SFC (S5=1, S9=0, S13=1)	264	60	11.0	03-05-0511 03+	
A, SFC (S5=0, S9=1, S13=1)	264	60	31.0	03-05-0511 03+	
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC(d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)	
N/A	-	-	-	-	
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 uA Type CF: N/A	
N/A	-	-	-	No unearthed metal accessible part	
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC;50 uA SFC (d.c. or a.c. current)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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B, NC (S1=0, S5=0, S7=1)	264	60	0.7	03-05-0511 03+ One sensor tested at a time with all others tied together
B, SFC (S1=0, S5=0, S7=0)	264	60	3.5	
A, NC (S1=0, S5=0, S7=1)	264	60	2.8	
A, SFC (S1=1, S5=0, S7=0)	264	60	8.5	
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
B, NC (S1=0, S5=1, S7=1)	264	60	2.2	03-05-0511 03+ All sensors tied together
B, SFC (S1=0, S5=0, S7=0)	264	60	9.3	
A, NC (S1=1, S5=0, S7=1)	264	60	15.9	
A, SFC (S1=0, S5=0, S7=0)	264	60	33.8	
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC;1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
N/A	-	-	-	-
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000uA Type CF: 100 uA
N/A	-	-	-	-
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 uA Type CF: N/A
N/A	-	-	-	NO unearthed accessible metal part

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device	A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				Pass
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
Sensor to Sensor connector (B-d)	BI	240	-	1500	No
Sensor to plastic enclosure (B-d)	BI	240	-	1500	No
Sensor to Primary(B-a)	BI	240	-	4000	No

Supplementary information: 03-05-0511 03+ before and after humidity condition

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Oximeter sensor 03-05-0511 03+

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TEST EQUIPMENT LIST (Tested 2013/09/09/ – 2013/09/20)					
Item	**Equipment Type**	**Make**	**Model No.**	**Serial No.**	**Next Cal. Due**
1	Weather condition station	Davis Instruments	Vue / 6351	G120425D113	01/29/2014
2	A/C Power Source	Chroma	6415	641500000517	12/20/2013
3	Medical/ITS/Industrial switch and leakage test box	ITS	JP2	SAF507	12/27/2013
4	True RMS Multimeter	Fluke	87 V	14840227	02/27/2014
5	Impulse Tester	Compliance West	MegaPulse Defib-5P	431777	Verified
6	High Voltage Probe	Tektronix	P6015A	B041429	03/11/2014
7	Electrical safety Compliance Analyzer	Associated Research	8006	9340041	01/30/2014
8	Digital Oscilloscope	Rigol Technologies	DS6104	DS6125200116	12/04/2013
9	Temp/Humidity Chamber	Envirotronics	SH27C	08015563S11263	10/18/2013
10	Temp/Humidity Chamber	Envirotronics	SH27C	08015563S11264	10/18/2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Report issued under the responsibility of:

Intertek

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No. ..... :	100742469BOX-001
Date of issue ..... :	2012, November 15 .....
Total number of pages ..... :	200 .....
CB Testing Laboratory ..... :	Intertek Testing Services NA Inc.
Address ..... :	70 Codman Hill Road Boxborough, MA 01719 USA
Applicant's name ..... :	CAS Medical Systems Inc.
Address ..... :	44 East Industrial Road Branford, CT 06405
Test specification:	
Standard ..... :	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
Test procedure ..... :	CB Scheme
Non-standard test method……..:	
Test Report Form No. ..... :	IEC60601_1G
Test Report Form Originator ..... :	Underwriters Laboratories Inc.
Master TRF ..... :	Dated 2010-11

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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo shall be removed

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description ..... :	Absolute Tissue Oximeter
Trade Mark ..... :	CASMED®
Manufacturer ..... :	CAS Medical Systems
Model/Type reference ..... :	FORE-SIGHT Elite 01-06-3000 (US) and 01-06-3005 (OUS)
Ratings ..... :	110-240 V~, 50/60 Hz, 1.5 A Max

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Testing procedure and testing location:		
☒ CB Testing Laboratory:	Intertek Testing Services NA Inc.	
Testing location/ address ..... :	70 Codman Hill Road Boxborough, MA 01719 USA	
☐ Associated CB Test Laboratory:		
Testing location/ address ..... :		
Tested by (name + signature) ..... :	Tell Bailey	*Signature on file*
Approved by (+ signature)..... :	Greg Wheeler	*Signature on file*
☐ Testing procedure: TMP		
Tested by (name + signature) ..... :		
Approved by (+ signature)..... :		
Testing location/ address ..... :		
☐ Testing procedure: WMT		
Tested by (name + signature) ..... :		
Witnessed by (+ signature) ..... :		
Approved by (+ signature)..... :		
Testing location/ address ..... :		
☐ Testing procedure: SMT		
Tested by (name + signature) ..... :		
Approved by (+ signature)..... :		
Supervised by (+ signature) ..... :		
Testing location/ address ..... :		
☐ Testing procedure: RMT		
Tested by (name + signature) ..... :		
Approved by (+ signature)..... :		
Supervised by (+ signature) ..... :		
Testing location/ address ..... :		

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List of Attachments (including a total number of pages in each attachment):

Attachment #	Description	Pages
1	Photographs of System	181-184
2	Country Deviations	185-196
3	Test Equipment List	195-198
4	CB certificate for power supply	199-200
100742469BOX-005A	IEC 60601-1-6	9
100742469BOX-005B	IEC 62366	13
100742469BOX-006	IEC 60601-1-8	18

Summary of testing:

Tests performed (name of test and test clause):

4.11	Power Input	8.11.3.6	Cord Guard Flexing (Cord Bending)
5.7	Humidity Preconditioning	9.3	Surfaces, Corners and Edges
5.9, 8.3	Determination of Applied Parts and Access ble Parts	9.4.2.1	Instability in Transport Position
7.1.2	Leg bility of Markings	9.4.2.2	Instability Excluding Transport
7.1.3	Durability of Markings	9.6.2.1	Sound Pressure Level Measurement
8.4.3	Residual Voltage in Attachment Plug	11.1	Temperatures
8.5.5.1a	Def brillation-Proof Applied Parts	11.6.3	Spillage
8.5.5.1b	Def brillation-Proof Recovery Time	11.6.6 11.6.7	Cleaning of ME equipment
8.5.5.2	Energy Reduction	11.8	Interruption of power supply
8.6.4	Earthing	13.2.7	Impairment of cooling
8.7	Leakage Current	15.3.2	Push Test (30mm dia plane)
8.8.3	Dielectric Strength	15.3.3	Impact Test (300 g steel ball)
8.8.4.1	Ball Pressure	15.3.4.1	Drop test hand-held ME equipment (drop test)
8.9.4	Creepage Distances and Air Clearance	15.3.4.2	Drop test portable ME equipment (rough handling)
8.11.3.5	Strain Relief (Cord Anchorage)	15.3.6	Mold Stress relief

Testing location:

Intertek Testing Services NA Inc.

70 Codman Hill Road

Boxborough, MA 01719 USA

Summary of compliance with National Differences

List of countries addressed: US, CA, CH, EN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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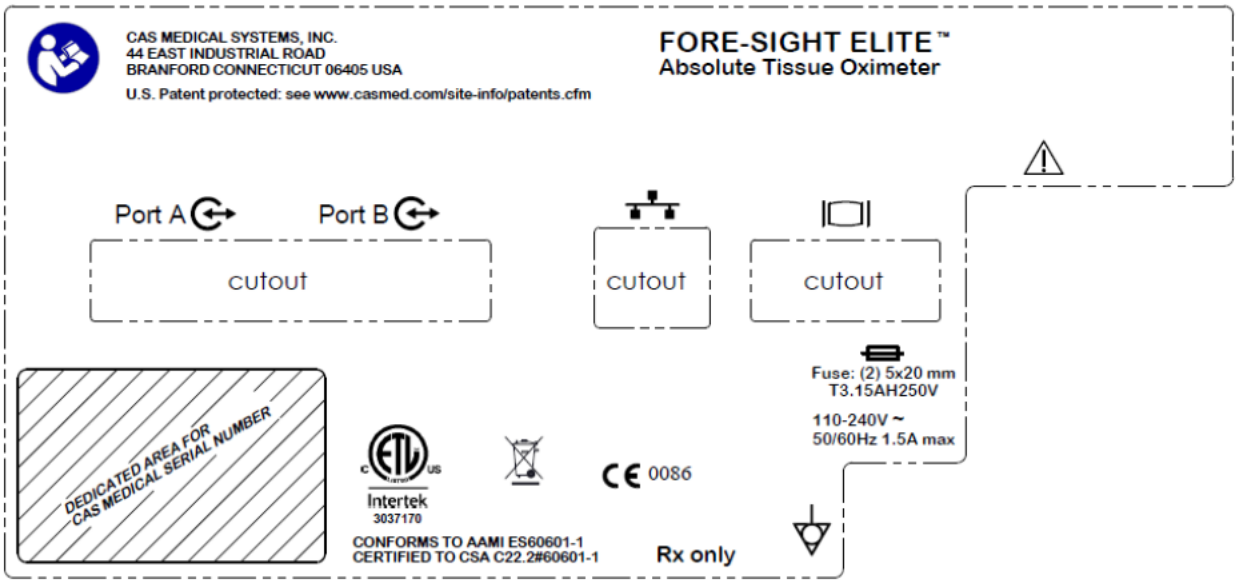
Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FORE-SIGHT
Absolute Tissue Oximetry ELITE™

x20

LARGE SENSORS
(includes alcohol prep pad)
REF 01-07-2103

SP: Sensor Grande **IT:** Sensore Grande **RU:** Большой Сенсор **FI:** Suuri Anturi
FR: Capteur Grand **NL:** Grote Sensor **DA:** Stor Sensor **NO:** Stor Sensor
PT: Sensor Grande **DE:** Großer Sensor **PL:** Duży Czujnik **CS:** Velký snímač

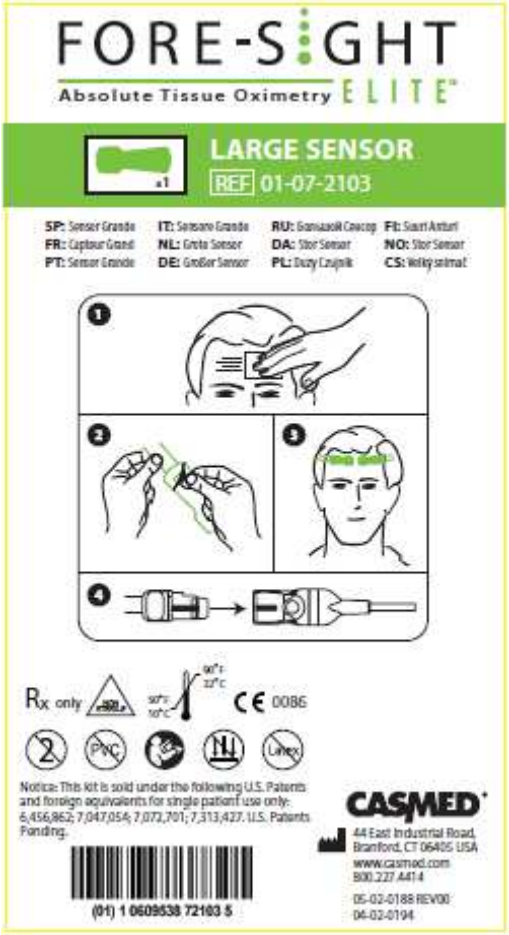
50°F 10°C / 90°F 32°C
Rx only
CE 0086

05-02-0188 REV00
04-02-0194

CASMED®
44 East Industrial Road,
Branford, CT 06405 USA
www.casmed.com
800.227.4414

EC REP
MediMark® Europe.
11 rue E. Zola 38100
Grenoble. France

(01) 1 0609538 72103 5



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GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	portable
Device type (component/sub-assembly/ equipment/ system). :	Equipment
Intended use (Including type of patient, application location) . :	continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle
Mode of operation ..... :	Continuous
Supply connection ..... :	internally powered / appliance coupler
Accessories and detachable parts included ..... :	Preamp cables, Sensors
Other options include..... :	N/A
Testing	
Date of receipt of test item(s) ..... :	2012/08/07
Dates tests performed ..... :	2012/08/07/2012 – 2012/11/15
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement.....:	N/E
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition .....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection .....: MOPP

General remarks:
"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

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Manufacturer's Declaration per sub-clause 6.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ Yes ☒ Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) ..... :	CAS Medical Systems 44 East Industrial Road Branford, CT 06405
General product information: The product covered in this report is a 110-240 VAC, Single Phase, ABSOLUTE TISSUE OXIMETER, intended to be installed indoors The Model FORE-SIGHT ELITE™ 01-06-3000 Series Monitor is a pre-configured monitor that can include the following measurement functions • Absolute tissue oxygen saturation (StO2) The FORE-SIGHT ELITE Oximeter is indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states.	

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

(b)(4)

[redacted]

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: To insulation diagram		Pass
Pollution degree .....:	II	—
Overvoltage category.....:	II	—
Altitude.....:	132.6 meters above sea level	—
Additional details on parts considered as applied parts.....:	☐ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage Vrms	Working voltage Vpk	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	Basic OP	IIIb	250	354	3	1.6	7.5	7.5	Between L and N Worst case is the appliance inlet also has a certified power supply
B	1 MOPP	IIIb	250	354	4	2.5	4.3	4.3	Primary trace near F2/C1 to PE
C	2 MOPP	IIIb	250	354	8	5	Certified power supply		Primary to secondary
D	1 MOPP	IIIb	250	354	4	2.5	4.3	4.3	From 15 VDC to the enclosure
F	1 MOPP	IIIb	250	354	4	2.5	4	4	Ethernet
G	1 MOPP	IIIb	250	354	4	2.5	4	4	SIPSOP
H	1 MOPP	IIIb	250	354	4	2.5	4	4	SIPSOP
L	1 MOPP	IIIb	250	354	4	2.5	11.3	11.3	Power switch
M	1 MOPP	IIIb	250	354	4	2.5	36	36	Screen
N	1 MOPP	IIIb	250	354	4	2.5	36	36	LEDs
R	1 MOPP 2 MOPP	IIIb	250 -	354 15	4 4	2.5 2.0	Met by solid insulation		Preamp enclosure to preamp connection
S	1 MOPP 2 MOPP	IIIb	250 -	354 15	4 4	2.5 2.0	Met by solid insulation		Sensor voltage to preamp enclosure
T	1 MOPP 2 MOPP	IIIb	250 -	354 15	4 4	2.5 2.0	4	4	Applied part to live parts

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

U	1 MOPP	IIIb	250	354	4	2.5	4	4	Sensor voltage to the enclosure

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4	GENERAL REQUIREMENTS		—
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		Pass
4.2	A RISK MANAGEMENT PROCESS complying with ISO 14971 was performed ..... :	Compliance with ISO 14971, as required by subclause 4.2, has been established by performing an inspection (desk-top audit) of the Risk Management File. See Appended RM Results Table 4.2	Pass
4.3	ESSENTIAL PERFORMANCE functions identified according to MANUFACTURER'S policy for RISK acceptability in RISK MANAGEMENT FILE ..... :	See Appended Table 4.3 and RM Results Table 4.3	Pass
	ESSENTIAL PERFORMANCE functions maintained following particular tests as applicable		Pass
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE..... :	21-07-0304 Section 3.2 Expected Service Life 11 yrs	Pass
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means equal to or less than RESIDUAL RISKS resulting from requirements of this standard ..... :	See Appended RM Results Table 4.5	N/A
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10 ..... :	See Appended Insulation Diagram Table and RM Results Table 4.6	Pass
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2..... :	See Appended RM Results Table 4.7	Pass
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically ..... :	See Appended Table 13.2 for simulated physical test,	Pass
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation		Pass
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, except as specified, or by RISK MANAGEMENT PROCESS ..... :	See Appended RM Results Table 4.8	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following:		N/A
	a) Applicable safety requirements of a relevant IEC or ISO standard		N/A
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		N/A
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK ..... :	See appended Table 8.10 & RM Results Table 4.9	N/A
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 4.9	N/A
4.10	Power supply		Pass
4.10.1	ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three ..... :	Supply mains or internally powered	Pass
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS is 250 V for HAND-HELD ME EQUIPMENT (V) ..... :	Not hand-held	N/A
	– 250 V d.c. or single-phase a.c., or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V) ..... :	110-240 VAC	Pass
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
4.11	Power input		Pass
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use did not exceed marked rating by more than 10%..... :	See appended Table 4.11	Pass
	– Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range :	See appended Table 4.11	Pass
	Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage ..... :	See appended Table 4.11	Pass
5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		—
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2		Pass
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods..... :	See Appended RM Results Table 5.1	N/A
	Results of RISK ANALYSIS used to determine combination(s) of simultaneous faults to be tested		Pass
5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected ..... :		Pass
5.3	a) Tests conducted within the environmental conditions specified in technical description		Pass
	Temperature (ºC), Relative Humidity (%) ..... :	10 °C to 40 °C, 30 to 75% RH, non-condensing	Pass
	Atmospheric Pressure (kPa) ..... :	680 hPa to 1060 hPa	Pass
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests		Pass
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained ..... :		N/A
5.4	a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use and identified during RISK ANALYSIS, except as noted ..... :	See Appended RM Results Table 5.4a	Pass
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favourable for the relevant test per instructions for use		Pass
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits in technical description..... :		N/A
	d) Potable water used for cooling		N/A
5.5	Supply voltage during tests was the least favorable of the voltages specified in 4.10 or voltages marked on ME EQUIPMENT (V) ..... :	110-240 V~	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz) .....:	50/60 Hz	Pass
	ME EQUIPMENT with more than one RATED voltage, or both a.c./ d.c. tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current.....:	110-240 V~	Pass
	ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions.....:	Accessories found in the IFU	Pass
	ME EQUIPMENT connected to a separate power supply as specified in instructions for use		Pass
5.6	When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample		Pass
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted		N/A
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3 .....:	No covers	N/A
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached	No such parts	N/A
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93 % ± 3 % and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h		Pass
	When RISK MANAGEMENT PROCESS indicated ME EQUIPMENT can be exposed to high humidity for extended periods (i.e., out-door use), test time extended proportionally (h) .....:	See Appended RM Results Table 5.7	N/A
5.8	Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent results of one test on a subsequent test		Pass
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		Pass
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS .....:	See clause 4.6 Remark	Pass
5.9.2	ACCESSIBLE PARTS		Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.9.2.1	Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position	See Appended Table 5.9.2	Pass
	Openings preventing entry of test finger of Fig. 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N		Pass
	When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening		N/A
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		Pass
	All additional parts that became accessible checked using standard test finger and by inspection		N/A
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS .....:		N/A
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL, and inspection of RISK MANAGEMENT FILE indicated the relevant part is unlikely to detach unintentionally during EXPECTED SERVICE LIFE of ME EQUIPMENT.:	See Appended RM Results Table 5.9.2.3	N/A
6	CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS		—
6.2	CLASS I ME EQUIPMENT, externally powered		Pass
	CLASS II ME EQUIPMENT, externally powered		N/A
	INTERNALLY POWERED ME EQUIPMENT		Pass
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		Pass
	TYPE B APPLIED PART		N/A
	TYPE BF APPLIED PART		Pass
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		Pass
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN_1N_2) as per IEC 60529.....:	IPX0 See RM Results Table 11.6.5.	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use .....:	No parts intended to be sterilized	N/A
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2		N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION .....:	Continuous	Pass
7	ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS		—
7.1.1	RISK of poor USABILITY associated with the design of ME EQUIPMENT'S identification and marking addressed in a USABILITY ENGINEERING PROCESS ... :		Pass
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6 .....:	See Appended Table 7.1.2	Pass
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE		Pass
	a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with requirements in Clause 7.1.2..... :	See appended Tables 7.1.3 and 8.10	Pass
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test..... :	See appended Tables 7.1.3 and 8.10	Pass
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		Pass
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ..... :	See attached copy of Marking Plate	Pass
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS..... :		Pass
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		Pass
	A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01)..... :		Pass
7.2.2	MANUFACTURER's name or trademark marked on ME EQUIPMENT and detachable components ..... :	Components inspected: entire unit	Pass
	Misidentification does not present an unacceptable risk	See Appended RM Results Table 7.2.2	N/A
	MODEL OR TYPE REFERENCE also marked, except when misidentification would not present an unacceptable RISK..... :	See attached copy of Marking Plate	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons..... :	Software version displayed on startup	Pass
7.2.3	Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		N/A
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		Pass
7.2.4	ACCESSORIES marked with name or trademark of MANUFACTURER or supplier, and with a MODEL or TYPE REFERENCE..... :	Accessories inspected: preamps	Pass
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		Pass
7.2.5	MODEL or TYPE REFERENCE of equipment to be connected to ME EQUIPMENT to provide power, is marked adjacent to the relevant connection point when this connection could result in an unacceptable RISK ..... :	See Appended RM Results Table 7.2.5	N/A
7.2.6	Connection to the Supply Mains		Pass
	Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point		Pass
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to supply connection terminals	Not permanently installed	N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V) ..... :	110-240	Pass
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..... :		N/A
	– Nature of supply (e.g., No. of phases, except single-phase) and type of current ..... :	Symbol 1 used	Pass
	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all DB: 2002-10) used, optionally, for same parameters ... :		Pass
	– RATED supply frequency or RATED frequency range in hertz ..... :	50/60 Hz	Pass
	– Symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02) used for CLASS II ME EQUIPMENT..... :	Class I	N/A
7.2.7	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)..... :	1.5 A	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W) :		N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)..... :		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)..... :		N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W) ..... :		N/A
7.2.8	Output connectors		N/A
7.2.8.1	See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT		N/A
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment		N/A
	Rated Voltage (V), Rated Current (A)..... :		N/A
	Rated Power (W), Output Frequency (Hz) ..... :		N/A
7.2.9	ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2)..... :	IPX0	N/A
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6):		Pass
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, DB: 2002-10), not applied in such a way as to give the impression of being inscribed within a square in order to distinguish it from symbol IEC 60417-5333 ..... :		N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, DB: 2002-10)..... :		Pass
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, DB: 2002-10)..... :		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 (IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336, all DB: 2002-10) :		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Proper symbol marked adjacent to or on connector for APPLIED PART, except marked on APPLIED PART when there is no connector, or connector used for more than one APPLIED PART and different APPLIED PARTS with different classifications ..... :		Pass
	Safety sign 2 of Table D.2 (ISO 7010-W001) placed near relevant outlet when protection against effect of discharge of a cardiac defibrillator is partly in the PATIENT cable ..... :		Pass
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use..... :	IFU: 21-22-3000 Rev 00Xe.pdf Pg 13	Pass
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION		Pass
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time..... :	No duty cycle	N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	Verified on equipment	Pass
	Fuse type ..... :	T3.15AH250V	Pass
	Voltage (V) and Current (A) rating ..... :	250V 3.15A	Pass
	Operating speed (s) and Breaking capacity ..... :	T, H	Pass
7.2.13	A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR..... :		N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use ..... :	See Appended RM Results Table 7.2.13	N/A
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10)		N/A
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air)..... :		N/A
7.2.16	ME EQUIPMENT with limited mechanical stability		N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage..... :	No special handling	N/A
	Permissible environmental conditions for transport and storage marked on outside of packaging .....:		Pass
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK ..... :	See Appended RM Results Table 7.2.17	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile	No sterile equipment or accessories	N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector .....:		N/A
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, DB:2002-10) marked on FUNCTIONAL EARTH TERMINAL..... :	no functional earth	N/A
7.2.20	Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed:		N/A
	No marking applied when an interlock provided		N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)..... :	No heating elements	N/A
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		N/A
7.3.2	Symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts ..... :		N/A
7.3.3	Type of battery and mode of insertion when applicable is marked .....:	Custom battery	N/A
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL ..... :	Not intended to be charged by service personnel	N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion).....:	No lithium batteries	N/A
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS ..... :	See Appended RM Results Table 7.3.3	N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL, marked by type and full rating at the component or by reference to ACCOMPANYING DOCUMENTS	Fuses marked	Pass
	Type ..... :	T3.15AH250V	Pass
	Voltage (V) and Current (A) rating .....:	250V 3.15A	Pass
	Operating speed (s) and Breaking capacity .....:	high	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, DB: 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1		Pass
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		Pass
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, DB: 2002 -10) marked on FUNCTIONAL EARTH TERMINALS	No functional earth terminals	N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when no HAZARD would result when interchanging connections	See Appended RM Results Table 7.3.7	N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445)		N/A
	Marking for connection to a 3-phase supply, if necessary, complies with IEC 60445		N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	“For supply connections, use wiring materials suitable for at least X °C” (where X > than max temperature measured in terminal box or wiring compartment under NORMAL USE), or equivalent, marked at the point of supply connections		N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	Marking of controls and instruments		Pass
7.4.1	The “on” & “off” positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 (IEC 60417-5007, DB: 2002-10, and IEC 60417-5008, DB: 2002-10), or		N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	The “on/off” positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 DB: 2002-10), and		Pass
	– status indicated by adjacent indicator light		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– status indicated by other unambiguous means		Pass
	The “on/off” positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 DB: 2002-10), or		N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means		Pass
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE, or	See Appended RM Results Table 7.4.2	Pass
	– an indication of direction in which magnitude of the function changes		N/A
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 31 except the base quantities listed in Table 1 expressed in the indicated units		Pass
	ISO 1000 applied for application of SI units, their multiples, and certain other units		Pass
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3	See Appended Tables 7.1.2 and 7.1.3.	Pass
7.5	Safety signs		Pass
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010	See Appended RM Results Table 7.5	Pass
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		N/A
	Specified colours in ISO 3864-1 used for safety signs..... :	Safety sign 10	Pass
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		Pass
	Safety signs including any supplementary text or symbols described in instructions for use		Pass
7.6	Symbols		Pass
7.6.1	Meanings of symbols used for marking described in instructions for use..... :	See Appended Instruction for Use.	Pass
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced		Pass
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.7	Colours of the insulation of conductors		Pass
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation		Pass
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		Pass
7.7.3	Green and yellow insulation identify only following conductors:		Pass
	– PROTECTIVE EARTH CONDUCTORS		Pass
	– conductors specified in 7.7.2		Pass
	– POTENTIAL EQUALIZATION CONDUCTORS		Pass
	– FUNCTIONAL EARTH CONDUCTORS		N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue” specified in IEC 60227-1 or IEC 60245-1	Enclosed cord	N/A
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1		Pass
7.8	Indicator lights and controls		Pass
7.8.1	Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)		Pass
	Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)		Pass
	Green indicator lights mean: Ready for use		Pass
	Other colours, if used: Meaning other than red, yellow, or green (colour, meaning) .....:		N/A
7.8.2	Red used only for emergency control		Pass
7.9	ACCOMPANYING DOCUMENTS		Pass
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description	21-22-3000 Rev 000Xb	Pass
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		Pass
	– Name or trade-name of MANUFACTURER and an address the RESPONSIBLE ORGANIZATION can be referred to .....:	CAS Medical Systems, Inc. 44 East Industrial Road Branford, CT 06405 U.S.A.	Pass
	– MODEL or TYPE REFERENCE .....:	FORE-SIGHT ELITE	Pass
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CDROM), RISK MANAGEMENT PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (for emergency operation)	See Appended RM Results Table 7.9.1	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	21-22-3000 Rev 000Xb Intended Audience	Pass
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		Pass
7.9.2	Instructions for use include the required information		Pass
7.9.2.1	– intended use of ME EQUIPMENT,	21-22-3000 Rev 000Xb Indications for Use	Pass
	– frequently used functions, and		Pass
	– known contraindication(s) to use of ME EQUIPMENT	21-22-3000 Rev 000Xb Contraindications	Pass
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	21-22-3000 Rev 000Xb Oximeter Classifications of Electrical Insulation, Symbols	Pass
	Instructions for use are in a language acceptable to the intended operator		Pass
7.9.2.2	Instructions for use include all warning and safety notices		Pass
	Warning statement for CLASS I ME EQUIPMENT indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"	IFU: 21-22-3000 Rev 00Xe.pdf Pg 13	Pass
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	21-22-3000 Rev 000Xb Warnings in Installation and Setup	Pass
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	21-22-3000 Rev 000Xb Manufacturer's Declaration of Conformity	Pass
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET indicating, "connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety"		N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	21-22-3000 Rev 000Xb Standards	Pass
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating "power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM"		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source		N/A
	Warning to remove primary batteries when ME EQUIPMENT is not likely to be used for some time when leakage from battery would result in an unacceptable RISK.....:	See Appended RM Results Table 7.9.2.4	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided.....:	No such source power	N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK.....:	See Appended RM Results Table 7.9.2.4	N/A
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	21-22-3000 Rev 000Xb Basic Operations	Pass
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such exposure can constitute an unacceptable RISK		N/A
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected		Pass
	APPLIED PARTS specified	21-22-3000 Rev 000Xb Symbols	Pass
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation	21-22-3000 Rev 00Xb Installation and Setup	Pass
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device when an APPLIANCE COUPLER or separable plug is used as isolation means to meet 8.11.1 a)	IFU: 21-22-3000 Rev 00Xe.pdf Pg 14	Pass
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation including initial control settings, and connection to or positioning of PATIENT prior to use of ME EQUIPMENT, its parts, or ACCESSORIES	21-22-3000 Rev 00Xb Basic Operations	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.9	Information provided to operate ME EQUIPMENT including explanation of controls, displays and signals, sequence of operation, connection of detachable parts or ACCESSORIES, replacement of material consumed during operation	21-22-3000 Rev 00Xb Basic Operations	Pass
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	21-22-3000 Rev 00Xb Symbols, Responding to System Conditions	Pass
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	21-22-3000 Rev 00Xb Responding to System Conditions	Pass
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	21-22-3000 Rev 00Xb Stop Monitoring Patient	Pass
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	21-22-3000 Rev 00Xb Cleaning	Pass
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	Sensors single use	Pass
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	21-22-3000 Rev 00Xb Maintenance	Pass
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	21-22-3000 Rev 00Xb Maintenance	Pass
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	IFU: 21-22-3000 Rev 00Xe.pdf	Pass
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	21-22-3000 Rev 00Xb Maintenance	Pass
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	IFU: 21-22-3000 Rev 00Xe.pdf Pg 49	Pass
	Other equipment providing power to ME SYSTEM sufficiently described (e.g. part number, RATED VOLTAGE, max or min power, protection class, intermittent or continuous service)		N/A
7.9.2.15	RISKS associated with disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified, and instructions provided on minimizing these RISKS ..... :	21-22-3000 Rev 00Xb Device Handling	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)		Pass
7.9.3	Technical description		Pass
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following:		Pass
	– information as in clause 7.2	21-22-3000 Rev 00Xb Appendix - Symbols	Pass
	– permissible environmental conditions of use including conditions for transport and storage	21-22-3000 Rev 00Xb Specifications - Operating Environment, Storage/Transport Environment	Pass
	– all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found	21-22-3000 Rev 00Xb Specifications - Measurement	Pass
	– special installation requirements such as max. permissible apparent impedance of SUPPLY MAINS	21-22-3000 Rev 00Xb General Information	Pass
	– permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling		N/A
	– a description of means of isolating ME EQUIPMENT from SUPPLY MAINS, when such means not in ME EQUIPMENT	21-22-3000 Rev 00Xb Installation and Setup Warnings	Pass
	– a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable		N/A
	– a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples	IFU: 21-22-3000 Rev 00Xe.pdf Pg 37	Pass
	"WARNING: No modification of this equipment is allowed"		Pass
	"WARNING: Do not modify this equipment without authorization of the manufacturer"		N/A
	"WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment"		N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	– information as in clause 7.2		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT		N/A
	– a brief description of ME EQUIPMENT, how it functions, and its significant physical and performance characteristics		N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		N/A
7.9.3.2	The technical description contains the following required information		Pass
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, when type and rating of fuses are not apparent from information on RATED current and mode of operation of ME EQUIPMENT.....:	See Appended RM Results Table 7.9.3.2	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure compliance with 8.11.3		N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and		Pass
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	IFU: 21-22-3000 Rev 00Xe.pdf Pg 13	Pass
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair	IFU: 21-22-3000 Rev 00Xe.pdf Pg 37	Pass
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	21-22-3000 Rev 00Xb Installation and Setup Warnings	Pass

8	PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT		—
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		Pass
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a)		Pass
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)..... :	See Appended RM Results Tables 8.1b(1), (2), (3)	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCESSIBLE PARTS determined according to 5.9		Pass
	LEAKAGE CURRENTS measured according to 8.7		Pass
8.2	Requirements related to power sources		N/A
8.2.1	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM		N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	No HAZARDOUS SITUATION other than absence of ESSENTIAL PERFORMANCE developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	See Appended RM Results Table 8.2.2	N/A
	ME EQUIPMENT connected with correct polarity did not present an unacceptable RISK		N/A
	Protective devices that can be reset by anyone without a TOOL restore correct operation on reset		N/A
8.3	Classification of APPLIED PARTS		Pass
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF		N/A
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		Pass
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF		N/A
	d) Requirements of a TYPE B APPLIED PART applied to a part in 4.6 to be subjected to requirements for an APPLIED PART (except marking)		N/A
	Requirements for a TYPE BF or CF APPLIED PART applied as in RISK MANAGEMENT PROCESS	See Appended RM Results Table 8.3d	N/A
8.4	Limitation of voltage, current or energy		Pass
8.4.1	PATIENT CONNECTIONS intended to deliver Current		N/A
	Limits in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE		N/A
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured according to Clause 8.7.4..... :	See appended Table 8.7	Pass
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA)..... :	See appended Table 8.7	Pass
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed	See Appended RM Results Table 8.4.2c	N/A
	– accessible contacts of connectors		N/A
	– contacts of fuseholders accessible during replacement of fuse		N/A
	– contacts of lampholders accessible after removal of lamp	No lampholders	N/A
	– parts inside an ACCESS COVER that can be opened without a TOOL, or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER	No such access covers	N/A
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.)..... :	See appended Table 8.4.2	N/A
	Limit of 60 V d.c applied with no more than 10% peak-to-peak ripple, and when ripple larger than specified value, 42.4 V peak limit applied (V d.c.):	See appended Table 8.4.2	N/A
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V (VA or J) ..... :	See appended Table 8.4.2	N/A
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA) ..... :	See appended Table 8.4.2	N/A
	d) Voltage and energy limits specified in c) above also applied to the following:		N/A
	– internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls using a TOOL		N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N/A
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		N/A
	Test repeated with a TOOL specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		N/A
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION		N/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnecting the plug of ME EQUIPMENT or its parts (V) ..... :	See appended Table 8.4.3	Pass
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform		Pass
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC..... :	See appended Table 8.4.3	N/A
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC..... :	See appended Table 8.4.4	N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, DB: 2002-10), and manual discharging device specified in technical description..... :		N/A
8.5	Separation of parts		Pass
8.5.1	MEANS OF PROTECTION (MOP)		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4		Pass
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account Clause 4.6, and flow chart in Fig A.12		Pass
	Varnishing, enameling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		Pass
	Coatings and other insulation intended as a MEANS OF PROTECTION complying with IEC 60950-1:2001 considered acceptable as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION	None used a MOP	N/A
	RISK MANAGEMENT PROCESS taken into consideration for MEANS OF PATIENT PROTECTION		Pass
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		Pass
	Insulation, CREEPAGE, CLEARANCES, components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION, and failure of these parts regarded as NORMAL CONDITION		Pass
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		Pass
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6		Pass
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		Pass
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		Pass
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF PATIENT PROTECTION considered equivalent to one MEANS OF PATIENT PROTECTION	See Appended Tables 8.8.3 and 8.10	Pass
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Not used	N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :	1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	Pass
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		Pass
	– dielectric strength test of 8.8 at test voltage of Table 6; or		Pass
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		Pass
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		Pass
	– limits of Tables 13 to 16 (inclusive); or		Pass
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		Pass
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6, or		Pass
	– requirements and tests of IEC 60950-1 for protective earthing ..... :		Pass
	A Y2 capacitor complying with IEC 60384-14 and passing dielectric strength test for one MEANS OF OPERATOR PROTECTION considered equivalent to one MEANS OF OPERATOR PROTECTION..... :	See Appended Tables 8.8.3 and 8.10 None used	N/A
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF OPERATOR PROTECTION considered equivalent to two MEANS OF OPERATOR PROTECTION ..... :	See Appended Tables 8.8.3 and 8.10	Pass
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Not used	N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :	1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	Pass
	Points at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION	No such points	N/A
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION..... :		Pass
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION ..... :		Pass
8.5.2	Separation of PATIENT CONNECTIONS		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to maximum MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT at 110 % of max. MAINS VOLTAGE ..... :	See appended Table 8.7	Pass
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		Pass
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		Pass
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :		Pass
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	BF, defibrillation proof	Pass
	LEAKAGE CURRENT tests conducted per 8.7.4 ..... :	See appended Table 8.7	Pass
	Dielectric strength test conducted per 8.8.3 ..... :	See appended Table 8.8.3	Pass
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		Pass
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		Pass
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED..... :	See Appended RM Results Table 8.5.2.2	N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N/A
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 ..... :	See appended Table 8.7	N/A
	Dielectric strength test conducted per 8.8.3 ..... :	See appended Table 8.8.3	N/A
	Relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		N/A
	The RISK MANAGEMENT FILE reviewed		N/A
8.5.2.3	A connector on a PATIENT lead located at the end of the lead remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT ..... :	No patient leads	N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N/A
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, except when RISK MANAGEMENT PROCESS indicated no unacceptable RISK existed from contact with objects other than a mains socket or a flat surface:	See Appended RM Results Table 8.5.2.3	N/A
8.5.3	MAXIMUM MAINS VOLTAGE		Pass
	– MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, as well as INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V) ..... :	240 VAC	Pass
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V		N/A
	– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V) ..... :		N/A
	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V	35VDC	Pass
8.5.4	WORKING VOLTAGE		N/A
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)..... :	Certified power supply	N/A
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V) ..... :	Certified power supply	N/A
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) ..... :	See Insulation Diagram and Insulation Table Certified power supply	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	Certified power supply	N/A
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V) ..... :	Certified power supply	N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	Certified power supply	N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) ..... :	Certified power supply	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS		Pass
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART		Pass
	Possibility of an OPERATOR receiving a shock from such parts taken into consideration in RISK MANAGEMENT PROCESS	21-07-0304 and 21-07-0306 Hazard 4.1.1.8	Pass
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		Pass
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :	See Appended Table 8.5.5.1a	Pass
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS ..... :	See Appended Table 8.5.5.1b	Pass
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90% of energy delivered to this load with ME EQUIPMENT disconnected ..... :	See Appended Table 8.5.5.2	Pass
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		Pass
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		Pass
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR..... :		Pass
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside ..... :		Pass
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		Pass
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		Pass
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE :	See Appended RM Results Table 8.6.3	Pass
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop	See appended Table 8.6.4	Pass
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits..... :	See appended Table 8.6.4 & Clause 8.7	Pass
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact		N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	Plugs and sockets		Pass
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		Pass
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		Pass
	– RISK of accidental disconnection minimized in NORMAL USE		Pass
	– Terminal allows conductor to be detached without a TOOL		Pass
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		Pass
	– Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021)		Pass
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		Pass
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		Pass
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	No functional earth	N/A
8.6.9	Class II ME EQUIPMENT		N/A
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow	Not Class II	N/A
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description ..... :		N/A
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		Pass
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3 .... :	See appended Tables 8.7	Pass
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7 ..... :	See appended Tables 8.7	Pass
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		Pass
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		Pass
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		Pass
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		Pass
8.7.3	Allowable Values		Pass
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b ..... :	See appended Tables 8.7	Pass
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz ..... :	See appended Tables 8.7	Pass
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})..... :	See appended Tables 8.7	Pass
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}) ..... :	See appended Tables 8.7	Pass
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 ..... :	See appended Tables 8.7	N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device..... :	See appended Tables 8.7	Pass
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements..... :	See appended Tables 8.7	Pass
8.8	Insulation		Pass
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER-CURRENT RELEASE		Pass
	Insulation exempted from test (complies with clause 4.8)	None exempt from testing	N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		Pass
8.8.2	Distance through solid insulation or use of thin sheet material		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	Not used	N/A
	a) 0.4 mm, min, distance through insulation, or		N/A
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N/A
	– at least two layers of material, each passed the appropriate dielectric strength test, or	See appended Table 8.8.3	N/A
	– three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test	See appended Table 8.8.3	N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		N/A
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N/A
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		N/A
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		N/A
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension ..... :		N/A
	Finished component complied with routine dielectric strength tests of 8.8.3 ..... :	See appended Table 8.8.3	Pass
	Tests of Annex L not repeated since material data sheets confirm compliance ..... :	See Table 8.10 and Material Information Attachment	N/A
8.8.3	Dielectric Strength		Pass
	Solid insulating materials with a safety function withstood dielectric strength test voltages ..... :	See appended Table 8.8.3	Pass
8.8.4	Insulation other than wire insulation		Pass
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		Pass
	ME EQUIPMENT and RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests ..... :	See Appended RM Results Table 8.8.4.1	Pass
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :	Test performed	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat..... :	Test performed	Pass
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using apparatus of Fig 21	See Table 8.8.4.1	Pass
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C) ..... :	See Table 8.8.4.1	N/A
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		N/A
8.8.4.2	Resistance to environmental stress		N/A
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples		N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		Pass
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15		Pass
8.9.1.2	Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested	Not used	N/A
8.9.1.3	Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics		Pass
8.9.1.4	When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE		Pass
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m		Pass
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m) ..... :		N/A
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used to determine multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor	Not pressurized	N/A
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.6	When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		Pass
	– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :	See Insulation Diagram/Table.	Pass
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :	See Insulation Diagram/Table.	Pass
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied		Pass
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group) ..... :	See Insulation Diagram/Table.	Pass
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112 ..... :	Not evaluated	N/A
	Material of unknown group considered IIIb		Pass
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N/A
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation		Pass
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation		N/A
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions		N/A
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION		N/A
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree		N/A
8.9.1.9	Overvoltage category classification; value of MAINS TRANSIENT VOLTAGE determined from overvoltage category per IEC60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10		Pass
	V_{MT} Peak (V) ..... :	2500	Pass
	V_{MN} r.m.s (V) ..... :	250	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.10	AIR CLEARANCE for MAINS PARTS (operating on RATED MAINS VOLTAGES up to 300 V) were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE	Max 250 VAC	N/A
8.9.1.11	SUPPLY MAINS overvoltage category II applied according to IEC 60664-1		Pass
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used		N/A
	When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for Cl. 8.9 used		N/A
8.9.1.12	A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)		N/A
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		N/A
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		Pass
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I		N/A
	Table 15 column for circuits not subject to transient overvoltages applied to:		N/A
	– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and		N/A
	– circuits in INTERNALLY POWERED ME EQUIPMENT		N/A
8.9.1.13	For PEAK WORKING VOLTAGES above 1400 V peak or d.c. Table 15 not applied since all the following conditions were met:		N/A
	– CLEARANCE was at least 5 mm		N/A
	– insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or		N/A
	– a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I		N/A
	Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material		N/A
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION		Pass
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1		Pass
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied..... :	See appended Table 8.9.2 Measurements applied	N/A
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		Pass
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by molding, or there is no reduction of a distance below specified value by deformation or movement of parts		Pass
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		Pass
8.9.3	Spaces filled by insulating compound		N/A
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound were such that CLEARANCES and CREEPAGE DISTANCES don't exist	No spaces filled with insulating compound	N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted		N/A
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6 ..... :	See appended Table 8.9.3.2	N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N/A
	A winding of solvent-based enameled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N/A
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage ..... :	See appended Table 8.9.3.4	N/A
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage		N/A
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times ..... :	See appended Table 8.9.3.4	N/A
8.10	Components and wiring		Pass
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely as indicated in RISK MANAGEMENT FILE.... :	See Appended RM Results Table 8.10.1	Pass
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION ..... :	See Appended RM Results Table 8.10.2	Pass
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION as indicated in RISK MANAGEMENT FILE		Pass
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION		Pass
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS due to poor contact		Pass
8.10.3	Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as shown by measurement or using test finger	See Appended Table 5.9.2	N/A
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION		N/A
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		N/A
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		N/A
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION		N/A
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION		N/A
8.10.5	Mechanical protection of wiring		Pass
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION. :	See Appended RM Results Table 8.10.5	Pass
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION as shown by manual tests and RISK MANAGEMENT FILE		Pass
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE		N/A
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed..... :	See appended Table 8.10	N/A
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		Pass
	c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation ..... :	See appended Table 8.10	N/A
8.11	MAINS PARTS, components and layout		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles..... :	See appended Table 8.10	Pass
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description ..... :	See appended Table 8.10	Pass
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV..... :	See appended Table 8.10	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		Pass
	e) Direction of movement of actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a) ..... :	See appended Table 8.10	Pass
	g) A fuse or a semiconductor device not used as an isolating means		Pass
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		Pass
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering		N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)		N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger of Fig 6 applied		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No multiple socket-outlets	N/A
8.11.3	POWER SUPPLY CORDS		Pass
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD		Pass
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design. 53)..... :	See appended Table 8.10	Pass
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ..... :	See appended Table 8.10	N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm^2 Cu) ..... :	18 G wire	Pass
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6..... :	See appended Table 8.10	Pass
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		N/A
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:		N/A
	– insulating material, or		N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N/A
	– metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails		N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 ..... :	See appended Table 8.11.3.5	N/A
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		N/A
8.11.3.6	POWER SUPPLY CORDS other than for STATIONARY ME EQUIPMENT protected against excessive bending at inlet opening of equipment or of MAINS CONNECTOR by means of an insulating cord guard or by means of an appropriately shaped opening		N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g) ..... :	See appended Table 8.11.3.6	N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D..... :	See appended Table 8.11.3.6	N/A
8.11.4	MAINS TERMINAL DEVICES		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection	Detachable power cord	N/A
	Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	Detachable power cord	N/A
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		N/A
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3		N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		N/A
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times		N/A
8.11.4.4	Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4		N/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a re-wirable POWER SUPPLY CORD to allow for connection of conductors, and covers fitted without damage to conductors or their insulation		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		Pass
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection per clause 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT ..... :	See appended Table 8.10 and Appended RM Results Table 8.11.5	Pass
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	portable	N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts of opposite polarity within MAINS PART, and between all parts of MAINS PART and earth, and such provisions continued within all components	Not omitted	N/A
	Effect of short-circuit fault conditions in other circuits taken into consideration before eliminating fuses or OVER-CURRENT RELEASES		N/A
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit ..... :	See appended Table 8.10	Pass
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		Pass
	Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current rating of the fuse, whichever is greater		Pass
	Justification for omission of fuses or OVER-CURRENT RELEASES is in RISK MANAGEMENT FILE	Fuses provided in the ME equipment; No omission of the fuses or over current releases	N/A
8.11.6	Internal wiring of the MAINS PART		N/A
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not less than minimum required for POWER SUPPLY CORD as in clause 8.11.3.3 (mm^2 Cu) ..... :	Certified power supply	N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents .. :	Certified power supply	N/A
	When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2	Certified power supply	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9	PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS		—
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)		Pass
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level ..... :	See Appended RM Results Table 9.2.1	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its function		N/A
	Warnings marked on ME EQUIPMENT or included in instructions for use when HAZARDS persisted after implementing all reasonable protective measures:	See provided Marking Labels	N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:		N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and protective measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20.....:	See appended Table 9.2.2.2	N/A
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13852 ..... :	See appended Table 9.2.2.2	N/A
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse		N/A
9.2.2.4	GUARDS and protective measures		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.4.1	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when GUARDS and protective measures were of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK based on results of applicable tests in 15.3 for ENCLOSURES:	See Appended Table 15.3	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that cannot be dismantled without a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open	See Appended RM Results Table 9.2.2.4.3	N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with all applicable tests as confirmed by review of RISK MANAGEMENT FILE		N/A
9.2.2.4.4	Protective measures provided in control system prevented moving parts from starting to move while in reach of persons .....:	See Appended RM Results Table 9.2.2.4.4	N/A
	– protective measures prevented TRAPPING ZONE from reach, or, when it was reached, system movement stopped once ME EQUIPMENT started to move, and in the latter case, no HAZARD or damage resulted		N/A
	– when protective measure was in a SINGLE FAULT CONDITION, and an unacceptable RISK could arise, one or more emergency stopping device(s) provided		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.2.5	Continuous activation		N/A
	TRAPPING ZONE not considered to present a MECHANICAL HAZARD where impractical to make TRAPPING ZONE inaccessible when:		N/A
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR as long as OPERATOR response to deactivate device relied upon to prevent HARM		N/A
	Manually operated movements complied with this clause since mass and velocity allowed adequate control of positioning without causing an unacceptable RISK		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) when in a SINGLE FAULT CONDITION of continuous activation system an unacceptable RISK could arise, one or more emergency stopping device(s) provided in ME EQUIPMENT .....:	See Appended RM Results Table 9.2.2.5 c)	N/A
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT, when contact with ME EQUIPMENT could result in a HAZARDOUS SITUATION, limited to allow OPERATOR control of positioning without resulting in an unacceptable RISK.....:	See Appended RM Results Table 9.2.2.6	N/A
	Over travel (stopping distance) of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
9.2.3	Other HAZARDS associated with moving parts		N/A
9.2.3.1	Controls positioned, recessed, or protected by other means and could not be accidentally actuated to result in unacceptable RISK, except when ergonomic considerations for a PATIENT with special needs require otherwise		N/A
9.2.3.2	RISK due to over travel (past range limits) of ME EQUIPMENT parts reduced to an acceptable level, and stops or other means with mechanical strength to withstand intended loading in NORMAL USE and foreseeable misuse provided limiting measure in NORMAL and SINGLE FAULT CONDITION .:	See appended Table 8.10 and Appended RM Results Table 9.2.3.2	N/A
9.2.4	Emergency stopping devices		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power :	See Appended RM Results Table 9.2.4	N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original HAZARD		N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 (symbol IEC 60417-5638, DB:2002-10) or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a protective measure, or emergency stopping, and	See Appended RM Results Table 9.2.5	N/A
	– Uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N/A
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered .....:	See Appended RM Results Table 9.3	Pass
9.4	Instability HAZARDS		Pass
9.4.1	ME EQUIPMENT, other than FIXED and hand-held, for placement on a surface did not overbalance (tip over) or move unexpectedly, to the degree that it could present an unacceptable RISK to PATIENT, or OPERATOR as tested in 9.4.2 to 9.4.4		Pass
9.4.2	Instability – overbalance		Pass
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when not specified, as in 9.4.2.2, and placed on a 10° inclined plane from horizontal consisting of a hard and flat surface (e.g., concrete floor covered with 2 to 4 mm thick vinyl material).....:	See Appended Table 9.4.2.1	Pass
9.4.2.2	Instability excluding transport		Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT or its parts prepared based on a) to g), inclusive, did not overbalance when placed in different positions of NORMAL USE, except transport positions, on a 5° inclined plane from horizontal (hard and flat surface)	See Appended Table 9.4.2.2	Pass
	A warning provided, stating "Transport only under conditions described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances" when overbalance occurred during 10° inclined plane test	Passed at 10°	N/A
9.4.2.3	Instability from horizontal and vertical forces		N/A
	a) ME EQUIPMENT with a mass of 25 kg or more, other than FIXED ME EQUIPMENT for use on floor, did not overbalance due to pushing or resting		N/A
	Surfaces of ME EQUIPMENT where a RISK of overbalancing exists from pushing, leaning, resting etc., permanently marked with a CLEARLY LEGIBLE warning of the RISK (e.g., safety sign 5 of Table D.2, safety sign ISO 7010-P017)		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a force of 25% of its weight, but not more than 220 N, applied in different directions, except a direction with an upward component		N/A
	b) ME EQUIPMENT, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping, except when a legible warning of this RISK provided on ME EQUIPMENT (e.g., safety signs 6 and 7 of Table D.2, safety signs ISO 7010-P018, or ISO 7010-P019 as appropriate)		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a constant force of 800 N applied at the point of maximum moment to working surfaces, offering an foothold or sitting surface of a min 20 x 20 cm area, and at a height ≤ 1 m from the floor .....:	See Appended Table 9.4.2.3	N/A
9.4.2.4	Castors and wheels		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT (e.g., castors or wheels) did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT along a hard and flat horizontal surface did not exceed 200 N applied at a height of 1 m above floor or highest point on ME EQUIPMENT when < 1 m high, except when instructions indicated more than one person needed (N) ..... :	See Appended Table 9.4.2.4.2	N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg configured with a SAFE WORKING LOAD, moved 10 times in forward direction over a solid vertical plane obstruction with wheels impacting the obstruction at a speed of 0.4 m/s ± 0.1 m/s for manual or with max speed for motor driven MOBILE ME EQUIPMENT ..... :	See Appended Table 9.4.2.4.3	N/A
	ME EQUIPMENT went up the obstruction without overbalancing or any other unacceptable RISK as determined by examination of RISK MANAGEMENT FILE, ME EQUIPMENT and its parts ..... :	See Appended RM Results Table 9.4.2.4.3	N/A
	There was no reduction of CREEPAGE and CLEARANCES below 8.9, no access to parts exceeding limits in 8.4, and no access to moving parts capable of causing HARM, and		N/A
	– Assessment criteria in Clause 9 and 11.6 used		N/A
	– Dielectric strength test of 8.8.3 conducted to evaluate integrity of solid SUPPLEMENTARY or REINFORCED INSULATION		N/A
	– CREEPAGE DISTANCES and AIR CLEARANCES measured compared favourably with min distances in clause 8.9		N/A
	Small chips not adversely affecting protection against electric shock or moisture, disregarded		N/A
9.4.3	Instability from unwanted lateral movement (including sliding)		N/A
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control		N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position		N/A
	c) No unacceptable RISK due to unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position or worst case NORMAL USE position with SAFE WORKING LOAD, and locking device activated, on a 10° inclined hard flat surface with castors in the worst-case position		N/A
	Following initial elastic movement, creepage, and pivoting of castors, no further movement of MOBILE ME EQUIPMENT > 50 mm (in relation to inclined plane) occurred (mm) ..... :	See Appended Table 9.4.3.1	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK due to any initial movement assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
9.4.3.2	Instability excluding transport		N/A
	a) Further movement of ME EQUIPMENT (after initial elastic movement) was less than 50 mm when MOBILE ME EQUIPMENT with a SAFE WORKING LOAD positioned on a 5° inclined hard flat surface with wheel locked or braking system activated (mm).. :	See Appended Table 9.4.3.2	N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
	b) TRANSPORTABLE or STATIONARY ME EQUIPMENT for use on the floor and with a SAFE WORKING LOAD prepared as in 9.4.2.2 and placed on a horizontal plane with locking device activated and castors, when supplied, in their worst –case position		N/A
	Further movement of ME EQUIPMENT (after initial elastic movement), was no more than 50 mm when a force of 25 % of weight of unit, but less than 220 N, applied in different directions, except a direction with an upwards component, at highest point of ME EQUIPMENT but ≤ 1.5 m from floor ..... :	See Appended Table 9.4.3.2	N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
9.4.4	Grips and other handling devices		N/A
	a) ME EQUIPMENT other than PORTABLE EQUIPMENT or its part with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method, except when handling is obvious and causing HAZARDS		N/A
	Handles, when supplied, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test ..... :	See Appended Table 9.4.4	N/A
9.5	Expelled parts HAZARD		Pass
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts determined by assessment and examination of RISK MANAGEMENT FILE..... :	See Appended RM Results Table 9.5.1	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .....:	See appended Table 8.10	N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		Pass
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK as confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and tests of 9.6.2 and 9.6.3...:	See Appended RM Results Table 9.6.1	Pass
9.6.2	Acoustic energy		Pass
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory alarm signals		Pass
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:		Pass
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:		Pass
	– 140 dB un-weighted sound pressure level for impulsive or impact acoustic energy (dB) .....:		Pass
9.6.2.2	RISK MANAGEMENT FILE examined for RISKS associated with infrasound or ultrasound, when present, addressed in RISK MANAGEMENT PROCESS	See Appended RM Results Table 9.6.2.2	N/A
9.6.3	Hand-transmitted vibration		N/A
	Means provided, except for INTENDED USE vibrations, to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values measured at points of hand contact with PATIENT or OPERATOR	No vibration	N/A
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2).....:		N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s^2) .....:		N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK		N/A
	Parts of a pneumatic or hydraulic system used as a support system, comply with 9.8		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met following requirements based on examination of RISK MANAGEMENT FILE .....:	See Appended RM Results Table 9.7.2	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:		N/A
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		N/A
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		N/A
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by examination of ME EQUIPMENT and RISK MANAGEMENT FILE, and by functional tests .....:	See Appended RM Results Table 9.7.4	N/A
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was > 50 kPa, and product of pressure and volume was more than 200 kPaI .....:	See Appended Table 9.7.5	N/A
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE .....:	See Appended RM Results Table 9.7.6	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests .....:	See Appended RM Results Table 9.7.7	N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
9.8	HAZARDS associated with support systems		N/A
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK .....:	See appended Table 8.10 and Appended RM Results Table 9.8.1	N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A
	– RISK ANALYSIS of support systems included HAZARDS from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions		N/A
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest		N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing .....:	See Appended RM Results Table 9.8.2	N/A
	When test results were part of information, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK .....:	See appended Table 8.10	N/A
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS minimize RISK of physical injuries and accidental loosening of secured joints	See Appended RM Results Table 9.8.3.1	N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance .....:	See copy of Marking Label	N/A
9.8.3.2	Part of SAFE WORKING LOAD representing mass of PATIENTS or OPERATORS is distributed on support/suspension surface representing human body as in Fig A.19		N/A
	Part of SAFE WORKING LOAD representing mass of ACCESSORIES deployed as in NORMAL USE and, when not defined, at worst case position permitted by configuration or ACCESSORIES attachment on support/suspension parts		N/A
	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR .....:	See Appended RM Results Table 9.8.3.2 a)	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and tests .....:	See appended Table 8.10	N/A
	PATIENT support/suspension system positioned horizontally in most disadvantageous position in NORMAL USE, and a mass 2 x 135 kg or twice intended person's load (the greater used), applied to foot rest over an area of 0.1 m^2 for 1 min (Kg) :	See appended Table 9.8.3.2	N/A
	Damage or deflection resulting in an unacceptable RISK did not occur on foot rest and its secured joints		N/A
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK .....:	See Appended RM Results Table 9.8.3.2 b)	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and by a test ..:	See appended Table 8.10	N/A
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass of 60 % of part of SAFE WORKING LOAD simulating PATIENT or OPERATOR, or a min 80 kg, placed on support or suspension system with centre of load 60 mm from outer edge of support or suspension system for at least one minute (Kg) .....:	See appended Table 9.8.3.2	N/A
	Deflection of support/suspension system resulting in an unacceptable RISK not occur		N/A
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE did not result in an unacceptable RISK as confirmed by following test:		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass equal to SAFE WORKING LOAD simulating PATIENT or OPERATOR dropped from 150 mm above seat area on an area of support/ suspension a PATIENT or OPERATOR can sit..... :	See appended Table 9.8.3.3	N/A
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		N/A
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided when a support system or its parts impaired by wear have a TENSILE SAFETY FACTOR ≥ to values in Table 21, rows 5 and 6, but less than 3 and 4 ....:	See Appended RM Results Table 9.8.4.1	N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD, and includes effects of SAFE WORKING LOAD when applicable		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel (movement) produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing .....:	See appended Table 8.10	N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE (e.g., a secondary cable)		N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	– Further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE ..:	See Appended RM Results Table 9.8.4.3	N/A
	– ACCOMPANYING DOCUMENTS instruct once MECHANICAL PROTECTIVE DEVICE is activated, SERVICE PERSONNEL shall be called, and MECHANICAL PROTECTIVE DEVICE must be replaced before ME EQUIPMENT can be used		N/A
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 (i.e., safety sign 7010-W001)		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE or its location relative to MECHANICAL PROTECTIVE DEVICE is obvious to service personnel		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Compliance confirmed by examination of ME EQUIPMENT, ACCOMPANYING DOCUMENTS, RISK MANAGEMENT FILE, specifications and processing of materials, and following test.....:	See appended Table 8.10	N/A
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support system parts have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 1 and 2, and are not impaired by wear .....:	See Appended RM Results Table 9.8.5	N/A
	Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 3 and 4		N/A
	Examination of ME EQUIPMENT and RISK MANAGEMENT FILE confirmed compliance		N/A

10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS		—
10.1	X-Radiation		N/A
10.1.1	X-radiation dose-rate was ≤ 36 pA/kg (5 µSv/h) (0.5 mR/h) 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation ..... :	See Table 10.1.1	N/A
	Amount of radiation measured by means of an ionizing chamber radiation monitor with an effective area of 10 cm^2 or by other instruments producing equal results		N/A
	ME EQUIPMENT operated as in NORMAL USE at most unfavourable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation		N/A
	Internal pre-set controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE (see IEC 60601-1-3 & 1.3) ..... :	See Appended RM Results Table 10.1.2	N/A
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE..... :	See Appended RM Results Table 10.2	N/A
10.3	RISK associated with microwave radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .. :	See Appended RM Results Table 10.3	N/A
10.4	Relevant requirements of IEC 60825-1:1993 applied to lasers, light emitting diodes (LEDs), and laser light barriers or similar products		N/A
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .. :	See Appended RM Results Table 10.5	N/A
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... :	See Appended RM Results Table 10.6	N/A
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 10.7	N/A
11	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS		—
11.1	Excessive temperatures in ME EQUIPMENT		Pass
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T .....:	See appended Table 11.1.1 and appended RM Results Table 11.1.1	Pass
	Surfaces of test corner did not exceed 90 °C		N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		N/A
11.1.2	Temperature of APPLIED PARTS		Pass
11.1.2.1	Temperatures, hot or cold surfaces, and when appropriate, clinical effects of APPLIED PARTS supplying heat to a PATIENT determined and documented in RISK MANAGEMENT FILE and instructions for use.....:	See appended Table 11.1.1 and appended RM Results Table 11.1.2.1	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.1.2.2	APPLIED PARTS not supplying heat to a PATIENT met Table 24 with max surface temperatures > 41 °C disclosed in instructions for use, and clinical effects regarding maturity of PATIENTS, body surface, surface pressure, medications taken, as shown in RISK MANAGEMENT FILE.....:	See appended Table 11.1.1 and appended RM Results Table 11.1.2.2	Pass
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS		N/A
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE .....:	See appended Table 11.1.3 and RM Results Table 11.1.3	N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE		N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE		Pass
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL		N/A
11.2	Fire prevention		Pass
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse and met mechanical strength tests for ENCLOSURES in 15.3		Pass
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of fire under NORMAL or SINGLE FAULT CONDITIONS when source of ignition in contact with ignitable material .....:	See appended Table 8.10	N/A
	Requirements of 13.1.1 applied to oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27.5 kPa for higher atmospheric pressures		N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT in NORMAL and SINGLE FAULT CONDITIONS under any of the following conditions . :		N/A
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE	See Appended RM Results Table 11.2.2.1	N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively..... :	See appended Table 11.2.2.1	N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :		N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... :	See Appended RM Results Table 11.2.2.1	N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3 ..... :	See appended Tables 4.11, 11.1.1 to 11.1.2.2, inclusive; and Table 13.2	N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%)..... :		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE ..... :		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases ..... :		N/A
11.2.2.2	RISK of ignition under least favourable conditions did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT when electrical components mounted outside of ME EQUIPMENT or ME SYSTEM		N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks due to loosening or breaking, except when limited in power and energy to values in 11.2.2.1 a) 5)		N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) ..... :		N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a)..... :		N/A
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a)..... :		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas..... :		N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		N/A
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 ..... :	See Appended RM Results Table 11.3 No fire enclosure claimed metal enclosure	N/A
	Constructional requirements were met, or		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE .....:	See Appended RM Results Table 11.3	N/A
	Justification, when requirement not met .....:		N/A
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials	See appended Table 8.10	N/A
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data .....:	See appended Table 8.10	N/A
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		N/A
	b) Fire ENCLOSURE met following:		N/A
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		N/A
	2) No openings on the sides within the area included within the inclined line C in Fig 39		N/A
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and made of appropriate metal or of non-metallic materials, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a) .....:	See appended Table 8.10	N/A
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable anaesthetics (CATEGORY AP) or anaesthetics with oxidants (CATEGORY APG) comply with Annex G		N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N/A
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE .....:	See Appended RM Results Table 11.5	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		Pass
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT .....:	See Appended Table 11.6.1	Pass
11.6.2	Overflow in ME EQUIPMENT		N/A
	Liquid reservoir liable to overflow in NORMAL USE completely filled and 15 % of its capacity poured in for over 1 min, and except when restricted, TRANSPORTABLE ME EQUIPMENT tilted through an angle of 15° in least favourable direction(s), and when necessary refilled starting from position of NORMAL USE ..... :	See Appended RM Results Table 11.6.2 and Table 11.6.1	N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet..... :	See appended Table 8.7and 8.8.3	N/A
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM		Pass
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill, point of contact, and test conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT..... :	See Appended RM Results Table 11.6.3 and Table 11.6.1	Pass
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet ..... :	See appended Table 8.7and 8.8.3	Pass
11.6.4	Leakage	See 13.2.6	N/A
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :	See Appended RM Results Table 11.6.5 and Table 11.6.1	N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in a SINGLE FAULT CONDITION	See appended Table 8.7and 8.8.3	N/A
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		Pass
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected once using methods specified in instructions for use including any cooling or drying period ..... :	See Appended RM Results Table 11.6.6 and Table 11.6.1	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests, with no deterioration resulting in an unacceptable RISK present ..... :	See appended Table 8.7and 8.8.3	Pass
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER and assurance that no unacceptable RISK will occur verified by RISK MANAGEMENT FILE review ..... :	See RM Results Table 11.6.6	Pass
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11134, ISO 11135, or ISO 11137 as appropriate ..... :	See Appended RM Results Table 11.6.7	N/A
	After the test, ME EQUIPMENT complied with the appropriate dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK ..... :	See appended Table 8.7and 8.8.3, and 11.6.1	N/A
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 11.6.8	N/A
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented per ISO 10993		Pass
11.8	Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function		Pass

12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		—
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review..... :	See Appended RM Results Table 12.1	Pass
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS as confirmed by review of provided records ..... :	See Report based on IEC 60601-1-6	Pass
12.3	The need for alarm systems as a means of RISK CONTROL and RISKS associated with operation or failure of alarm system addressed in RISK MANAGEMENT PROCESS ..... :	See Report based on IEC 60601-1-8 and appended RM Results Table 12.3	Pass
12.4	Protection against hazardous output		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.1	N/A
12.4.2	When applicable, need for indication of parameters associated with hazardous output addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.2	Pass
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit designed to provide low and high-intensity outputs for different treatments addressed in RISK MANAGEMENT PROCESS, confirmed in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.3	N/A
12.4.4	When applicable, RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE..... :	See Appended RM Results Table 12.4.4	N/A
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation emitted by ME EQUIPMENT designed to produce radiation for diagnostic/therapeutic purposes		N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	RISKS associated with diagnostic X-rays addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :	See appended RM Results Table 12.4.5.2	N/A
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE..... :	See Appended RM Results Table 12.4.5.3	N/A
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.5.4	N/A
12.4.6	When applicable, RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.6	N/A

13	HAZARDOUS SITUATIONS AND FAULT CONDITIONS		—
13.1	Specific HAZARDOUS SITUATIONS		Pass
13.1.1	None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2		Pass
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		Pass
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		Pass
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3 ..... :	See appended Tables 11.1.1, 11.1.2.1, and 11.1.2.2	Pass
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3 ..... :	See appended Tables 11.1.1, 11.1.2.1, and 11.1.2.2	Pass
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded		Pass
	Limits for windings in Tables 26, 27, and 31 not exceeded		N/A
	Table 22 not exceeded in all other cases		Pass
	Temperatures measured according to 11.1.3		Pass
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:		Pass
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit, or	See appended Table 13.1.2	N/A
	– Parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation		N/A
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed..... :	See appended Table 8.7	Pass
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed ..... :	See appended Table 8.7	Pass
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS		Pass
13. 2	SINGLE FAULT CONDITIONS		Pass
13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination ..... :	See appended Table 13.2	N/A
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12 ..... :	See appended Table 13.2 and RM Results Table 13.2.6	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to room temperature		N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		N/A
13.2.13.2	ME EQUIPMENT with heating elements		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests of 13.2.13.2 b) & 13.2.13.2 c)		N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests of 13.2.13.2 b) and 13.2.13.2 c)		N/A
	a 3) other ME EQUIPMENT with heating elements met test of 13.2.13.2 b)		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) ME EQUIPMENT with heating elements tested per 11.1without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V) ..... :		N/A
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	ME EQUIPMENT with motors		N/A
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable		N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A
	b) Motor met running overload protection test of this clause when:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) ..... :		N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification) ..... :		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		N/A
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N/A
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated		N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N/A
	Motor winding temperatures did not exceed values in 13.2.10 ..... :		N/A
	Insulation Class..... :		N/A
	Maximum temperature measured (°C) ..... :		N/A
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		—
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or		N/A
	- when application of ISO 14971 showed that failure of PESS does not lead to unacceptable RISK ..... :	See Appended RM Results Table 14.1	N/A
	Every PROCESS has been followed throughout the PEMS DEVELOPMENT LIFE-CYCLE and a RECORD of PROCESS has been made available as confirmed by RISK MANAGEMENT FILE REVIEW and assessment of PROCESSES cited in this Clause		Pass
	MANUFACTURER considered the need for additional RISK CONTROL measures when unable to follow all PROCESSES identified in Clause 14 for each constituent component of PEMS as confirmed by RISK MANAGEMENT FILE review and assessment of PROCESSES cited in this Clause	No OTS or subsystems of non-medical origin used	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Assessment of PROCESSES cited in this Clause made by internal audits	audit Quality Systems Procedure QSP2016 – Internal Quality Audits QSP2016.pdf 2012 Internal Audit Summary. Notice process step 8 for risk management 2012 Internal Audit Schedule.pdf audit checklist which includes risk management and its application to PEMS Risk Management Audit Checklist.docx	Pass
14.2	Documents produced from application of Clause 14 are maintained and form a part of RISK MANAGEMENT FILE in addition to RECORDS and documents required by ISO 14971 ..... :	21-07-0303rev03.pdf Item5.5	Pass
14.3	RISK MANAGEMENT plan required by 3.5 of ISO 14971 includes reference to PEMS VALIDATION plan		Pass
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	Gemini Design Schedule 21-07-0300 Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	Gemini Design Schedule 21-07-0300 Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	Gemini Design Schedule 21-07-0300 Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	Gemini Design Schedule 21-07-0300	Pass
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	Gemini Design Schedule 21-07-0300 Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained where appropriate	QSP4002 Software Life Cycle Procedure Section 5.4.2 QSP4007, Design Verification and Validation Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass
	Problem resolution system meets the prescribed criteria depending on type of product:		Pass
	– it is documented as a part of PEMS DEVELOPMENT LIFE-CYCLE		Pass
	– it allows reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE		Pass
	– it includes an assessment of each problem for associated RISKS		Pass
	– it identifies criteria that must be met for the issue to be closed		Pass
	– it identifies the action to be taken to resolve each problem		Pass
14.6	RISK MANAGEMENT PROCESS		Pass
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including NETWORK/DATA COUPLING, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS	See Appended RM Results Table 14.6.1	Pass
	In addition to the material in ISO 14971, Annex D, list of possible sources for HAZARDS associated with PEMS includes specified causes		Pass
	– failure of NETWORK/DATA COUPLING to provide characteristics necessary for PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE	No network/data coupling	N/A
	– undesired feedback [physical and data] (such as unsolicited/ out of range/ inconsistent input or input from electromagnetic interference)		Pass
	– unavailable data		Pass
	– lack of integrity of data		Pass
	– incorrect data		Pass
	– incorrect timing of data		Pass
	– unintended interactions within & among PESS		Pass
	– unknown aspects or quality of third-party software	No third party software used	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– unknown aspects or quality of third-party PESS	No third party PESS	N/A
	– lack of data security, particularly vulnerability to tampering, unintended interaction with other programs and viruses	No interaction with other programs	N/A
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 6.1 of ISO 14971 ..... :	See Appended RM Results Table 14.6.2	Pass
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem ..... :	See Appended RM Results Table 14.7	Pass
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems ..... :	See Appended RM Results Table 14.8	Pass
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:		Pass
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS	No high-integrity components	N/A
	b) fail-safe functions		Pass
	c) redundancy		Pass
	d) diversity;		Pass
	e) partitioning of functionality		Pass
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators		Pass
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS		Pass
	h) failure modes of components and their effects;		Pass
	i) common cause failures		Pass
	j) systematic failures		Pass
	k) test interval duration and diagnostic coverage		Pass
	l) maintainability		Pass
	m) protection from reasonably foreseeable misuse		Pass
	n) NETWORK/DATA COUPLING specification, when applicable	No Network/Data coupling implementation	N/A
14.9	Design is broken up into subsystems, each with a design and test specification where appropriate, and descriptive data on design environment included in RISK MANAGEMENT FILE..... :	See Appended RM Results Table 14.9	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures.....:	See Appended RM Results Table 14.10	Pass
	– milestone(s) when VERIFICATION is to be performed for each function		Pass
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		Pass
	– selection and utilization of VERIFICATION tools		Pass
	– coverage criteria for VERIFICATION		Pass
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE and requiring checks for unintended functioning of PEMS to perform and document PEMS VALIDATION	See Appended RM Results Table 14.11	Pass
	The person with overall responsibility for PEMS VALIDATION is independent of design team, and no member of a design team is responsible for PEMS VALIDATION of their own design		Pass
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE providing methods & results of PEMS VALIDATION		Pass
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	This design is not a result of an earlier design	N/A
14.13	Technical description includes the following information when PEMS is to be connected to other equipment outside control of PEMS MANUFACTURER by NETWORK/DATA COUPLING.....:	See Appended RM Results Table 14.13 device not intended to connect to Network/Data coupling	N/A
	a) characteristics of NETWORK/DATA COUPLING necessary for PEMS to achieve its INTENDED USE		N/A
	b) list of HAZARDOUS SITUATIONS resulting from a failure of NETWORK/DATA COUPLING to provide the specified characteristics addressed in RMF and ...		N/A
	Listed in technical description		N/A
	c) instructions to RESPONSIBLE ORGANIZATION containing required information and warnings		N/A
	– connection of PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS and RESPONSIBLE ORGANIZATION shall identify, analyze, and control such RISKS		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– subsequent changes to NETWORK/DATA COUPLING introducing new RISKS and requiring new analysis; and changes to NETWORK/DATA COUPLING include:		N/A
	– The technical description shall instruct the responsible organization that changes to the network/data coupling include…		N/A
	– connection of additional items to NETWORK/DATA COUPLING		N/A
	– disconnecting items from NETWORK/DATA COUPLING		N/A
	– update of equipment connected to NETWORK/DATA COUPLING		N/A
	– upgrade of equipment connected to NETWORK/DATA COUPLING		N/A
15	CONSTRUCTION OF ME EQUIPMENT		—
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS, as confirmed by examination of RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 15.1	Pass
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance		Pass
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		Pass
15.3	Mechanical strength		Pass
15.3.1	Mold stress relief, push, impact, drop, and rough handling tests did not result in unacceptable RISK and ME EQUIPMENT displayed adequate mechanical strength		Pass
15.3.2	Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular (30mm) plane surface, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool ..... :	See Appended Table 15.3 and RM Results Table 15.3.2	Pass
	No damage resulting in an unacceptable RISK sustained as determined by examination of RISK MANAGEMENT FILE		Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.3.3	Impact test conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m ..... :	See Appended Table 15.3 and RM Results Table 15.3.3	Pass
	Test not applied to flat panel displays, platen glass of ME EQUIPMENT, or cathode ray tubes		Pass
	No damage resulting in an unacceptable RISK sustained as shown in RISK MANAGEMENT FILE		Pass
15.3.4	Drop test		Pass
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT and HAND-HELD part with SAFE WORKING LOAD allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board lying flat on a concrete or rigid base ..... :	See Appended Table 15.3	Pass
	No unacceptable RISK resulted		Pass
15.3.4.2	Sample of PORTABLE ME EQUIPMENT and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 ± 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm) ..... :	See Appended Table 15.3 and RM Table 15.3.4.2	Pass
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		Pass
15.3.5	Each sample of MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests ..... :	See Appended Table 15.3 and RM Results Table 15.3.5	N/A
	a) Ascending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s against an ascending hardwood step obstruction without the sample going over the obstruction		N/A
	b) Descending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s in order to fall over a vertical step affixed flat on a rigid base with direction of movement perpendicular to face of the step until full descent achieved		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Door frame shock test conducted on the sample by moving it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s, or for motor driven EQUIPMENT, at maximum possible speed against a hardwood vertical obstacle higher than EQUIPMENT contact point(s)		N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		N/A
15.3.6	Examination of ENCLOSURE made from molded or formed thermoplastic material indicated that material distortion due to release of internal stresses by molding or forming operations will not result in an unacceptable RISK		Pass
	Mold-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C ..... :		Pass
	No damage resulting in an unacceptable RISK		Pass
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		Pass
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		Pass
15.4	ME EQUIPMENT components and general assembly		Pass
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular ..... :	See Appended RM Results Table 15.4.1	N/A
	a) Plugs for connection of PATIENT leads cannot be connected to other outlets on same ME EQUIPMENT intended for other functions, except when RISK MANAGEMENT FILE provides proof that no unacceptable RISK could result ..... :	Unique connection design	N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable as verified by review of RISK MANAGEMENT FILE ..... :		N/A
15.4.2	Temperature and overload control devices		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could result in a HAZARDOUS SITUATION by resetting action as verified by review of RISK MANAGEMENT FILE .....:	See Appended RM Results Table 15.4.2.1 a)	N/A
	b) THERMAL CUT-OUTS with a safety function to be reset by a soldering operation affecting operating value not fitted in ME EQUIPMENT as verified by examination of design and RISK MANAGEMENT FILE:	See Appended RM Results Table 15.4.2.1 b)	N/A
	c) An independent non-SELF-RESETTING THERMAL CUT-OUT is, additionally, provided where a failure of a THERMOSTAT could constitute a HAZARD as verified by examination of design and RISK MANAGEMENT FILE .....:	See Appended RM Results Table 15.4.2.1 c)	N/A
	d) Based on design and RISK MANAGEMENT FILE review, loss of function of ME EQUIPMENT due to operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION	See Appended RM Results Table 15.4.2.1 d)	N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests:		N/A
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 1999, clauses 15, 17, J.15, and J.17 as applicable		N/A
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 .....:	See appended Table 13.2	N/A
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards		N/A
	In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	When certification based on IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function is not available, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating in both leads where a conductive connection to earth could result in overheating as verified by review of design and RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 15.4.2.1 h)	N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N/A
15.4.3	Batteries		Pass
15.4.3.1	Battery housings from which gases can escape during charging or discharging likely to result in a HAZARD ventilated to minimize RISK of accumulation and ignition as verified by review of design and RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 15.4.3.1	Pass
	Battery compartments prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as verified by examination of design and RISK MANAGEMENT FILE		Pass
15.4.3.2	Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery ..... :	See Appended RM Results Table 15.4.3.2	Pass
15.4.3.3	Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design ..... :	See Appended RM Results Table 15.4.3.3	Pass
15.4.3.4	Lithium batteries that could become a HAZARD complied with appropriate tests of IEC 60086-4	See Appended RM Results Table 15.4.3.4	N/A
	Tests of IEC 60086-4 waived on the lithium battery based on examination of design		N/A
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents when (in case of a short circuit) layout of internal wiring, cross-sectional area, rating of connected components can result in a fire ..... :	See Appended RM Results Table 15.4.3.5	Pass
	Protective device has adequate breaking capacity to interrupt the maximum fault current		Pass
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is included in RISK MANAGEMENT FILE	Fuses not omitted	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose..:	See Appended RM Results Table 15.4.4	N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position		N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational when a HAZARDOUS SITUATION could exist, except when apparent to OPERATOR from normal operating position		N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION		Pass
	Colours of indicator lights complied with 7.8.1		Pass
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE		Pass
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS when applicable as verified by review of RISK MANAGEMENT FILE.....:	See Appended RM Results Table 15.4.5	N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT		N/A
15.4.6.1	a) Actuating parts cannot be pulled off or loosened up during NORMAL USE		N/A
	b) Indication of scales (e.g., “on” “off” positions, etc.) always corresponds to position of controls with adjustment that can result in a HAZARDOUS SITUATION for PATIENT or OPERATOR while ME EQUIPMENT is in use		N/A
	c) Incorrect connection of indicating device to relevant component prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values per Table 30 applied between control knob and shaft of rotating controls for not less than 2 s, 10 times in each direction, knobs did not rotate .....:	See appended Table 15.4.6	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Tests conducted by applying an axial force of 60 N for electrical components and 100 N for other components for 1 min when an axial pull was required in NORMAL USE with no unacceptable RISK ..... :	See appended Table 15.4.6	N/A
15.4.6.2	Stops of adequate mechanical strength provided on rotating/ movable parts of controls of ME EQUIPMENT where necessary to prevent an unexpected change from max to min, or vice-versa, of the controlled parameter when this could cause a HAZARDOUS SITUATION ..... :	See appended Table 15.4.6	N/A
	Torque values in Table 30 applied 10 times in each direction to rotating controls for 2 sec ..... :	See appended Table 15.4.6	N/A
	Application of an axial force of 60 N for electrical components and 100 N for other components to rotating or movable parts of controls for 1 min when an axial pull was required in NORMAL USE ... :	See appended Table 15.4.6	N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N/A
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1		N/A
	b) Foot-operated control device supported an actuating force of 1350 N for 1 min applied over an area of 30 mm diameter in its position of NORMAL USE with no damage to device causing an unacceptable RISK ..... :		N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :		N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least IPX1 & complies with tests of IEC 60529 (IP Code) ..... :	See appended Table 11.6.1	N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6 and complies with IEC 60529 if in NORMAL USE liquids are likely to be found (IP Code) ..... :	See appended Table 11.6.1 and RM Results Table 15.4.7.3 b)	N/A
	Probability of occurrence estimated as part of RISK MANAGEMENT PROCESS		N/A
15.4.8	Aluminum wires less than 16 mm^2 in cross-sectional area are not used		Pass
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed to prevent loss of oil in any position		N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	A pressure-release device operating during NORMAL USE is, optionally, provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		N/A
15.5.1	Overheating		N/A
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 – 3 ..... :	See appended Tables 15.5.1.2 and 15.5.1.3	N/A
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		N/A
	Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests :	See appended Table 15.5.2	N/A
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ..... :	See appended Table 15.5.1.2	N/A
	Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2		N/A
15.5.1.3	Multiple overload tests conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection..... :	See appended Table 15.5.1.3	N/A
15.5.2	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION		N/A
	Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer ..... :	See appended Table 15.5.2	N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12..... :	See appended Table 8.10	N/A

16	ME SYSTEMS		—
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	See Appended RM Results Table 16.1	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	– tests performed in NORMAL CONDITION, except as specified		N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N/A
	RISK MANAGEMENT methods, optionally, used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR to determine configurations with highest RISKS and measures to ensure any configuration of ME SYSTEM will not present unacceptable RISKS		N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS are, optionally, provided in electronic format (e.g. electronic file format or CD ROM) and ME SYSTEM is capable of displaying or printing these documents		N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N/A
	c) the required information is provided:		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		N/A
	– additional safety measures to be applied during installation of ME SYSTEM		N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		N/A
	– additional measures to be applied during preventive maintenance		N/A
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor		N/A
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM		N/A
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		N/A
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM		N/A
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM		N/A
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer		N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		N/A
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		N/A
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		N/A
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements		N/A
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors, etc., without use of a TOOL operated at a voltage ≤ voltage in 8.4.2 c) supplied from a source separated from SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION		N/A
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed		N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for highest voltage occurring across SEPARATION DEVICE during a fault condition		N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :		N/A
16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION, from or between parts of ME SYSTEM within the PATIENT ENVIRONMENT, did not exceed 100 µA..... :	See appended Table 16.6.1	N/A
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, from or between parts of ME SYSTEM within PATIENT ENVIRONMENT . :	See appended Table 16.6.1	N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET did not exceed 5 mA..... :		N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values specified for ME EQUIPMENT in Tables 3 and 4 ..... :	See appended Tables 8.7 and 16.6.1	N/A
	Measurements made using a device as in clause 8.7.4.4		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
16.7	ME SYSTEM complied with applicable requirements of Clause 9 when a MECHANICAL HAZARD existed ..:	See applicable appended Tables in section 9	N/A
16.8	Interruption and restoration of relevant power connections of ME SYSTEM one at a time and all connections simultaneously did not result in a HAZARDOUS SITUATION other than interruption of its intended function		N/A
16.9	ME SYSTEM connections and wiring		N/A
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where a HAZARDOUS SITUATION could otherwise exist .....:	See Appended RM Results Table 16.9.1	N/A
	– Connectors complied with Clause 15.4.1		N/A
	– Plugs for connection of PATIENT leads could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no HAZARDOUS SITUATION could result		N/A
16.9.2	MAINS PARTS, components and layout		N/A
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 (i.e., safety sign ISO 7010-W001) visible in NORMAL USE, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6, except total impedance for ME SYSTEM was up to 400 mΩ, or higher when conditions of 8.6.4 b) met (mΩ) ..... :		N/A
	– ENCLOSURE complied with 8.4.2 d)		N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	– RATINGS of components are not in conflict with conditions of use ..... :	See appended Table 8.10	N/A
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	– POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	– Separating transformer complied with IEC 61558-2-1, except requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 were not applied..... :	See appended Table 8.10	N/A
	– Separating transformer is CLASS I		N/A
	– Degree of protection against ingress of water specified as in IEC 60529		N/A
	– Separating transformer assembly marked according to 7.2 and 7.3		N/A
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N/A
16.9.2.2	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part		N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL		N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		N/A

17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		—
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review..... :	See Appended RM Results Table 17	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :		Pass
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		Pass
ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES		—
G.2	Locations and basic requirements		N/A
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	Not Category AP or APG equipment	N/A
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH AIR occurring due to a leakage or discharge of a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE from an ENCLOSURE considered 5 to 25 cm from point of occurrence		N/A
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE contained in a completely / partly enclosed ME EQUIPMENT part and in PATIENT'S respiratory tract 5 cm from an ENCLOSURE part where leakage or discharge occurs	Not used with anesthetic mixture	N/A
G.2.4	ME EQUIPMENT or parts thereof specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR (in a location as in G.2.2) are CATEGORY AP or APG ME EQUIPMENT and complied with G.4 and G.5		N/A
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (location per G.2.2) are CATEGORY APG ME EQUIPMENT and comply with G.4 and G.6		N/A
	ME EQUIPMENT in G.2.3 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	Marking, ACCOMPANYING DOCUMENTS		N/A
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked. with a green-coloured band ≥ 2 cm wide with letters "APG" according to symbol 23 in Table D.1 :	See copies of Marking Labels Not Category APG equipment	N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A
	When above marking not possible, relevant information included in instructions for use ..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle ≥ 2 cm in diameter, with characters "AP" according to symbol 22 in Table D.1 ..... :	See copies of Marking Labels Not AP equipment	N/A
	Marking is as large as possible for the particular case		N/A
	When above marking not possible, the relevant information included in instructions for use ..... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.3	The marking according to G.3.2 and G.3.3 placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts, and not repeated on detachable parts that can only be used with the marked EQUIPMENT		N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts		N/A
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG		N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES between points of POWER SUPPLY CORD connection are according to Table 12 for one MEANS OF PATIENT PROTECTION	Not Category AP or APG equipment	N/A
	b) Connections, except those in circuits described in G.5.3 and G.6.3, protected against accidental disconnection in NORMAL USE or connection and disconnection can be performed only with a TOOL		N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD, except when circuit complied with G.5.3 and G.6.3		N/A
G.4.2	Construction details		N/A
	a) Opening of an ENCLOSURE providing protection against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL		N/A
	b) ENCLOSURE complies with requirements to minimize arcing and sparking due to penetration of foreign objects..... :	See appended Table 8.10	N/A
	– no openings on top covers of ENCLOSURE, except for openings for controls covered by control knobs		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– openings in side-covers prevented penetration of a solid cylindrical test rod of 4 mm in diameter applied in all possible directions without appreciable force		N/A
	– openings in base plates prevented penetration of a solid cylindrical test rod of 12 mm in diameter applied in all directions without appreciable force		N/A
	c) Short circuiting conductor(s) to a conductive part without presence of explosive gasses where insulation may contact a part containing a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE, ignitable gases alone, or oxygen, did not result in loss of integrity of the part, an unacceptable temperature, or other HAZARD		N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	Not Category AP or APG equipment	N/A
	– Use of antistatic materials with a limited electrical resistance as specified in G.4.3 b)..... :	See appended Table 8.10	N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor of medical room		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses and pads, castor tires, and other antistatic material complied with ISO 2882 based on measurements according to ISO 1853, ISO 2878 and ISO 23529..... :		N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N/A
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components		N/A
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5 (inclusive)	Not Category AP equipment	N/A
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
G.5.2	ME EQUIPMENT, its parts, and components in contact with gas mixtures in NORMAL USE and CONDITIONS not producing sparks and not resulting in surface temperatures above 150 °C in case of restricted or 200 °C in case of unrestricted vertical air circulation measured at 25 °C comply with G.5.1 ..... :		N/A
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1..... :		N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ..... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :		N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N/A
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2		N/A
	No extrapolation made for voltages above 242V		N/A
	U_{max}, additionally, determined using actual resistance R when the equivalent resistance R was less than 8000 Ω		N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		N/A
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open, taking into consideration MAINS VOLTAGE variations in 4.10		N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed, taking into consideration MAINS VOLTAGE variations required in 4.10		N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		N/A
	– Peak value considered when a.c. supplied		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3..... :		N/A
	Alternatively, compliance was verified by examination of design data..... :		N/A
G.5.4	External ventilation with internal overpressure		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR that might have penetrated into ENCLOSURE of ME EQUIPMENT or part removed by ventilation before EQUIPMENT energized, and penetration of such mixtures during operation was prevented by maintenance of overpressure by means of air without flammable gases, or by physiologically acceptable inert gas (e.g., nitrogen)		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa) ..... :		N/A
	Overpressure maintained at the site of potential ignition even when air or inert gas could escape through openings in ENCLOSURE necessary for normal operation of ME EQUIPMENT or its parts		N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE so that the displaced volume of air or inert gas was at least five times the volume of ENCLOSURE		N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically by means used where G.4 does not apply, or complied with G.5 when during operation overpressure dropped below 50 Pa (Pa)..... :		N/A
	d) External surface of ENCLOSURE in which internal overpressure was maintained did not exceed 150 °C in 25 °C ambient under NORMAL USE and CONDITION (°C)..... :		N/A
G.5.5	ENCLOSURES with restricted breathing		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:	No restricted breathing	N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing when it was surrounded by a FLAMMABLE AESTHETIC MIXTURE WITH AIR of a high concentration for at least 30 min without any pressure difference inside ENCLOSURE		N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h.. :		N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained when the cords were stressed by bending or pulling		N/A
	Cords are fitted with adequate anchorages to limit stresses		N/A
	After the test in G.5.4 b), an internal overpressure of 400 Pa was created and 30 pulls of the value in Table G.1 applied to each flexible cord in axial direction of cord inlet and in the least favourable direction for 1 s		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C) ..... :		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C) ..... :		N/A
G.6	CATEGORY APG ME EQUIPMENT, parts and components thereof		N/A
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION	Not Category APG equipment	N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test after attaining thermal steady state (max. 3 h) over a period of 10 min in a 12.2 % ± 0.4 ether by volume/oxygen mixture		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION ..... :		N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS ..... :		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or		N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 ..... :		N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5 ..... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :		N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N/A
	– C_{max} and L_{max} are values occurring in relevant circuit		N/A
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value taken into consideration when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		N/A
	Above requirement not applied to transformers complying with this standard		N/A
	Above requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N/A
	Temperature measurements made in accordance with 11.1, or		N/A
	U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6..... :		N/A
	Alternatively, compliance verified by comparison with design data..... :		N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 ..... :		N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	Test apparatus for flammable mixtures		N/A
	Test apparatus used was in accordance with this Clause and Fig G.7	No flammable mixtures	N/A

ANNEX L	INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION		—
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters	No insulated windings wires for use without interleaved insulation	N/A
L.2	Wire construction		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
L.3	Type Test		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified		N/A
	Temperature (°C) ..... :		N/A
	Humidity (%) ..... :		N/A
L.3.1	Dielectric strength		N/A
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 & 7, but not less than below with no breakdown:		N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 6000 V for REINFORCED INSULATION (V) ..... :		N/A
L.3.2	Flexibility and adherence		N/A
	Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1		N/A
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown		N/A
	Test voltage was at least the voltage in Tables 6 and 7but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :		N/A
L.3.3	Heat Shock		N/A
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Oven temperature based on Table L.2 (°C) ..... :		—

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2) ..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
L.3.4	Retention of electric strength after bending		N/A
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Test voltage applied between the shot and conductor.		N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2) ..... :		N/A
L.4	Tests during manufacture		N/A
L.4.1	Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3 :		N/A
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:		N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)..... :		N/A
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)		N/A
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		N/A
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION		N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.2	RM RESULTS TABLE: Risk Management Process for ME Equipment or ME Systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
3.3a	QSP1003 Rev 19 21-07-0303 Rev 03-Xa	Management Review, Section – Procedure Gemini Risk Management Plan, Section 2 - Assignment of Responsibilities and Authorities	Pass
3.5e	QSP1026 Rev 08 21-07-0303 Rev 03-Xa	Risk Management Procedure, Section 5.2 – Risk Management Plans Gemini Risk Management Plan	Pass
4.1	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.4 – Risk Analysis Gemini Risk Analysis, Section 3 - Risk Analysis	Pass
4.2	QSP1026 Rev 08 21-07-0304 Rev 01-Xa	Risk Management Procedure, Section 5.3.10 Hazard Identification, Section 3.1 – Identification of Intended Use	Pass
4.3	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.3 – Hazard Identification Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
4.4	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.5 – Initial Risk Evaluation Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
5	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.5 – Initial Risk Evaluation Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
6.1	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.6.1 – Risk Control Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
6.2	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.6.2 – Risk Control Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.2	RM RESULTS TABLE: Risk Management Process for ME Equipment or ME Systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.6.5 – Risk Control Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
6.4	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.7 – Residual Risk Evaluation Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
6.5	QSP1026 Rev 08 21-07-0307 Rev 01-Xa	Risk Management Procedure, Section 5.6.5, 5.7.4, 5.8.4 Section 3 – Risk Management Report	Pass
6.6	QSP1026 Rev 08 21-07-0307 Rev 01-Xa	Risk Management Procedure, Section 5.6.6 Section 3 – Risk Management Report	Pass
6.7	QSP1026 Rev 08 21-07-0307 Rev 01-Xa	Risk Management Procedure, Section 5.8.7 Section 3 – Risk Management Report	Pass
7	QSP1026 Rev 08 21-07-0307 Rev 01-Xa	Risk Management Procedure, Section 5.8.3, 5.8.4 Section 3 – Risk Management Report	Pass

4.3	TABLE: ESSENTIAL PERFORMANCE	Pass
List of ESSENTIAL PERFORMANCE functions	MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)	Remarks
Operation and annunciation of patient alarm indicators	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Accurate StO2 measurement	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Detection of equipment conditions triggering shutdown	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Signal inadequacy	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Sensor/preamp detection and management	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Resume StO2 measurement within specifications after defibrillation event	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Resume StO2 measurement within specifications after	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.3	TABLE: ESSENTIAL PERFORMANCE		Pass
List of ESSENTIAL PERFORMANCE functions	MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)	Remarks	
external noise event			
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.			

4.3	RM RESULTS TABLE: Essential Performance		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification	Section 3.2	Pass
4.3			Pass
4.4			Pass
5			Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.5	RM RESULTS TABLE: Equivalent Safety for ME Equipment of ME System		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No alternative means of addressing risk used	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

4.6	RM RESULTS TABLE: ME Equipment or system parts contacting the patient		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification	Section 3.3	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5	No risk benefit analysis		N/A

4.7	RM RESULTS TABLE: Single Fault Condition for ME Equipment		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification	Section 3.13, Section 4	Pass
4.3			Pass
4.4	21-07-0306 Gemini Risk Analysis	Section 4	Pass

4.8	RM RESULTS TABLE: Components of ME Equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No components used outside their ratings	
4.3			
4.4			
5			
6.2			
6.3			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.8	RM RESULTS TABLE: Components of ME Equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.4			
6.5			

4.9	RM RESULTS TABLE: Use of components with high-integrity characteristics		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No high-integrity components	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

4.11	TABLE: Power Input				Pass
Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Power factor (cos φ)
Normal Operation, All 4 sensors in use	99	50	0.62	35.9	0.58
	110	50	0.57	35.5	0.57
	240	50	0.40	36.0	0.37
	264	50	0.40	36.3	0.34
	99	60	0.61	35.8	0.59
	110	60	0.56	35.4	0.57
	240	60	0.43	35.9	0.35
	264	60	0.61	36.3	0.31
Supplementary Information:					

5.1	RM RESULTS TABLE: Type Tests		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		All type tests performed	
4.3			
4.4			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

5.4 a)	RM RESULTS TABLE: Other Conditions		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification	Section 3.12	Pass
4.3			Pass
4.4			Pass

5.7	RM RESULTS TABLE: Humidity preconditioning treatment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not intended to be exposed to high humidity for extended periods	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

5.9.2	TABLE: Determination of ACCESSIBLE parts	Pass
Location	Determination method (NOTE1)	Comments
Enclosure	V	
Vent Opening	J	Did not enter
Vent Opening	U	Did not enter
Vent Opening	H	test finger did not enter
Connectors	V	
Preamp Cable	V	
Sensor	V	Type BF applied part
Supplementary information: NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

5.9.2.3	RM RESULTS TABLE: Actuating mechanisms		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No actuating mechanisms	
4.3			
4.4			
5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

5.9.2.3	RM RESULTS TABLE: Actuating mechanisms		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

7.1.2	TABLE: Legibility of Marking		Pass
Markings tested		Ambient illuminance (lx)	Remarks
Outside Markings (Clause 7.2) .....:		385	Pass
Inside Markings (Clause 7.3) .....:		N/A	No internal markings
Controls & Instruments (Clause 7.4) .....:		385	Pass
Safety Signs (Clause 7.5) .....:		385	Pass
Symbols (Clause 7.6) .....:		385	Pass

Supplementary information:

Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

7.1.3	TABLE: Durability of marking test	Pass
Characteristics of the Marking Label tested:		Remarks
Material of Marking Label .....:	Lexan* 8B35 Film	Remained Clear
Ink/other printing material or process .....:	Norcote international 88 matte series	Remained Clear
Material (composition) of Warning Label .....:	-	-
Ink/other printing material or process .....:	-	-
Other.....:	-	-

Supplementary information:

Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

7.2.2	RM RESULTS TABLE: Identification		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Product is suitably marked	
4.3			
4.4			
5			
6.4			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

7.2.5	RM RESULTS TABLE: ME EQUIPMENT powered from other equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not intended to receive power from other equipment	
4.3			
4.4			
5			
6.4			

7.2.13	RM RESULTS TABLE: Physiological effects (safety signs and warning)		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such physiological effects	
4.3			
4.4			
5			
6.3			

7.2.17	RM RESULTS TABLE: Protective packaging		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No risk in unpacking	
4.3			
4.4			
5			
6.3			
6.4			

7.3.3	RM RESULTS TABLE: Batteries		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No lithium batteries	
4.3			
4.4			
5			
6.3			

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Clause	Requirement + Test	Result - Remark	Verdict

7.3.7	RM RESULTS TABLE: Supply terminals		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No supply terminals	

7.4.2	RM RESULTS TABLE: Control devices		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.5.10.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass

7.5	RM RESULTS TABLE: Safety signs		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.1.2.2, 4.1.3.1, 4.1.3.3, 4.1.3.4, 4.1.3.5, 4.1.3.6, 4.1.7.1, 4.2.1.1, 4.2.5.1, 4.2.6.1, 4.3.1.1, 4.3.1.2, 4.3.2.1, 4.3.5.1, 4.3.6.1, 4.5.5.1, 4.5.5.6, 4.5.5.8, 4.5.5.9, 4.5.10.2, 4.7.3.1, 4.10.1.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.3			Pass

7.9.1	RM RESULTS TABLE: General accompanying documents (See Table C.4)		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.8.1.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

7.9.2.4	RM RESULTS TABLE: Electrical power source		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.10.2.1, 4.3.3.2	Pass
4.3			Pass
4.4			Pass
5			Pass
6.3			Pass

7.9.3.2	RM RESULTS TABLE: Replacement of fuses, power supply cords, other parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not permanently installed	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

8.1 b(1)	RM RESULTS TABLE: Fundamental rule of protection against electric shock - interruption of any one power-carrying conductor		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		There are no separate enclosure connection; ME equipment is part of the single enclosure	
4.4			

8.1 b(2)	RM RESULTS TABLE: Fundamental rule of protection against electric shock - unintended movement of a component		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.1.5	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk/benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.1 b(3)	RM RESULTS TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.1.5	Pass

8.2.2	RM RESULTS TABLE: Connection to an external d.c. power sources		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No external D.C. power source	
4.3			
4.4			
5			

8.3 d	RM RESULTS TABLE: Requirements of Type BF or CF Applied Parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2		See also RM Table for 4.6	

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					N/A
Test supply voltage/frequency (V/Hz)[1] ..... :						
Location From/To	Measured values					Remarks
	Vrms	Vpk or Vdc	Peak-to-peak ripple[2]	Power W/VA	Energy (J)	

Supplementary Information:

1. The input supply voltage to the ME EQUIPMENT shall be the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.
2. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.4.2 c	RM RESULTS TABLE: Accessible parts including applied parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Limits applied	
4.3			
4.4			

8.4.3	TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply									Pass
Maximum allowable voltage (V) .....:										60
Voltage measured (V)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	4.04	0.02	2.03	2.03	2.03	4.04	2.03	0.02	2.03	4.04
Plug pin 1 and plug earth pin	7.04	10.06	15.09	17.10	18.10	18.10	16.09	14.08	18.10	17.10
Plug pin 2 and plug earth pin	16.09	15.09	14.08	11.07	10.06	19.11	14.08	14.08	13.08	10.06
Plug pin 1 and enclosure	7.04	10.06	15.09	17.10	18.10	18.10	16.09	14.08	18.10	17.10
Plug pin 2 and enclosure	16.09	15.09	14.08	11.07	10.06	19.11	14.08	14.08	13.08	10.06
Maximum allowable stored charge when measured voltage exceeded 60 v (µc) ..... :										45
Calculated stored charge (µc)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 1 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 2 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 1 and enclosure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 2 and enclosure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Supplementary information:										

8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT		N/A
Maximum allowable residual voltage (V):			60 V
Maximum allowable stored charge when residual voltage exceeded 60 V :			45 µC
Description of the capacitive circuit	Measured residual	Calculated stored	

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

(i.e., accessible capacitor or circuit parts)	voltage (V)	charge (µC)	Remarks
Supplementary information:			

8.5.2.2	RM RESULTS TABLE: Type B applied parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Type BF applied part	
4.3			
4.4			
5			

8.5.2.3	RM RESULTS TABLE: PATIENT Leads		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No patient leads	
4.3			
4.4			
5			

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies				Pass
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
9	Foil underneath equipment	Sensors tied together	+	93.9	Pass
9	Foil underneath equipment	Sensors tied together	-	187.8	Pass
9	Foil on enclosure	Sensors tied together	+	93.9	Pass
9	Foil on enclosure	Sensors tied together	-	156.5	Pass
9	Monitor SIP SOP	Sensors tied together	+	125.2	Pass
9	Monitor SIP SOP	Sensors tied together	-	93.9	Pass
9	Ethernet	Sensors tied	+	125.2	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

		together			
9	Ethernet	Sensors tied together	-	156.5	Pass
9	Port A	Sensors tied together	+	125.2	Pass
9	Port A	Sensors tied together	-	156.5	Pass
9	Port B	Sensors tied together	+	93.9	Pass
9	Port B	Sensors tied together	-	187.8	Pass
9	USB	Sensors tied together	+	93.9	Pass
9	USB	Sensors tied together	-	62.6	Pass
9	USB front	Sensors tied together	+	93.9	Pass
9	USB front	Sensors tied together	-	62.6	Pass
10	Foil underneath equipment	Sensor 1 rest tied to ground	+	125.2	Pass
10	Foil underneath equipment	Sensor 1 rest tied to ground	-	219.1	Pass
10	Foil on enclosure	Sensor 1 rest tied to ground	+	250.4	Pass
10	Foil on enclosure	Sensor 1 rest tied to ground	-	156.5	Pass
10	Monitor SIP SOP	Sensor 1 rest tied to ground	+	62.6	Pass
10	Monitor SIP SOP	Sensor 1 rest tied to ground	-	219.2	Pass
10	Ethernet	Sensor 1 rest tied to ground	+	62.6	Pass
10	Ethernet	Sensor 1 rest tied to ground	-	125.2	Pass
10	Port A	Sensor 1 rest tied to ground	+	281.7	Pass
10	Port A	Sensor 1 rest tied to ground	-	219.1	Pass
10	Port B	Sensor 1 rest tied to ground	+	93.9	Pass
10	Port B	Sensor 1 rest tied to ground	-	156.5	Pass
10	USB	Sensor 1 rest tied to ground	+	250.4	Pass
10	USB	Sensor 1 rest tied to ground	-	125.2	Pass
10	USB front	Sensor 1 rest tied to ground	+	93.9	Pass

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IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
10	USB front	Sensor 1 rest tied to ground	-	125.2	Pass
10	Foil underneath equipment	Sensor 2 rest tied to ground	+	93.9	Pass
10	Foil underneath equipment	Sensor 2 rest tied to ground	-	156.5	Pass
10	Foil on enclosure	Sensor 2 rest tied to ground	+	125.2	Pass
10	Foil on enclosure	Sensor 2 rest tied to ground	-	250.4	Pass
10	Monitor SIP SOP	Sensor 2 rest tied to ground	+	125.2	Pass
10	Monitor SIP SOP	Sensor 2 rest tied to ground	-	125.3	Pass
10	Ethernet	Sensor 2 rest tied to ground	+	125.2	Pass
10	Ethernet	Sensor 2 rest tied to ground	-	219.1	Pass
10	Port A	Sensor 2 rest tied to ground	+	125.2	Pass
10	Port A	Sensor 2 rest tied to ground	-	156.5	Pass
10	Port B	Sensor 2 rest tied to ground	+	187.8	Pass
10	Port B	Sensor 2 rest tied to ground	-	93.9	Pass
10	USB	Sensor 2 rest tied to ground	+	187.8	Pass
10	USB	Sensor 2 rest tied to ground	-	187.9	Pass
10	USB front	Sensor 2 rest tied to ground	+	219.1	Pass
10	USB front	Sensor 2 rest tied to ground	-	219.1	Pass
10	Foil underneath equipment	Sensor 3 rest tied to ground	+	125.2	Pass
10	Foil underneath equipment	Sensor 3 rest tied to ground	-	313.0	Pass
10	Foil on enclosure	Sensor 3 rest tied to ground	+	187.8	Pass
10	Foil on enclosure	Sensor 3 rest tied to ground	-	219.1	Pass
10	Monitor SIP SOP	Sensor 3 rest tied to ground	+	187.8	Pass
10	Monitor SIP SOP	Sensor 3 rest tied to ground	-	187.8	Pass
10	Ethernet	Sensor 3 rest tied to ground	+	125.1	Pass
10	Ethernet	Sensor 3 rest tied to ground	-	187.7	Pass
10	Port A	Sensor 3 rest tied to ground	+	156.4	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
10	Port A	Sensor 3 rest tied to ground	-	125.2	Pass
10	Port B	Sensor 3 rest tied to ground	+	125.2	Pass
10	Port B	Sensor 3 rest tied to ground	-	156.4	Pass
10	USB	Sensor 3 rest tied to ground	+	125.2	Pass
10	USB	Sensor 3 rest tied to ground	-	156.5	Pass
10	USB front	Sensor 3 rest tied to ground	+	93.8	Pass
10	USB front	Sensor 3 rest tied to ground	-	125.1	Pass
10	Foil underneath equipment	Sensor 4rest tied to ground	+	156.5	Pass
10	Foil underneath equipment	Sensor 4 rest tied to ground	-	125.2	Pass
10	Foil on enclosure	Sensor 4 rest tied to ground	+	187.7	Pass
10	Foil on enclosure	Sensor 4 rest tied to ground	-	219.0	Pass
10	Monitor SIP SOP	Sensor 4 rest tied to ground	+	156.4	Pass
10	Monitor SIP SOP	Sensor 4 rest tied to ground	-	125.1	Pass
10	Ethernet	Sensor 4 rest tied to ground	+	125.1	Pass
10	Ethernet	Sensor 4 rest tied to ground	-	125.2	Pass
10	Port A	Sensor 4 rest tied to ground	+	125.2	Pass
10	Port A	Sensor 4 rest tied to ground	-	156.4	Pass
10	Port B	Sensor 4 rest tied to ground	+	125.2	Pass
10	Port B	Sensor 4 rest tied to ground	-	125.1	Pass
10	USB	Sensor 4 rest tied to ground	+	125.1	Pass
10	USB	Sensor 4 rest tied to ground	-	219.2	Pass
10	USB front	Sensor 4 rest tied to ground	+	187.8	Pass
10	USB front	Sensor 4 rest tied to ground	-	156.4	Pass
Supplementary information:					

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time			Pass
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
Sensors tied together	+	20	0	Remained 0 at all measurements made above
Supplementary information:				

8.5.5.2	TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load		Pass
Test Voltage applied to	Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy E1 as % of E2 (%)
+ sensor 1 with sensors 2, 3, and 4 of the same connected to earth	354.7	354.8	99.9
+ sensor 2 with sensors 1, 3, and 4 of the same connected to earth	353.0	355.9	99.2
+ sensor 3 with sensors 2, 1, and 4 of the same connected to earth	355.5	357.1	99.6
+ sensor 4 with sensors 2, 3, and 1 of the same connected to earth	355.3	357.2	99.5
- sensor 1 with sensors 2, 3, and 4 of the same connected to earth	311.2	319.3	97.5
- sensor 2 with sensors 1, 3, and 4 of the same connected to earth	330.2	338.7	97.4
- sensor 3 with sensors 2, 1, and 4 of the same connected to earth	336.9	337.4	99.8
- sensor 4 with sensors 2, 3, and 1 of the same connected to earth	313.5	319.3	98.2
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 Ω with ME Equipment connected; E2= Measured energy delivered to 100 Ω without ME equipment connected.			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.6.3	RM RESULTS TABLE: Protective earthing of moving parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Protective earth terminal fixed to ME chassis	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS			Pass
Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part	N/A	N/A	N/A	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part	40A/120S	-	8.2	100
ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part	N/A	N/A	N/A	200
Supplementary information:				

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks	
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
B, NC (S1=1, S5=1, S7=1, S12=1)	264	60	252.7	-	
B, SFC (S1=0, S5=1, S7=1, S12=1)	264	60	466.8	-	
A, NC (S1=1, S5=0, S7=1, S12=0)	264	60	67.9	-	
A, SFC (S1=0, S5=1, S7=1, S12=1)	264	60	128.4	-	
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC	
B, NC (S1=1, S5=1, S7=1, S12=1)	264	60	9.4	Plastic enclosure	
B, SFC (S1=1, S5=1, S7=0, S12=1)	264	60	20.9	Plastic enclosure	
A, NC (S1=1, S5=0, S7=1, S12=1)	264	60	3.2	Plastic enclosure	
A, SFC (S1=0, S5=0, S7=1, S12=0)	264	60	15.3	Plastic enclosure	
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)	
B, NC (S1=1, S5=1, S7=1, S12=1)	264	60	2.2	-	
B, SFC (S1=1, S5=0, S7=0, S12=0)	264	60	5.4	-	
A, NC (S1=1, S5=1, S7=1, S12=1)	264	60	0.9	-	
A, SFC (S1=1, S5=0, S7=0, S12=0)	264	60	1.6	-	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 uA Type CF AP: 50 uA	
B, NC (S5=1, S9=1, S13=1)	264	60	37.0	-	
B, SFC (S5=1, S9=0, S13=0)	264	60	36.6	-	
A, NC (S5=1, S9=1, S13=1)	264	60	37.4	-	
A, SFC (S5=0, S9=0, S13=0)	264	60	37.4	-	
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC(d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)	
N/A	-	-	-	-	
N/A	-	-	-	-	

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IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 uA Type CF: N/A
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC;50 uA SFC (d.c. or a.c. current)
B, NC (S1=1, S5=0, S7=1)	264	60	1.6	One sensor tested at a time with all others tied together
B, SFC (S1=1, S5=1, S7=0)	264	60	4.5	One sensor tested at a time with all others tied together
A, NC (S1=1, S5=0, S7=1)	264	60	1.5	One sensor tested at a time with all others tied together
A, SFC (S1=1, S5=0, S7=0)	264	60	4.4	One sensor tested at a time with all others tied together
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
B, NC (S1=1, S5=1, S7=1, S12=1)	264	60	1.3	All sensors tied together
B, SFC (S1=0, S5=0, S7=1, S12=1)	264	60	1.4	All sensors tied together
A, NC (S1=1, S5=1, S7=1, S12=1)	264	60	0.9	All sensors tied together
A, SFC (S1=1, S5=1, S7=0, S12=0)	264	60	1.0	All sensors tied together
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC;1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-

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IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict

Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000uA Type CF: 100 uA
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 uA Type CF: N/A
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER - Earth leakage current
TC – Touch current
P - Patient leakage current
PA – Patient auxiliary current
TP – Total Patient current
PM - Patient leakage current with mains on the applied parts
MD - Measuring device

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				Pass
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
Primary to Metal Enclosure	BI	240	-	1500	No

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Secondary to Metal Enclosure	BI	240	-	1500	No
Preamp connector to preamp enclosure	BI	240	-	1500	No
Sensor connection to Preamp enclosure	BI	240	-	1500	No
Sensor to Sensor connector	BI	240	-	1500	No
Sensor connection to Metal Enclosure	BI	240	-	1500	No
Primary to Plastic Enclosure	RI	240	-	4000	No
Sensor Connection to Primary	BI	240	-	1500	No

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		Pass
	Allowed impression diameter (mm) .....:	≤ 2 mm	—
	Force (N).....:	20	—

Part/material	Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts	75	0.6
Insulating material supporting uninsulated Mains Parts	N/A	N/A
Supplementary information:		

8.8.4.1	RM RESULTS TABLE: Mechanical strength and resistance to heat		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.1.2.5	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

8.9.2	TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4		N/A
Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1]	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
Supplementary information: Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		

Supplementary information:

[1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.4	Table: Thermal cycling tests on one sample of cemented joint (see 8.9.3.3)		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		

Supplementary information:

[1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.10	TABLE: List of critical components				Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity [1]
CAS Medical Hospital Grade Power Cord with Ferrite Bead	Feller Power Cords CCA-WESCO	Part No. 6922 CBL-PWR-SP30-FB-UK	SJT 3x 18AWG, rated 125VAC, 10A H05VV-F 32/0.2 BAx3C 250Vac,13A	UL62	UL, CSA VDE
AC Power Entry Module, Filtered	Tyco / Corcom	PE000DL6C	250VAC, 6A	UL 544, IEC 60601-1	UL, CSA, TUV
Primary Fuses (2 Provided)	Littelfuse	02153.15P	5x20mm type, T3.15AH250V, rated 250V, 3.15A slow-blow	IEC 60127	UL, CSA, TUV
Power Supply	Emerson / Astec	NPS-44M	100/250 VAC, 50/60Hz 2.5A	UL 60601-1/A2:1995	UL, CSA, TUV
Battery	Panasonic	LC-R122R2P	12V, 2.2aH, 0.33A Trickle Charge Current	UL 1989	UL
92x22mm Tube Axial Cooling Fan	NIDEC	U92T12MUA7-58 T92T12MUA7-58	12VDC, 0.25A, 3.0W, 3100RPM, 52CFM	UL 507	UL, CSA, TUV
Power Line Filter	Tyco / Corcom	3EHQ3	250VAC, 3A Medical Grade	UL60601-1	UL, CSA, TUV
F1	Littlefuse	0154002.DR	FUSEBLOCK W/2.0A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
F2,F4	Littlefuse	154.250DR	FUSEBLOCK W/.250A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
F3,F5	Littlefuse	154.125DR	FUSEBLOCK W/.125A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
T1	HALO	TGS110-S055NCRL	ETHERNET ISOLATION TRANSFORMER, UL, 1500V, 4MM CREEPAGE	UL 60601-1/A2:1995	UL
U44,U46	Linear Technology	LTM2882CY-3#PBF	IC, Transceiver, RS232, Isolated Isolated 2500 VRMS	UL 60950,RoHS	UR
U63	RECOM	RSO-1205S/H3 RS-1205S/H3	DC-DC Converter, 9-18V in, 5V out, Isolated 3kV	Tested in end system	-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

C280 on PCB Assy # 03-59-0402	TDK	CD85-E2GA102MYNS	Cap, Cer, 1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	IEC/EN 60384-14 IEC/EN 60065 UL 1414 CSA C22.2 No.0 & No.1	UL, VDE, CSA, BSI, SEMKO, SEV, FIMKO, DEMKO, NEMKO, IMQ
C1 on PCB assy # 03-59-0403	TDK	CD85-E2GA102MYNS	Cap, Cer, 1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	IEC/EN 60384-14 IEC/EN 60065 UL 1414 CSA C22.2 No.0 & No.1	UL, VDE, CSA, BSI, SEMKO, SEV, FIMKO, DEMKO, NEMKO, IMQ
Coin cell battery on PCB assy 03-59-0402	Panasonic	BR1225	Battery, Coin Cell, Lithium, 48 mAh, 12.5 mm	UL 1642	UL
U64,U65,U66,U67	Silicon Laboratories	Si8640ED-B-IS Si8640BD-B-IS	IC, Digital Isolator, Quad channel, Wide Body SOIC-16, RoHS	IEC 60950-1, 61010-1, 60601-1 (reinforced insulation)	UL, CSA, VDE
Teflon FEP FluorocarbonFilm Tape	CS Hyde DuPont High Performance Films	23-FEP	FEP (Teflon®) film w/ Silicone Adhesive, 0.0035" Thick	Tested by Intertek met 5000VAC dielectric withstand	-
Poron Foam	Rogers Corp.	4701-30-25035-34	Urethane foam 0.0035" thick	Tested by Intertek met 2500VAC dielectric withstand	-
Plastic enclosure	Plastic Design International	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene	UL 94	UR
Metal enclosure	Metalmen	Aluminum 5052-H32	Aluminum 5052-H32	Tested in end system	-
Sensors	CASMEDICAL	03-05-0511	Disposable oximeter sensor	Tested in end system	-
Mylar Tape	3M™	Polyimide Film Tape 5413	Kapton® Polyimide Film Silicone Dielectric Strength: 7000 volts	UL 94 Tested by Intertek met 4000 VAC dielectric withstand	UL

Supplementary information:
1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.10.1	RM RESULTS TABLE: Fixing of components		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.1.1.1-4.1.1.7, 4.1.3.1-4.1.3.8	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

8.10.2	RM RESULTS TABLE: Fixing of wiring		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.1.5-4.1.1.7	Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

8.10.5	RM RESULTS TABLE: Mechanical protection of wiring		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.1.6, 4.1.1.7	Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.11.3.5	TABLE: Cord anchorages			Pass
Cord under test	Mass of equipment (kg)	Pull (N)	Torque Nm)	Remarks
Preamp to Monitor	0.40	30	0.1	Pass
Sensor to Preamp	0.40	30	0.1	Pass
Supplementary information:				

8.11.3.6	TABLE: Cord guard		Pass
Cord under test	Test mass	Measured curvature	Remarks
Preamp to Monitor	435 g	12.7 mm	Pass
Sensor to Preamp	250 g	9.5 mm	Pass
Supplementary information:			

8.11.5	RM RESULTS TABLE: Mains fuses and over-current releases		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		Fuses provided in the ME equipment; No omission of the fuses or over current releases	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.2.1	RM RESULTS TABLE: HAZARDS associated with moving parts - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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Clause	Requirement + Test	Result - Remark	Verdict

9.2.2.2	TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)			N/A
Part of body	Allowable adult gap[1], mm	Measured adult gap, mm	Allowable children gap[1], mm	Measured children gap, mm
Body	> 500		> 500	
Head	> 300 or < 120		> 300 or < 60	
Leg	> 180		> 180	
Foot	> 120 or < 35		> 120 or < 25	
Toes	> 50		> 50	
Arm	> 120		> 120	
Hand, wrist, fist	> 100		> 100	
Finger	> 25 or < 8		> 25 or < 4	

Supplementary information: No moving parts

[1] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.

9.2.2.4.3	RM RESULTS TABLE: Movable guards		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.2.2.4.4	RM RESULTS TABLE: Protective measures		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.2.2.5 c)	RM RESULTS TABLE: Continuous activation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.2.2.6	RM RESULTS TABLE: Speed of movement(s)		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.2.3.2	RM RESULTS TABLE: Over travel		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.2.4	RM RESULTS TABLE: Emergency stopping devices		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
6.6			

9.2.5	RM RESULTS TABLE: Release of patient		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.3	RM RESULTS TABLE: Hazards associated with surfaces, corners and edges		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.5.8.1, 4.5.8.2	Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

9.4.2.1	TABLE: Instability—overbalance in transport position	Pass
ME EQUIPMENT preparation	Test Condition (transport position)	Remarks
In case, laying down, wheels facing up plane	10 ° incline	Remained stable

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

In case, laying down, wheels facing down plane	10 ° incline	Remained stable
In case, on end, wheels facing up plane	10 ° incline	Remained stable
In case, on end, wheels facing down plane	10 ° incline	Remained stable
Supplementary information:		

9.4.2.2	TABLE: Instability—overbalance excluding transport position	Pass
ME EQUIPMENT preparation	Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)	Remarks
Front side facing down plane	10 ° incline	Remained stable
Right side facing down plane	10 ° incline	Remained stable
Rear side facing down plane	10 ° incline	Remained stable
Left side facing down plane	10 ° incline	Remained stable
Supplementary information:		

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces	N/A
ME EQUIPMENT preparation	Test Condition (force used, direction of force, weight of equipment, location of force	Remarks
Supplementary information:		

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion	N/A
ME EQUIPMENT preparation	Test Condition (force location and height)	Remarks
Supplementary information:		

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold	N/A
ME EQUIPMENT preparation	Test Condition (speed of movement)	Remarks
Supplementary information:		

9.4.2.4.3	RM RESULTS TABLE: Movement over a threshold		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not mobile	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position	N/A
ME EQUIPMENT Preparation	Test Condition (transport position, working load, locking device(s), caster position)	Remarks
Supplementary information:		

9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position	N/A
ME EQUIPMENT Preparation	Test Condition (working load, locking device(s), caster position, force, force location, force direction)	Remarks
Supplementary information:		

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.4.4	TABLE: Grips and other handling devices	N/A
Clause and Name of Test	Test Condition	Remarks
Supplementary information:		

9.5.1	RM RESULTS TABLE: Protective means		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.7.3.3	Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

9.6.1	RM RESULTS TABLE: Acoustic energy - General		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.5.2	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.6.2.2	RM RESULTS TABLE: Infrasound and ultrasound energy		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No infrasound or ultrasound energy	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.7.2	RM RESULTS TABLE: Pneumatic and hydraulic parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No pneumatic or hydraulic parts	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.7.4	RM RESULTS TABLE: Pressure rating of ME equipment parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		ME equipment contains no parts using or generating working pressure	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.7.5	TABLE: Pressure vessels				N/A
Hydraulic, Pneumatic or Suitable Media and Test Pressure	Vessel Burst	Permanent Deformation	Leaks	Vessel fluid substance	Remarks
Supplementary Information: ME equipment contains no parts using or generating working pressure					

9.7.6	RM RESULTS TABLE: Pressure-control device		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		ME equipment contains no parts using or generating working pressure	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.7.7	RM RESULTS TABLE: Pressure-relief device		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		ME equipment contains no parts using or generating working pressure	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.8.1	RM RESULTS TABLE: Hazards associated with support systems - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No support systems	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.2	RM RESULTS TABLE: Tensile safety factor		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.3.1	RM RESULTS TABLE: Strength of patient or operator support or suspension systems - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No support systems	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.8.3.2	TABLE: PATIENT support/suspension system - Static forces			N/A
ME EQUIPMENT part or area	Position	Load	Area	Remarks
Supplementary Information: No support systems				

9.8.3.2a, b	RM RESULTS TABLE: Static forces due to loading from persons		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.3.3	TABLE: Support/Suspension System – Dynamic forces due to loading from persons			N/A
ME EQUIPMENT part or area	Position	Safe Working Load	Area	Remarks
Supplementary Information: No support systems				

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.8.4.1	RM RESULTS TABLE: Systems with mechanical protective devices - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.4.3	RM RESULTS TABLE: Mechanical protective device for single activation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.5	RM RESULTS TABLE: Systems without mechanical protective devices		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.1	TABLE: Measurement of X - radiation		N/A
Maximum allowable radiation pA/kg (µSv/h) (mR/h)		36 (5 µSv/h) (0.5 mR/h)	
Surface area under test Surface no./ Description[1]		Measured Radiation, pA/kg (µSv/h) (mR/h)	Remarks
1/ /			
2/ /			
3/ /			
4/ /			
5/ /			
6/ /			
7/ /			
8/ /			
9/ /			
10/ /			
Supplementary information: [1] Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access			

10.1.2	RM RESULTS TABLE: ME equipment intended to produce diagnostic or therapeutic X-radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce diagnostic or therapeutic X-radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

10.2	RM RESULTS TABLE: Alpha, beta, gamma, neutron & other particle radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce any particle radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

10.3	RM RESULTS TABLE: Microwave radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce microwave radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

10.5	RM RESULTS TABLE: Other visible electromagnetic radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce other radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

10.6	RM RESULTS TABLE: RISK associated with infrared radiation other than emitted by lasers and LEDs		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce qualifying infrared radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

10.7	RM RESULTS TABLE: RISK associated with ultraviolet radiation other than emitted by lasers and LEDs		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce qualifying ultraviolet radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No. .....:	FORE-SIGHT Elite				
Test ambient (°C) .....:	25.6				
Test supply voltage/frequency (V/Hz)[4] .....:	99VAC/ 50HZ				
Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	26.6	-
Elite	3	Power Supply, Transformer Primary	155	52.2	-
Elite	4	Power Supply, Transformer Secondary	155	50.5	-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Elite	6	Power Supply, C6	105	45.5	-
Elite	7	Power Supply, Mains Wire Connector	75	33.5	-
Elite	8	Line filter	75	27.6	-
Elite	9	Appliance inlet	40	25.8	-
Elite	10	Battery	104	27.1	-
Elite	11	TGS110	70	29.5	-
Elite	12	Button Battery	80	30.8	-
Elite	13	Relay	85	42.5	-
Elite	14	Screen	48	26.3	-
Elite	15	Preamp Enclosure	48	26.3	-
Elite	17	Sensor 1	41	25.1	-
Elite	18	Sensor 2	41	24.7	-
Elite	19	Sensor 3	41	25.9	-
Elite	20	Sensor 4	41	25.6	-

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT	Pass
Model No. .....:	FORE-SIGHT Elite	
Test ambient (°C) .....:	25.7	
Test supply voltage/frequency (V/Hz)[4] .....:	99VAC/ 60HZ	

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	26.1	-

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IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
Elite	3	Power Supply, Transformer Primary	155	52.1	-
Elite	4	Power Supply, Transformer Secondary	155	50.3	-
Elite	6	Power Supply, C6	105	45.4	-
Elite	7	Power Supply, Mains Wire Connector	75	33.5	-
Elite	8	Line filter	75	27.7	-
Elite	9	Appliance inlet	40	25.9	-
Elite	10	Battery	104	27.2	-
Elite	11	TGS110	70	29.5	-
Elite	12	Button Battery	80	30.8	-
Elite	13	Relay	85	42.4	-
Elite	14	Screen	48	26.4	-
Elite	15	Preamp Enclosure	48	26.3	-
Elite	17	Sensor 1	41	25.6	-
Elite	18	Sensor 2	41	24.4	-
Elite	19	Sensor 3	41	24.7	-
Elite	20	Sensor 4	41	24.5	-

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT	Pass
Model No. .....:	FORE-SIGHT Elite	
Test ambient (°C) .....:	25.6	
Test supply voltage/frequency (V/Hz)[4] .....:	264VAC/ 50HZ	

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	26.1	-
Elite	3	Power Supply, Transformer Primary	155	55.8	-
Elite	4	Power Supply, Transformer Secondary	155	53.9	-
Elite	6	Power Supply, C6	105	44.4	-
Elite	7	Power Supply, Mains Wire Connector	75	33.0	-
Elite	8	Line filter	75	27.8	-
Elite	9	Appliance inlet	40	26.6	-
Elite	10	Battery	104	27.4	-
Elite	11	TGS110	70	29.6	-
Elite	12	Button Battery	80	30.8	-
Elite	13	Relay	85	42.5	-
Elite	14	Screen	48	26.4	-
Elite	15	Preamp Enclosure	48	26.5	-
Elite	17	Sensor 1	41	24.4	-
Elite	18	Sensor 2	41	24.4	-
Elite	19	Sensor 3	41	24.8	-
Elite	20	Sensor 4	41	24.4	-

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT	Pass
Model No. .....:	FORE-SIGHT Elite	
Test ambient (°C) .....:	26.0	
Test supply voltage/frequency (V/Hz)[4] .....:	264VAC/ 60HZ	

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	26.3	-
Elite	3	Power Supply, Transformer Primary	155	55.7	-
Elite	4	Power Supply, Transformer Secondary	155	53.6	-
Elite	6	Power Supply, C6	105	41.9	-
Elite	7	Power Supply, Mains Wire Connector	75	31.1	-
Elite	8	Line filter	75	27.8	-
Elite	9	Appliance inlet	40	26.8	-
Elite	10	Battery	104	27.5	-
Elite	11	TGS110	70	29.6	-
Elite	12	Button Battery	80	30.8	-
Elite	13	Relay	85	42.7	-
Elite	14	Screen	48	26.3	-
Elite	15	Preamp Enclosure	48	26.8	-
Elite	17	Sensor 1	41	24.4	-
Elite	18	Sensor 2	41	24.3	-
Elite	19	Sensor 3	41	24.7	-
Elite	20	Sensor 4	41	24.4	-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT	Pass
Model No. .....:	FORE-SIGHT Elite	
Test ambient (°C) .....:	24.3	
Test supply voltage/frequency (V/Hz)[4] .....:	12VDC/	

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	23.2	-
Elite	10	Battery	104	24.5	-
Elite	11	TGS110	70	25.4	-
Elite	12	Button Battery	80	24.9	-
Elite	13	Relay	85	33.8	-
Elite	14	Screen	48	24.8	-
Elite	15	Preamp Enclosure	48	24.8	-
Elite	17	Sensor 1	41	25.2	-
Elite	18	Sensor 2	41	22.8	-
Elite	19	Sensor 3	41	23.2	-
Elite	20	Sensor 4	41	25.5	-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

11.1.1	RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.1.2.6	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.2.1	RM RESULTS TABLE: Applied parts intended to supply heat to patient		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Applied parts not intended to supply heat.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.1.2.2	RM RESULTS TABLE: Applied parts not intended to supply heat to patient		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Applied part did not exceed 41°C	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.1.3	TABLE: Temperature of windings by change-of-resistance method						N/A
Temperature T of winding:	t_1 (°C)	R_1 (Ω)	t_2 (°C)	R_2 (Ω)	T (°C)	Allowed T_{max} (°C)	Insulation class
Supplementary information:							

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.3	RM RESULTS TABLE: Measurements		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Section 3.11	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5	No risk benefit analysis performed		N/A

11.2.2.1	RM RESULTS TABLE: Risk of fire in an oxygen rich environment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not used in an oxygen rich environment	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.2.2.1	TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source	N/A
Areas where sparking might cause ignition:		Remarks
1.		
2.		
3.		
5.		
6.		
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		Remarks
1.		
2.		
3.		

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.		
5.		
6.		
Test parameters selected representing worst case conditions for ME EQUIPMENT:		Remarks
Oxygen concentration (%) ..... :		
Fuel..... :		
Current (A)..... :		
Voltage (V) ..... :		
Capacitance (µF) ..... :		
Inductance or resistance (h or Ω)..... :		
No. of trials (300 Min)..... :		
Sparks resulted in ignition (Yes/No).... :		
Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.		

11.3	RM RESULTS TABLE: Constructional requirements for fire enclosures of ME equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		alternate means not used	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.5	RM RESULTS TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not intended for use in conjunction with flammable agents.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances		Pass
Clause / Test Name	Test Condition	Part under test	Remarks
11.6.3 Spillage	8 oz. of water spilled on top of the monitor, in one event lasting < 15 sec liter of water spilled on the preamp housing, in one event lasting < 30 sec	Unit	Pass
11.6.6 / Cleaning	Cleaned with 10% bleach solution per IFU	Unit	Pass
11.6.6 / Cleaning	Windex per IFU	Screen	Pass
Supplementary information:			

11.6.2	RM RESULTS TABLE: Overflow in ME equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No liquid reservoir	
4.3			
4.4			
5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.6.3	RM RESULTS TABLE: Spillage on ME equipment and ME system		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification Rev 01-xc	Items 4.5.5.11, 4.5.5.12, 4.5.5.13	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5	No risk benefit analysis performed		N/A

11.6.5	RM RESULTS TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	IPX0		N/A
4.3			N/A
4.4			N/A
5			N/A

11.6.6	RM RESULTS TABLE: Cleaning and disinfection of ME equipment and ME systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.10.3.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.6.7	RM RESULTS TABLE: Sterilization of ME equipment and ME systems		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		ME equipment and its accessories are not intended to be sterilized.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.6.8	RM RESULTS TABLE: Compatibility with substances used		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No substances used	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.1	RM RESULTS TABLE: Accuracy of controls and equipment		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Section 3.6 # 5 Hazard 4.4.1.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

12.3	RM RESULTS TABLE: Alarm systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazards 4.11.1.1 – 4.11.1.3	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

12.4.1	RM RESULTS TABLE: Intentional exceeding of safety limits		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Safety limits cannot be exceeded	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.2	RM RESULTS TABLE: Indication of parameters relevant to safety		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.5.9.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

12.4.3	RM RESULTS TABLE: Accidental selection of excessive output values		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		The FORE-SIGHT is not a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments Body location does not change any settings for output of the Oximeter, but is used to improve measurement accuracy. See note in 21-07-0304 Section 3.6, sub-section 5.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.4	RM RESULTS TABLE: Incorrect output		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		See note in 21-07-0304 Section 3.6, sub-section 5 Body location does not change any settings for output of the Oximeter, but is used to improve measurement accuracy	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.5.2	RM RESULTS TABLE: Diagnostic X-ray equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not diagnostic X-ray equipment	
4.3			
4.4			
5			
6.2			
6.3			
6.4			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

12.4.5.2	RM RESULTS TABLE: Diagnostic X-ray equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

12.4.5.3	RM RESULTS TABLE: Radiotherapy equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Monitor does not provide radio therapy.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.5.4	RM RESULTS TABLE: Other ME equipment producing diagnostic or therapeutic radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Monitor does not provide diagnostic or therapeutic radiation.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.6	RM RESULTS TABLE: Diagnostic or therapeutic acoustic pressure		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Monitor does not provide diagnostic or therapeutic acoustic pressure.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.1.2	TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances	N/A

Power dissipated less than (W)..... :	15
Energy dissipated less than (J) .....:	900

Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks

Supplementary information:

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive	Pass

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Clause 8.1:	—	—
			N/A
13.2.3	Overheating of transformers per Clause 15.5:	—	—
			N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
			N/A
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
			N/A
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
			N/A
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
	Single ventilation fans locked consecutively	Unit continued to operate without overheating or exceeding temperature limits	PASS
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	Unit continued to operate without overheating or exceeding temperature limits	PASS
	Simulated blocking of filters		N/A
	Flow of a cooling agent interrupted		N/A
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
			N/A
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
		V measured =	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
		V measured =	N/A
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:		N/A
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		N/A
	Temperatures measured as specified in 11.1.3 d)		N/A
	Temperatures did not exceed limits of Table 26		N/A
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
			N/A
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
			N/A

Supplementary information:
[1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

13.2.6	RM RESULTS TABLE: Leakage of liquid		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Does not contain liquids	
4.3			
4.4			
5			
6.2			
6.3			
6.4			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.2.6	RM RESULTS TABLE: Leakage of liquid		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

14.1	RM RESULTS TABLE: Programmable electrical medical systems - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Clause 14 applied	
4.3			
4.4			
5			

14.6.1	RM RESULTS TABLE: Identification of known and foreseeable hazards		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0306 Rev 01-Xa Gemini Risk Analysis 21-07-0334 Rev 00 Gemini NSAM Boot Life Cycle 21-07-0336 Rev 00 Gemini Main Boot Life Cycle	Software Hazards 4.1.2.1, 4.1.2.3, 4.1.3.6, 4.3.1.1, 4.3.4.1, 4.4.1.1, 4.4.1.2, 4.4.2.1, 4.4.3.1, 4.4.4.1, 4.4.4.2, 4.4.5.1, 4.4.5.2, 4.4.5.3, 4.4.6.2, 4.4.6.3, 4.4.6.4, 4.5.1.1, 4.5.1.2, 4.5.2.1, 4.5.3.1, 4.5.3.2, 4.5.4.1, 4.5.5.1, 4.5.6.1, 4.6.1.1., 4.6.1.2, 4.6.1.3, 4.6.2.1, 4.6.4.1, 4.6.5.1, 4.6.5.2, 4.6.5.4, 4.7.1.1	Pass

14.6.2	RM RESULTS TABLE: Risk control		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.1	21-07-0333 Rev 00 21-07-0334 Rev 00 21-07-0335 Rev 00 21-07-0336 Rev 00	Gemini Main App Life Cycle Gemini NSAM Boot Life Cycle Gemini NSAM Main Life Cycle Gemini Main Boot Life Cycle	Pass

14.7	RM RESULTS TABLE: Requirement specification		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	21-07-0324 Rev 00 21-07-0325 Rev 00 21-07-0326 Rev 00 21-07-0327 Rev 00	Gemini Boot SW Req Gemini Main SW Req Gemini NSAM Main Boot SW Req Gemini NSAM Main App SW Req	Pass

14.8	RM RESULTS TABLE: Architecture		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	21-07-0328 Rev 00 21-07-0329 Rev 00 21-07-0330 Rev 00 21-07-0331 Rev 01	Gemini Main Boot Architecture Gemini Main App Architecture Gemini NSAM Boot Architecture Gemini NSAM App Architecture	Pass

14.9	RM RESULTS TABLE: Design and Implementation	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2	21-07-0328 Rev 00 21-07-0329 Rev 00 21-07-0330 Rev 00 21-07-0331 Rev 01	Gemini Main Boot Architecture Gemini Main App Architecture Gemini NSAM Boot Architecture Gemini NSAM App Architecture	Pass
6.3	21-07-0333 Rev 00 21-07-0334 Rev 00 21-07-0335 Rev 00 21-07-0336 Rev 00	Gemini Main App Life Cycle Gemini NSAM Boot Life Cycle Gemini NSAM Main Life Cycle Gemini Main Boot Life Cycle	Pass

14.10	RM RESULTS TABLE: Verification		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	VeP 120017 R00-Xa	Elite Software Verification Plan	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

14.11	RM RESULTS TABLE: PEMS validation		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	VaP 120019 Rev01	Elite Software Validation Plan	Pass

14.13	RM RESULTS TABLE: Connection of PEMS by NETWORK/DATA COUPLING to other equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		device not intended to connect to Network/Data coupling	
4.3			
4.4			
5			
6.2			
6.3			

15.1	RM RESULTS TABLE: Construction of ME equipment – Arrangements of controls and indicators of ME equipment		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Section 4.6.1.3	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5	No risk benefit analysis performed		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.3	TABLE: Mechanical Strength tests [1)]			Pass
Clause	Name of Test	Test conditions	Observed results/Remarks	
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No damage	
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No damage on plastic, small dent on metal	
15.3.4.1	Drop Test (hand-held)	Free fall height (m) = 1	Preamp, No damage	
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	Monitor, No damage	
15.3.5	Rough handling test	Travel speed (m/s) = N/A	N/A	
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 70	Pass	
Supplementary information: [1)]As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).				

15.3.2	RM RESULTS TABLE: Push test		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.3.5.1	Pass
4.3			Pass
4.4			Pass
5			Pass

15.3.3	RM RESULTS TABLE: Impact test		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.3.5.1	Pass
4.3			Pass
4.4			Pass
5			Pass

15.3.4.2	RM RESULTS TABLE: Portable ME equipment		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.3.5.4	Pass
4.3			Pass
4.4			Pass
5			Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.3.5	RM RESULTS TABLE: Rough handling test		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not Mobile	
4.3			
4.4			
5			

15.4.1	RM RESULTS TABLE: Construction of connectors		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		All patient connections have the same functions	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

15.4.2.1 a	RM RESULTS TABLE: THERMAL CUT-OUTS and OVER-CURRENT RELEASES		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such automatic resetting devices.	
4.3			
4.4			
5			

15.4.2.1 b	RM RESULTS TABLE: THERMAL CUT-OUTS with a safety function		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such devices	
4.3			
4.4			

15.4.2.1 c	RM RESULTS TABLE: Independent non-SELF-RESETTING THERMAL CUT-OUT		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such parts	
4.3			
4.4			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.4.2.1 d	RM RESULTS TABLE: Loss of function of ME EQUIPMENT		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such parts	
4.3			
4.4			

15.4.2.1 h	RM RESULTS TABLE: ME EQUIPMENT with tubular heating elements		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		no such tubular heating elements	
4.3			
4.4			

15.4.3.1	RM RESULTS TABLE: Housing		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.1.4.2	Pass
4.3			Pass
4.4			Pass

15.4.3.2	RM RESULTS TABLE: Connection		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.1.1.4	Pass
4.3			Pass
4.4			Pass

15.4.3.3	RM RESULTS TABLE: Protection against overcharging		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazards 4.1.2.7, 4.1.4.3	Pass
4.3			Pass
4.4			Pass

15.4.3.4	RM RESULTS TABLE: Lithium batteries		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No lithium batteries	

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.4.3.4	RM RESULTS TABLE: Lithium batteries		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3			
4.4			

15.4.3.5	RM RESULTS TABLE: Excessive current and voltage protection		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.1.2.8	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

15.4.4	RM RESULTS TABLE: Indicators		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Apparent from normal use	
4.3			
4.4			

15.4.5	RM RESULTS TABLE: Pre-set controls		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No preset controls	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

15.4.6	TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests				N/A
Rotating control under test	Gripping diameter "d" of control knob (mm) [1]	Torque from Table 30 (Nm)	Axial force applied (N)	Unacceptable RISK occurred Yes/No	Remarks

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information: [1] Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

15.4.7.3 b	RM RESULTS TABLE: Entry of liquids		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No foot operated control devices	
4.3			
4.4			

15.5.1.2	TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION		N/A
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)[1] .:			—
RATED input frequency (Hz).....:			—

Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (when protective device did not operate)(Min)	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

Supplementary information:
[1] Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated	N/A

Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1] ..... :	
RATED input frequency (Hz)..... :	
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A)..... :	
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A)..... :	

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

Supplementary information:
[1] Loads on other windings between no load and their NORMAL USE load.
Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32.
Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7	N/A

Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
	Primary & secondary windings				
	Primary winding & frame				
	Secondary winding & frame				

Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

16.1	RM RESULTS TABLE: General requirements for ME Systems		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not an ME system	
4.3			
4.4			
5			

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS			N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (µA)	Measured TOUCH CURRENT in NORMAL CONDITION (µA)	Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)	Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
Supplementary information: Not an ME system				

16.9.1	RM RESULTS TABLE: Connection terminals and connectors		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not an ME system	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

17	RM RESULTS TABLE: Electromagnetic compatibility of ME equipment and ME systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazards 4.3.1.1, 4.3.1.2, 4.3.2.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

SP	TABLE: Additional or special tests conducted	N/A
Clause and Name of Test	Test type and condition	Observed results
Supplementary information:		

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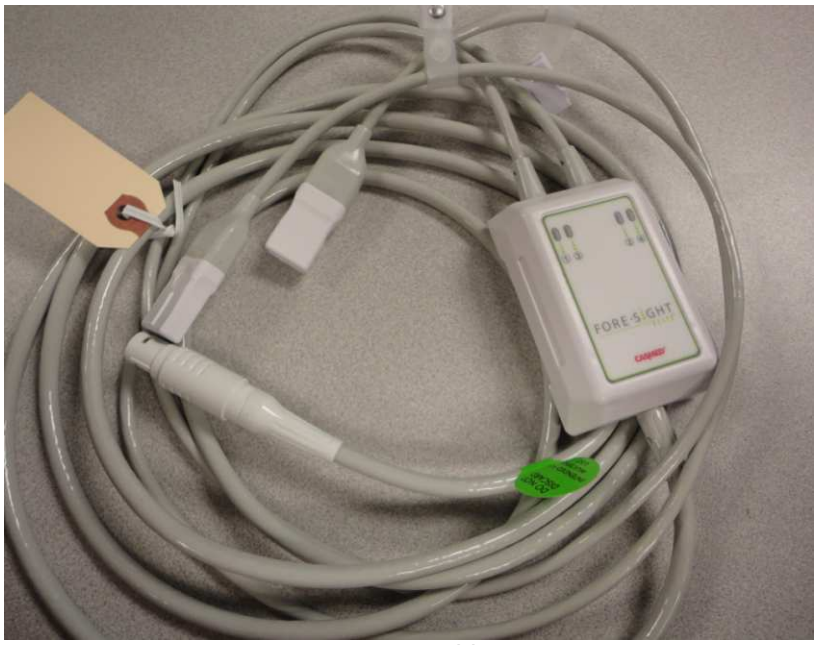
IEC 60601-1
Attachment 1: Photographs of System

External view



Preamp cable

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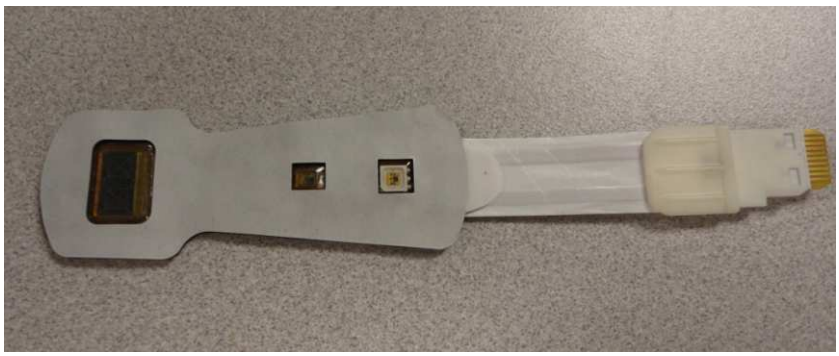
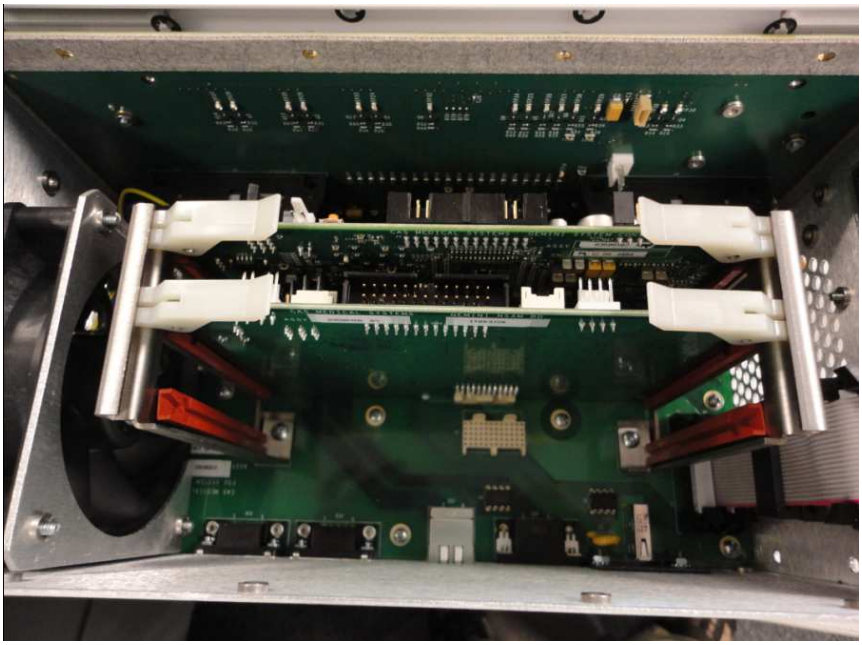
IEC 60601-1
Attachment 1: Photographs of System

Back view of sensor



Front view of sensor



Internal View

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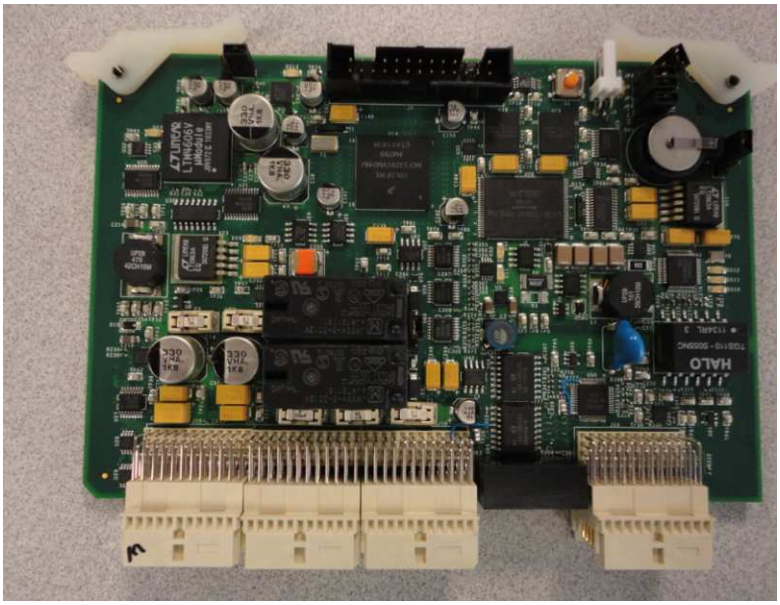
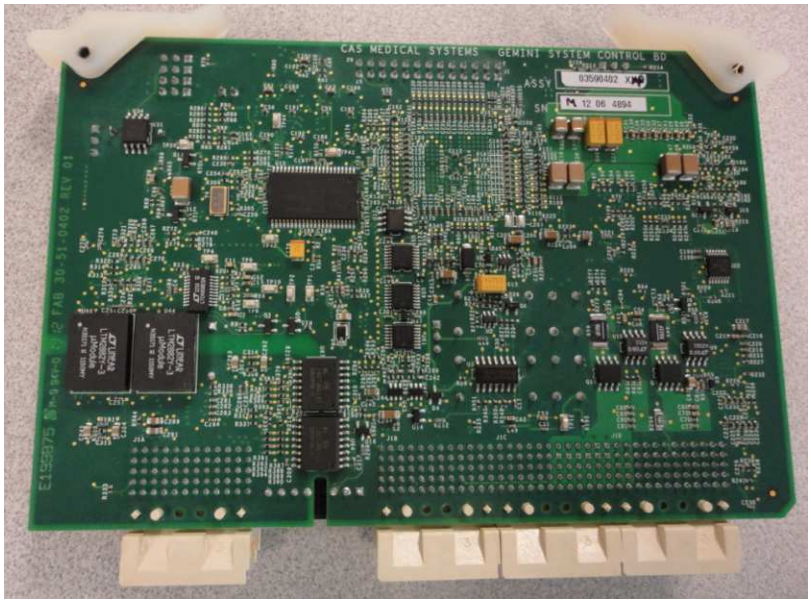
IEC 60601-1
Attachment 1: Photographs of System



Control board side A



Control board side B

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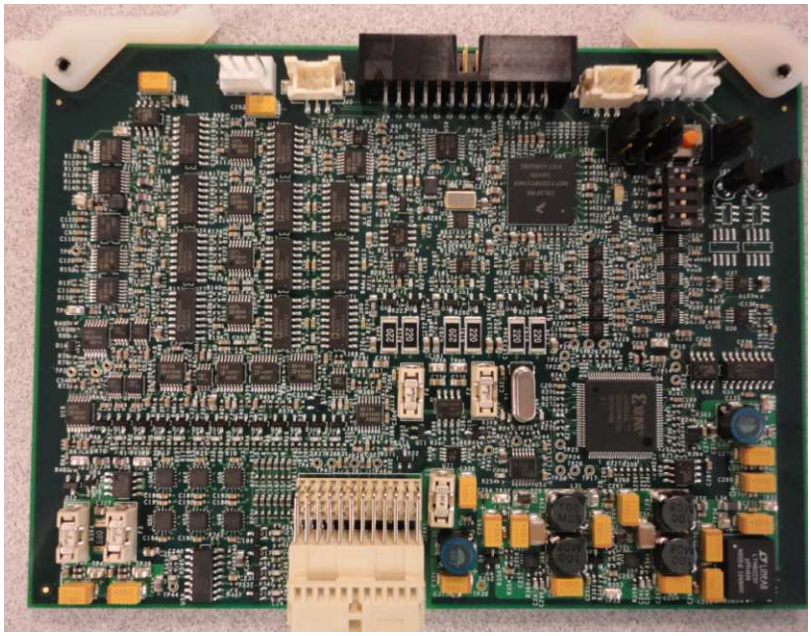
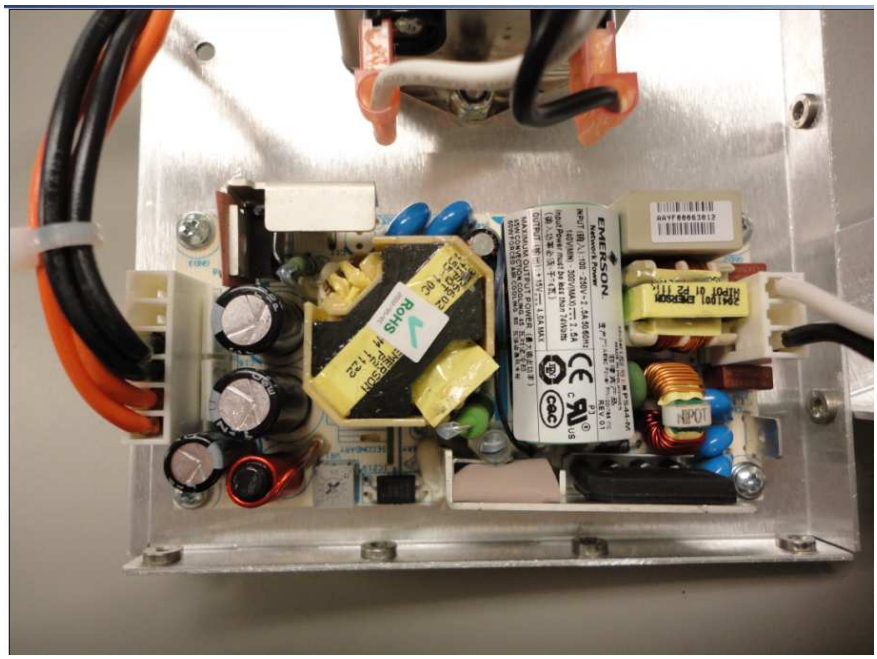
IEC 60601-1
Attachment 1: Photographs of System



Logic Board



Power supply

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 US NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Differences according to ..... :	National standard ANSI/AAMI ES60601-1: 2005		
Attachment Form No. ..... :	US_ND_IEC60601_1E		
Attachment Originator..... :	Underwriters Laboratories Inc.		
Master Attachment..... :	2009-08		
Copyright © 2009 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.			
4.8 b	Replacement: where there was no relevant IEC/ISO standard, the relevant US ANSI standard applied		Pass
	- when no relevant US ANSI standard existed, the requirements of this standard applied		Pass
4.10.2	Replacement: Rated voltage not exceeding 250V dc or single phase ac. or 600V poly-phase ac for ME EQUIPMENT and ME SYSTEMS up to 4kVA	240V	Pass
	Rated voltage not exceeding 600 V for all other ME EQUIPMENT and ME SYSTEMS		Pass
8.2	Addition: All FIXED ME EQUIPMENT & PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT		N/A
8.7.3 d	EARTH LEAKAGE CURRENT values are not higher than the stated values		Pass
	5 mA in NORMAL CONDITION		Pass
	10 mA in SINGLE FAULT CONDITION		Pass
8.11	Addition: PERMANENTLY CONNECTED ME EQUIPMENT provided with field wiring provision in accordance with NEC	Not permanent	N/A
	Installation of connecting cords between EQUIPMENT parts comply with NEC	No connection cord	N/A
	Cable used as external interconnection between units		Pass
	1) Exposed to abuse: Type SJT, SJTO, SJO, ST, SO, STO, or equivalent, or similar multiple-conductor appliance-wiring material,	SJT	Pass
	2) Not exposed to abuse: The cable was as in item 1) above, or		N/A
	i) Type SPT-2, SP-2, or SPE-2, or equivalent		N/A
	ii) Type SVr, SVRO, SVE, or equivalent or similar multiple-conductor appliance wiring material,		N/A

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict
	iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more,		Pass
	- enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more		Pass
	Receptacles provided as part of ME EQUIPMENT and ME SYSTEMS for use in the patient care areas of pediatric wards, rooms, or areas are Listed tamper resistant	No recepticals	N/A
	- or employ a Listed tamper resistant cover in accordance with NEC		N/A
8.11.3.2	Addition: The flexible cord is a type acceptable for the particular application,		Pass
	- and it is acceptable for use at a voltage not less than the rated voltage of the appliance		Pass
	- and has an ampacity as in NEC, not less than the current rating of the appliance		Pass

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition CA - CANADIAN NATIONAL DIFFERENCES to CAN/CSA-C22.2 No. 60601-1:08			
Differences according to.....:	Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08		
Attachment Form No. .....:	CA_ND_IEC60601_1G		
Attachment Originator .....:	CSA International		
Master Attachment .....:	2010-12		
Copyright © 2010 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.			
CA - Canadian National Differences as per CAN/CSA-C22.2 No. 60601-1:08			
1	**Scope, object and related documents**		---
1.1	**Scope**		Pass
	This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the *Canadian Electrical Code (CEC), Part I*, CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.		Pass
	NOTE 1A: *In the IEC 60601 standards series adopted for use in Canada, the Canadian-particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.*		Pass
1.3	**Collateral standards**		Pass
	Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard.		Pass
	NOTE 1: *When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards.*		Pass
1.4	**Particular standards**		Pass
	A requirement of a Canadian-particular safety standard takes precedence over this standard.		Pass
3	**Terminology and definitions**		N/A
3.41	**HIGH VOLTAGE**	Not high voltage	N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

	any voltage above 750 V, 1 050 V peak, as defined in the *Canadian Electrical Code (CEC), Part I*		N/A

4	**General requirements**		Pass
4.8	**Components of ME EQUIPMENT**		Pass
	a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; or		Pass
	NOTE 1: *For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.*		Pass
	b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied		Pass
	NOTE 2: *If there are neither requirements in this standard nor in a CSA, IEC, or ISO standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.*		Pass
4.10.2	**SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS**		Pass
	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1:		Pass
7	**ME EQUIPMENT identification, marking and documents**		Pass
7.7.1 to 7.7.5	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1		Pass
	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the *Canadian Electrical Code (CEC), Part I*, CSA C22.2 No. 21, and CSA C22.2 No. 49……..:		Pass
8	**Protection against electrical HAZARDS from ME EQUIPMENT**		Pass
8.7.3	**Allowable values**		Pass
	Allowable values shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1.		Pass

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

8.11.3	**POWER SUPPLY CORDS**		Pass
8.11.3.2	**Types**		Pass
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be		Pass
	i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21;……..…:		N/A
	ii) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or……..:		Pass
	iii) Class II equipment having fuses on the line side/sides and neutral and may use a non-polarized attachment plug or a polarized attachment plug — CSA configuration type 1-15P shall be required and shall meet all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42. Where a polarized attachment plug is used, the POWER SUPPLY CORD shall be connected to the wiring of the EQUIPMENT on the ungrounded side of the line when any of the following devices are used in the primary circuit:…….:		N/A
	1- the centre contact of an Edison base lampholder;		N/A
	2- a single pole switch;		N/A
	3- an automatic control with a marked off position;		N/A
	4- a solitary fuse/fuse holder; or		N/A
	5- any other single pole overcurrent protective device		N/A
	b) Detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that		Pass
	i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety HAZARD to a PATIENT or OPERATOR;		Pass
	ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and		Pass

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict
	iii) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable POWER SUPPLY CORD which could create a HAZARDOUS SITUATION		Pass
	c) A detachable POWER SUPPLY CORD shall		Pass
	i) comply with the applicable requirements of CSA C22.2 No. 21; and……..:		Pass
	ii) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than…….:		Pass
	1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT; and…..:	Not mobile equipment	N/A
	2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature)…..:		Pass
	NOTE 1A: *See CSA C22.2 No. 49 for requirements on the cord types mentioned in Sub-item 2).*		Pass
	d) Power supply cords shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:		Pass
	Connecting cords between equipment parts shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:		Pass
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		Pass
	Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……..:		Pass
9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**		N/A
9.7.5	**Pressure vessels**		N/A
	Pressure vessels shall comply with the requirements of CSA B51, as applicable……..:	No Pressure	N/A
9.7.7	**Pressure-relief device**		N/A
	A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements……..:		N/A

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

15	**Construction of ME EQUIPMENT**		---
15.4.1	**Construction of connectors**		N/A
	bA) The point of connection of gas cylinders to EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be	No gas connections	N/A
	i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or……..:		N/A
	ii) DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359……..:		N/A
	NOTE 1A: *Users of this standard should consult the CSA Z305 series of standards, CAN/CSA-Z9170-1, CAN/CSA-Z9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke-type valve connections; and ISO 32 for colour coding.*		N/A

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

15.4.8	**Internal wiring of ME EQUIPMENT**		Pass
	Internal wiring of ME EQUIPMENT shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……..:		Pass
16	**ME SYSTEMS**		N/A
16.1	**General requirements for the ME SYSTEMS**	Not an ME SYSTEM	N/A
	An ME SYSTEM shall provide		N/A
	- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and		N/A
	- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA, IEC, or ISO safety standards		N/A
	Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with CSA, IEC, or ISO safety standards that are relevant to that equipment.		N/A
16.9.2.1	**MULTIPLE SOCKET OUTLET**		N/A
	c) The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements……::		N/A
	- The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding		N/A
	- 1 kVA for single-phase transformers; and		N/A
	- 5 kVA for polyphase transformers The separating transformer shall also have a degree of protection not exceeding IPX4.		N/A

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition
CH - SWITZERLAND NATIONAL DIFFERENCES to
SN EN 60601-1:06

	SWITZERLAND NATIONAL DIFFERENCES		—
4	Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7, Mercury - Annex 1.7 of SR 814.81 applies for mercury. Switches containing mercury such as thermostats, relays and level controllers are not allowed. Ordinance on chemical hazardous risk reduction SR 814.81, Annex 2.15 Batteries Annex 2.15 of SR 814.81 applies for batteries containing cadmium and mercury. Note: Ordinance relating to environmentally hazardous substances, SR 814.013 of 1986-06-09 is not longer in force and superseded by SR 814.81 of 2009-02-01 (ChemRRV).		Pass
	Supply cords of portable electrical appliances having a rated current not exceeding 10 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 6533-2:2009 Plug type 11, L + N, 250V 10A - SEV 6534-2:2009 Plug type 12, L + N + PE, 250V 10A - SEV 6532-2:2009 Plug type 15, 3L + N + PE, 250/400V 10A Supply cords of portable electrical appliances having a rated current not exceeding 16 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 5933-2:2009 Plug type 21 L + N, 250 V, 16A - SEV 5934-2:2009 Plug type 23 L + N + PE, 250 V, 16A - SEV 5932-2:2009 Plug type 25 3L + N + PE, 250/400V 16A NOTE 16 A plugs are not often used in Swiss domestic installation system. See TRF template regulatory requirements Switzerland on IECEE Website R.R. TRF templates.		Pass

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 EN DIFFERENCES Medical electrical equipment, Part 1: General Requirements	
Differences according to .....:	National standard EN 60601-1:2005
Attachment Form No. .....:	EN_ND_IEC60601_1E
Attachment Originator.....:	Underwriters Laboratories Inc.
Master Attachment.....:	2009-08

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Annex ZA (normative)	Normative references to international publications with their corresponding European publications The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.		Pass
Annex ZZ (informative)	Coverage of Essential Requirements of EC Directives This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directives 90/385/EEC and 93/42/EEC. Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned. WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.		Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1
Attachment 3: Test Equipment List

TEST EQUIPMENT LIST					
Item	Equipment Type	Make	Model No.	Serial No.	Next Cal. Due
1	Weatherstation	Davis Instruments	Perception II	PE00729A02	02/14/2013
2	True RMS Multimeter	Fluke	87 V	19020163	04/23/2013
3	Articulated Test Finger Probe	E.D.&D.	TFP-01	00036	01/13/2013
4	Rigid Test Finger	Ergonomics	UFP20	ITSB-TF-001	04/02/2013
5	Test Hook	Ergonomics	601TH	SAF496	11/30/2012
6	Force Gauge	Wagner	FDK60	DSGFDK-60-B	08/25/2012
7	Programmable AC Source	QuadTech	31020A	QT31020A0067	02/20/2013
8	Power Analyzer	Extech	380801	B987393	12/05/2012
9	Digital Storage Oscilloscope	Agilent Technolgies	DSO-X 2002A	MY52013497	02/15/2013
10	Medical / ITS / Industrial switch and leakage box	Intertek	JP2	SAF720	12/28/2012
11	High Voltage Probe	Tektronix	P6015A	B040308	01/30/2013
12	10 Deg slope ramp for 601	ITS	10 Deg. Slope	SAF450	Verified
13	Digital Clinometer	Smart Tool	None	SAF235	04/12/2013
14	AC/DC Withstand Voltage Tester	Associated Research	HyPot II 3570D	A010675	03/30/2013
15	Power Analyzer	Extech	380803	10510502	10/11/2012
16	Force Gauge	Extech	475040	L621555	02/28/2013
17	Electronic Clock-Timer	Fisher Scientific	870A	20397972	11/10/2012
18	Digital Torque Gauge	Ametek (Chatillon)	DTG-100	A38712	01/13/2013

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IEC 60601-1
Attachment 3: Test Equipment List

TEST EQUIPMENT LIST					
Item	Equipment Type	Make	Model No.	Serial No.	Next Cal. Due
19	Electronic Digital Caliper	Starrett	721A	04285629	09/08/2012
20	Dowel 1" dia.	ITS	Rod-1	SAF675	Verified
21	Dowel 0.875" Dia	ITS	Rod-0.875	SAF675	Verified
22	Scale Capacity 5 lb/ 2.2 kg	Sunbeam	SP5	DC:1203	05/23/2013
23	5 Foot Aluminum Ruler	C S Osborne	161	none	09/23/2012
24	Digital Lightmeter	Omega	HHLM-2	010045	02/10/2013
25	90.0% Ethanol, 9.5% Methanol and 0.5% Pyidine	ITS	Methylated Spirit	SAF648	Verified
26	Isopropyl Alcohol	ITS	Isopropyl Alcohol	SAF485	Verified
27	Electronic Clock-Timer	Fisher Scientific	870A	20397972	11/10/2012
28	Force Gauge	Wagner	FDK60	DSGFDK-60-A	09/09/2012
29	Flat Plane Pressure Probe	ITS	30 mm	SAF885	12/21/2012
30	Impact Test Ball 50mm 500gr	ED&D	ITB-01	SAF381	04/12/2013
31	Drop tube for 1M and 1.3M test	ITS	DT13	SAF565	Verified
32	Drop Test Platform (Large 50mm x 750 mm x 750 mm) used for UL335 Testing 707.5 Kg/cubic meter	ITS	SAF425	SAF425	07/25/2012
33	Data Logger	Fluke	2625A	6169601	06/25/2013
34	Thermocouple Modules (nos. 1-25)	Fluke	2620A-019	SAF067	06/25/2013
35	Laptop Computer ITS - Asset tag 17466	Compaq	NC6000	CNU45168CR	Verified
36	Sound Level Meter	Cirrus Research	CR:831C	D21956FF	01/24/2013
37	Electronic Clock-Timer	Fisher Scientific	870A	20341250	11/28/2012
38	Optical Comparitor	Finescale	OC-20	SAF220	01/13/2013

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IEC 60601-1
Attachment 3: Test Equipment List

TEST EQUIPMENT LIST					
Item	Equipment Type	Make	Model No.	Serial No.	Next Cal. Due
39	Small Temperature/Humidity Chamber	Bryant Manufacturing	TH-5S	1207	12/02/2012
40	Chart Recorder (TH-5S)	Honeywell	DR45AT	0028Y0471539000	12/01/2012
41	Ball Pressure Tester	E.D.&D.	BPT-01	C05430462	06/19/2013
42	Ball Pressure Test Stand	E.D.&D.	BPA-01	C04430435	06/19/2013
43	Data Logger	Fluke	2625A	6593601	10/28/2012
44	Thermocouple Modules (nos. 1-25)	Fluke	2620A-100	T828S-A	10/31/2012
45	Micrometer	Mitutoyo	293-761-30	N029S	02/14/2013
46	Netbook	Gateway	LT2016U	0060150AEE81601	Verified
47	Data Acquisition/Switch Unit	Agilent	34970A	MY44060938	06/06/2013
48	20 Channel Multiplexer	Agilent	34901A	MY41135281	06/22/2013

TEST EQUIPMENT LIST					
Item	**Equipment Type**	**Make**	**Model No.**	**Serial No.**	**Next Cal. Due**
1	Weatherstation	Davis Instruments	Perception II	PE00729A02	02/14/2013
2	Impulse Tester	Compliance West	MegaPulse Defib-5P	431777	Verified
3	High Voltage Probe	Tektronix	P6015A	B041429	01/30/2013
4	Digital Storage Oscilloscope	Agilent Technolgies	DSO-X 2002A	MY52013497	02/15/2013
5	Clock/Timer 1" numbers	Sportline	Giant Timer	SAF451	02/13/2013
6	Scopemeter	Fluke	199C	DM8120327	04/26/2012
7	High Current Sourcing Milliohmeter	Hypatia	309	0480	03/27/2013

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IEC 60601-1
Attachment 3: Test Equipment List

TEST EQUIPMENT LIST					
Item	**Equipment Type**	**Make**	**Model No.**	**Serial No.**	**Next Cal. Due**
8	Small Temperature/Humidity Chamber	Bryant Manufacturing	TH-5S	1207	12/02/2012
9	Chart Recorder (TH-5S)	Honeywell	DR45AT	0028Y0471539000	12/01/2012
10	Data Logger	Fluke	2625A	6593601	10/28/2012
11	Thermocouple Modules (nos. 1-25)	Fluke	2620A-100	T828S-A	10/31/2012
12	Optical Comparitor	Finescale	OC-20	SAF221	05/24/2013
13	Netbook	ASUS	X101CH	C3OAAS017535	Verified
14	AC Power Source	California Instr. Co	5001iLM	58545	04/13/2013
15	Data Acquistion/Switch Unit	Agilent	34970A	MY44060897	06/21/2013
16	Hipot Tester	QuadTech	Sentry Plus	S00300001101	04/12/2013
17	Medical/ITS/Industrial switch and leakage test box	ITS	JP2	SAF510	02/25/2013
18	Walk-In Humidity Chamber/Controller	Associated Env. Sys.	WR-601	8769	12/05/2012
19	Sound level meter	Simpson	886	034722	07/05/2013
20	Digital Storage Oscilloscope	Agilent Technolgies	DSO-X 2002A	MY52013497	02/15/2013
21	High Speed Si Photo Detector, 1ns Rise Time	ThorLabs Inc	DET210	SAF455	01/03/2013
22	Large 10 Degree Slope	ITS	Large 10 Deg Sect 1	SAF477	Verified
23	Hipot Tester	QuadTech	Sentry Plus	S00300001101	04/12/2013
24	Digital Multimeter	Fluke	87	66470936	12/05/2012
25	Medical/ITS/Industrial switch and leakage test box	ITS	JP2	SAF510	02/25/2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1
Attachment 4: CB Certificate for Power Supply

IEC IECEE CB SCHEME

Ref. Certif. No.

SG-MD-00165

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE)METHODE OC

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product Produit	Switch mode power supplies (Switch Mode Power Supply for Building-In)
Name and address of the applicant Nom et adresse du demandeur	Astec International Limited - Philippine Branch 3rd & 4th Floor, Techno Plaza One Bldg, #18 Orchard Road, Eastwood City Cyberpark, Bagumbayan 1110 Quezon City, PHILIPPINES
Name and address of the manufacturer Nom et adresse du fabricant	Astec International Limited - Philippine Branch, 3rd & 4th Floor, Techno Plaza One Bldg, #18 Orchard Road, Eastwood City Cyberpark, Bagumbayan, 1110 Quezon City, PHILIPPINES
Name and address of the factory Nom et adresse de l'usine	Astec Power Philippines Inc., Main Avenue Corner Rd "J", Cavite Export Processing Zone, Rosario, Cavite, PHILIPPINES For further information please see attachment
Rating and principal characteristics Valeurs nominales et caractéristiques principales	Rated AC Input : 100-250VAC, 50/60Hz, 2.5A Rated DC Input : 140-300V, 2.5A Rated DC Output : see test report for details Protection Class : I Degree of Protection : IPX0
Trade mark (if any) Marque de fabrique (si elle existe)	EMERSON
Model/type Ref. Réf. de type	NPS42-M, NPS43-M, NPS44-M, NPS45-M, NPS48-M
Additional information (if necessary) Information complémentaire (si nécessaire)	See Test Report for National Differences and Group Differences
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1:2005
as shown in the Test Report Ref. No. which form part of this certificate comme indiqué dans le Rapport d'essais numéro de référence qui constitue une partie de ce certificat	TÜV SÜD PSB Pte Ltd 211-300664-000

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

Date, 2012-02-06
CBS 12 01 51485 01028

(Jimmy Huang)

TÜV SÜD PSB Pte Ltd · 1 Science Park Drive · Singapore 118221

TÜV SÜD PSB Singapore

Page 1 of 2

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IEC 60601-1
Attachment 4: CB Certificate for Power Supply

IEC IECEE CB SCHEME

Ref. Certif. No.

SG-MD-00165

Additional factory information:

Name and address of the factory *Nom et adresse de l'usine*	Astec Electronics (Luoding) Co. Ltd. No. 68 Baocheng Road East, Fucheng Luoding, 527200 Guangdong, People's Republic of China Astec Electronics Co. Ltd. Emerson Industrial Park, Feng Tang Road, Fu Yong, Bao'an District, 518103 Shenzhen, Guangdong Province, People's Republic of China Astec Power Philippine Inc. 104 Laguna Boulevard, Laguna Technopark, 4026 Sta Rosa Laguna Philippines

Date, 2012-02-08
CBS 12 01 51485 01028

Signature : Jimmy Huang

TÜV SÜD PSB Pte Ltd • 1 Science Park Drive • Singapore 118221

TÜV SÜD PSB Singapore

Page 2 of 2

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19. Performance Testing - Bench

See Clinical Section.

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20. Performance Testing – Animal

Not Applicable

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21. Performance Testing - Clinical

The clinical case for supporting cerebral use of the FORE-SIGHT Elite Absolute Tissue Oximeter Monitor in found in the document:

Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO2%) in Adult and Transitional Adolescent Subjects

See Attachment G

Note: The author of this section uses the term(s):

- FORE-SIGHT II Elite;
- FORE-SIGHT II;
- FS2, and
- Second Generation FORE-SIGHT

In each case this refers to the FORE-SIGHT Elite™ Absolute Tissue Oximeter

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Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO_2%) in Adult and Transitional Adolescent Subjects

Paul Benni Ph.D.

November 17, 2013

1. INTRODUCTION

1.1 Primary Objective of this 510(K) Application

This is an expanded regulatory clearance of the next generation FORE-SIGHT monitor called the FORE-SIGHT Elite Absolute Tissue Oximeter (a.k.a FORE-SIGHT II Elite to avoid confusion with the first generation FORE-SIGHT monitor) to be indicated for tissue oxygen saturation (StO2%) measurements of adult and transitional adolescent subjects using the FORE-SIGHT II Elite Large sensor.

The initial regulatory clearance (K123700) of the FORE-SIGHT Elite Absolute Tissue Oximeter was indicated for **Cerebral** tissue oxygen saturation (StO2%) measurements of adult and transitional adolescent subjects using the FORE-SIGHT II Elite Large sensor. This application expands the indication for use with **Body** or **Somatic** StO2 data validation of the FORE-SIGHT II Elite using the same Large sensor model for adults and transitional adolescents, for measurement of regional hemoglobin oxygen saturation of blood under the sensor.

Data from the Medium and Small sensors for all populations, including cerebral and somatic, will be presented in future 510(K) applications.

1.2 Proposed Indications for Use

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows: When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 Kg.

1.3. NIRS Principles –Light Interrogation of Tissues

Referring to **Figures 1 & 2**, light enters the body from a NIRS sensor light source placed on the skin. Individual photons travel on different paths because of the high light scattering characteristics of tissue; a small amount of photons reach the NIRS sensor's far light detector placed 50 mm (FORE-SIGHT Large sensor) away from the light source. The sensor also has a near detector to detect light primarily from overlying tissues for compensation of possible overlying tissue interference. The FORE-SIGHT algorithm calculates tissue oxygen saturation (StO_2) by measuring light absorption due to oxy- and deoxy-hemoglobin at five different LED light sources at wavelengths (680, 730, 770, 805, and 870 nm). The FORE-SIGHT algorithm also compensates for background tissue light absorption and scattering, as well as skin pigmentation effects.

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Figure 1: FORE-SIGHT NIRS placed on the body over a target organ with mean photon path

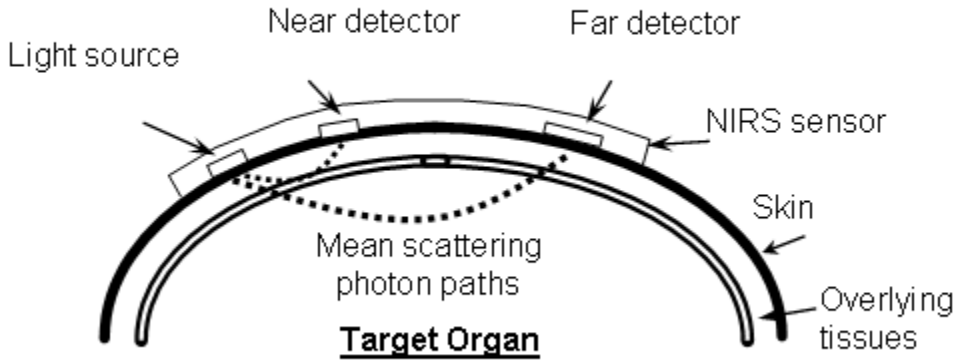
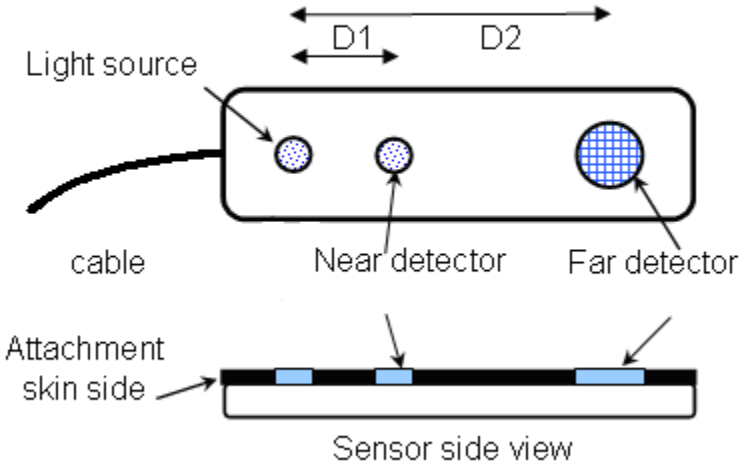


Figure 2: FORE-SIGHT Sensor design (face profile) showing placement of detectors relative to light source.



1.4. Sensor Light Interrogation Depth

As photons travel different paths and depths in tissue before reaching the NIRS sensor light detector, a banana shaped light path is formed. A general rule in NIRS sensor design is that the mean photon interrogation depth of the banana shaped light path is **½ the distance** between the sensor light source and far detector (D2 in Figure 2)[1] (Strangman et al., *Biol Psychiatry* 2002;52:679-93). When considering organ interrogation, the mean photon interrogation depth should be inside the organ to insure an adequate sample of organ tissue. Based on this information, the following table summarizes the average interrogation depths of the FORE-SIGHT sensors: For this 510(K) application, only data from adult tissue oxygen saturation application of the Large sensor will be presented.

Table 1: FORE-SIGHT sensors type and average optical photon interrogation depth

Sensor Type	Number of photodetectors	Light source to detector separation (D1 & D2)	Sensor mean photon interrogation depth in tissue (=D2 x ½)
Large	2, Near & Far detector	D1=15 mm Near, D2=50 mm Far	25 mm Far detector

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1.5 Primary predicate devices: FORE-SIGHT Elite Tissue Oximeter (K123700) and Nonin Model 7600 Equanox (K102715)

From FORE-SIGHT 510(k) K051257 and the latest K112820, the IFUs are as follows:

FORE-SIGHT Elite Cleared Indications for Use for Adults from K123700
The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated as follows: *When used with Large sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of adults and transitional adolescents ≥ 40 Kg.*

Nonin Model 7600 Equanox Cleared Indications for Use from K102715
Nonin's non-invasive Model 7600 4-Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult or pediatric patients weighting greater than 88 pounds (>40kg). It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

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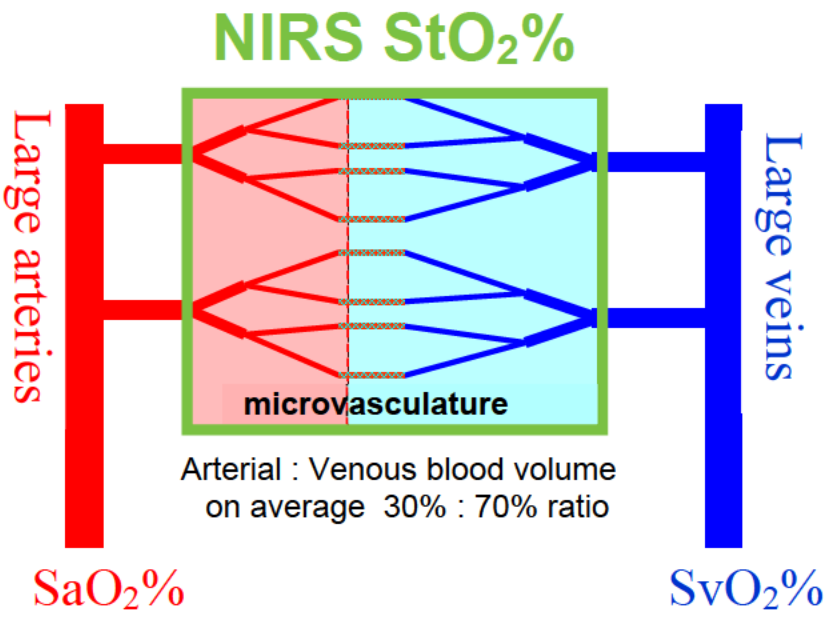
1.6. NIRS StO_2 in Relation to Venous & Arterial Vasculature and Relative Blood Volume
Because NIRS technology mainly interrogates the microvasculature of tissue, which includes arterioles, venules, and capillaries as shown in **Figure 3**, a NIRS tissue oxygen saturation (StO_2) measurement is made on a mixture of both venous and arterial blood. The mean ratio of this mixture for brain was determined to be a 70% venous to 30% arterial blood volume[2] (Ito et al. *Ann Nucl Med* 2001;15:111-6). **The same mean ratio of 70% venous to 30% arterial blood volume applies to the whole body**[3] (Pang CC, Measurement of body venous tone. *J Pharmacol Toxicol Methods* 2000;44(2):341-60). Therefore, to validate NIRS, oxygenation measurements of both venous and arterial blood need to be considered from the venous output and arterial input of a target organ. .

For body or somatic measurements, an average adult male is made up of 42% skeletal muscle plus skin and an average adult female is made up of 36% (as a percentage of body mass)[4], therefore it is reasonable to estimate that skeletal muscle contains the same mean ratio of 70% venous to 30% arterial blood volume.

Figure 3: NIRS light interrogates the microvasculature of tissue to calculate StO_2%



1.7 Arterial and Venous Hemoglobin Oxygen Saturations of Different Organs
Referring to **Figure 4**, an organ receives oxygenated blood from one or more arteries. After the tissue of the organ extracts oxygen from the arterial blood for metabolism in the capillary bed, blood returns to the heart by one or more veins. Depending on the organ's metabolism level, the hemoglobin oxygen saturation of venous blood is typically low and can vary depending on the particular organ. Smaller veins drain into larger veins and then into the superior vena cava (SVC) or inferior vena cava (IVC) into the heart's right atrium (RA) and right ventricle (RV). Blood drawn from these locations can be called "central" venous (CV) blood, which will have an oxygen saturation somewhere in between the highest and lowest individual venous oxygen saturations of the organs. Besides the usual organs, skin and skeletal muscle metabolize oxygen significantly as well, because of the skin's large surface area and skeletal muscle's large mass relative to the rest of the body. For **brain**, arterial blood supply is primarily from the carotid arteries and the primary venous drainage is by the internal jugular vein / jugular bulb. For body / somatic locations, arterial blood supply is branched off the aorta at different places and the primary venous drainage is a central venous location around the right atrium of the heart.

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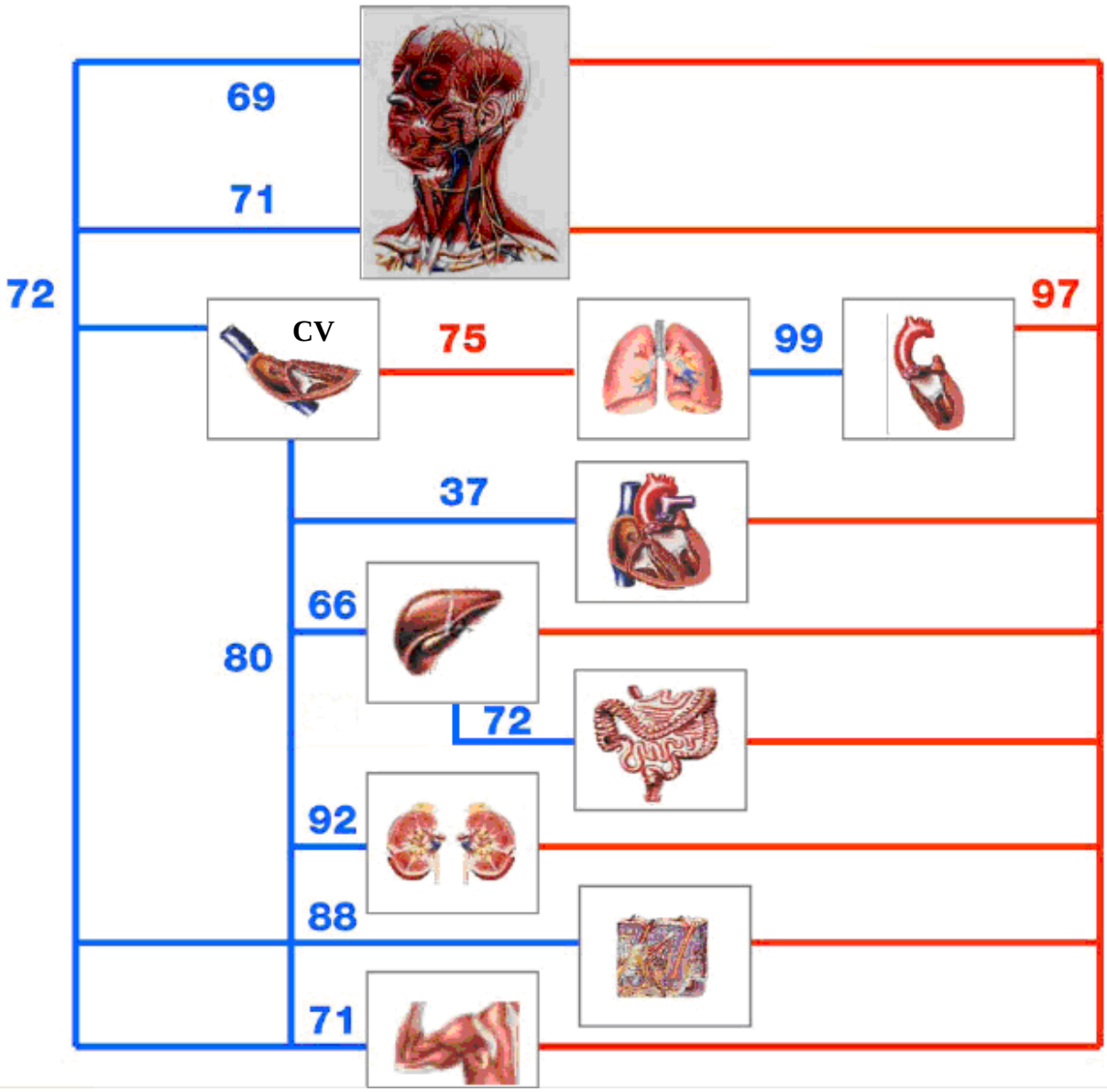
Figure 4: Arterial and venous supply to various organs with their respective hemoglobin oxygen saturation values (modified from Reinhart K in Lewis Pfeiffer (editors) : Practical Applications of Fiber Optics in Critical Care Monitoring, Springer Verlag Berlin – Heidelberg – New York 1990, pp 11-23.)[5]. The liver (or hepatic) venous oxygen saturation tends to be lower than the intestine/mesenteric portal vein oxygen saturation since the portal vein supplies low oxygenated blood to the liver.



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2. METHODS
2.1. HUMAN PROTOCOLS TO VALIDATE FORE-SIGHT SENSORS

2.2. Protocol Title:
Validation of the Second Generation of CAS Medical's FORE-SIGHT II Elite Near Infrared Spectroscopy (NIRS) Cerebral & Somatic Tissue Oxygen Saturation Sensors on Adult Subjects.

2.3 Purpose of the Study:
Primary Objectives:

1. To validate that the second generation FORE-SIGHT II Elite sensor accurately measures **Body** or **Somatic** tissue oxygen saturation (StO_2) in healthy adults and transitional adolescent adults when comparing to co-oximetry measurements of invasively drawn blood to expand the usage of FORE-SIGHT II Elite StO2 measurements for the body. The Cerebral tissue validation of the FORE-SIGHT II Elite monitor and sensor model used in this 510K application was already cleared by the FDA (K123700).
   A similar procedure for body/somatic/tissue under sensor StO2 measurements were used in predicate 510Ks: K094030 (FORE-SIGHT first generation), K112820 (FORE-SIGHT first generation), and K102715 (Nonin Equanox).

Transitional Adolescent considerations: Transitional adolescent adults (age 18-21) have been enrolled in the predicate FORE-SIGHT adult validation data submitted in previous 510(k) K123700. Based on this previous data, no special considerations are needed for transitional adolescents when validating the FORE-SIGHT II Elite monitor.

2.4 Background & Significance:
Near-infrared spectroscopy (NIRS) can be used to non-invasively estimate cerebral and somatic tissue oxygen saturation (StO_2). For brain, NIR light easily passes through skull bone and absorption of NIR light by brain tissue is dependent upon chromophores (light absorbing tissue) within the path of the transmitted light. The same is true for somatic except there is no bone in the sensor's light path. In both brain and somatic tissues the only significant chromophore is hemoglobin, which is present within both arterioles and venules. Pulse oximetry only estimates arterial oxygen saturation whereas StO_2 represents tissue oxygen saturation of the smaller blood vessels. Several continuous wave (CW) cerebral oximeters have obtained FDA 510k clearance and are currently commercially available in the USA, including the CAS Medical FORE-SIGHT device. The device has been used extensively in the clinical area of anesthesia and several recent studies have demonstrated the benefit of monitoring StO_2 in patients undergoing different surgical procedures.

The FORE-SIGHT sensor is applied to the forehead or somatic locations, preferable at larger muscle masses. The emitter and sensor are separated by a distance of 50 mm for the Large sensor. The path of NIR light is not a straight path but instead curved ('banana-shaped'). Of the light emitted approximately 80% is dispersed by scatter, the remaining 20% is absorbed by chromophores, such as oxy- and deoxyhemoglobin. The development of the second generation sensor represents the continued efforts to improve the quality of signal processing when tissue is interrogated by NIRS.

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2.5 Design & Procedures:

This study evaluates the performance of the CAS Medical FORE-SIGHT II Elite in healthy volunteers during a controlled hypoxia sequence at steady-state $ETCO_2$ levels to measure body/somatic tissue StO_2. This protocol is very similar to validating cerebral StO2 except the venous reference is drawn from a catheter placed in the vena cava (as opposed to jugular bulb for cerebral) to obtain SvO2.

Somatic StO2 Validation

Sequence 1: Two CAS Medical FORE-SIGHT II Elite Large sensors will be placed on Flank skeletal muscle on the left or right side of the spine and on the quadriceps (Quad) muscle on the right or left leg. The monitor's values will be compared to the calculated whole body oxygen saturation derived from co-oximeter measured arterial and central venous (blood from the vena cava) oxygen saturations during the sequential desaturation study. The positions of the sensors will be alternately placed on left or right sides of the Flank and Quad so that half of the subjects will have left side StO2 measurements and the other half of the subjects will have right side StO2 measurements, depending if the subject number was odd or even.

Sequence	FORE-SIGHT II Elite Sensor type	Stepped hypoxia phases	Invasive blood draws for co-oximetry reference	Inter-Sensor body location variability test- Alternating sensor location on left & right of the body
1	FORE-SIGHT II Elite Large sensors	YES	YES	YES

Different combinations of FORE-SIGHT II Elite monitors and preamp cables, were used with different subjects to avoid monitor bias. Sensors are single use in design, so different sensors were used on each subject.

The level of oxygen within the blood will be reduced in a controlled manner by altering the inspired oxygen concentration (FiO_2) to achieve arterial oxygen saturation plateaus between 100% and 70%, measured by a finger pulse oximeter on the finger.

Each subject will be studied individually. An attending anesthesiologist will be present for each individual study. The anesthesiologist will continuously monitor subject's safety and manage the conduct of the study protocol. The subject's tolerance of the study procedures will be continually assessed and the study will be terminated by subject request or clinical discretion.

Subjects will include healthy adult volunteers who will be compensated for their participation. Written informed consent will be obtained from each subject prior to the initiation of any pre-study examination. Each subject will receive a screening health examination. Subjects will be required to fast from solid foods for 6 hours and from liquids for 2 hours prior to the study treatment in accordance with ASA guidelines. The duration of the entire clinical study is not expected to exceed 6 months, including subject recruitment, individual subject studies, and data analysis.

First, the controlled hypoxia evaluation will be conducted. The level of oxygen within the blood will be reduced in a controlled manner by the RespirAct® sequential gas delivery system (consisting of

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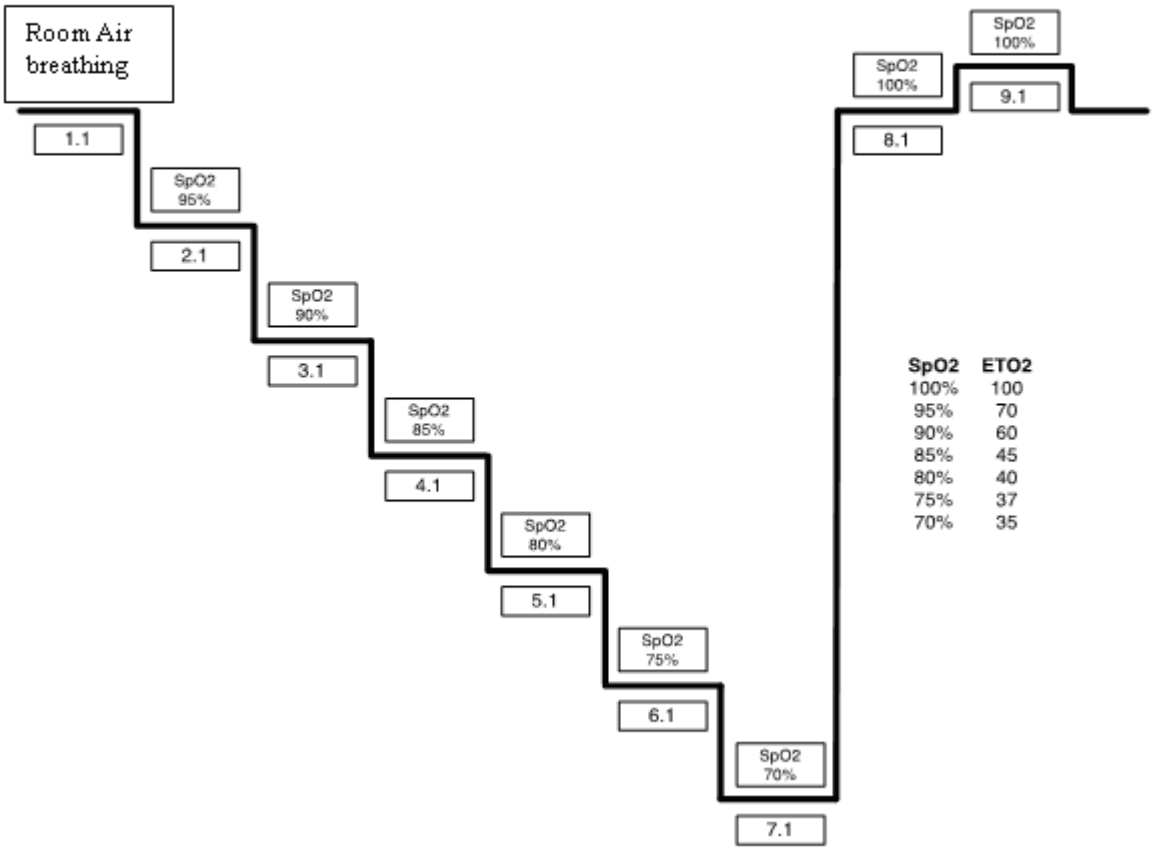
gas tanks, gas blender, facemask and control laptop with continuously displayed O_2 and CO_2) which permits control of the both the ETO_2 and ET CO_2 to reach target values. The measured ETO_2 and $ETCO_2$ equate with arterial O_2 and CO_2 (PaO_2 and $PaCO_2$ respectively). The attained PaO_2 then determines the SpO_2. One (1) Room Air and Eight (8) ETO_2 plateaus will be targeted, with resulting eight SpO_2 plateaus between 70 – 100%. Measurements and blood samples will be taken at each plateau. ECG, pulse, blood pressure, SpO_2, $ETCO_2$, and ET O_2 will be monitored throughout the study.

Prior to discharge, the subject will be given written instructions on how to contact the study doctor in the event of any concerns or adverse events. Within 48 hours of discharge, the study doctor or designee will contact the subject by phone to confirm the subject's well being and enquire to the presence of any unexpected symptoms. Following contact, the subject's participation in the study will be completed.

Figure 5: Stepped Hypoxia Sequence Protocol



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2.6 Selection of Subjects:

Advertisements will be posted around campus to recruit healthy volunteers to participate. Subject must pass study eligibility requirements prior to beginning any study treatment.

Inclusion Criteria:

1. 18 to 50 years of age, inclusive. Note transitional adolescent 18-21 year old subjects will be recruited as well.
2. Weight ≥ 40 kg and BMI of 18 to 30, inclusive
3. Does not take anticoagulants or platelet inhibitors on a regular schedule
4. Has not ingested an anticoagulant or platelet inhibitor in the 24 hour period prior to the study
5. $SpO_2 \geq 95\%$ on room air
6. Able to tolerate breathing mask apparatus
7. Expected to be able to tolerate controlled hypoxia to the levels called for in this protocol with minimal medical risk
8. Is not a resident or fellow in the Anesthesia department where study is being conducted
9. Is not an employee of sponsor company
10. Written informed consent form signed and dated by the subject

Exclusion Criteria:

Subjects with any of the conditions listed below are NOT eligible for study participation.

1. Female with positive pregnancy test
2. Beard or history of or anatomy suggestive of difficult airway
3. Hemoglobin concentration outside normal range for the clinical site
4. Platelet count outside normal range for the clinical site
5. History of cigarette smoking or currently a cigarette smoker
6. Current drug or alcohol abuse
7. History of high blood pressure or blood pressure > 140/90 at screening examination
8. Significant history of cardiac or pulmonary disease
9. Known allergy to lidocaine or heparin
10. History of sleep apnea
11. History of gastroesophageal reflux
12. ECG not within normal limits
13. History of hemoglobinopathy or coagulation abnormality, including and not limited to: sickle cell disease and/or thalassemia
14. May be placed at undue medical risk by any procedures in this protocol (e.g. arterial cannulation or hypoxia)
15. Any other condition that may, in the opinion of the investigator, increase the risk to the subject

2.7 Subject's Capacity to Give Legally Effective Consent:

All subjects will be healthy volunteers with capacity to give consent. Subjects will be excluded if they do not possess the capacity to give consent. No legally authorized representatives will be used.

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2.8 Risk/Benefit Assessment:

Risks and discomforts will be minimized through careful monitoring of the tests and procedures performed during this study to maximize safety and minimize the risks to the subject. All tests and procedures will be performed by appropriately trained staff. The CAS Medical FORE-SIGHT monitors are non-invasive devices that pose minimal risk. FORE-SIGHT employs infrared light to measure hemoglobin saturation. The trial may be stopped for safety purposes if risks associated with the use of the study device are identified. This study presents minimal risk in healthy volunteers. Controlled hypoxia will be induced by decreasing the ETO_2 in a stepwise manner. Published studies, conducted under similar conditions to those defined for this study, demonstrate that healthy subjects tolerate the mild hypoxia well and without untoward effects. This study employs methods similar to the standard protocols recommended by the FDA for testing pulse and cerebral oximeters in healthy volunteers.

As a result of participation in this study, subjects are at risk for the following:

- If the subject is highly allergic to the lidocaine, there is a risk of allergic reaction and the subject could possibly have a reaction that is severe enough to cause cardiac arrest and/or respiratory arrest.
- The other risks of this study are discomfort, tachycardia (fast heart rate), dizziness, nausea and vomiting, and the possibility of fainting (from getting needle sticks and/or breathing low oxygen). Subjects will receive standard treatment for these effects if they occur.
- Risks associated with drawing blood from the arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.
- Light headedness, headache, drowsiness, fainting, tachycardia, and hyperventilation (fast breathing rate) are the risks from breathing air for several minutes that is low in oxygen. The normal oxygen saturation for healthy individuals is greater than 96%. In a commercial airliner, the cabin pressure is set to an altitude (height) of 8,000 feet and the oxygen saturation is typically between 90 – 95%. The Federal Aviation Agency allows pilots in unpressurized airplanes to fly as high as 14,500 feet for as long as 30 minutes without supplemental oxygen. Healthy volunteers can usually tolerate an oxygen saturation of 70% and will not lose consciousness (being awake and aware) until the oxygen saturation is below 55%. This type of testing with the subject breathing air that is low in oxygen has been performed in other research studies down to an oxygen saturation of 60% without any known serious side effects. Each subject will be observed and monitored closely throughout the study by the study doctor.
- The risks of placement of the arterial catheter are bleeding, bruising, and infection, which are all rare. The radial and ulnar arteries are the two major blood vessels supplying the hand. If the color does not return immediately after release of the ulnar artery, the test is positive for potential difficulties of blood flow to the hand if a radial arterial line was present. In the event this occurs, the subject will not be allowed to continue to participate. The risks of placement of the radial and ulnar catheters are bleeding, bruising, infection, radial artery aneurysm (swelling) and loss of hand, all of which are rare.
- The risks of inserting and using any central venous (jugular vein for example) catheter placements include, but are not limited to the following:
    - Risks that do not need regimen or can be treated with medications: pain, allergic reaction to the local anesthetic, catheter migration (catheter movement from the insertion place), phlebitis (inflamed vein), nerve injury, infection, sepsis (bloodstream infection), trauma at the insertion site (redness, bleeding, blood clot, hematoma), fever, and catheter-related difficulties (insertion difficulty, leakage, blocked lines).

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  - Risks that can require surgical interventions: bleeding, hematoma (blood mass under the skin), air embolism (air bubble blocking the vein), accidental puncture of the carotid artery (supplies oxygenated blood to head and neck), hemomediastinum (blood in the space between organs in the chest), catheter embolism (catheter blocking the vein), thrombosis (blood clot in the vein), vessel perforation (puncture of the blood vessel), vascular damage (injury to blood vessel), pneumothorax (air in the chest), hydromediastinum (fluid in the space between organs in the chest) and hydrothorax (fluid in the lung membrane).
  - These complications can usually be resolved without long term problems. However, on rare occasions, some of these complications may result in permanent complications, stroke or death. In the unlikely event that such an event were to occur, the subject would be cared for by a team of health care providers including a fully trained anesthesiologist.
- The risks associated with a skull and chest x-ray are exposure to radiation. In this study, subjects will receive about the same amount of radiation as an individual would get from living in a high altitude city such as Denver for 4 weeks, or taking 8 airplane flights from New York to Los Angeles.

2.9 Data Analysis & Statistical Considerations:

2.9.1 Body/Somatic Tissue Oximetry Primary Invasive Reference Measurement: As previously described, the FORE-SIGHT II Elite Tissue Oximeter's cerebral tissue oxygen saturation (StO2) readings will be compared to the established weighted co-oximetry reference will be calculated and presented (REF CX) from the following equation:

$$\textbf{REF CX} = (0.7 \times S_vO_2) + (0.3 \times S_aO_2)$$

where S_vO_2 and S_aO_2 are the functional oxygen saturations from the blood samples drawn simultaneously from a central venous location (vena cava) and systemic arterial catheters, respectively, and measured using a co-oximeter. A similar procedure was used in predicate 510Ks: K094030 (FORE-SIGHT first generation), K112820 (FORE-SIGHT first generation), K123700 (FORE-SIGHT II), and K102715 (Nonin Equanox).

2.9.2 Sample Size Justification

This 510(k) application: 432 data points were obtained from 24 subjects where 9 data points were obtained per sensor (2 sensors used) per subject from FORE-SIGHT II Elite sensors on the Flank and Quadriceps muscle tissues.

As a reference, the number of subjects and number of data points obtained from the two Equanox sensors 8000CA (K090807) and 8004CA (K102715)[16] were compared to FORE-SIGHT II Elite cerebral and somatic applications. **Table 7** below demonstrates the comparable sample sizes of the FORE-SIGHT II Elite and Equanox data sets.

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Table 2: Comparison of sample size FORE-SIGHT II Elite and Equanox.

Model & Sensor	Number of Subjects	Number of FiO2 Plateaus (co-oximetry measurements)	Number of data points	510(K)
FORE-SIGHT II Elite *Somatic*	24	216	432 (2 sensors)*	**This application**
FORE-SIGHT II Elite Cerebral	25	225	225 (1 sensor)	K123700
Equanox 8000CA Cerebral	18	218	218 (1 sensor)[16]	K090807
Equanox 8004CA Cerebral	23	219	219 (1 sensor)[16]	K102715
FORE-SIGHT I	17	233	457 (2 sensors)**	K051257
	***NOTE**: Two sensors doubles number of data points per FiO2 plateau. **Data was also represented by left and right hemisphere sensor data, in which 16 subjects had 224 total data points for each side, while 1 subject had one sensor (contributing 9 co-oximetry measurements).			

2.9.3 Comparison of FORE-SIGHT II Elite to Co-oximetry Reference REF CX

Agreement between FORE-SIGHT II Elite and REF CX: We will use five methods to evaluate the agreement between FORE-SIGHT II Elite StO2 data vs. the reference REF CX data. The methods will include:
(1) Scatter plot of the FORE-SIGHT II Elite StO2 data vs. the reference REF CX data: visual inspection of whether the plot falls closely on the 45 degree line with the origin;
(2) Bland Altman plot (Bland and Altman, 1986)[6]: a straightforward and an intuitive approach to assess agreement by plotting the differences against the averages between two measurements;
(3) An advanced subject dependent data analysis using Deming regression (Linnet, 1993)[7]: similar to the traditional linear regression analysis but corrects the estimates of intercept and slope when both the FORE-SIGHT II Elite, and the REF CX data are subject to random errors;
(4) Traditional linear regression using Random Coefficients Model as a secondary analysis; and
(5) Concordance correlation coefficient (CCC) analysis (Lin, 1989)[8]: similar to the Pearson's correlation coefficient analysis but consists of a measure of precision multiplied by a measure of accuracy. Results between (3) Deming regression and (4) traditional linear regression will also allow visual comparison to demonstrate consistency and similarity of the two methods to compensate for any possible weaknesses of the two methods. Estimates of the regression coefficients (slope and intercept) and CCC will be presented with the 95% confidence intervals.

Regression Analysis Considerations: Because each subject has 9 data points per sensor (18 data points total), the data is not independent. Therefore the analysis will be more complex as follows.

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Deming regression assumes the reference (REF CX) is subject to measurement error. From previous 510K submissions, the FDA favors the use of Deming regression. A Deming regression line will be fitted for each subject resulting in 24 regression lines with slope and intercept for the 24 subjects. Initial Q statistic analysis showed that the estimated standard errors for the regression coefficients are not homogeneous as some subjects have larger variation than others due to subject effect (not pure instrumental random error). This factor is taken into account when we will "pool" the estimates of intercepts and slopes together. Specifically, in Step 1, the Deming regression coefficients will be determined for each subject, and then their standard errors will be determined based on the Jackknife method (Linnet 1990)[9] (Linnet 1998)[10]. In Step 2, the "Meta Analysis" technique will be used to pool these estimates together to generate a weighted average intercept and a weighted average slope (Laird and DerSimonian 1986)[11]. The pooled analysis will consider that subjects are random samples from a general population.

Random Coefficients Model is one traditional method of linear regression for subject dependent data. It assumes that each subject has his/her trajectory or inherent trend of the repeated measurements. The inherent trajectories are "high" or "low" with different steepness across subjects, suggesting that the subject-specific intercept and slope (Fitzmaurice, Laird, and Ware, 2004)[12]. The difference between Deming regression and the typical linear regression is that traditional linear regression does not assume that the reference (REF CX) is subject to measurement error.

CCC Calculation: The concordance correlation coefficient (CCC) will be used to demonstrate agreement for continuous data. It can be used in the context of multiple repeated measurements per subject, and thus is valid for this study. (Carrasco and Jover, 2003)[13]

2.9.4 Validation of Regression and CCC Analysis Methods Used

Bootstrap Validation: The regression methods (*Deming regression* and *Random Coefficients Model*) and CCC calculation will be validated by two bootstrapping methods, *Bootstrap I* and *Bootstrap II*. The Bootstrap 95% confidence interval (CI) method will be computed two different ways: "Normal" – normal approximation; and "Bias Corr" – bias-corrected percentile method.

Bootstrap I: Individual subject data will be bootstrapped without doing any moving block bootstrapping for repeated measurements within subjects. Sherman and le Cessie[14] present an 'all block bootstrap' by resampling blocks of individual subjects. They argued that, by bootstrapping these blocks, the correlation structure within each block could be maintained and the bootstrap intervals could be produced in an automatic way so that the correlation structure can be left unspecified.

Bootstrap II: We will do a second bootstrap method which does double bootstrapping for panel data (i.e., bootstrap for both subjects and time series data) based on Davison and Hinkley [15]. For this method, we will bootstrap individual subjects first and then bootstrap observations within individual subjects using the moving block method with block size 3 and overlap size 2. This is determined from the dataset, where there were 9 observations per subject where the desire block size is $n^{**(1/3)}$ which is $9^{**(1/3)}$~2 or 3[15].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2.10 Data & Safety Monitoring:

All clinically significant adverse events will be reported to the Sponsor on the adverse event (AE) case report form (CRF). Standard of care should be implemented whenever an AE occurs to treat and/or resolve the AE and to monitor the subject. Any subject who is withdrawn from the study due to an AE shall be followed until the outcome is resolved or, in case of permanent impairment, until the event stabilizes and the overall clinical outcome has been ascertained.

An anesthesiologist will be present for the each study. An anesthesiologist will perform cannulation of the radial artery and the jugular vein. Insertion of a vena cava catheter and a radial artery catheter are low-risk procedures when performed by experienced personnel and are widely used for patient monitoring in a variety of clinical settings. The risks associated with jugular vein cannulation include infection, hematoma, and inadvertent injury to nearby structures such as the carotid artery. The latter complication will be minimized by using ultrasound image guidance for insertion of the catheter and x-ray confirmation of catheter placement. The risks associated with radial artery cannulation include infection, hematoma, and impaired blood supply to the hand. The latter complication will be minimized by using ultrasound scanning to ensure the adequacy of collateral flow before catheter insertion and by continuous oxygen saturation measurement in the hand after catheter insertion.

At the completion of the 48 hour follow-up call, a report will be generated detailing the following:

1. Cardiovascular parameters: continuous arterial systolic & diastolic blood (SBP/DBP) pressure and heart rate (HR).
2. Respiratory parameter: continuous SpO_2.
3. Blood oxygen parameters: intermittent arterial and jugular venous oxygen saturations (PaO_2 / $PjvO_2$) generated from blood gas co-oximeter analyzer (samples taken at each plateau).
4. Any adverse events reported by the PI.

Adverse events related to desaturation are most likely to present on the study day while the subject is present with the research lab. Any further adverse events are most likely to be related to arterial and jugular catheter placement and will be reported by the subject when contacted by telephone by the study staff within 48 hours of the study day.

Note that there were no adverse events reported at the completion of this study.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3. RESULTS:

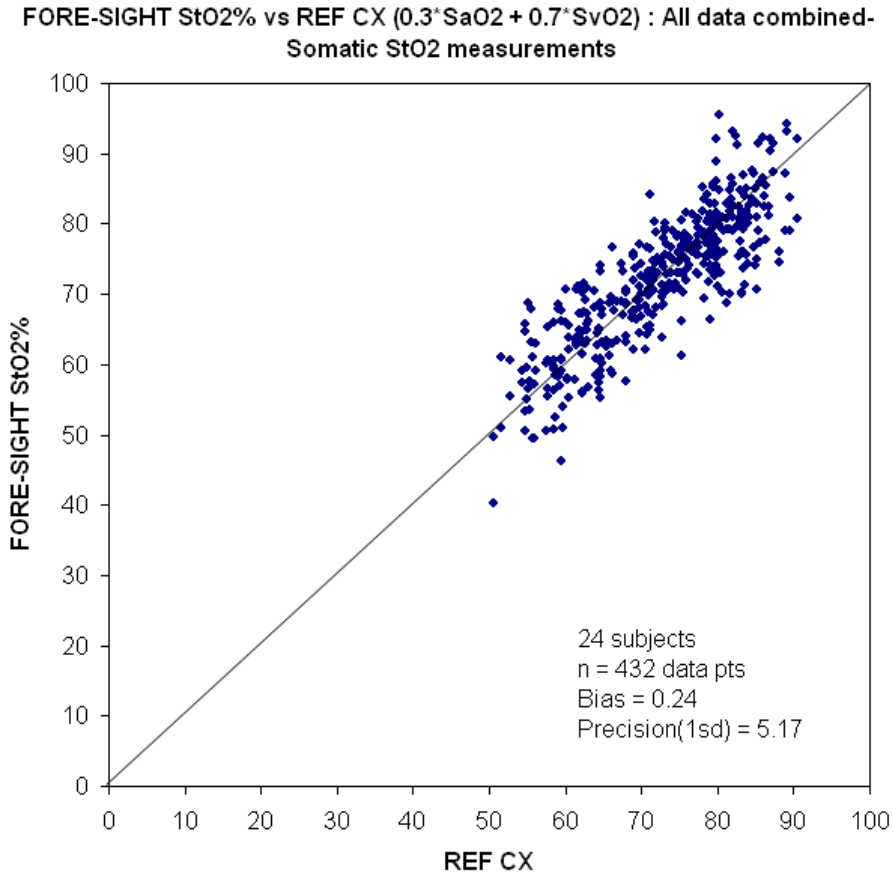
3.1 Table 3: Subject Demographics Data - Race Information: 8 White (Caucasian), 14 Black (African American), & 2 Asian subjects. Gender Information: 15 Male & 9 Female. Weight Range: 51.0 to 96.5 kg. Age range: 19 to 40 years. FORE-SIGHT II Elite Large sensors placed on Flank and Quad (quadraceps) for all subjects at alternating left and right positions depending if the subject number was odd or even.

Subject	Race	Gender	Age	Weight(Kg)	Height(m)
1	W	F	28	62.8	1.72
2	W	M	26	85.9	1.78
3	W	M	40	94.9	1.81
4	AS	M	19	81.2	1.75
5	W	F	20	66.5	1.72
6	BK	M	32	96.5	1.85
7	BK	M	27	96.4	1.96
8	BK	M	40	86.0	1.73
9	BK	M	35	90.8	1.78
10	BK	M	26	94.7	1.89
11	BK	F	38	67.7	1.56
12	BK	M	32	87.3	1.74
13	BK	M	24	95.6	1.81
14	BK	F	26	51.0	1.58
15	BK	F	19	56.0	1.57
16	BK	M	24	89.6	1.74
17	W	F	39	70.8	1.75
18	BK	F	26	69.1	1.64
19	W	M	22	74.9	1.86
20	BK	M	29	81.0	1.88
21	BK	F	19	60.3	1.59
22	W	M	20	77.6	1.84
23	W	M	19	84.1	1.90
24	AS	F	19	64.9	1.76
W=White(Caucasian); AS=Asian; & BK=Black(African American)					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3.2 Body/Somatic FORE-SIGHT II Elite vs Co-Oximetry Reference (REF CX): Scatterplots and Bland-Altman.

Figures 6-7: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Scatter-plot and Bland-Altman plot *for all Somatic measurement data collected*



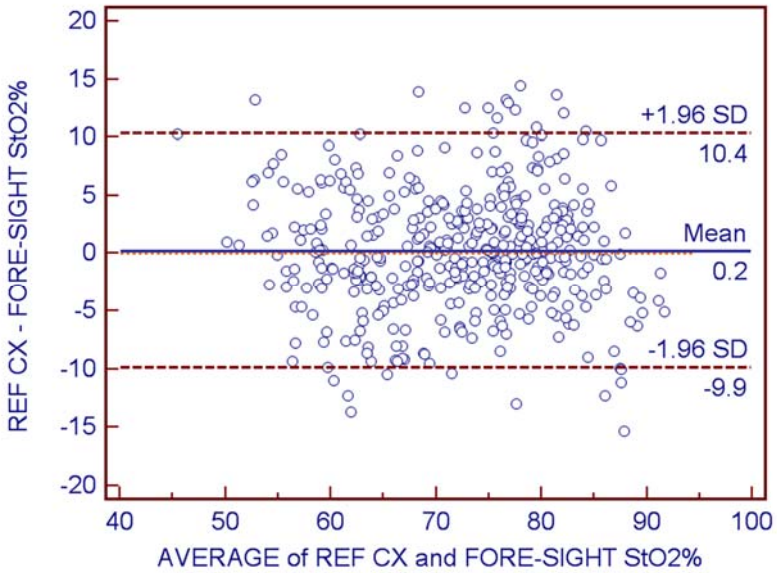


Figure 8: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Scatter-plot and Bland-Altman *with Somatic StO2 measurements of Flank and Quad data indicated*.

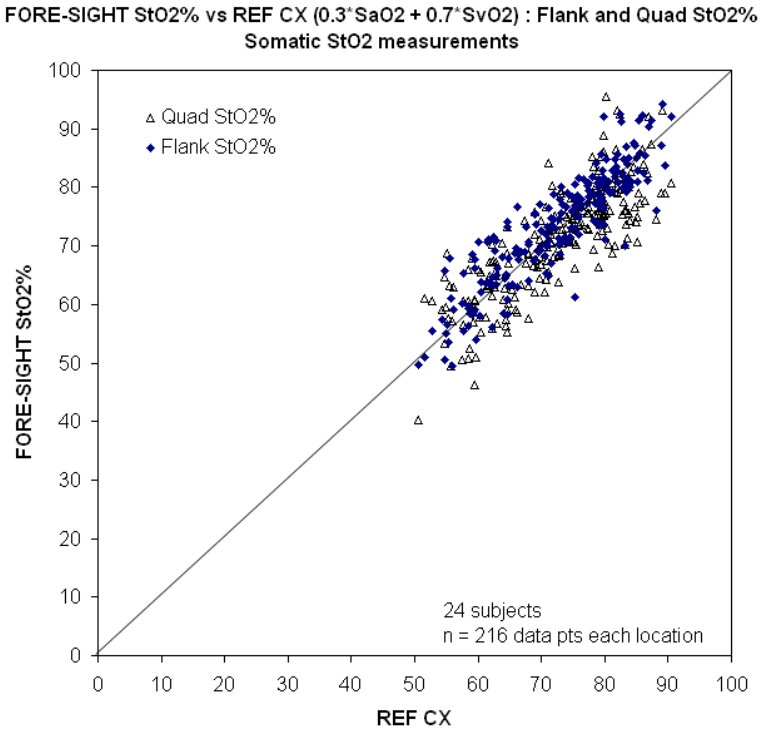
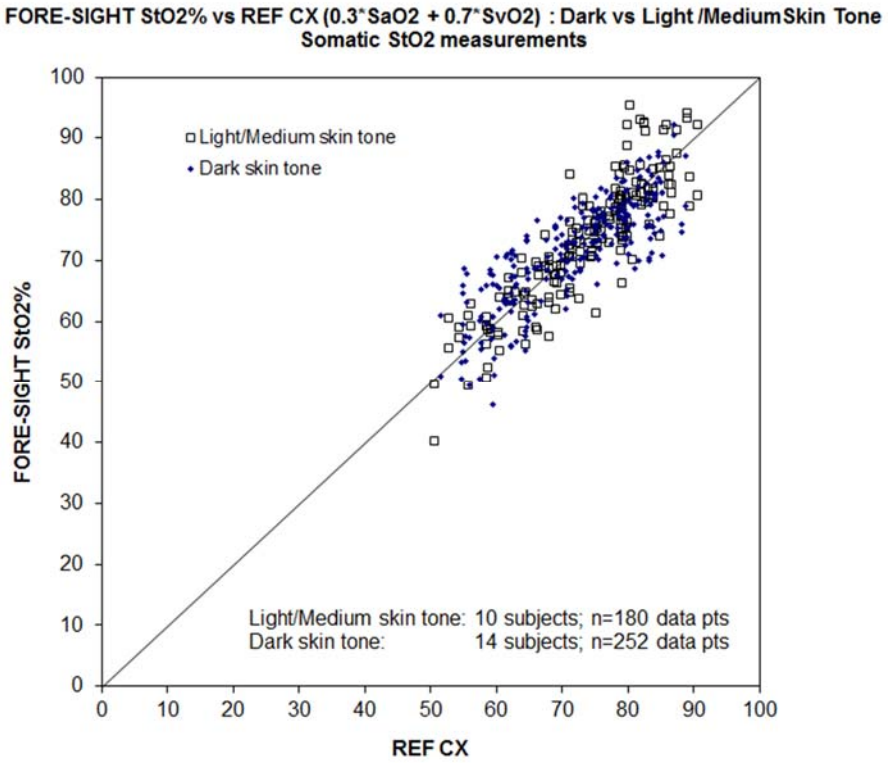


Figure 9: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Scatter-plot *with Somatic StO2 measurements of Light/Medium and Dark subject skin tones*.



3.2.1 FORE-SIGHT II Elite Somatic Tissue StO2 Bias & Precision Results Comments: Results from the Scatterplot and Bland-Altman analysis (**Figures 6-7**) shows that FORE-SIGHT II Elite StO2 Somatic tissue measurements demonstrated an overall bias ± precision (1 standard deviation) of 0.24 ± 5.17% compared to the co-oximetry reference REF CX. **Figure 8** is the same scatterplot of Figure 6 but identifies the Flank and Quad StO2 measurements. FORE-SIGHT II Elite StO2 Somatic tissue measurements from the Flank muscle tissue sensor demonstrated an overall bias ± precision (1 standard deviation) of -0.97 ± 4.29%, while the Quad muscle tissue sensor demonstrated an overall bias ± precision (1 standard deviation) of 1.45 ± 5.67%. See **Section 3.3** for Regression analysis and Bootstrap validation.

3.2.2 FORE-SIGHT II Elite Somatic Tissue StO2 Measurement Performance by Skin Tone Groups

The Light/Medium skin tone group consisted of White (Caucasian) and Asian subjects and the Dark skin tone group consisted of Black (African Americans). The bias and precision (1 standard deviation) of FORE-SIGHT II Elite StO2 vs REF CX for two skin tone groups (light/medium and dark skin tones) as demonstrated by **Table 6** and by observation in the scatterplot (**Figure 9)** clearly show consistent performance of FORE-SIGHT II Elite Somatic StO2 measurements across different skin tone types.

Table 4: Bias and precision of FORE-SIGHT II Elite StO2 vs REF CX for the two skin tone groups (light/medium and dark skin tones).

Skin Tone Groups	Subjects (n)	Data points (n)	Bias	Precision (1sd)
ALL	24	432	0.24	5.17
Light/Medium	10	180	0.33	4.92
Dark	14	252	0.18	5.35
Comparison of Light/ Medium tone vs Dark tone was not statistically significant (P = 0.76 two-tailed, t-test for means).				

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3.3 Body/Somatic FORE-SIGHT II Elite vs Co-Oximetry Reference (REF CX): Regression analysis and Bootstrap Validation Results- ALL DATA

Table 5: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Deming and Random Coefficients Model Regression, CCC, and Bootstrap I and Bootstrap II Validation. (Bootstrap sample = 200). Data from **Figure 6**.

All somatic data		Original or Bias–corrected (bootstrap) Statistic	Approx Bias	Bootstrap mean	Standard Error	Approx. Lower 95% Confidence Limit	Approx. Upper 95% Confidence Limit	Bootstrap CI Method
Deming regression - intercept	**Observed**	1.289	NA	NA	4.835	-8.188	10.765	
	Bootstrap I	1.222	0.067	1.355	4.497	-7.591	10.035	Normal
						-7.403	9.844	Bias Corr.
	Bootstrap II	2.709	-1.420	-0.131	5.180	-7.443	12.860	Normal
						-7.261	11.674	Bias Corr.
Deming regression - slope	**Observed**	0.976	NA	NA	0.065	0.849	1.102	
	Bootstrap I	0.977	-0.001	0.975	0.060	0.858	1.095	Normal
						0.862	1.086	Bias Corr.
	Bootstrap II	0.957	0.019	0.995	0.070	0.819	1.094	Normal
						0.835	1.088	Bias Corr.
Random coefficients models - intercept	**Observed**	7.632	NA	NA	3.920	-0.477	15.740	
	Bootstrap I	7.584	0.047	7.679	3.965	-0.188	15.356	Normal
						-0.189	14.977	Bias Corr.
	Bootstrap II	8.076	-0.445	7.189	4.543	-0.827	16.980	Normal
						-0.608	17.429	Bias Corr.
Random coefficients models - slope	**Observed**	0.888	NA	NA	0.053	0.777	0.998	
	Bootstrap I	0.889	-0.001	0.886	0.054	0.784	0.993	Normal
						0.783	0.989	Bias Corr.
	Bootstrap II	0.881	0.006	0.894	0.061	0.762	1.001	Normal
						0.761	1.004	Bias Corr.
Concordance Correlation Coefficient (CCC)	**Observed**	0.861	NA	NA	0.037	0.789	0.932	
	Bootstrap I	0.876	-0.015	0.846	0.055	0.767	0.984	Normal
						0.737	0.930	Bias Corr.
	Bootstrap II	0.778	0.083	0.944	0.024	0.732	0.825	Normal
						0.819	0.819	Bias Corr.

Bootstrap I : Single Bootstrapping for dependent data -- bootstrap individuals only and then sample entire block for each selected subject.
Bootstrap II: Double Bootstrapping for dependent data -- bootstrap individuals and then bootstrap observations within individuals using the moving block method with block size 3 and overlap size 2.
Bootstrap CI method: Normal – normal approximation. Bias Corr – bias-corrected percentile method.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3.3.1 Somatic FORE-SIGHT II Elite vs Co-Oximetry Reference (REF CX): Regression analysis and Bootstrap Validation Results - FLANK muscle tissue data.

Table 6: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Deming and Random Coefficients Model Regression, CCC, and Bootstrap I and Bootstrap II Validation. (Bootstrap sample = 200). Flank muscle tissue data from **Figure 8**.

Flank		Original or Bias–corrected (bootstrap) Statistic	Approx Bias	Bootstrap mean	Standard Error	Approx. Lower 95% Confidence Limit	Approx. Upper 95% Confidence Limit	Bootstrap CI Method
Deming regression - intercept	Observed	4.676	NA	NA	4.063	-3.287	12.639	
	Bootstrap I	4.396	0.280	4.956	4.036	-3.515	12.306	Normal
						-2.034	12.638	Bias Corr.
	Bootstrap II	4.307	0.370	5.046	4.748	-4.999	13.612	Normal
						-3.309	14.870	Bias Corr.
Deming regression - slope	Observed	0.944	NA	NA	0.053	0.839	1.049	
	Bootstrap I	0.947	-0.003	0.941	0.052	0.845	1.050	Normal
						0.844	1.037	Bias Corr.
	Bootstrap II	0.948	-0.004	0.941	0.062	0.827	1.068	Normal
						0.810	1.054	Bias Corr.
Random coefficients models - intercept	Observed	6.824	NA	NA	3.701	-0.833	14.481	
	Bootstrap I	6.578	0.247	7.071	3.712	-0.699	13.854	Normal
						0.547	14.681	Bias Corr.
	Bootstrap II	6.411	0.240	7.238	4.320	-2.056	14.878	Normal
						-1.809	15.845	Bias Corr.
Random coefficients models - slope	Observed	0.915	NA	NA	0.049	0.814	1.016	
	Bootstrap I	0.918	-0.003	0.912	0.048	0.823	1.013	Normal
						0.810	0.999	Bias Corr.
	Bootstrap II	0.920	-0.005	0.910	0.057	0.809	1.031	Normal
						0.791	1.019	Bias Corr.
Concordance Correlation Coefficient (CCC)	Observed	0.803	NA	NA	0.050	0.704	0.902	
	Bootstrap I	0.823	-0.020	0.783	0.080	0.667	0.979	Normal
						0.586	0.910	Bias Corr.

Bootstrap I : Single Bootstrapping for dependent data -- bootstrap individuals only and then sample entire block for each selected subject.
Bootstrap II: Double Bootstrapping for dependent data -- bootstrap individuals and then bootstrap observations within individuals using the moving block method with block size 3 and overlap size 2.
Bootstrap CI method: Normal – normal approximation. Bias Corr – bias-corrected percentile method.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3.3.2 Somatic FORE-SIGHT II Elite vs Co-Oximetry Reference (REF CX): Regression analysis and Bootstrap Validation Results - QUAD muscle tissue data.

Table 7: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Deming and Random Coefficients Model Regression, CCC, and Bootstrap I and Bootstrap II Validation. (Bootstrap sample = 200). Quadriceps muscle tissue (Quad) data from **Figure 8**.

QUAD		Original or Bias–corrected (bootstrap) Statistic	Approx Bias	Bootstrap mean	Standard Error	Approx. Lower 95% Confidence Limit	Approx. Upper 95% Confidence Limit	Bootstrap CI Method
Deming regression - intercept	**Observed**	5.149	NA	NA	5.186	-5.015	15.314	
	Bootstrap I	5.363	-0.214	4.936	5.273	-4.972	15.699	Normal
						-5.489	14.798	Bias Corr.
	Bootstrap II	4.638	0.511	5.661	6.481	-8.065	17.341	Normal
						-8.658	17.339	Bias Corr.
Deming regression - slope	**Observed**	0.906	NA	NA	0.068	0.773	1.039	
	Bootstrap I	0.904	0.002	0.908	0.074	0.760	1.048	Normal
						0.768	1.052	Bias Corr.
	Bootstrap II	0.914	-0.008	0.898	0.088	0.741	1.087	Normal
						0.755	1.114	Bias Corr.
Random coefficients models - intercept	**Observed**	7.940	NA	NA	5.036	-2.476	18.356	
	Bootstrap I	8.137	-0.198	7.742	4.736	-1.145	17.420	Normal
						-0.201	16.902	Bias Corr.
	Bootstrap II	7.322	0.617	8.557	5.826	-4.097	18.742	Normal
						-1.995	19.125	Bias Corr.
Random coefficients models - slope	**Observed**	0.867	NA	NA	0.070	0.724	1.011	
	Bootstrap I	0.866	0.002	0.869	0.066	0.737	0.994	Normal
						0.728	0.975	Bias Corr.
	Bootstrap II	0.875	-0.008	0.860	0.080	0.719	1.031	Normal
						0.718	1.022	Bias Corr.
Concordance Correlation Coefficient (CCC)	**Observed**	0.702	NA	NA	0.069	0.567	0.836	
	Bootstrap I	0.721	-0.019	0.683	0.077	0.569	0.872	Normal
						0.537	0.816	Bias Corr.

Bootstrap I : Single Bootstrapping for dependent data -- bootstrap individuals only and then sample entire block for each selected subject.
Bootstrap II: Double Bootstrapping for dependent data -- bootstrap individuals and then bootstrap observations within individuals using the moving block method with block size 3 and overlap size 2.
Bootstrap CI method: Normal – normal approximation. Bias Corr – bias-corrected percentile method.

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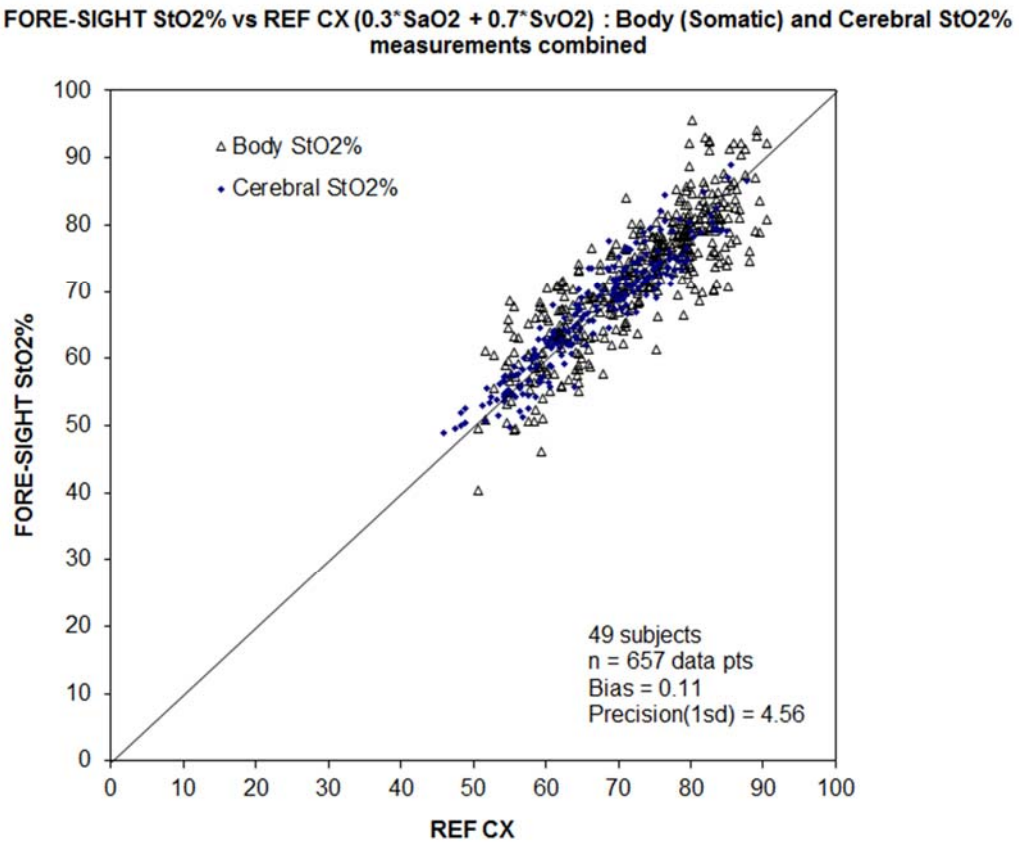
3.3.3 Regression and Bootstrap Validation Result Comments: The ***Deming Regression*** results demonstrate that the 95% confidence intervals (CI) include the desired regression coefficients of slope=1 and intercept=0 with a CCC = 0.861 for ALL DATA (**Table 5**) combined as well as Flank (**Table 6**) and Quad (**Table 7**) StO2 measurements separated. The two bootstrap validations methods Bootstrap I and Bootstrap II results also were very similar to the original *Deming Regression* results, as well to each other. The consistency of the results from the *Deming Regression* and corresponding bootstrap validation methods demonstrate the robustness of the analysis.

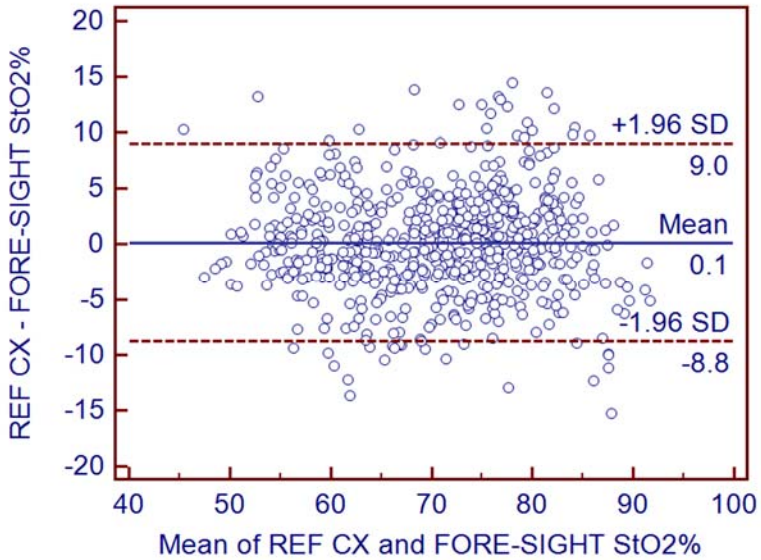
While the ***Deming Regression*** is the preferred regression method to analyze these results due to possible error in the reference measurement REF CX, the ***Random Coefficients Model*** was also used for regression analysis as a secondary analysis. The ***Random Coefficients Model*** results demonstrate that the 95% confidence intervals (CI) very nearly include the desired regression coefficients of slope=1 (>0.99 in most cases) and intercept=0 for ALL DATA (**Table 5**) combined as well as Flank (**Table 6**) and Quad (**Table 7**) StO2 measurements separated. The two bootstrap validations methods Bootstrap I and Bootstrap II results also were very similar to the original *Random Coefficients Model* results, as well to each other. Because the *Random Coefficients Model* does not consider errors in the reference measurement REF CX, which could cause some deviation of the slope and intercept, this analysis is secondary to the *Deming Regression* results.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3.4 Combination of Body /Somatic and Cerebral StO2 data to support proposed IFU

Figures 10 & 11 shows the combined FORE-SIGHT II Elite Somatic StO2 data (this application) with Cerebral StO2 (See K123700) to support our proposed IFU (See **Section 1.5**) displayed as a scatterplot and Bland-Altman plot. There were a total of 657 data points from 49 enrolled subjects (24 somatic and 25 cerebral subjects). Overall bias and precision was 0.11 ± 4.56% (1sd).





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3.5 Conclusion

The results show that FORE-SIGHT II Elite Tissue Oximeter Body/Somatic (This application) and Cerebral (K123700) StO2 measurements demonstrate a very high correlation, Deming Regression fit, and good accuracy compared to the Co-Oximetry Reference (REF CX) when using Large sensors for adult and transitional adolescent subjects ≥ 40 kg.

Table 8: Summary of Results for FORE-SIGHT II Elite Large sensors to support proposed IFU

FORE-SIGHT II Elite Large sensor StO2 measurement validation summary	**Bias ± Precision (1 standard deviation) from Bland-Altman**	**Number of subjects studied**	**Subject Population**	**Reference Document**
Body/Somatic FORE-SIGHT II Elite StO2 vs REF CX	0.24 ± 5.17%	24	Adults & Transitional Adolescents ≥ 40kg	This Application
Cerebral FORE-SIGHT II Elite StO2 vs REF CX	-0.14 ± 3.05%	25	Adults & Transitional Adolescents ≥ 40kg	K123700
Body/Somatic & Cerebral FORE-SIGHT II Elite StO2 vs REF CX	0.11 ± 4.56%	49	Adults & Transitional Adolescents ≥ 40kg	This Application combined with K123700

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. REFERENCES

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22. Risk Analysis

Risk Analysis Documentation has been updated for the changes in this submission.

- 21-07-0306 FORE-SIGHT Elite Risk Analysis
- 21-07-0307 FORE-SIGHT Elite Risk Management Summary Report

See Attachment H

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Authors: H. Triebel **Date:** 15-Oct-13

APPROVALS:

By signing this document you are giving approval to the comments, actions and outcomes documented here & on any appended pages.

10/25/2013	10/28/13	11/15/13
Marketing Product Mgr M. Aceves — Date	**Operations** G. Brocksieper — Date	**Project Leader VSM Eng** H. Triebel — Date
10/15/13	10/23/13	10/31/13
Clinical - App B. Kopotic — Date	**Quality Assurance Regulatory Affairs** R. Jeffrey — Date	**Sensor Eng** K. Duffy — Date
11/5/13	11/5/2013	See attached email for Approval 11/15/13
Service L. Hottin — Date	**R & D** J. Gamelin — Date	**Chief Medical officer** R. Mecca — Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Triebel, Harry

From: Mecca, Roger
Sent: Tuesday, October 15, 2013 12:12 PM
To: Triebel, Harry
Subject: Re: Update Gemini FORE-SIGHT ELITE Risk Management file docs

Ok by me

Roger S. Mecca MD
(b) (6) [redacted]

On Oct 15, 2013, at 5:35 AM, "Triebel, Harry" <Htriebel@CASMED.com> wrote:

> Roger & Bob,
>
> Attached are the latest Gemini/FORE-SIGHT ELITE Risk Management File documents, there were reviewed earlier this year and I thought I started their circulation (you both approved via email in April) but have not been released. Nothing has changes since the last emailing except to update the dates These will be needed for ELITE Project Phase 1.5 Design documentation. Please review and id acceptable print the 1st page, sign, scan and return OR simply respond to this email with your approval, I will start the process of the circulating these 3 docs internally for the remaining approvals. Thanks in advance.
>
> Harry
>
> <21-07-0304 R03.pdf>
> <21-07-0306 R03.pdf>
> <21-07-0307 R03.pdf>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Document Revision History			
Rev	**Date**	**Editor(s)**	**Reason for Change**
00	17-May-12	HT	Original release
01	13-Nov-12	HT	Updated per ITS ISO 14971 Checklist review of FORE-SIGHT project
		JG	Updated to add 4.1.1.8 for defib. hazard to operator and expanded description of ac accessories (sectio
		HT	Updated 4.1.1.1, 4.1.1.2, 4.7.3.1 & 4.1.2.8, Added 4.5.5.11, 4.5.5.12, 4.5.5.13 & 4.11.1.4
		HT	Updated 4.5.5.11 & 4.10.1.1 for fluid ingress
02	03-Dec-12	HT	Remove Age/Weight feature, update RMF documentation
			Remove sections: 4.5.1.2, 4.5.5.3, 4.5.6.4, 4.5.10.1 & 4.6.1.2
03	15-Oct-13	HT	Add 4.5.6.4 Display of valid StO2 values from a non-human tissue site.
			Add 4.3.5.5 User cuts/trims the sensor to allow it to fit on patient w/other sensors causing the integrity of the isolation layer to be compromised exposing the patient to excessive leakage current and/or damage to the system to during defibrillation.
			Change "Poorly assembled…" to "Improperly assembled…" for numerous Risks
			Update IFU in Haz ID Doc, Review/Update Risk Analysis for new IFU
			Haz ID: Change "Electronic copy" of User Manual to "Paper copy"
			Haz ID: Remove "A hard copy version of the FORE-SIGHT ELITE Warnings Guide, 21-03-0332, …"
			Remove reference to FORE-SIGHT ELITE Warning Guide 21-03-0332 & Quick Reference Guide 21-

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1. INTRODUCTION

1.1 Purpose

The document describes the Risk Analysis for the Gemini Project (Product name: FORE-SIGHT® ELITE Absolute Tissue Oximeter). The Gemini Oximeter is a medical device comprised of a Color 10.4" display, user interface controls (touchscreen) and hardware to support the acquisition of a patient's tissue oxygen concentration. The term Gemini refers to the Eng Project Name, where the term FORE-SIGHT ELITE refers to the Product Name & may be interchangeably.

1.1 Scope

This document describes the risk analysis as it applies to the FORE-SIGHT ELITE Absolute Tissue Monitor, Model 3000 Series sensors and accessories.

This analysis defines the Risk Management concepts and their documentation due to the requirement to meet the 3rd Edition of the general safety standard (60601-1:2005) as it becomes mandatory beginning in 2012. This analysis also addresses a product software update to expand the indications for use for additional tissue claims as well as the inclusion of a Video Output function. The analysis forms one part of the Risk Management process as defined in QSP1026, Risk Management Procedure.

The product's Life Cycle Phases for which each element of plan is applicable are identified as:

* Product Realization;
* Design Controls;
* Production and Distribution, and
* Post Market Surveillance.

Risk acceptability criteria are based upon: ANSI/AAMI ESES60601-1: 2005, CAN/CSAC22.2, No. 60601-1: 2008, CENELEC EN, 60601-1: 2006, - IEC 60601-1: 2005, IEC 60601-1-8: 2006, IEC 60601-1-6:2010, ISO 14971: 2007, ISO 14971: 2000 (If CB is required), FDA, Health Canada, Medical Device Directive and IEC60825-1:2007.

1.2 PHASE DESIGN

Project Gemini shall be divided into 3 Phases: Phase 1-Adult, Phase 2-Pediatric & Phase-3 Neonatal. The Risk Analysis shall attempt to capture all the Risks associated with Phase 1 design. The Risk Analysis will be updated with more actuate Phase 2 & 3 Hazard information becomes available.

2. REFERENCE DOCUMENTS

Standards:

IEC 60601-1 2nd edition Medical Electronic Equipment, Part 1: General Requirements for Safety
IEC 60601-1:2005 3rd edition General Requirements for Safety
ISO 14971:2007 Medical devices: Application of risk management to medical devices
IEC 60601-1-8:2010 Medical electrical equipment - Part 1-8: General requirements test and guidance for alarm systems in medical electrical equipment
Council Directive 93/42/EEC Concerning Medical Devices
ANSI/AAMI/IEC 62304:2005 Medical Device Software – Software Life Cycle Processes

CAS Medical Systems, Inc:

QSM1001, Quality System Manual
QSP1026, Risk Management

21-07-0301, Gemini Project Design Plan
21-07-0302, Gemini Product Specification
21-07-0303, Gemini Risk Management Plan
21-07-0306, Gemini Risk Analysis
21-07-0307, Gemini Risk Management Summary Report
21-07-0308, Gemini Usability Specifications & Requirements
21-07-0314, Gemini Large Sensor Specifications
21-07-0321, Gemini Residual Risk(s) Judged Acceptable and the Disclosure Process
21-03-0336, FORE-SIGHT ELITE Large Sensor Multilanguage DFU (Directions for Use)
21-22-3000, FORE-SIGHT ELITE Absolute Tissue Oximeter User Manual (English)

VaP/VaR 120018, Gemini/ FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan
VaP/VaR 120019 , Gemini / FORE-SIGHT ELITE Software PEMS Validation
VaP/VaR 120020, Gemini / FORE-SIGHT ELITE Fluid Ingress Verification Plan

Mfg PS 03-58-3000 Process Sheet for 03-58-3000 Series Gemini Oximeter
Mfg PS 03-58-3008 Process Sheet for 03-58-3008 Gemini Preamp
Mfg PS 03-58-0500 Process Sheet for 03-58-0500 Series Gemini Sensors

Change Control Sheet (CCS) 03-58-3000 for Mfg PS 03-58-3000 Series Gemini Oximeter
Change Control Sheet (CCS) 03-58-3008 for Mfg PS 03-58-3008 Gemini Preamp
Change Control Sheet (CCS) 03-58-0500 for Mfg PS 03-58-0500 Series Gemini Sensors

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3. RISK ANALYSIS

3.1 Hazard Identification to Risk Analysis procedure

3.1.1 For each Gemini Hazard identified in CAS 21-07-0304, Gemini Hazard Identification, there shall be a Risk Analysis performed.

3.1.2 For each category of Hazards, the foreseeable sequence of events, hazardous situations and the Harm shall be listed. Each Hazard shall be identified present under Normal and/or Fault conditions. The associated Risk to Patient, User, Bystander, Service or Environment shall also be indicated.

3.1.3 The formal Risk Analysis procedure shall indicate the Initial Risk Evaluation, Risk Control Measures and the Residual Risk based on the Risk Control Measures using the format outlined in QSP1026 Risk Management.

3.2 Risk Evaluation (Initial)

3.2.1 For each Gemini hazard that is identified there shall be a risk estimation, which is based on the likelihood of that hazard and the severity of the consequence of that hazard.

3.2.1.1 Estimation is based on available information and data, but where the likelihood of the occurrence of harm cannot be estimated, a listing of possible consequences shall be prepared.

3.2.1.2 The likelihood of risk for the Gemini hazards shall be estimated quantitatively using the procedure outlined in QSP1026 Risk Management.

3.2.1.3 Estimation of the likelihood of harm from the Gemini may employ these approaches:

a) Use of relevant historical data;
b) Prediction of probabilities using analytical or simulation techniques;
c) Use of expert judgment.

3.2.2 The severity of risk for the Gemini hazards identified will use the qualitative descriptors outlined in QSP1026 Risk Management.

3.2.3 From the risk estimation table defined in QSP1026 Risk Management the Gemini risks shall be evaluated into three broad classes:

a. ■ **Insignificant Risk (IR)** - A negligible risk is an acceptable risk not requiring further risk control or other action;
b. ■ **Investigate Further Risk Reduction (IFRR)** - A tolerable risk if the cost of risk reduction would exceed the improved gain;
c. ■ **Unacceptable Risk (UR)** - An intolerable risk is so severe that a system in which they exist would not be tolerated.

3.3 Risk Control Measures

3.3.1 Risks identified for the Gemini shall be controlled so that the estimated risk for each identified hazard is made acceptable.

3.3.2 A risk is acceptable if the risk is less than or equal to the maximum tolerable risk and the risk is made as low as reasonably practicable. Controls, directed at the cause, can be applied to either or both, likelihood & severity.

3.3.3 One or more of the following Risk Control measures shall be employed (refer to QSP1026 Risk Management):

a. Inherently safety by design
b. Protective measures in the device or Mfg process
c. Information for safety

3.4 Risk Evaluation (Residual)

3.4.1 Identified risks for the Gemini shall be re-evaluated based upon the estimated or actual effectiveness of the Risk Control measures.
3.4.2 Residual risks, their acceptability, and effectiveness of controls used, shall be documented in the Risk Management File
3.4.3 Refer to 21-07-0321, Gemini Residual Risk(s) Judged Acceptable and the Disclosure Process

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4. LIST OF IDENTIFED HAZARDS AND ASSOCIATED RISKS

Category	4.1 Energy Hazards & Contributing Factors				
Hazard	4.1.1 Electricity				
Hazardous Situation	4.1.1.1 Improperly assembled or damaged (from fall or impact with hard object) monitor creates a broken electrical connection in Medical Device causing an electrical potential on the monitor case resulting in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	NSAM modules use 15 VDC, Chassis leakage current < 5 mA, patient leakage current < Table 3 of IEC60601-1, No exposed or access to AC components, Medical grade power supply, Fused power entry module w/fuses accessible w/o line cord, Sensor patient contact area, housing electrical components, use non-conductive plastic material, 2 points of cable retention for AC signals	Designed to meet IEC 60601-1 100% visual inspection & testing of Sensors VaR 120018, 120019	IEC 60601-1 Compliance Review of daily Sensor Visual Inspection reports Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU contains warning regarding proper operation, handling and service of medical device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.1.2 Improperly assembled or damaged (from fall or impact with hard object) monitor creates a broken electrical connection in Medical Device or patient cable allowing human contact resulting in electrical burn or associated injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	NSAM modules use 15 VDC, Chassis leakage current < 5 mA, patient leakage current < Table 3 of IEC60601-1, No exposed or access to AC components, Medical grade power supply, Fused power entry module w/fuses accessible w/o line cord, Sensor patient contact area, housing electrical components, use non-conductive plastic material	Designed to meet IEC 60601-1 100% visual inspection & testing of Sensors VaR 120018, 120019	IEC 60601-1 Compliance Review of daily Sensor Visual Inspection reports Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU contains warnings regarding proper operation, handling and service of medical device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.1.3 Broken battery connections allows shorting of battery terminals in Medical Device allowing for high DC currents resulting in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Battery wire harness connections are fully insulated & double crimped, Battery wires length design that is wire breaks at connection cannot reach other battery terminal	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

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Hazardous Situation	4.1.1.4 Mis-connected battery connections allows shorting of battery terminals allowing for high DC currents resulting in shock or affecting heart rhythm.			Risk to:	Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Battery wire harness are color coded (red-Pos., Black-Neg.), Battery only fits into battery enclosure one way, Battery board only fits into battery enclosure one way, length of battery terminals cannot be reach wrong terminals and battery & and connected battery board only fits inside battery enclosure one way	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates batteries within Battery enclosure are not user replaceable and Battery pack should only be serviced by qualified Service personnel			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.1.5 Unintended movement of cable and wires that could cause connections to loosen or accidental short circuit that results in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All wire harness connections are fully insulated & double crimped, cable connections have locking mechanism to retain connector to header, Wire harnesses are captured with tie wraps to limit movement, shrink wrap tubing is applied to solder terminals	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazardous Situation	4.1.1.6 Unintended movement of cables and wire that could damage the wire's insulation causing short circuit resulting in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All wire harnesses that pass through or are in close proximity to metal edges are protected by a chaffing guard or the wires are bundled together with a tie wraps, wire harnesses have a limited service loop to limit movement, circuits protected by fuses	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

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Hazardous Situation	4.1.1.7 Unintended movement of cable and wires during assembly (e.g. pinched cables) that could damage to the wire's insulation causing short circuit resulting in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Wire harnesses have a limited service loop to limit movement during assembly and re-assembly, all wire harnesses that pass through or are in close proximity to metal edges are protected by a chaffing guard or the wires are bundled together with a tie wrap, circuits protected by fuses	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazardous Situation	4.1.1.8 Applied parts accidentally contacted during the application of defibrillation causing possible serious injury or death.			Risk to:	Patient, User, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Applied parts and cables have minimum 500V double or re-enforced isolation, 1500V basic isolation & 5000V total isolation.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU includes warning not to touch patient during defibrillation, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	**4.1.2 Heat**				
Hazardous Situation	4.1.2.1 Improperly assembled or damaged (from fall or impact with hard object) monitor creates a broken electrical connection causing heat to be generated in Medical Device resulting in thermal injury (burns) at contact site.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All devices that produce heat are not in contact with the housing; dual means to secure wires; Sensors LEDs produce little or no heat; (b)(4) [redacted] (b)(4) [redacted] Error message is ndicated on display when excessive power is attempted to be delivered to LEDs output & LEDs turned off;	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp.	VaR 120018, 120019 CCS 03-58-3000 CCS 03-58-3008	Approved VP Approved PS	
	Information for Safety	DFU states that user should check Sensor before use & Sensor site periodically.	VaR 120018, 120019	Approved VP	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.2.2 Improperly assembled or damaged (from fall or impact with hard object) monitor creates a broken electrical connection allowing arcing in Medical Device causing fire or explosion in presence of flammable anesthetic gas resulting in injury or death.			Risk to:	Patient, User, Service, Bystander, Environment
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All devices that produce heat are not in contact with the housing; dual means to secure wires, Sensors LEDs produce little or no heat; Power to LEDs output is limited; Current limiting preamp.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines warning for explosion hazard in presence of flammable anesthetics, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.2.3 Sensor LED design, damaged (from fall or impact with hard object) monitor or a Software issue that allows excessive current to drive LEDs causing localized tissue injury (burn).			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensors use LEDs that produces little or no heat; Power to LEDs output is limited (current & duty cycle); Current limiting preamp.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensors; Temp measurement in Sensor will shut off LEDS if max Temp exceeded.	CCS 03-58-0500 VaR 120018, 120019	Approved PS Approved VaR	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.2.4 Thermal failure of wire and other insulation used to provide resistance to heat over the expected service life, leading to short circuiting, excessive heat or fire resulting in serious injury or death.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	PCBs, Connectors and all internal wire is UL approved with 94V0 rating, Widespread use of the product has met the Expected Service Life without any problems related to thermal failure, Medical Device monitors internal temperature and shuts down when max temp reached (less than wire rating)	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU indicates not to use damaged medical device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.2.5 Thermal failure of plastic bezel before end of expected service life of Medical Device creates an exposed electrical connection allowing for personal contact resulting in electrical shock.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Plastic enclosure uses 94V0 plastic from UL approved molder, Medical Device monitors internal temperature and shuts down when max temp reached	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU indicates not to use damaged medical device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.2.6 Applied Sensor raises the temperature under the Sensor to > 41.0℃ resulting in thermal tissue injury (heat) at Sensor site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	LED output creates little or no additional heat at sensor site, Sensor footprint is small	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines max Operating temp as 41℃ minus the max rise in temp under a Sensor	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.2.7 Batteries are subjected to over-charging that produces excessive heat that increases the ambient temperature causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Charge circuit limits amount of current to batteries, Current limiting fuse, SW monitors internal device temp-shuts down if temp exceeds max limit, Charge circuit shuts off charger if fault detected	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.2.8 Internal power source in inadequately protected against excessive current draw due to short circuit that may cause a fire resulting in thermal injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Power Entry Module fuse min rating based on power supply max current requirements, Slow blow fuse used to allow for momentary high current inrush on power up: T3.15AH250V	Fuse rating & specifications VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper rating for replacement fuse and the proper procedures for changing fuses	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.1.3 Unintended motion**				
Hazardous Situation	4.1.3.1 Medical Device is pulled by hanging connected cable(s) causing the Medical Device to move/fall resulting in contact injury, contusions, broken bones, etc.			Risk to:	Patient, User, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Rubber feet on unit; 4 meter Preamp allows routing away from travel areas; low center of gravity in enclosure.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper installation & operating procedures\Statement(s) in DFU includes risk disclosure, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.3.2 Patient with Sensor attached & Medical Device moves in opposing directions causing Sensor to pull off patient resulting in tissue injury at Sensor site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp clip use to retain Sensor/preamp at patient's location; medical grade adhesive w/only moderate retention capabilities; Limited retention force between sensor & Preamp connection.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper installation & operating procedures.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.3.3 Sensor or Preamp cable(s) become entangled around head or extremities resulting in suffocation or circulation injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Shape of Sensors & direction off side of head & away from patient's face & neck.	Visual inspection, Sensor Design	Weekly Sensor Cell defect report, Customer complaint numbers	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes that cables should be secured to prevent them from being entangled, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.3.4 Medical Device on mobile/transport device (e.g. roll stand) has wheels that contacts an object or is system is subjected to rough handling causing the device to tip and fall over resulting contact injury (contusions, broken bones, etc.)			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Design of Roll Stand has wide 5-arm base with large swivel casters; low center of gravity & mechanical method of securing monitor to Roll Stand.	Designed to meet IEC 60601-1, 21.6 Mobile Equipment 24.1 Stability	IEC 60601-1 Compliance	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper installation and operating procedures, Instructions for use of Roll Stand with monitor from Roll Stand vendor describes installation procedure, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.3.5 Failure of fixed mount (e.g., swing arm), or locking pin for mount not being engaged or unapproved mount, with Medical Device attached, causing device to fall resulting in contusions, broken bones, etc. type injuries at contact site.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Design of Wall Mount has x4 safety factor for weight; mechanical method of securing arm to Wall Mount (or pole mount) & mechanical method of securing monitor to Roll Stand.	Designed to meet IEC 60601-1, 21.6 Mobile Equipment 24.1 Stability	IEC 60601-1 Compliance	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper installation and operating procedures, Instructions for use of Wall Mount with monitor from Wall Mount vendor describes installation procedure, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazardous Situation	4.1.3.6 Patient moves/turns or loss of adhesion due to perspiration or inadequate placement causing Sensor to move from original position causing sensor to cover nose or mouth resulting in suffocation or injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Patient connected vital signs monitor should alert user to changes in physiological values; Standard Hospital practice for periodic patient surveillance; Ambient light detection to alert User; Limited retention force between sensor & Preamp connection.	Visual inspection, Sensor Design, Sampling of Hospital Practices using Tissue Oximeters, VaR 120018, 120019	Weekly Sensor Cell defect report Customer complaint numbers Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes the proper application of the Sensor & to check Sensor site every 8 hours, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.3.7 Preamp cable accidently pulled while the Sensor is attached to patient causing Sensor to pull off patient resulting in tissue injury at Sensor site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp clip use to retain Sensor/preamp at patient's location; Limited retention force between sensor & Preamp connection; Medical grade adhesive w/moderate retention capabilities; Standard Hospital practice for periodic patient surveillance.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes the proper application of the Sensor & to check Sensor site every 8 hours.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.3.8 Patient moves or is moved to position Sensor underneath the body which can lead to the Sensor being pressed against the patient and resulting in injury to the tissue.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor construction attempts to minimize pressure points on top of sensor	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes the proper application of the Sensor, not to allow patient to lie on sensor and to check Sensor site every 8 hours	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.3.9 Medical Device on mobile/transport device (e.g. roll stand) has wheels that contacts an object or is system is subjected to rough handling causing the device to tip and fall over causing connections to loosen or accidental short circuit that results in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All wire harness connections are fully insulated & double crimped, cable connections have locking mechanism to retain connector to header, Wire harnesses are captured with spiral wrap to limit movement, shrink wrap tubing is applied to solder terminals	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU indicates not to use damaged medical device, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	**4.1.4 Pressure**				
Hazardous Situation	4.1.4.1 Good Batteries charging at a high rate or defective Batteries charging at a normal rate produce excessive internal pressure causing battery to fail resulting in battery burn type injury at contact site.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Batteries use relief valve devices to exhaust internal pressure, Numerous chassis venting holes & Fan allow for air exchange normal charge circuit limits amount of current to batteries, Current limiting fuse, Charge circuit shuts off charger if fault detected	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.4.2 Discharging, charging or overcharging internal batteries vent gas that could ignite causing fire or explosion resulting in serious injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Numerous chassis vent holes along with exhaust fan allow for air exchange, Normal charge circuit limits amount of current to batteries, Current limiting fuse, Charge circuit shuts charger off if fault detected, Battery vent regulate amount of gas released	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries, DFU indicates not to use device in presence of flammable gases	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.4.3 Batteries are subjected to over-charging that produce excessive internal pressure causing battery to fail releasing battery fluid resulting in battery burn (acid) type injury at contact site.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification	Fault Conditions
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Charge circuit limits amount of current to batteries, Current limiting fuse for battery charge, Charge circuit shuts charger off if fault detected	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.1.5 Acoustic Pressure**				
Hazardous Situation	4.1.5.1 Normal components or improperly assembled/damaged (from fall or impact with hard object) Medical Device causing excessive loud sounds to be generated resulting in minor hearing injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification	Normal Fault Conditions
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Unit contains mechanical parts (fan) that produces < 31 dB at 1 meter under normal temperature.	Designed to meet IEC 60601-1-2 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor.	CCS 03-58-3000	Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazardous Situation	4.1.5.2 Speaker is allowed to generate excessive loud tones resulting in minor hearing injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification	Normal Conditions
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Unit contains Speaker that produces audible tones (max volume) < 50 dB at 1 meter with user in normal position	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

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Hazard	4.1.6 Vibration				
Hazardous Situation	4.1.6.1 Medical Device damaged in rugged environment allowing loss of mechanical integrity causing shape edges and pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Small component to system mass ration, use of thread lock & mechanical locks to secure threaded fasteners	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazard	4.1.7 Magnetic fields				
Hazardous Situation	4.1.7.1 Electromagnetic components (e.g. ESU device) produce excessive magnetic fields causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Unit speaker & NSAM modules designed for minimal magnetic field emissions Power Supply and associated components UL listed	Designed to meet IEC 60601-1-2 VaR 120018, 120019	IEC 60601-1-2 compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU provides warning statement regarding ESU interference, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Category	4.2 Biological Hazards & Contributing Factors				
Hazard	4.2.1 Bio-contamination				
Hazardous Situation	4.2.1.1 Contaminated individual contacts the Medical Device or Accessories causing contamination to remain on device resulting in a bio-contamination illness.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Device & accessories are designed for easy cleaning & disinfecting; Sensor are designed for single patient use; Standard Hospital practice for decontamination and/or safe disposal of contaminated equipment.	Biocompatibility report is available & correct, VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved bio-report Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU includes procedure for proper cleaning, Sensor packaging labeling indicates single patient use, DFU indicates risk of cross contamination/infection from used sensors, DFU indicates disposal should follow local institute policies, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazard	4.2.2 Bio-incompatibility				
Hazardous Situation	4.2.2.1 Prolonged contact by sensitive individuals with Medical Device or Accessories cause a bio-incompatibility condition resulting in illness.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All patient contacts (e.g., Sensor, etc.) are not made without Latex & are tested for biocompatibility; Standard Hospital practice for periodic patient surveillance.	Biocompatibility report is available & correct, VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved bio-report Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean; new materials; no Latex.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	CAS Manufactured products include written procedure for proper cleaning & disposal; non-latex label on Sensor package.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.2.2.2 Physiological change in patient (e.g., swelling under Sensor) that makes tissue change size rigid Sensor components remain in place causing mechanical pressure resulting in tissue injury at sensor site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Smooth Sensor surface, no sharp edges on Sensor; medical grade adhesive w/only moderate retention capabilities; Sensor design bends to conform to tissue shape; Standard Hospital practice for periodic patient surveillance.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean; new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU states that user should check Sensor site periodically.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.2.3 Toxicity				
Hazardous Situation	4.2.3.1 Good Batteries charging at a high rate or defective Batteries charging at a normal rate may produce excessive internal pressure causing battery to fail resulting in injury by exposure to battery acid.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Batteries use relief valve devices to exhaust internal pressure, Numerous venting holes always allows some air flow, normal charge circuit limits amount of current to batteries, Current limiting fuse, Charge circuit shuts charger off if fault detected	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.2.4 Allergenicity				
Hazardous Situation	4.2.4.1 Sensitive individuals repeatedly contact Medical Device or Accessories causing an allergic reaction or allergic illness.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Patient cable/Sensor, headband and all patient contacts designed using historically hypo-allergenic material	Biocompatibility report VaR 120018, 120019	Approved bio-report Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials,	Incoming inspection reports VaR 120018, 120019	Review of Incoming reports Approved VaR	
	Information for Safety	DFU indicates to examine of Sensor application surrounding area, non-latex label on Sensor packaging	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.2.5 Re- and/or cross-infection				
Hazardous Situation	4.2.5.1 Improperly cleaned or disinfected Medical Device or Accessories may allow biologic or caustic contaminants to be transferred between individuals resulting in illness or injury.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Service personnel are provided with a procedure to safely handle returned goods; Sensor is designed for single patient use; Standard hospital practice is for decontamination and/or safe disposal of contaminated equipment.	Service Procedure SVC1000, VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved Service Procedure Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU includes procedure for proper cleaning, DFU Sensor packaging labeling indicates single patient use, DFU indicates risk of cross Contamination/infection from used sensors, DFU indicates disposal should follow local institute policies, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	4.2.6 Inability to maintain hygienic safety				
Hazardous Situation	4.2.6.1 Medical Device or Accessories are incapable of being cleaned or disinfected causing in re- and / or cross-infection / contamination resulting in illness.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device, Preamp & Sensor are designed with smooth surfaces & minimal areas that cannot be readily cleaned or disinfected; Sensor are designed for single patient use; Standard Hospital practice for decontamination and/or safe disposal of contaminated equipment.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU defines the cleaning procedure for the medical device, and accessories, DFU defines single use for Sensor, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Category	**4.3 Environmental Hazards & Contributing Factors**				
Hazard	**4.3.1 Susceptibility to electromagnetic interference**				
Hazardous Situation	4.3.1.1 Medical Device is inoperable due to susceptibility of electromagnetic fields (EMC) from other devices causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply, Metal chassis; shielded Preamp & Sensor wires, Data filter attempts to eliminate noise signals, Value captured & not updated during noisy periods, sustained noisy conditions will blank numeric & recover when noise is removed.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates not to operate device in the presence of strong electromagnetic fields, DFU provides warning statement regarding EMC, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.3.1.2 Electromagnetic components (ESU device) produce excessive magnetic fields causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply, Metal chassis, shielded Preamp & Sensor wires, Standard Hospital practice for proper patient monitoring procedures, Data filter attempts to eliminate noise signals, Value captured & not updated during noisy periods, sustained noisy conditions will blank numeric & recover when noise is removed.	Designed to meet IEC 60601-1 VaR 120018, 120019 Sampling of Hospital Practices using Tissue Oximeters	IEC 60601-1 Compliance Approved VaR Compile Customer surveys	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used, DFU provides warning statement regarding EMC, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	**4.3.2 Emission of electromagnetic interference**				
Hazardous Situation	4.3.2.1 Improperly assembled or damaged (from fall or impact with hard object) devices allows excessive emission of electromagnetic fields (EMC) causing other device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply; metal chassis; shielded Preamp & Sensor wires.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU provides warning statement regarding EMC, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Hazard	4.3.3 Inadequate supply of power				
Hazardous Situation	4.3.3.1 Medical Device is inoperable due to low external AC supply causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply; battery backup to operate for a min of 0.5 hrs when fully charged, batteries charged whenever connected to AC.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes power supply troubleshooting guide.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.3.3.2 Medical Device is inoperable due to loss of external AC supply causing loss of device readings resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Battery backup to operate for a minimum of 1 5 hrs when fully charged, batteries charged whenever unit connected to AC	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes power supply troubleshooting guide, DFU indicates to charge batteries when Device is not in use	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.3.4 Storage or operation outside the prescribed environmental conditions				
Hazardous Situation	4.3.4.1 Medical Device is inoperable due to extreme temperature, humidity or atmospheric pressure causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device design to operate in broadly accepted range of environmental conditions; SW monitors internal temp & adjusts fan speed accordingly; detects inoperable fan; shut device down if max temp exceeded.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines operating & storage temperatures for the medical device & accessories; Shipping label defines storage temperatures for the medical device.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.3.5 Mechanical damage				
Hazardous Situation	4.3.5.1 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor can cause electrical burns or exposure to high electrical currents resulting in injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Enclosure & accessories designed to meet mechanical requirements of standard.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU includes warning not to touch patient during defibrillation, DFU indicates not to use damaged medical device or accessories, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.3.5.2 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor causing shape edges & pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device & accessories are designed to have no sharp edges.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.3.5.3 Sensor flex circuit damaged by repeated bending back upon itself causing circuit to break & expose sharp/pointed edges & circuit contacts resulting in electrical shock and/or cut/laceration type injury.			Risk to:	Patient, User
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	(b)(4) [redacted] (b)(4) [redacted] Sensors use 15 VDC, Chassis leakage current < 300 µA; patient leakage current < 10 µA; flex circuits conformal coated; protective flex cover on top & bottom.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor.	CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.3.5.4 Mechanical damage to device handle due to fall or impact with hard object, causing unit to fall while attempting to be moved.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Cross hatch ribs in handle, tongue and groove seam between top and lower handle assembles, 4 points of attachment (screws) to retain handle, Increased wall thickness of handle assemblies, Handles tested to x4 load rating	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor.	CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.3.5.5 User cuts/trims the sensor to allow it to fit on patient w/other sensors causing the integrity of the isolation layer to be compromised exposing the patient to excessive leakage current and/or damage to the system to during defibrillation.			Risk to:	Patient, User, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor designed with wide foam edge, Isolation tape areas not along edge of sensor	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor.	CCS 03-58-0500	Approved PS	
	Information for Safety	Sensor DFU includes an appropriate "do not cut" symbol (e.g., scissor with a slash through it)	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.3.6 Contamination due to waste products and/or Medical Device disposal**				
Hazardous Situation	4.3.6.1 Contaminated Medical Device or Accessories are improperly disposed causing re- and/or cross-infection / contamination resulting in illness.			Risk to:	Patient, User, Service, Bystander, Environment
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All patient contacts (e.g., Sensor, etc.) are tested for biocompatibility; Standard Hospital practice for safe disposal of contaminated equipment.	Biocompatibility report is available & correct, VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU defines the safe disposal procedure medical device and accessories, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Category	**4.4 Hazards resulting from the incorrect output of energy and substances**				
Hazard	**4.4.1 Radiation**				
Hazardous Situation	4.4.1.1 Sensor LEDs output becomes out of specification allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Near-infrared light (690nm-880nm) LEDS are specified to be low drift, tight tolerance on LED wavelengths, (b)(4) [redacted] (b)(4)	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensors	CCS 03-58-3000	Approved PS	
	Information for Safety	DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.4.1.2 Sensor LEDs calibration values invalid allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Cal values stored within Sensor memory, Values need to inputted by NSAM, Checksum of Cal values must be correct in order for Sensors to be used and error message generated	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensors	CCS 03-58-3000	Approved PS	
	Information for Safety	DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used, DFU describes the Sensor Fault error message	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Category	**4.5 Hazards related to the use of the Medical Device & contributing factors**				
Hazard	**4.5.1 Inadequate labeling or operating instructions or over-complicated instructions**				
Hazardous Situation	4.5.1.1 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Body location for Sensor prominently indicated on display; Sensor body location saved.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.5.1.2 Improperly designed medical device labeling leads to an incorrect interpretation and lack of understanding resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor on body location prominently indicated on display, a Tissue Perfusion Index (TPI) shall be displayed on the main screen for each channel and values described under a Help menu. Any icons or abbreviations used are consistence with medical industry standards	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used, DFU indicates to read before operating device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.5.2 Inadequate specifications of accessories to be used with Medical Device or incompatibility with other Medical**				
Hazardous Situation	4.5.2.1 Medical Device used with inappropriate accessory allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp & Sensors connections are unique to Gemini; Software detection of connection to an approved accessory or external medical device.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the approved accessories to be used with the medical device; DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used; Medical device shipped with correct accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.5.3 Inadequate specifications of pre-use checks or specifications of service or maintenance**				
Hazardous Situation	4.5.3.1 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor on body location prominently indicated on display; Sensor body location saved.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Hazard	4.5.4 Used by unskilled/untrained personnel				
Hazardous Situation	4.5.4.1 Medical Device used by unskilled/untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Standard Hospital practice for proper patient monitoring procedures; TPI displayed on the main screen for each channel & value.	Sampling of Hospital Practices using Tissue Oximeters VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that only trained personnel should operate the medical device; DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used; Label stating US Federal law restricts this device to sale on or by the order of a physician.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.4.2 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Body location of Sensor prominently indicated on display; Sensor body location saved.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that only trained personnel should operate medical device; DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used; US Federal law restricts this device to sale on or by order of a physician.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.5.5 Reasonable foreseeable misuse				
Hazardous Situation	4.5.5.1 Medical Device used by unskilled/untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Standard Hospital practice for proper patient monitoring procedures; TPI displayed on the main screen for each channel & value.	Sampling of Hospital Practices using Tissue Oximeters VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that only trained personnel should operate medical device, DFU indicates proper method to enter the Sensor body location, DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used, DFU indicates medical device should not be used in the presence of anesthetic gas, DFU provides warning statement regarding EMC, US Federal law restricts this device to sale on or by the order of a physician, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazardous Situation	4.5.5.2 Medical Device used with an inappropriate Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor connections are unique to Gemini; Sensor on body location prominently indicated on display; Sensor body location saved; LEDs will not turn on if incorrect Sensor attached.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the approved Sensors to be used with medical device; DFU indicates: Proper method to enter the Sensor body location; Appropriate procedure for Sensor attachment to patient; Only trained personnel should operate medical device, If measurements are in doubt alternate means to assess patient's condition should be used; Device label indicates US Federal law restricts this device to sale on or by order of a physician.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.5.3 Sensor remains on Patient & Patient is placed in MRI device that produces excessive magnetic fields causing sensor components to heat up resulting in localize tissue damage (burn).			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Active LED area of Sensor is very small, and limits the tissue area exposure; Standard Hospital practice for proper patient monitoring procedures.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that special precautions may be required if the device is placed close to a strong transmitter such as X-ray equipment, MRI devices, etc , The "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.5.4 ESU device used too close to Sensor allowing current to pass through sensor components causing the components to heat up resulting in localized tissue injury (burn).			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Active LED area of Sensor is very small, and limits the tissue area exposure; Standard Hospital practice for proper patient monitoring procedures; Dielectric isolation strength for sensor design; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters. CCS 03-58-0500	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates Recommended distance from an applied Sensor for proper use of ESU equipment; Read before operating device.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.5.5.5 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor can cause electrical burns or exposure to high electrical currents resulting in injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Enclosure and Sensor designed to meet mechanical requirements of standard	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use, DFU indicates not to use damaged medical device or accessories, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.5.5.6 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor causing shape edges and pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device or patient cable/Sensor are designed to have no sharp edges	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU indicates not to use damaged medical device or accessories	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.5.7 Sensor, preamp, or monitor used near and attracted to MRI magnet causing damage to equipment, physical injury to nearby personnel or patient due to unintended motion, or injury to patient due to pull on Sensor/cabling.			Risk to:	Patient, User
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	N/A			
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that special precautions may be required if the device is placed close to a strong transmitter such as X-ray equipment, MRI devices, etc , "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazardous Situation	4.5.5.8 Sensor, preamp, or monitor stored in acceptable environment (temp & humidity) and is used before acclimated to acceptable operating environment allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	N/A			
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates to allow device to adjust to the current operating environment, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.5.5.9 Mechanical damage to device handle due to fall or impact with hard object, causing unit to fall while attempting to be moved.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Cross hatch ribs in handle, tongue and groove seam between top and lower handle assembles, 4 points of attachment (screws) to retain handle, Increased wall thickness of handle assemblies, Handles tested to x4 load rating	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor.	CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.5.10 During normal operations, liquids (8 oz. of water) may be spilled on top of the monitor, in one event lasting < 15 sec and wet internal parts that can cause exposure to high electrical currents resulting in injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supplies; No direct opening near AC components; Baffled framework on bottom of chassis allows for fluid egress.	Designed to meet IEC 60601-1 VaR 120020	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU directs user to keep all fluids away from device and to thoroughly dry device (min 1 hr) in event device gets wet, DFU indicates proper cleaning procedure when using cleaning solutions, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazardous Situation	4.5.5.11 During normal operations, liquids (1 liter of water) may be spilled on the preamp housing, in one event lasting < 30 sec and wet internal parts that can cause exposure to high electrical currents			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	NSAM modules use 15 VDC, housing electrical components use non-conductive plastic material, Cable openings use rubber grommets to limit fluid ingress	Designed to meet IEC 60601-1 VaR 120020	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU directs user to thoroughly dry device in event device gets wet (min 1 hr), DFU indicates proper cleaning procedure when using cleaning solutions, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.5.5.12 During normal operations, liquids (12 cc of water, 4cc/hr) may be dripped on the preamp housing, over a 4 hour period and wet internal parts that can cause exposure to high electrical currents resulting in injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	NSAM modules use 15 VDC, housing electrical components use non-conductive plastic material	Designed to meet IEC 60601-1 VaR 120020	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU directs user to thoroughly dry device in event device gets wet (min 1 hr), DFU indicates proper cleaning procedure when using cleaning solutions, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	**4.5.6 Incorrect measurement & other metrological aspects**				
Hazardous Situation	4.5.6.1 Sensor positioned improperly over wrong body location allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	A Tissue Perfusion Index (TPI) shall be displayed on the main screen for each channel & value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU & labeling define the procedure for attachment of the Sensor to the patient; DFU indicates that if measurements are in doubt alternate means to assess patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.5.6.2 Medical Device used with an inappropriate size Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Error message displayed; LEDs will not turn on if incorrect Sensor attached.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the approved Sensors to be used with the medical device; DFU & Labeling define the procedure for attachment of the Sensor to the patient; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.6.3 Software performance issue in Medical Device allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	POST & periodic system checks; Software algorithm output verified against development SW (used to obtain clinical data) output for all Sensor sizes based on body locations.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines interval for service or maintenance; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.6.4 Display of valid StO2 values from a non-human tissue site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor off warning/alarm messages and/or StO2 invalidation when raw input levels too low, measurement values not in physiological range, or spectral characteristics not representative of tissue.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.5.7 Incompatibility with consumables/accessories/other Medical Devices				
Hazardous Situation	4.5.7.1 Medical Device used in an inappropriate manner with incompatible consumables/accessories allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Software recognition application for detection of connection to an approved medical device	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates approved for use consumables / accessories / other medical device, DFU indicates that if measurements are in doubt, alternate means to assess patient's condition should be used, Medical Device shipped with proper accessories	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.5.8 Sharp edges or points				
Hazardous Situation	4.5.8.1 Medical Device designed with shape edges and/or pinch points (external & internal) resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device exterior designed to have no sharp edges, internal sharp edges are rolled or protected with guard	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates there are no user serviceable parts inside the device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.8.2 Medical Device is used in a manner allowing the housing to lose mechanical integrity and becomes broken causing shape edges and pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device or patient cable/Sensor are designed to have no sharp edges	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance VaR 120018, 120019	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU defines inspection of medical device and cable/Sensor prior to use	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.5.9 Lack of indication of output				
Hazardous Situation	4.5.9.1 Continuous LED output to patient Sensor site causes increase of temperature at Sensor site resulting in tissue injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensors LEDs produce little or no heat, Power to LED output is limited	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper application of Sensor & to check Sensor site every 8 hours, DFU indicates LEDs on preamp are used as channel ID not that output LEDs are enabled	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.5.10 Inadvertent / accidental change to a control				
Hazardous Situation	4.5.10.1 Alarm Volume altered to lowest setting, allowing user to miss the Alarm tones resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Alarm Volume cannot be turned off, Lowest Alarm volume setting still audible in normal use environment, Alarm message and alarm icons visible on screen, Always visible Alarm LED	Designed to meet IEC 60601-1-8 VaR 120018, 120019	IEC 60601-1-8 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU includes statement that adjustment of alarm volume to a low level during patient monitoring may result in a hazard, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.5.10.2 Display brightness altered to lowest setting, allowing user to not see Alarm message resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Always visible Alarm LED, Alarm annunciation always includes audio tones regardless of display brightness, Brightness cannot be turned off, Lowest brightness setting still allows viewing of screen in normal use environment	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines proper operating instructions for medical device, DFU indicates to read before operating device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Category	**4.6 Inappropriate, Inadequate or over-complicated user interface**				
Hazard	**4.6.1 Mistakes & judgment errors or lapses & cognitive recall errors**				
Hazardous Situation	4.6.1.1 Medical Device presents information that are mistaken/ misinterpreted for actual values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Parameter name & units displayed adjacent to Numeric value; TPI displayed on the main screen for each channel & value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates Only skilled/trained personnel should operate the medical device; If measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.6.1.2 Arrangement of front panel controls allows user to incorrectly configure Medical Device for current type patient leading to incorrect readings and inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	User interface uses touchscreen with icons, Menu interface driven by touchscreen allow for navigation & selection; Current selections on screen are highlighted to indicate location, Feature state indicated by checkbox, numeric value or outline	VaR 120018, 120019 Usability V&V Plan 21-07-0308	Approved VaR Usability Results	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes display icons	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.6.2 Violations of abbreviation of instructions, procedures, etc.**				
Hazardous Situation	4.6.2.1 Abbreviations used with the Medical Device allow for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Parameter name & units displayed adjacent to Numeric value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used; Any icons or abbreviations used are consistence with medical industry standards; Translations performed by a company fluent in the target language & is familiar with Medical terminology.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.6.2.2 Abbreviations used with Medical Device DFU allow for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Translations performed by a company fluent in the target language & is familiar with Medical terminology.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used; Any icons or abbreviations used are consistence with medical industry standards.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.6.3 Complex, confusing, ambiguous or unclear device state**				
Hazardous Situation	4.6.3.1 Medical Device displays ambiguous or unclear states that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Invalid information shall be presented as dashes & messages; Limit violation & Equipment alarm messages displayed; TPI displayed on main screen for each channel & value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.6.3.2 Wrong size Sensor used on an inappropriate type/size patient allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor on body location prominently indicated on display, Sensor body location saved; TPI displayed on the main screen for each channel & value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the pre-use checks prior to patient usage; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.6.4 Ambiguous or unclear presentation of setting, measurement or other information state				
Hazardous Situation	4.6.4.1 Medical Device displays ambiguous or unclear settings that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Invalid information shall be presented as dashes & messages; Limit violation & Equipment alarm messages displayed; TPI displayed on main screen for each channel & values described in DFU; USB saved data output indicate Sensor locations & patient parameters.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.6.5 Insufficient Visibility				
Hazardous Situation	4.6.5.1 Erroneous or lack of visual information (e.g., limited viewing angle of display) on Medical Device that allows for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Unit provides brightness adjustments for improved visibility in varying light conditions; Anti-glare coating on display lens; Wide-viewing angle LCD selected; POST & periodic Power Supply checks; Highly visible numerics & traces due to high contrast of colors.	OEM Display design documentation, VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.6.6 Insufficient Audibility				
Hazardous Situation	4.6.6.1 Lack of audible feedback on Medical Device that allows for missing Alarm conditions causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Audible output may be allowed to be turned down, and not turned off, POST Audio test; Speaker position in front of device; Visual indicators remain even if audio is muted/silenced.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used; DFU indicates to verify operation of tones via Limit testing.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Category	**4.7 Hazards arising from functional failure, maintenance & aging & contributing factors**				
Hazard	**4.7.1 Erroneous data transfer**				
Hazardous Situation	4.7.1.1 Internal data transfer is erroneous allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	POST & periodic RS232 checks; Communications between NSAM & Main ctrl board uses checksum'ed information; Invalid received data not use/displayed; Lack of continuous missing data will cause system alarm; Mfg PS 03-58-3000 Process Sheet for Gemini Monitor.	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.1.2 Calculated FS Data is collected erroneous due to a software performance issue allowing FS Data readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Software calculations for FS Data Collection are based on simple algorithms; FS Data transfer to USB Patient data file or snapshot/print feature.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.1.3 Medical Device readings are transmitted erroneously due to a software performance issue or faulty connection allowing remote readings to be incorrect causing inaccurate diagnoses resulting in wrong course of patient treatment leading to ischemic or hypoxic injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	POST & periodic RS232 checks; Serial output protocol based on documented format;	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor.	CCS 03-58-3000	Approved PS	
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.7.2 lack/delay of, or inadequate specifications for maintenance, including inadequate specification of post maintenance functional checks.				
Hazardous Situation	4.7.2.1 Medical Device readings are displayed erroneously due to lack/delay of specifications of maintenance checks allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	No NSAM user calibration required; Sensor Calibration performed at factory; POST & periodic hardware checks (Power Supply, Memory, USB, VGA & RS232).	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the interval for pre maintenance functional checks; DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used; DFU indicates only authorized personnel should service medical device.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.7.3 Loss of electrical/mechanical integrity				
Hazardous Situation	4.7.3.1 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor can cause electrical burns or exposure to high electrical currents resulting in injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply, Fused power entry module w/fuses accessible w/o line cord, Chassis leakage current < 100 µA, patient leakage current < 10 µA, No exposed or access to AC components, rigid metal chassis; Preamp & Sensor contains only low voltage.	Designed to meet IEC 60601-1	IEC 60601-1 Compliance	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3009 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device; Preamp & Sensor prior to use; DFU indicates not to use damaged medical device or accessories, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.7.3.2 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor causing shape edges & pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Designed for standard hospital environments; Medical device, Preamp & Sensor are designed to have no sharp edges.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.7.3.3 Improperly assembled Monitor, Preamp or Sensor can cause electrical components (caps, diodes rectifiers, etc.) to be expelled resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply; Sensor, Preamp & NSAM modules use <15 VDC; No exposed components; Use of non-conductive plastic material covering; Monitor has no exposed components; Use of internal metal cage & outer plastic cover; Sensor uses soft plastic cover capable of containing expelled components.	Designed to meet IEC 60601-1 VaR 120018, 120019 100% visual inspection & testing of Sensors, Burning procedure for monitor & preamps	IEC 60601-1 Compliance Approved VaR Sensor visual reports	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.7.4 Re-use and/or improper re-use**				
Hazardous Situation	4.7.4.1 Re-use of disposable, single-use Sensor (e.g., by user reprocessing, or non-removal of release liner on adhesive type Sensors) allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Standard Hospital practice for proper use of single use medical devices; Software recognition software for detection of connection to an approved medical device.	Sampling of Hospital Practices using Tissue Oximeters VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU & labeling defines the use of disposable Sensor; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.7.5 Deterioration in function as a result of repeated use**				
Hazardous Situation	4.7.5.1 Medical Device controls become inoperable due to age/use & not allowing user to enter proper patient data or forced to use existing patient case allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Touchscreen has >1 million actuations in same location; POST & periodic power supply checks; User may need to start acquisition before values displayed; TPI displayed on the main screen for each channel & value.	OEM Documentation VaR 120018, 120019	Approved PN & BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines inspection of medical device prior to use.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	1 Negligible		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.7.5.2 Medical Device LCD become partially inoperable due to age/use & not allowing user to fully view patient data & causes inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	MTBF for LCD Backlight > (b)(4) [redacted] brightness; POST & periodic power supply checks.	OEM Documentation VaR 120018, 120019	Approved PN & BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines inspection of medical device prior to use; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.5.3 Medical Device calibration data incorrect that allows device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor Flash R/W check; Redundant checksum storage of critical calibration data.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor	CCS 03-58-0500	Approved PS	
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.5.4 Patient connectors become inoperable due to age/use & mechanical insertion/extraction allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp to Sensor connectors have a minimum (b)(4) [redacted]; Invalid computed information shall either present as dashes or a warning message.	OEM Documentation VaR 120018, 120019	Approved PN & BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hazardous Situation	4.7.5.5 Medical Device or Accessories warning/safety labels becomes unreadable due to cleaning over long period of time that allows for improper use of device & causes delay of treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Labels & printing specified to withstand multiple cleanings; Touchscreen & bezel assembly is designed to be limit fluid ingress; Adhesives & materials are UL approved.	OEM Documentation VaR 120018, 120019	Approved PN & BOM	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU contains explanation of markings on device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.5.6 Patient connectors become inoperable due to age/use and mechanical insertion/extraction allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp-Sensor connectors have a minimum (b (b)(4) [redacted] a (b)(4) [redacted] Invalid computed information shall either presented as dashes with warning message	OEM Documentation VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.5.7 Fans become inoperable due to age/use leading to an internal temp above stated environmental limits allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Fan has a (b)(4) [redacted] If fan stops and the internal device temp reaches a maximum threshold device will perform auto-shut off	OEM Documentation VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Category	**4.8 DFU provided electronically**				
Hazard	**4.8.1 Instructions for Use regarding safety not available to User**				
Hazardous Situation	4.8.1.1 User does not have access to view provided electronic copy of DFU safety instructions, that allows for improper use of device & causes delay of treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Required labeling: Fuse AC ratings, IPX & RX statement found on rear Label; Ambient light detection; SW confirmation of proper sensor w/ valid body location; Sensor generate small amount of heat.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	Warnings are provided to the user as a paper copy User Manual and Large Sensor DFU	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Category	**4.9 Replacement Parts**				
Hazard	**4.9.1 Lack of, or inadequate specifications for replacement parts**				
Hazardous Situation	4.9.1.1 Medical Device becomes inoperative due to lack of specifications of replacement parts (Lower rated fuse) allowing for delay of treatment of patient. Note: Higher rated fuse may cause delay to become inoperable with second fault (short).			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Fuse & AC ratings presented on rear Label; Warrantee void label across part seem deters user from opening device; Only Fuses are allowed to be replace by User (Biomed), no other serviceable parts.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates that there are no user serviceable parts.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Category	**4.10 Fluid ingress**				
Hazard	**4.10.1 Electricity**				
Hazardous Situation	4.10.1.1 Medical Device allows fluid ingress that allows shorted AC electrical connection in Medical Device causing an electrical potential on the monitor case resulting in shock or affecting heart rhythm.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supplies; No direct opening near AC components; Baffled framework on bottom of chassis allows for fluid egress.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU directs user to keep all fluids away from device and to thoroughly dry device in event device gets wet (min 1 hr), DFU indicates proper cleaning procedure when using cleaning solutions, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hazard	4.10.2 Battery				
Hazardous Situation	4.10.2.1 Medical Device not used (battery not charged or discharged) for extended period of time and battery leaks fluids out of Medical Device resulting in possible acid contact injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Battery is re-chargeable gel type (no liquids) & can remain idle for extended periods w/o leaking, battery has self-regulating pressure relief valves-permits venting of gases only; Bottom of chassis has vent/weep holes	Battery Mfg Specifications VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazard	4.10.3 Cleaning				
Hazardous Situation	4.10.3.1 Medical Device cleaned or disinfected with solutions that causes the markings on the device to be unreadable resulting in the delay of treatment of patient.			Risk to:	User
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Labels made of UL approved material, Touchscreen made with scratch resistant material	Touchscreen & Label Specifications VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU describes proper cleaning & disinfecting procedures, DFU indicates not to use sharp objects when touching the screen	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Category	4.11 Alarms				
Hazard	4.11.1 Annunciation failures				
Hazardous Situation	4.11.1.1 Disconnected, faulty Sensor, preamp or device causes the Medical Device to be inoperable resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensing of Sensor & Preamp connect & disconnect, Periodic Sensors & Preamp fault testing, Periodic device hardware fault testing, Fault conditions indicated & annunciated, Always visible Alarm LED	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Full system test on Medical Device, Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety (DFU)	DFU lists Alarm Conditions with possible causes & mitigation	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.11.1.2 Lack of notification by Medical Device of the decrease in a patient's StO2 values resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Low Alarm limits available to alert user of decrease in StO2 value, Visual & audible annunciation of Low StO2 Alarm	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates proper operation of Alarm Limit setting, DFU lists Alarm Conditions with possible causes & mitigation	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.11.1.3 Lack of notification by Medical Device of the increase in a patient's StO2 values resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	High Alarm limits available to alert user of increase in StO2 value, Visual & audible annunciation of High StO2 Alarm	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates proper operation of Alarm Limit setting, DFU lists Alarm Conditions with possible causes & mitigation	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.11.1.4 Annunciation of flashing visual Alarm conditions on screen may cause spasms and/or convulsions in people prone to seizures (e.g., epilepsy).			Risk to:	Patient, User, Service,
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Visual Alarm Flashing conforms to IEC 60601-1-8 flash rates of alarm LEDs	VaR 120018, 120019	Approved VRs	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.11.2 Limits				
Hazardous Situation	4.11.2.1 StO2 High/Low Alarm Limit selection cannot be accurately tested against the actual Patient StO2 value allowing a possible undetected change in physiological condition to exist resulting in circulatory injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	StO2 computed value & StO2 High & Low Alarm Limits have resolution of 1% High Alarm: StO2 value > High StO2 Limit Low Alarm: StO2 value < Low StO2 Limit	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates proper operation of Alarm Limit setting, DFU lists Alarm Conditions with possible causes & mitigation	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Authors:	H. Triebel	Date:	15-Oct-13

APPROVALS:

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

10/25/2013	10/28/13	11/05/13
Marketing Product Mgr Date M. Aceves	**Operations** Date G. Brocksieper	**Project Leader VSM Eng** Date H. Triebel
10/15/13	10/23/13	11/5/13
Clinical - App Date B. Kopotic	**Quality Assurance Regulatory Affairs** Date R. Jeffrey	**Sensor Eng** Date K. Duffy
11/5/13	11/5/2013	see attached email for Approval 11/15/13
Service Date L. Hottin	**R&D** Date J. Gamelin	**Chief Medical Officer** Date R. Mecca

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Triebel, Harry

From: Mecca, Roger
Sent: Tuesday, October 15, 2013 12:12 PM
To: Triebel, Harry
Subject: Re: Update Gemini FORE-SIGHT ELITE Risk Management file docs

Ok by me

Roger S. Mecca MD
(b) (6) [redacted]

On Oct 15, 2013, at 5:35 AM, "Triebel, Harry" <Htriebel@CASMED.com> wrote:

> Roger & Bob,
>
> Attached are the latest Gemini/FORE-SIGHT ELITE Risk Management File documents, there were reviewed earlier this year and I thought I started their circulation (you both approved via email in April) but have not been released. Nothing has changes since the last emailing except to update the dates These will be needed for ELITE Project Phase 1.5 Design documentation. Please review and id acceptable print the 1st page, sign, scan and return OR simply respond to this email with your approval, I will start the process of the circulating these 3 docs internally for the remaining approvals. Thanks in advance.
>
> Harry
>
> <21-07-0304 R03.pdf>
> <21-07-0306 R03.pdf>
> <21-07-0307 R03.pdf>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Document Revision History

Rev	Date	Editor(s)	Reason for Change
00	17-May-12	HT	Original release
01	3-Nov-12	HT	Updated per ITS ISO 14971 Checklist review of FORE-SIGHT
		JG	Updated to add 4.1.1.8 Hazard Identification & Risk Analysis docs
		HT	Updated 4.1.1.1, 4.1.1.2, 4.7.3.1 & 4.1.2.8, Added 4.5.5.11, 4.5.5.12, 4.5.5.13 & 4.11.1.4
		HT	Updated 4.5.5.11 & 4.10.1.1 for fluid ingress
02	03-Dec-12	HT	Remove Age/Weight feature, update RMF documentation
			Remove sections: 4.5.1.2, 4.5.5.3, 4.5.6.4, 4.5.10.1 & 4.6.1.2
03	15-Oct-13	HT	Add 4.5.6.4 Display of valid StO2 values from a non-human tissue site.
			Add 4.3.5.5 User cuts/trims the sensor to allow it to fit on patient w/other sensors causing the integrity of the isolation layer to be compromised exposing the patient to excessive leakage current and/or damage to the system to during defibrillation.
			Change "Poorly assembled…" to "Improperly assembled…" for numerous Risks
			Update IFU in Haz ID Doc, Review/Update Risk Management Summary/Report for new IFU
			Remove reference to FORE-SIGHT ELITE Warning Guide 21-03-0332 & Quick Reference Guide 21-03-033
			Haz ID: Change "Electronic copy" of User Manual to "Paper copy"
			Haz ID: Remove "A hard copy version of the FORE-SIGHT ELITE Warnings Guide, 21-03-0332, …"

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1. INTRODUCTION

The document describes the Risk Analysis for the Gemini Project (Product name: FORE-SIGHT® ELITE Absolute Tissue Oximeter). The CAS Gemini Oximeter is a medical device comprised of a Color 10.4" display, user interface controls (touchscreen) and hardware to support the acquisition of a patient's tissue oxygen concentration. The term Gemini refers to the Eng Project Name, where the term FORE-SIGHT ELITE refers to the Product Name and may be used interchangeably.

1.1 SCOPE

This document summarizes the identified hazards and associated Risk as they apply to the Gemini Oximeter, Sensors and accessories.

This analysis defines the Risk Management concepts and their documentation due to the requirement to meet the 3rd Edition of the general safety standard (60601-1:2005) as it becomes mandatory beginning in 2012. The analysis forms one part of the Risk Management process, as defined in QSP1026.

1.2 PHASE DESIGN

Project Gemini shall be divided into 3 Phases: Phase 1-Adult, Phase 2-Pediatric and Phase 3-Neonatal. The Risk Management Summary/Report shall attempt to summarize all the Hazards and Risks associated with Phase 1 design. The Risk Management Summary/Report will be updated with more accurate as Phase 2 & 3 Hazard and Risk information becomes available.

1.3 SUMMARY

The Risk Management program consists of the Gemini Risk Management Plan (21-07-0303), the Gemini Hazard Identification document (21-07-0304), the Gemini Risk Analysis (21-07-0305) and this summary report. The Project Manager served as the project Risk Manager with team members comprised of those designated in the plan.

2. REFERENCE DOCUMENTS

Standards:

IEC 60601-1 2nd edition Medical Electronic Equipment, Part 1: General Requirements for Safety
IEC 60601-1:2005 3rd edition General Requirements for Safety
ISO 14971:2007 Medical devices: Application of risk management to medical devices
IEC 60601-1-8:2010 Medical electrical equipment - Part 1-8: General requirements test and guidance for alarm systems in medical electrical equipment
ANSI/AAMI/IEC 62304:2005 Medical Device Software – Software Life Cycle Processes
Council Directive 93/42/EEC Concerning Medical Devices

CAS Medical Systems, Inc:

QSM1001, Quality System Manual
QSP1026, Risk Management

21-07-0303, Gemini Risk Management Plan
21-07-0307, Gemini Risk Management Summary Report
21-07-0321, Gemini Residual Risk(s) Judges Acceptable and the Disclosure Process
21-03-0336, FORE-SIGHT ELITE Large Sensor Multilanguage DFU (Directions for Use)
21-22-3000, FORE-SIGHT ELITE Absolute Tissue Oximeter User Manual (English)

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3. REPORT

3.1 Initial Risk Evaluation & Accompanying Documents

The Directions For Use; FORE-SIGHT ELITE 21-22-3000 User Manual & 21-03-0336 Large Sensor Multilanguage DFU, shall be delivered in paper form.

The FORE-SIGHT User Manual was reviewed for consideration of information that needs to be provided as paper copy beyond the labeling on the device. All statements regarding the safe operation of the Oximeter shall be provided in a paper copy of the DFUs

Markings for all fuses and AC input range mitigate Risk 4.8.1.1 and no other marks on the device are deemed necessary.

3.2 Residual Risk Evaluation

Since the highest Residual Risk is estimated to be "Insignificant Risk", no further investigation to reduce any Risk is deemed necessary.

Refer to 21-07-0321 Gemini Residual Risk(s) Judged Acceptable and the Disclosure Process

3.3 Risk Benefit Analysis

For the reasons stated above in 3.2, No Risk Benefit Analysis in required

3.4 Risks Arising from Risk Control Measures

All existing, new or changed risks due to risk control measures, have been evaluated to not introduce any additional risks deemed significant.

Residual risks remaining, and judged acceptable (an insignificant risk) were evaluated for residual risk disclosure in the accompanying documents. All such disclosures have been made.

3.5 Evaluation of Overall Risk Acceptability and Conclusion

A review of the risks from all identified hazardous situations has been considered.

A review of the Summary of Risks outlined, in Section 4.0 of CAS 21-07-0306, Gemini Risk Analysis document indicates the highest Residual Risk Evaluation is found to be IR (Insignificant Risk).

CAS concludes that it has met is obligation to provide a safe device to its customers by reducing identified hazards to present no more than an Insignificant Risk. CAS has also evaluated the overall residual risks by the means identified in QSP1026 Section 5.8, concluding the acceptability of the product.

CAS has appropriate methods in place to obtain relevant production and post-production information applicable to, and by the means stated in the Scope section of this document

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT A

PRODUCT SPECIFICATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT B

INDICATIONS FOR USE – ODE FORMAT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number:

Device Name: FORE-SIGHT Elite™ Absolute Tissue Oximeter.

Indications for Use: The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT Oximeter is indicated for use on adults and transitional adolescents ≥ 40 kg.

Prescription Use ✔ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT C

PROPOSED LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT D

BIOCOMPATIBILITY REPORTS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT E

SOFTWARE EXHIBITS (6)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT F

SAFETY AND EMC REPORTS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT G

CLINICAL REPORT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT H

RISK ANALYSIS

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Regarding: K133879 – Administrative Review Errors

To Whom It May Concern:

This letter and the accompanying documents will address the (3) noted deficiencies during the administrative review of our submission brought to our attention on January 7, 2014. Note that per the instruction of the reviewer there is a newly added section to the eCopy document. This response letter and its referenced attachments are in VOL_010.

Reference	Criteria / Deficiency	FDA has requested	CASMED reply
Organizational Elements (question # 3)	All pages of the submission are numbered.	Resubmit with all pages numbered.	Some of the automatic numbering was obscured. As requested, and clarified by the reviewer (1/10/13) there are page numbers on all pages, including the newly added sections.
Section F. Shelf Life (question # 28)	Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	Please provide a summary of methods used to establish that device performance is not adversely affected by aging or include a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	It has been established that device performance is not adversely affected by aging and as such there is no overall effect on safety and effectiveness. A study was conducted verifying that conclusion. Storage conditions are a part of the study. Attached to this reply is the study See VeP & VeR 110023.
Section H. Software (question # 33)	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has	While your submission includes some information from the Software Guidance Document, it does not clearly identify the Software Requirements Specification, Software Design Specification, Revision Level history, and Unresolved Anomalies. Please	Part of our reply is to identify where the requirements are in documents already provided. There are (2) additional documents included here as well. The Software Requirements Specification are found in the following (2) documents: - Vol 005, PDF 002, Doc #21-07-0325 & - Vol 005, PDF 003, Doc # 21-07-0327. The Software Design Specifications are found in the following (2) documents:

CAS Medical Systems, Inc.
44 East Industrial Road, Branford CT 06405, USA
Tel: (203) 488 6056 • Toll Free: (800) 227 4414 • Fax: (203) 488 9438
www.casmed.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

	provided an alternative approach with a rationale.	amend your submission to include this information.	- Vol 005, PDF 004, Doc #21-07-0329 & - Vol 006, PDF 005, Doc #21-07-0231. The missing Revision Level History can be found in new document 21-07-0339 rev. 11 "Project Gemini – Software Revision History". The missing Unresolved Anomalies can be found in new document(s) "What's in This Release" 15-06-0284 version 1.1.1. and 15-06-0283 version 2.0.0.

We hope the information provided will satisfy the questions raised and this submission can move to the next phase.

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs.

CAS Medical Systems, Inc.
44 East Industrial Road, Branford CT 06405, USA
Tel: (203) 488 6056 • Toll Free: (800) 227 4414 • Fax: (203) 488 9438
www.casmed.com

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TRADITIONAL 510(K)

FORE-SIGHT ELITE™ ABSOLUTE TISSUE OXIMETER

December 16, 2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Table of Contents

Section	Description	Page No.
1.	Medical Device User Fee Cover Sheet (form 3601)	3.
2.	CDRH Premarket Review Cover Sheet (form 3514)	6.
3.	510(k) Cover Letter	12.
4.	Screening Checklist for Traditional Premarket Notification Submissions	15.
5.	Indications for Use Statement	17.
6.	510(k) Summary	18.
7.	Truthful and Accuracy	19.
8.	Class III Summary and Certification	20.
9.	Financial Certification and Disclosure Statement(s)	21.
10.	Declarations of Conformity and Summary Reports (form 3654)	27.
11.	Executive Summary	33.
12.	Device Description	34.
13.	Substantial Equivalence Discussion	37.
14.	Proposed Labeling	40.
15.	Sterilization and Shelf Life	41.
16.	Biocompatibility	42.
17.	Software	43.
18.	Electromagnetic Compatibility and Electrical Safety	44.
19.	Performance Testing – Bench	45.
20.	Performance Testing – Animal	46.
21.	Performance Testing – Clinical	47.
22.	Risk Analysis	48.
Att. A	Product Specification (21-07-0302)	49.
Att. B	Indications for Use (ODE Format)	87.
Att. C	Proposed Labeling	89.
Att. D	Biocompatibility Reports	162.
Att. E	Software Exhibit(s) – Requirements, Specifications and Verification	220.
Att. F	Safety and EMC reports	360.
Att. G	Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO2%) in Adult and Transitional Adolescent Subjects	680.
Att. H	Risk Management (Analysis and Summary Report	706.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Medical Device User Fee Cover Sheet

Attached is a signed copy of form 3601. It designates a payment of $2,585., because CAS Medical Systems, Inc. has qualified as a small business.

Payment Identification Number: (b)(4) [redacted]

Small Business Decision Number: (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

CAS MEDICAL SYSTEMS INC
44 EAST INDUSTRIAL RD
BRANFORD
CT 06405
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****3096

2. CONTACT NAME
Ron Jeffrey

2.1 E-MAIL ADDRESS
rjeffrey@casmed.com

2.2 TELEPHONE NUMBER (include Area code)
2034886056

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: (b)(4) [redacted]

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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the collection of information, send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted]

18-Oct-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

10/18/13

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2. CDRH Premarket Review Cover Sheet

The following forms (# 3514) make up the submission cover sheet.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
December 16, 2013	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: CAS Medical Systems, Inc.	Establishment Registration Number *(if known)*: (b)(4) [redacted]		
Division Name *(if applicable)*: NA	Phone Number *(including area code)*: 203-488-6056		
Street Address: 44 East Industrial Road	FAX Number *(including area code)*: 203-488-9438		
City: Branford	State / Province: Connecticut	ZIP/Postal Code: 06405	Country: USA
Contact Name: Ron Jeffrey			
Contact Title: Director, Regulatory Affairs	Contact E-mail Address: rjeffrey@casmed.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [x] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	MUD	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K102715	1	Model 7600 Regional Oximeter "Equanox"	1	Nonin Medical, Inc.
2	K123700	2	FORE-SIGHT Elite Absolute Tissue Oximeter	2	CAS Medical Systems, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Tissue Oximeter

	Trade or Proprietary or Model Name for This Device		Model Number
1	FORE-SIGHT Elite Absolute Tissue Oximeter	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K051257	2 K061960	3 K073036	4 K083892	5 K091452	6 K094030
7 K112820	8 K123700	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [x] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
MUD	870.2700	[ ] Class I [x] Class II
Classification Panel		[ ] Class III [ ] Unclassified
74 Cardiovascular		

Indications *(from labeling)*

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: CAS Medical Systems, Inc.		Establishment Registration Number: 2244861
Division Name *(if applicable)*		Phone Number *(including area code)*: 203-488-6056
Street Address: 44 East Industrial Road		FAX Number *(including area code)*: 203-488-9438
City: Branford	State / Province: Connecticut	ZIP Code: 06405 / Country: USA
Contact Name: Ron Jeffrey	Contact Title: Director, Regulatory Affairs	Contact E-mail Address: rjeffrey@casmed.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ES60601-1	AAMI	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance		01/01/2005
2	C22.2#60601-1	CSA	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance	Edition 3	01/02/2008
3	60601-1	IEC	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance	Edition 3	01/01/2005
4	60601-1-6	IEC	Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance	Edition 3	01/27/2008
5	62366	IEC	Medical Devices - Application of Usability Engineering to Medical Devices	Edition 1	10/01/2007
6	60601-1-8	IEC	Part 1-8 General Requirements for Basic Safety and Essential Performance - General Requirements, Tests and guidance for Alarm Systems in Medical Equipment and Medical Electrical Systems	Edition 2	10/25/2006
7	60601-1-2	IEC	Medical Electrical Equipment Part 1-2:General Requirements for Basic Safety and Essential Performance - collateral Standard: Electromagnetic Compatibility - Requirements for Tests	Edition 3	03/01/2007

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. 510(k) Cover Letter

December 16, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Re: Traditional 510(k) NOTIFICATION – FORE-SIGHT Elite™ Absolute Tissue Oximeter

Dear Sir/Madam:

Pursuant to 21 CFR 807.90, CAS Medical Systems, is submitting the required copies of the 510(k) notification for the FORE-SIGHT Elite Absolute Tissue Oximeter. The FORE-SIGHT non-invasive monitor is an optically based device that will continuously provide immediate measurement of absolute tissue blood oxygenation saturation and circulatory homodynamic changes. This is now an established device technology in the market and the documentation presented here represents our ninth premarket notification for this technology.

The purpose of this submission is to seek clearance for additional claims for the FORE-SIGHT Elite Absolute Tissue Oximeter. The current intended use and indications statement is:

K123700

The noninvasive FORE-SIGHT® Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with Large sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of adults and transitional adolescents ≥ 40 Kg.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CAS will demonstrate that there is substantial equivalence regarding intended use between this proposed device and the predicates 1) Nonin Model 7600 (K102715), with a claim of blood underneath the sensor on adult and pediatric patients > 40kg., and 2) CASMED's FORE-SIGHT Elite Absolute Tissue Oximeter (K123700) predicate, indicated as stated above.

The proposed intended use and indications statement is as follows:

> *The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:*
>
> - *When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.*

The table below is supplied as suggested in the FDA Guidance Document, "Format for Traditional and Abbreviated 510(k)s," August 12, 2005.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

As part of the enclosed traditional 510(k) notification, Section 2 of this document contains a copy of a completed CDRH Premarket Review Submission Cover Sheet, while Section 4 contains the Premarket Notification 510(k) "Screening Checklist" with reference to the appropriate sections of this document that contain the required information. Additionally, the

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

510(k) Summary of Safety and Effectiveness Information can be found in Section 6 and Section 7 contains the signed truthful and accuracy certification statement. A full description of all contents for this submission can be found in the Table of Contents.

It is the understanding of CAS Medical Systems that written notification will be received from FDA if this device is subject to § 522 of the Federal Food, Drug and Cosmetic Act, i.e. Postmarket Surveillance.

The documents are prepared and submitted in accordance with the requirements of the eCopy Program for Medical Device Submissions (October 10, 2013).

The eCopy is an exact duplicate of the paper copy.

CAS Medical Systems has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, CAS Medical Systems requests that the FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b). CAS Medical Systems also requests that the FDA keep and maintain confidential the contents of this letter.

If you have any questions about this notification, the contact person is:

Name:	Ron Jeffrey
Address:	44 East Industrial Rd. Branford, CT 06405
Telephone number:	203-488-6056
Fax number:	203-488-9438
Email:	rjeffrey@casmed.com

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs

Enclosures

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

4. Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions based on Guidance for Industry and FDA Staff

Title	Section	Present	N/A
MDUFMA Cover Sheet	1	√	
CDRH Premarket Review Submission Cover Sheet	2	√	
510(k) Cover Letter	3	√	
Screening Checklist for Traditional 510(k)	4	√	
Indications for Use Statement	5	√	
510(k) Summary or 510(k) Statement	6	√	
Truthful and Accuracy Statement	7	√	
Class III Summary and Certification	8	√	
Financial Certification or Disclosure Statement Form 3454 Form 3455	9	√	√
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)			√
Executive Summary	11	√	
Device Description	12	√	
Substantial Equivalence Discussion	13	√	
Proposed Labeling	14	√	
Sterilization/Shelf Life	15		√
Biocompatibility	16	√	
Software	17	√	
Electromagnetic	18	√	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Title	Section	Present	N/A
Compatibility/Electrical Safety			
Performance Testing – Bench	19		√
Performance Testing – Animal	20		√
Performance Testing – Clinical	21	√	
FORM FDA 3654, Standards Data Report for 510(k)s	10	√	
Kit Certification			√

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

5. Indications for Use Statement

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.

See Attachment E for this statement in the ODE format.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

6. 510(k) Summary

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	CAS Medical Systems, Inc.
Address:	44 East Industrial Rd. Branford CT. 06405 USA
Contact:	Ron Jeffrey – Director, Regulatory Affairs Phone - (203) 488-6056 Fax – (203) 488-9438 Email – rjeffrey@casmed.com
Prepared:	December 16, 2013
Trade Name:	FORE-SIGHT Elite™ Absolute Tissue Oximeter
Common Name:	FORE-SIGHT Oximeter
Classification Name:	Oximeter, Tissue Saturation (870.2700) (MUD)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EQUIVALENCE (Predicate Device)

The FORE-SIGHT Elite™ Absolute Tissue Oximeter is equivalent to the following devices:

- Nonin Model 7600 Regional Oximeter Equanox (K102715)
- FORE-SIGHT Absolute Tissue Oximeter Monitor (K112820)

DESCRIPTION

The FORE-SIGHT Elite Absolute Tissue Oximeter measures hemoglobin under the Sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation saturation in the tissue (StO2).

The Oximeter consists of a monitor unit, preamplifier assembly, and sensor. The sensor uses multiple wavelengths in the range of 660 to 900 nm to precisely measure light absorption in tissue. Sensors are sized to provide targeted penetration depths appropriate for the tissue and patient populations of interest. The monitor unit controls the measurement sequence, generating the sensor LED currents and processing the detected light signals after amplification by the dual-channel preamplifier assembly. The FORE-SIGHT algorithm determines the StO2 values for the tissue under the sensor from the light absorption values and measured patient characteristics. The monitor unit provides simultaneous measurements on up to four sensors with both numeric and real-time graphical display formats.

The monitor unit is a mains-powered device with a field-replaceable battery backup module. A touchscreen user interface allows configuration of the Oximeter including audible, on-screen, and dedicated visual alarm indicators. The monitor display can be replicated for simultaneous remote viewing through an auxiliary VGA video output. Measurement data can be exported through various interfaces such as USB, RS-232 serial or wireless communications.

FORE-SIGHT Oximeter Monitor Intended Use

The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated as follows:

When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.

FORE-SIGHT Monitor Technology Compared to Predicate Devices

The FORE-SIGHT Elite Absolute Tissue Oximeter compares substantially to the cited predicate devices in that they use fundamentally the same optical operating principle, called multi-distance diffuse reflectance spectroscopy. All cited monitors use light to examine a cross-section tissue microvasculature (a mixed bed of arterioles, capillaries and venules). The FORE-SIGHT Elite Monitor and predicate devices analyze the light that is returned after having passed through tissues. The spectroscopic analysis determines concentrations of hemoglobin in its oxygenated and deoxygenated states. All cited monitors calculate oxygen saturation which reflects the percentage of oxygenated hemoglobin in the sampled tissue.

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The FORE-SIGHT Elite Absolute Tissue Oximeter compares substantially to the predicates. All have 4-channel capability, an LED light source, similar user interface features and the benefits of portability.

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The FORE-SIGHT Elite Absolute tissue Oximeter has successfully undergone extensive performance, safety, electromagnetic, clinical, software and environmental testing to ensure it has been found to be substantially equivalent to the predicate devices. In addition to the above laboratory tests, CAS has conducted a full program of individual hardware, software, systems verification and validation studies of the FORE-SIGHT monitor and sensors.

Clinical Testing to Show Substantial Equivalence

The FORE-SIGHT Elite Absolute Tissue Oximeter has successfully undergone extensive clinical validation for the indicated use. The premarket notification cites a validation report: **Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO2%) in Adult and Transitional Adolescent Subjects.**

Conclusions Drawn from Clinical and Non-Clinical Testing

Clinical evaluation, safety testing and software validation demonstrate the FORE-SIGHT Elite Absolute Tissue Oximeter is substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7. Truthful and Accuracy

I certify that, in my capacity as Director of Regulatory Affairs of CAS Medical Systems Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Ron Jeffrey

(Name)

December 16, 2013

(Dated)

Not assigned at this time

(Premarket Notification [510(k)] Number)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8. Class III Summary and Certification

Not applicable. The FORE-SIGHT Elite Absolute Tissue Oximeter is a class II monitor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9. Financial Certification and Disclosure Statement(s)

The following pages contain form # 3454. Form # 3455 was not necessary.

Also enclosed here is form # 3674 a Certificate of Compliance to section 402(j) of the Public Health Service Act

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: December 31, 2015

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	
(b) (6) [redacted]	Duke University Medical Center

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Ron Jeffrey	Director, Regulatory Affairs
FIRM/ORGANIZATION CAS Medical Systems, Inc.	
SIGNATURE	DATE *(mm/dd/yyyy)* 12/05/2013

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
CAS Medical Systems, Inc.

2. Date of the Application/Submission Which This Certification Accompanies
11/01/2013

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
44 East Industrial Road

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City: Branford
State/Province/Region: Connecticut
Country: USA
ZIP or Postal Code: 06405

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*
(Tel): 203-488-6056
(Fax): 203-488-9438

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

FORE-SIGHT Elite Absolute Tissue Oximeter

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Ron Jeffrey	Director, Regulatory Affairs

12. Address

Address 1 *(Street address, P.O. box, company name c/o)* 44 East Industrial Road	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City: Branford	State/Province/Region: Connecticut
Country: USA	ZIP or Postal Code: 06405

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 203-488-6056

(Fax): 203-488-9438

14. Date of Certification

11/01/2013

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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10. Declarations of Conformity and Summary Reports

The following (5) pages contain form # 3654, one for each of the (5) national or international standards to which CASMED claims compliance. A nationally recognized test laboratory (NRTL) was used for all testing listed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ES60601-1 Medical Electrical Equipment, Part 1: General REquirements for Basic Safety and Essential Performance, 2005

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-71		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1 Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance, 2005

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1-2 Part 1-2: General Requirements for Basic Safety and Essential Performance - Electromagnetic Compatibility

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-53		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1-8 Basic Safety and Essential Performance - General Requirements, Test and Guidance for Alarm Systems

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-55		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC62366 Medical Devices - Application of Usability Engineering to Medical Devices, 2007

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-67		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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11. Executive Summary

This submission represents the ninth Pre-Market Notification for the FORE-SIGHT Device. CAS Medical began marketing tissue oximeters (MUD) for cerebral indications after our first adult cerebral market clearance K051257 was granted in December 2005.

Clearance for K061960 was granted in September 2006. This version introduced the trade name FORE-SIGHT and expanded indications to the cerebral monitoring of adults and children greater than 40 Kg as well as infants, using the large and small sensor sizes.

Our third submission cleared in February 2008 under K073036 was also for cerebral monitoring, this time adding a neonatal population of 2.5Kg and above for small sensor use. The indication remained for adults and children over 40Kg using the large sensor.

Clearance for K083892 was granted in March 2009. This version introduced the medium sensor, completing the full line of sensors, large, medium, and small. The indications for use permitted "cerebral" use on any individual but with a contraindication for use on low birth weight individuals <2.5Kg.

Our fifth submission cleared in August 2009 under K091452 was also for cerebral use with all three sensor sizes. The contraindication was removed and the small sensor became indicated for infants and neonates ≤ 8Kg.

Clearance for K094030 was granted in December 2009 expanding it use for skeletal muscle for the 5 to 50 Kg patient group using the medium sensors. The cerebral indications remained as they were from K091452.

Our seventh clearance (K112820), granted in January 2012, expanded the indications for abdominal use in neonates less than 4 Kg with the small sensor. With more validation data available, the indications for the medium sensor went from 5 to 50 Kg to 4 – 50 Kg.

The eighth clearance (K123700) introduced the FORE-SIGHT Elite Absolute tissue Oximeter to the FORE-SIGHT line. This monitor was cleared for a cerebral indication using its large sensor.

For each indication for use CAS Medical has provided clinical data to demonstrate that the FORE-SIGHT Tissue Oximeter provided accurate and reproducible monitoring measurements when compared to an appropriate reference measurement over a wide variety of patient groups.

The purpose of this Premarket Notification 510(k) submission is to obtain clearance for additional claims for the FORE-SIGHT Elite Absolute Tissue Oximeter. The current intended use and indications statement is for cerebral use whereas CASMED is seeking a broader use for non-cerebral tissue in the same patient population.

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12. Device Description

FORE-SIGHT Elite™ Absolute Tissue Oximeter - Purpose:

The FORE-SIGHT Elite Oximeter measures a single parameter of oxygenated hemoglobin under the Sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation in the tissue.

< Monitor

< Pre-Amp

< Large Sensors

Figure 1

The FORE-SIGHT Elite System:

The FORE-SIGHT Elite System (Figure 1) consists of three distinct components. None can be used independently of the others in this system.

The **Monitor** (01-06-3000/01-05-3005) contains the systems software, power supply, display, user interface, communication ports, and other electronics. The Monitor is responsible for all configuration, display, surveillance, and alarm management functions. The Monitor electronics also coordinate all measurement activities including light generation, processing of detected signals, and computation of the tissue oxygenation.

The **Dual Preamp Monitor Cable** (01-06-3100) is a reusable assembly consisting of electrical cabling, connectors, and a preamplifier circuit to pre-process the signals

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received from the sensors. Each preamp assembly connects to the monitor with a single connector, but provides the capability to monitor tissue oxygen saturation levels for two sensors. The monitor has connection ports for two preamps enabling simultaneous monitoring on up to 4 sensors.

The **Sensors** (01-07-2103) are the single use patient applied part. They connect to the Preamp Monitor Cable delivering modulated light of predetermined wavelengths into the tissue and converting the detected light into electrical signals for subsequent processing.

Figure 2 depicts a representative illustration of a Large Sensors components and full assembly.

(b)(4)

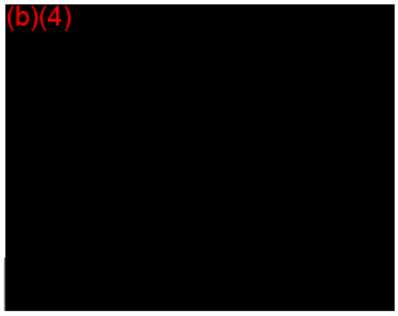

Figure 2

Performance Specifications:

The method of %StO2 measurement is derived from a modified Beer-Lambert equation using the Near Infrared Spectroscopy (NIRS) wavelengths of 690, 735, 810 & 870 nm. The information outputted is as absolute tissue oxygen saturation (%StO2) in a measurement range of 0 to 99%. The display resolution is 1% and the data acquisition rate is approximately10Hz. The measurement refresh rate is every 2 seconds. System diagnostics are performed during a power-on self-test.

Bias ± Precision has been determined for the range 45% to 95% as follows:

Large Sensors (Somatic): 0.24 ± 5.17% to 1 SD (this submission)
Large Sensors (Cerebral): -0.14 ± 3.05% to 1 SD (cleared under K123700)

The FORE-SIGHT Monitor generates alarms for (user-selectable) high or low limit violations. Equipment and system status messages are displayed independently for each sensor and augmented with audible enunciation when appropriate.

Power is provided by input voltages of 100-240 VAC, 50-60 Hz with a field-replaceable battery module.

The operating environment is rated for 10°C to 40°c at 30% - 75% RH non-condensing. Storage conditions are rated for -20 C to 60°C with 90% RH @ 50°C to 15% RH @ 0°C

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General Design Features:

- The monitor is transportable for use in various hospital locations;
- The monitor uses a LED light source;
- The monitor uses one size sensor to monitor adults and transitional adolescent's;
- The monitor's measurement accuracy is not affected by melanin, temperature, or perfusion;
- The monitor displays an StO_2 numeric value in the range of 01-99%;
- The monitor displays an indicator of optimal sensor placement called a Tissue Perfusion Index (TPI);
- The monitor contains an easy to read 10.4" color LCD VGA touch-screen display;
- The monitor provides a 24 hour review of historical data during or after a case;
- The monitor has modes for demonstration, servicing, programming and operating;
- The monitor provides patient data storage via USB memory sticks;
- The monitor provides a serial data output for compatibility with several third-party data review, charting, and acquisition systems;
- The monitor documentation and software, is available in multiple languages.

FORE-SIGHT Elite Models:

There are two models of the FORE-SIGHT Elite Absolute Tissue Oximeter. They are designated as part number(s) 01-06-3000 and 01-06-3005. They are identical. See figure 1.

FORE-SIGHT Accessories:

Part Number	Name	Function
01-06-3100 01-06-3005	FORE-SIGHT Elite Absolute Tissue Oximeter Dual Pre-Amp	Necessary part of the operating system. Included with monitor.
01-06-3014	FORE-SIGHT Elite Oximeter Battery Pack	For short term operation while not on mains power.
01-06-3036	User Manual on CD (English)	Included with each monitor
01-02-0395	Replacement Power Cord	Included with each monitor
01-07-2103	FORE-SIGHT Elite Large Sensor. Carton of 20.	Necessary part of the operating system. Patient contact part. Purchased separately.
01-06-0238	FS Roll Stand	A hospital grade roll stand, making the FS portable.

Full descriptive information may be found in the Project Gemini Product Specification 21-07-0302 Rev. 02. See Attachment A

Note: "Gemini" is the project name used during development. That name will appear on some documents that actually refer to FORE-SIGHT Elite Absolute Tissue Oximeter.

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13. Substantial Equivalence Discussion

For this submission there are two predicate devices. The Nonin 7600 Regional Oximeter System primarily, cleared under (K102715). Secondarily is our own device, the CASMED FORE-SIGHT Absolute Tissue Oximeter, cleared under (K123700).

PREDICATE DEVICE COMPARISON TABLE				
Device ► / Characteristic Comparison ▼	CASMED FORE-SIGHT Elite Absolute Tissue Oximeter **(Proposed)**	Nonin 7600 Regional Oximeter System (K102715)	CASMED FORE-SIGHT Elite Absolute Tissue Oximeter (K123700)	Differences and Similarities
Classifications	Class 2, 870.2700, MUD	Class 2, 870.2700, MUD	Class 2, 870.2700, MUD	Same
Parameters Monitored	Single parameter - Regional hemoglobin oxygen saturation of blood under the sensor.	Single parameter - Regional hemoglobin oxygen saturation of blood underneath the sensor.	Single parameter - Regional hemoglobin oxygen saturation of blood under the sensor.	All are single parameter monitoring devices.
Patient Population	Adults and transitional adolescents ≥ 40kg	Adult and pediatric >40 kg.	Adults and transitional adolescents ≥ 40kg	The patient populations are roughly equivalent.
Anatomical sites – all non-invasively	Blood under the sensor	Blood beneath the sensor	Brain via forehead.	The proposed device is seeking clearance for that already cleared in the predicate device(s).
Sensor type	Disposable large sensor with biocompatible patient contact surface.	Disposable, single size.	Disposable large sensor with biocompatible patient contact surface.	The FORE-SIGHT Sensors are identical.
Depth of penetration	Up to 25 mm	Up to 20 mm	Up to 25 mm	The FORE-SIGHT devices are identical.
Light source	Five wavelength near-infrared LED assembly comprising 690, 735, 770, 810, and 870 nm wavelengths. Maxim um total output energy of 50 mJ at 10 Hz repetition rate.	Four Wavelengths LED source 730,760,810, and 880 nm.	Five wavelength near-infrared LED assembly comprising 690, 735, 770, 810, and 870 nm wavelengths. Maximum total output energy of 50 mJ at 10 Hz repetition rate.	The Nonin device is similar and the FORE-SIGHT devices are identical.
Validation model	Accuracy has been demonstrated by direct validation to co-oximetry measurement of blood draws from invasive reference	It is not clear how accuracy has been demonstrated for somatic use.	Accuracy has been demonstrated by direct validation to co-oximetry measurement of blood draws from invasive reference	The validation methodology between the proposed device and the predicate CASMED device is

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PREDICATE DEVICE COMPARISON TABLE				
Device ► / Characteristic Comparison ▼	CASMED FORE-SIGHT Elite Absolute Tissue Oximeter **(Proposed)**	Nonin 7600 Regional Oximeter System (K102715)	CASMED FORE-SIGHT Elite Absolute Tissue Oximeter (K123700)	Differences and Similarities
	blood vessels in human subjects. Reference blood vessels are specific to the region monitored		blood vessels in human subjects. Reference blood vessels are specific to the region monitored	equivalent for the tissue examined.
Performance Accuracy	Cerebral – 45% - 95% ± 3.05% 1 standard deviation with large sensors Somatic – 45% - 95% ± 5.17% 1 standard deviation with large sensors	Cerebral—4.1 % (1 standard deviation) Arms with adult 8004CA sensors (unknown range) Accuracy unknown for Somatic use	Cerebral – 45% - 95% ± 3.05% 1 standard deviation with large sensors	Comparable clinical accuracy between the proposed device and the predicate device

Substantial Equivalence Discussion

CASMED has reviewed the criteria described in FDA's various Premarket Notification Guidance documents and below is a summary of the justification for substantial equivalence organized to be consistent with the decision process steps defined in FDA guidance, Description of 510(k) "Substantial Equivalence" Decision-Making Process. The predicate device(s) used to make this determination are the Nonin 7600 Regional Oximeter System (K102715) and the CASMED FORE-SIGHT Elite Absolute Tissue Oximeter, most recently cleared under K123700.

Intended Use

The FORE-SIGHT Elite Absolute Tissue Oximeter that is the subject of this 510(k) submission has the same intended use as the predicate devices, meaning it is intended for use as a tissue oximeter in any individual at risk for reduced flow or low flow ischemic states. The purpose of this submission is to seek clearance for a use in adjunct monitoring of regional hemoglobin oxygen saturation of blood underneath the sensor. CASMED is seeking clearance to indicate the monitor for use with large sensors on adults and transitional adolescents ≥ 40 Kg.

This indication that is proposed for the FORE-SIGHT Elite Absolute Tissue Oximeter does not affect the therapeutic/diagnostic effect and does not have an adverse impact on safety and effectiveness. To support the validity of this claim the necessary clinical

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evaluations have been conducted. These evaluations are based on accepted scientific methods designed to have a clinical and scientific rationale consistent with that used to support the predicate device indications. Namely, the use of reference measurements from one or more arterial and/or venous locations compared to measurements obtained by the system in the anatomical area of interest in individuals representing the same patient population (weight and maturity) for which the new indication is intended to be used. The results of the clinical evaluations conducted demonstrate that the accuracy and reproducibility of the system in measuring tissue oxygen levels for the new and modified indications are acceptable and consistent with the accuracy and reproducibility criteria used to support the current indications.

Technological Characteristics and Performance Testing

As it is evident in the table above, there are no changes to the design and technological characteristics of the FORE-SIGHT Elite Absolute Tissue Oximeter for this submission. Software comprises the only update to permit the updated indications. The software validation for these changes has been completed.

In conclusion, based upon the above considerations of intended use, indications for use, technological characteristics, and performance testing, the FORE-SIGHT Elite Absolute Tissue Oximeter meets the criteria for substantial equivalence.

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Indications for Use

510(k) Number:

Device Name: FORE-SIGHT Elite™ Absolute Tissue Oximeter.

Indications for Use:

The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT Oximeter is indicated for use on adults and transitional adolescents ≥ 40 kg.

Prescription Use ✔ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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CASMED®	Document Number 21-07-0302	Rev 02
Title: Project Gemini Product Specification		

Author: H. Triebel **Date:** 10-Oct-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

10/18/13	10·17·13	10/15/13
Product Mgr Marketing M. Aceves — Date	Operations G. Brocksieper — Date	Project Leader VSM Engineering H. Triebel — Date
10/15/13	10/16/13	10/22/13
Clinical - Applications B. Kopotic — Date	Quality Assurance Regulatory Affairs R. Jeffrey — Date	Sensor Engineering K. Duffy — Date
see attached email approval 10/23/13	10/23/13	10/18/2013
Clinical - Technical P. Benni — Date	Service L. Hottin — Date	R & D G. Gamelin — Date

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From: Benni, Paul
Sent: Wednesday, October 23, 2013 9:10 AM
To: Triebel, Harry
Subject: RE: Gemini Phase 1.5 new IFU & associated Project Documentation

These are ok
Paul

From: Triebel, Harry
Sent: Tuesday, October 22, 2013 4:51 PM
To: Benni, Paul
Subject: FW: Gemini Phase 1.5 new IFU & associated Project Documentation

Paul,

Sorry to push, but have you had a chance to review the updated Product Spec and Design Plan. If you approve of the changes, an email with that statement is all I need. Thanks.

Harry

From: Triebel, Harry
Sent: Tuesday, October 15, 2013 8:09 AM
To: Benni, Paul; Kopotic, Robert
Cc: Aceves, Mauro; Brocksieper, George; Jeffrey, Ron; Duffy, Karen; Hottin, Lenny; Gamelin, John
Subject: RE: Gemini Phase 1.5 new IFU & associated Project Documentation

Paul & Bob,

Attached are the latest Gemini/FORE-SIGHT ELITE Product Spec and Phase 1.5 Design Plan incorporating the Adult Tissue under Sensor IFU. Nothing has changes since the last emailing except to update the Revs to 02 and 00 respectively. If you could print the 1st page, sign, scan and return OR simply respond to this email with your approval, I will start the process of the circulating these 2 docs internally for the remaining approvals. Thanks in advance.

Harry

From: Triebel, Harry
Sent: Tuesday, October 08, 2013 10:33 AM
To: Aceves, Mauro; Brocksieper, George; Benni, Paul; Jeffrey, Ron; Duffy, Karen; Kopotic, Robert; Hottin, Lenny; Gamelin, John
Subject: Gemini Phase 1.5 new IFU & associated Project Documentation

To All,

To support the Gemini Phase 1.5 development, attached is the updated Product Spec -0359 as well as a new Design Plan -0302.
The Product Spec includes the following updates:

- Update IFU for new Indications for use: Adult under tissue
- Change VAC rating from 100-240 to 110 to 240;
- Change Max RH from 95 to 90%
- Section 4.9.1.1 & 4.9.1.2 change to CISPR 11 Class A
- Add new/missing design documents
- Add 21-07-0359 Gemini Phase 1.5 Design Plan (Adult Somatic IFU)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Revision History

Rev	Date	Editor(s)	Reason for Change
00	26-Mar-12	HMT	Initial Release
01	29-Oct-12	HMT	• Update to latest IFU, include Phase 1.0 reference; • Update list of Project Documents; • Add Low priority Alarms; • Change Eng, Mfg & Srv screen access by Password or USB Key; • Change to FORE-SIGHT ELITE™ to where appropriate; • Remove sections dealing with ability to turn High/Low Limits Off; • Add reference to the specific standards for Shock and Vibration; • Add new section "4.13.2.4 The system shall meet European Standard - Part 1-6 Collateral std: Usability"; • Remove Age & Weight inputs; • Update Battery icons; • Add Phase 1.5 & update Phase descriptions; • Update description of overlay Power On/Off button icon; • Update description of on-screen Alarm Silence/Reset button icon; • Update Section 4.5.1 Sensor for new Phases; • Remove Preamps in estimated cost of unit, Section 7.1;
02	10-Oct-13	HMT	• Update IFU for new Indications for use: Adult Tissue under Sensor; • Specify size of Sensors for at least Phase 1.0 and 1.5 • Change Max RH from 95 to 90%; • Section 4.9.1.1 & 4.9.1.2 change to CISPR 11 Class A; • Include new & missing Project Design documents; • Add new 21-07-0359 Gemini Phase 1.5 Design Plan (Adult Tissue under Sensor IFU); • Included Cerebral & Tissue under Sensor numeric field icons

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Table of Contents

1 INTRODUCTION 5
1.1 PURPOSE OF SPECIFICATION 5
1.2 SCOPE OF SPECIFICATION 5
1.3 PROJECT OBJECTIVES 5
1.4 SCOPE OF DEVELOPMENT 5
1.5 INDICATIONS FOR USE 6
1.6 CONTRAINDICATIONS 6
1.7 REGULATORY 6
2 REFERENCE DOCUMENTS 7
2.1 AGENCY REGULATIONS, STANDARDS AND GUIDANCE'S 7
3 SYSTEM DEFINITION 11
3.1 PURPOSE AND FUNCTION 11
3.2 VITAL SIGN MONITORING FUNCTIONS 11
3.3 SYSTEM FUNCTIONS 11
3.4 ENVIRONMENTS OF USE 12
3.5 TYPE OF EQUIPMENT 12
4 PRODUCT DEFINITION 12
4.1 HUMAN FACTORS 12
4.2 USER INTERFACE 15
4.3 LABELING 16
4.4 LANGUAGES 19
4.5 SYSTEM REQUIREMENTS 19
4.6 MESSAGES 22
4.7 MONITORING 23
4.8 ENVIRONMENTAL CONDITIONS 24
4.9 ELECTROMAGNETIC COMPATIBILITY 25
4.10 ELECTRICAL AND MECHANICAL SAFETY REQUIREMENTS 25
4.11 PHYSICAL 26
4.12 ACCESSORIES 26
4.13 REGULATORY APPROVAL AND STANDARDS REQUIREMENTS 27
4.14 CLASSIFICATIONS 28
4.15 FIELD SERVICE / TECHNICAL SUPPORT FUNCTIONS 29
4.16 WARRANTY 29
5 PRODUCT ARCHITECTURE 30
5.1 SYSTEM ARCHITECTURE 30
5.2 PRODUCT INTERFACES 30
5.3 PREDICATE DEVICE(S) 30
6 DESIGN AND CONSTRUCTION 31
6.1 WORKMANSHIP 31
6.2 INTERCHANGEABILITY 31
7 CONSTRAINTS AND LIMITATIONS 31
7.1 COST 31
7.2 COMPONENT AND CONDUCTOR SPACING 31
7.3 DIAGNOSTIC TECHNIQUES 31
7.4 INDUSTRIAL DESIGN 31
7.5 TECHNOLOGICAL 31

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

7.6 FIELD SERVICE 31
8 PARTS, MATERIALS AND PROCESSES 32
8.1 ELECTRONIC AND ELECTRICAL PARTS 32
8.2 MECHANICAL PARTS 32
8.3 LABELS 32
8.4 MATERIALS 32
8.5 PROCESSES 32
8.6 MANUFACTURING PROCESS 32
9 PRODUCT ASSURANCE 33
9.1 GENERAL 33
9.2 VERIFICATION AND VALIDATION 33
9.3 DOCUMENTATION 33
10 HANDLING AND SHIPPING 35
11 TECHNOLOGICAL RISKS 35
11.1 PRODUCT PERFORMANCE & DEVELOPMENT RISKS 35

SAMPLE

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

1 INTRODUCTION

1.1 PURPOSE OF SPECIFICATION

This specification exists for the purposes of:

a) Defining the scope of the CAS Next Generation Tissue Oximeter;
b) Defining the functions, performance, and interfaces of the product;
c) Determining the risks involved with the project;
d) Ensuring that all individuals involved in the project have the same understanding of the product's requirements; and
e) Provide a method of tracing the design input requirements to the design output for verification.

1.2 SCOPE OF SPECIFICATION

This document covers the entire design for Project Gemini. The various electrical, mechanical, human-factors, regulatory, and system requirements are detailed in this specification. This specification provides a means for tracing requirements through the verification and validation stages to insure that all stated requirements are met by the design implementation. The Project Gemini device[1] utilizes a 10.4" color VGA LCD Display integrated into a front bezel with a touchscreen overlay. Project Gemini shall be constructed using a metal internal enclosure with a plastic cover. Project Gemini shall incorporate a proprietary algorithm and a Sensor[2] that is placed on the body. The front panel shall allow connection to a USB memory device. The left side panel shall allow connection to the patient connections. The rear panel shall allow connection to other devices including, but not limited to: serial interface, Ethernet capability and video output. Project Gemini shall be capable of operating on AC or internal batteries. When on AC, the batteries shall be charging.

Project Gemini shall be divided into 4 Phases:

- Phase 1.0 – Adult cerebral (using Large Sensor)
- Phase 1.5 – Adult Tissue under Sensor (using Large Sensors)
- Phase 2.0 – Pediatric (using Medium Sensors)
- Phase 3.0 – Neonatal (using Small Sensors)

The Product Specifications shall capture all the design specifications associated with Phase 1 features. The Product Specifications will be updated when more Phase 1.5, 2 & 3 design specifications becomes available. If known and available, some aspects of the design related to Phase 1.5, 2 & 3 may be included in the Product Specification. Refer to latest Marketing Specifications Appendix I - PDR Phase Release Schedule and Appendix II - Software Release Schedule.

1.3 PROJECT OBJECTIVES

The objective of this project is to develop a replacement for the current FORE-SIGHT® (G1) Tissue Oximeter. The FORE-SIGHT ELITE™[3] platform shall: be lower cost, increase the number of channels (2 to 4), have a larger display, have a touchscreen interface, improved reliability of connector & mechanical design and incorporate the existing NIRS algorithm that reports absolute tissue blood oxygen saturation.

1.4 SCOPE OF DEVELOPMENT

The development of Project Gemini and Sensor will be accomplished by a dedicated CAS team. Time to market is critical and is the reason to limit initial feature and enhancements. While it is recognized that there will be additional opportunities to add features, improve performance and reduce cost, these will need to be implemented in future software releases.

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[1] The term **Device** refers to Gemini Oximeter (Monitor) and is the Engineering Design Project name.

[2] The term **Sensor** refers the patient applied part, whereas the term **Preamp Cable** refers to the electrical cables assembly connecting the **Sensor** to the **Device**.

[3] FORE-SIGHT ELITE™ is the Product name and differentiates it from the FORE-SIGHT G1 product and accessories. The terms GEMINI and FORE-SIGHT ELITE may be used interchangeably.

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1.5 INDICATIONS FOR USE

(Phase 1.0): The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescent's ≥40 Kg.

1.6 CONTRAINDICATIONS

- The Gemini Sensor is contraindicated for use on patients with physical site area too limited for proper Sensor placement.
- The Gemini Sensor is contraindicated for use on patients with allergic reactions to electrode adhesive.
- The Sensor site must be checked at least every eight hours; if the circulatory condition or skin integrity has deteriorated, the Sensor should be applied to a different site.
- Do not adhere Sensors to underdeveloped, immature, compromised, or healing skin.
- No other contraindications are known at this time.

1.7 REGULATORY

1.7.1 Product Trade Name:
FORE-SIGHT ELITE Absolute Tissue Oximeter

1.7.2 FDA Regulatory Classification:
2

1.7.3 FDA Regulation Name:
Oximeter, Tissue Saturation

1.7.4 FDA Regulation Number:
CFR 21 part 870.2700

1.7.5 FDA Product Code:
MUD

1.7.6 FDA Premarket Notification:
New 510k required

1.7.7 Canada Device Class:
Monitor: 3, Sensors: 2, Preamp Cable: 2

1.7.8 Canada Product License(s):
(3) New or amended licenses required

1.7.9 CE Certificate (CE01416):
Suitable for this product

1.7.10 CE Certificate (CE547432):
Update with new model numbers

1.7.11 EU Product Class/Rule/Annex:
2b/Rule 10/Annex IX

1.7.12 EU Technical File:
Update required

1.7.13 EU Declaration of Conformity:
Update required

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1.7.14 GMDN Code(s):

(b)(4) [redacted]

1.7.15 Product Manufacturing Life:

(b)(4) [redacted]

1.7.16 Shelf Life:

Monitor unlimited, Sensors unlimited, but 2 years recommended

1.7.17 Lifetime of the device:

Refer to Medical Device Directive, Annex 1 #7

1.7.18 Expected Service Life:

Refer to 60601-1:2005, section 4.4 and 21-07-0304 Project Gemini Hazard Identification document, Section 3.2 Expect Service Life

1.7.19 Record Retention:

Equivalent to the life of the device and greater than 5 years

1.7.20 Software System Safety Class:

Class B - Refer to ANSI/AAMI/IEC 62304:2006, section 4.3 and to 21-07-0333 Project Gemini Main Bootloader Software Life Cycle Worksheet, 21-07-0334 Project Gemini Main Application Software Life Cycle Worksheet, 21-07-0335 Project Gemini NSAM Bootloader Software Life Cycle Worksheet, 21-07-0336 Project Gemini NSAM Application Software Life Cycle Worksheet documents.

1.7.21 Software Level of Concern:

Moderate – Refer to CDRH Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005 and 21-07-0337 Gemini Software Level of Concern Document.

2 REFERENCE DOCUMENTS

The following documents, with revision levels in effect on the date of issuance of this specification, are applicable to, and shall be considered part of this specification to the extent specified herein. Subsidiary documents, which are referenced in the applicable documents are also applicable and shall be considered part of this specification to the extent required to complete the specification of the applicable requirements.

2.1 AGENCY REGULATIONS, STANDARDS AND GUIDANCE'S

2.1.1 Food and Drug Administration (CDRH)

- The New 510K Paradigm - Alternate Approaches to 510k, March 1998;
- Deciding When to Submit a 510k for a Change to an Existing Device, January 1997;
- General Principles of Software Validation - Final Guidance for Industry and FDA Staff, January 2002;
- Guidance on the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005;
- Design Control Guidance for Medical Device Manufacturers, March 1997;
- Medical Devices; Current Good Manufacturing Practice - Quality System Regulation, October 1996.
- Labeling Regulatory Requirements for Medical Devices, August 1998;

2.1.2 Industry Standards - United States & International

- ANSI/AAMI ES 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI/IEC 60529:2004 Degrees of Protection Provided by Enclosures (IP Code)
- UL 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1:2005 w/Amendments Medical Electrical Equipment - General Requirements for Safety (3rd Edition)

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- IEC 60601-1-2:2007 Medical Electrical Equipment - General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests.
- IEC 60601-1-6:2010-01 Medical electrical equipment - General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8:2006 Medical Electrical Equipment - General Requirements for Safety – Collateral Standard: General requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60068-2-27:2008 Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
- IEC 60068-2-68:2008 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance
- IEC 61000-4-2 Ed. 2.0 b:2008 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
- IEC 61000-4-3 Amd.2 Ed. 3.0 b:2010 Amendment 1 - Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- IEC 61000-4-4 Amd.1 Ed. 2.0 b:2010 Amendment 1 - Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
- IEC 61000-4-5 Ed. 2.0 b Cor.1:2009 Corrigendum 1 - Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
- IEC 61000-4-6 Ed. 3.0 b:2008 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
- IEC 61000-4-8 Ed. 2.0 b:2009 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
- IEC 61000-4-11 Ed. 2.0 b:2004 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
- IEC 61000-3-2 Ed. 3.2 b:2009 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
- IEC 61000-3-3 Ed. 2.0 b:2008 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection
- ISO 14971:2007 Medical Devices - Application of Risk Analysis Management to Medical Devices
- ISO 13485:2003 Quality Systems - Medical Devices
- ISO 10993-1:2009 Biological evaluation of medical devices
- ANSI/AAMI/IEC 62366:2007, Medical devices - Application of usability engineering to medical devices
- ANSI/AAMI/IEC 62304:2006 Medical Device Software Life Cycle Processes
- Directive 2002/96/EC of the European Parliament and of the Council WEEE directive
- CAN/CSA-C22.2 No. 50501.1:2008 Safety Standard for Medical Devices. Note: Obtained through US safety testing (ETL/UL)
- International Safe Transit Association (ISTA) Pre-shipment Test Procedures, Project 1-A
- BS EN 55011:2009+A1:2010 Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement

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2.1.3 CAS Medical Documents

Design Inputs:

- Project Gemini Product Profile
- Project Gemini Marketing Requirements

Procedures:

- QSP1005 Engineering Change Procedure
- QSP1010 Product Labeling
- QSP1015 Product Regulatory File
- QSP1017 Regulatory Requirements
- QSP1019 Clinical Investigation
- QSP1025 Product Planning and Risk Management
- QSP1026 Risk Management
- QSP4001 Product Design Procedure
- QSP4002 Software Life Cycle Procedure
- QSP4003 Process Validation
- QSP4004 System Performance Report (SPR), Product Request (PR) Procedure
- QSP4005 Printed Circuit Board (PCB) Fabrication and Assembly Procedure
- QSP4006 Compliance Requirements for the EU Directive on the Restriction of the Use of Certain Hazardous Substances (RoHS) in Electrical and Electronic Equipment
- QSP4007 Design Verification and Validation
- QSP4008 Product Specifications Procedure
- QSP4009 Product Usability Process Procedure
- QSP4010 Design For Manufacturing & Assembly Guideline Procedure

Design Documentation:

- 21-07-0300 Gemini Project Schedule
- 21-07-0301 Gemini Design Plan
- 21-07-0302 Gemini Product Specification
- 21-07-0303 Gemini Risk Management Plan
- 21-07-0304 Gemini Hazard Identification
- 21-07-0305 Gemini Monitor & Preamp dFMEA Analysis
- 21-07-0306 Gemini Risk Analysis
- 21-07-0307 Gemini Risk Management Summary
- 21-07-0308 Gemini Usability Specifications and Requirements
- 21-07-0309 Gemini System Controller Board Programmer Reference
- 21-07-0310 Gemini Mechanical Design Overview
- 21-07-0311 Gemini Prototype Plan
- 21-07-0312 Gemini GUI Specifications
- 21-07-0313 Gemini NIRS Signal Acquisition Module (NSAM) Reference Guide
- 21-07-0314 Gemini Large Sensor Specifications
- 21-07-0315 Gemini Medium Sensor Specifications
- 21-07-0316 Gemini Small Sensor Specifications
- 21-07-0317 Gemini Download & Eng/Mfg/Srv GUI Specifications
- 21-07-0318 Gemini 1-Wire Memory Device Specifications: Boards
- 21-07-0319 Gemini NSAM Serial Protocol Specifications
- 21-07-0321 Gemini Residual Risk(s) Judged Acceptable and the Disclosure Process

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- 21-07-0322 Gemini Philips VueLink Translation Document
- 21-07-0323 Gemini Software Icons Specifications
- 21-07-0324 Gemini Main Bootloader Software Requirement Specifications
- 21-07-0325 Gemini Main Application Software Requirement Specifications
- 21-07-0326 Gemini NSAM Bootloader Software Requirement Specifications
- 21-07-0327 Gemini NSAM Application Software Requirement Specifications
- 21-07-0328 Gemini Main Bootloader Software Architecture & Specification
- 21-07-0329 Gemini Main Application Software Architecture & Specification
- 21-07-0330 Gemini NSAM Bootloader Software Architecture & Specification
- 21-07-0331 Gemini NSAM Application Software Architecture & Specification
- 21-07-0332 Gemini 1-Wire Memory Device Specifications: Sensors
- 21-07-0333 Gemini Main Bootloader Software Life Cycle Worksheet
- 21-07-0334 Gemini Main Application Software Life Cycle Worksheet
- 21-07-0335 Gemini NSAM Bootloader Software Life Cycle Worksheet
- 21-07-0336 Gemini NSAM Application Software Life Cycle Worksheet
- 21-07-0337 Gemini Software Level of Concern Document
- 21-07-0338 Gemini Software V&V History
- 21-07-0339 Gemini Software Revision History
- 21-07-0340 Gemini Sensor dFMEA Analysis
- 21-07-0341 Gemini Obsolescence Plan for FORE-SIGHT G1
- 21-07-0342 Gemini USB Patient Data File Storage Format
- 21-07-0343 Gemini Displayed Message Priority Assignment Document
- 21-07-0344 Gemini Help Screen Specifications
- 21-07-0345 Gemini Scientific Data Serial Output Protocol
- 21-07-0346 Gemini 4-Ch Comma Separated Value Serial Output Format
- 21-07-0347 Gemini Sensor Monitoring and Memory Capabilities
- 21-07-0348 FS-Elite Sensor Test Fixture Requirements
- 21-07-0349 Gemini Sensor dFMEA Analysis
- 21-07-0352 FS-Elite Preamp Test Fixture Requirements
- 21-07-0353 FS-Elite Sensor Test Fixture Architecture and Operation
- 21-07-0354 Gemini Programming 1-Wire PCB PC-Application Requirements
- 21-07-0355 Gemini/FORE-SIGHT ELITE GUI Text Translations (Fre, Spa, Dut, Ger, Ita, Rus)
- 21-07-0356 Gemini/FORE-SIGHT ELITE Sensor Simulator Requirements
- 21-07-0357 FORE-SIGHT ELITE Pre-Release Clinical Field Studies
- 21-07-0358 Gemini Research Mode Guidelines
- 21-07-0359 Gemini Phase 1.5 Design Plan

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3 SYSTEM DEFINITION

Section	Customer Needs / Intended Use	Performance Requirements	PLAN
3.1	**PURPOSE AND FUNCTION**		
3.1.1	The System[5] will be applied for a specific set of patient populations Product Profile[6]	Refer to the Indications For Use (section 0, page 6)	Marketing planning and strategy
3.1.2	The System will be operated by a wide range of Users Product Profile	For use as prescribed by physicians, physician assistants, registered nurses, certified registered nurse anesthetists, clinical specialists, clinical investigators or other qualified medical personnel trained in the use of the equipment	Marketing planning and strategy
3.1.3	The System will be operated by a wide range of User profiles Product Profile	The User profile shall include: • Adult (e.g., > 21 years old OR required experience) • Ability to read text on screen & labels from < 2' distance • Able to read simple screen prompts in Oximeter's currently-selected language as well as User Manual • Able to perform simple interface tasks (touchscreen, connections) with left or right hand • Able to apply appropriate Sensor to selected monitoring site successfully • Professional clinician responsible for patient care • Trained (in person or via User manual) in the proper operation of the Gemini Oximeter • Average degree of aging-related short term memory impairment or age-related reduced hand/finger dexterity	Marketing planning and strategy
3.2	**VITAL SIGN MONITORING FUNCTIONS**		
3.2.1	The System shall report absolute tissue blood oxygen saturation values Mktg Req 2.A[7]	The product shall monitor and display up to 4 channels of a patient's local tissue blood oxygen saturation for the following patient types: • Phase 1.0 Adult cerebral using large Sensors • Phase 1.5 Adult Tissue under Sensor using Large Sensors • Phase 2.0 Pediatric using Medium Sensor • Phase 3.0 Neonatal using Small Sensors Refer to the most current Project Gemini FDA submission and approved Indications For Use (IFU)	21-07-0338 Gemini Software V&V History Gemini Project FDA submission
3.2.2	The System shall present notification of patient and equipment status Mktg Req 6.A, 6.D	Gives notification of patient and system status via visual indication and audible tones	21-07-0338 Gemini Software V&V History
3.3	**SYSTEM FUNCTIONS**		
3.3.1	The System shall have provide a graphical user interface (GUI) Mktg Req 7.all	The User Interface consists of: • Backlit Color LCD Display • Power and Equipment/Patient state LEDs • Touchscreen interface	21-07-0338 Gemini Software V&V History
3.3.2	The System shall display tissue blood oxygen saturation values as a numeric and trended waveform Mktg Req 4.A, 6.C, 7.B.j	The product shall monitor and display up to 4 channels of a patient's local tissue blood oxygen saturation	21-07-0338 Gemini Software V&V History
3.3.3	The System shall use single use Sensors	Sensors are intended to be applied to a single patient	21-07-0338 Gemini Software V&V

[4] Design Inputs are based upon the approved Product Profile and Marketing Requirements (refer to Section 2 REFERENCE DOCUMENTS).

[5] The System refers to the Oximeter, Preamp Cable(s) and Sensor(s), while the term Device refers to the Oximeter itself.

[6] Refer to Gemini Product Profile document for additional details for Customer Needs and Intended Uses

[7] Mktg Req X.Y.Z - Refer to Gemini Marketing Requirements Phase 1 (unless otherwise noted), Section X, Sub-Section Y, Paragraph Z

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	Mktg Req 17.C		History
3.4	**ENVIRONMENTS OF USE**		
3.4.1	The System shall be used in professional medical facilities Product Profile	Environments include, but are not limited to, operating room (OR), anesthesia, intensive care unit (ICU) , post anesthesia care unit (PACU) , EP and Cath labs	Marketing planning and strategy
3.5	**TYPE OF EQUIPMENT**		
3.5.1	The System shall be mobile as well as stationary Mktg Req 1.B, 1.C, 3.A, 3.B	Equipment is intended to be stationary (including wall or pool mount arm), affixed to a roll stand or carried by hand	21-07-0338 Gemini Software V&V History

4 PRODUCT DEFINITION

SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.1	**HUMAN FACTORS**		
4.1.1	**User Controls**		
4.1.1.1	The controls shall be ergonomically designed Mktg Req 7.A, 7.B.a-j, 7.C	The arrangement of the User Controls shall allow the user to use a single hand to operate the Device The User Controls shall be positioned so that they do to not interfere with any cables	21-07-0338 Gemini Software V&V History
4.1.1.2	There shall be a "On / Standby" power switch Mktg Req 7.C	The "On / Standby" switch shall have a Power button symbol (circle with line IEC 60417-5010) near it. The switch shall turn the Device on and off when connected to AC or while on battery and no AC When the Device is connected to AC power, the Device is fully operational in "On" mode, but only the battery charger is operational in "Standby" mode When the Device is NOT connected to AC power, the Device is fully operational in "On" mode, but is completely powered off in "Standby" mode	21-07-0338 Gemini Software V&V History
4.1.2	**Displays Indicators**		
4.1.2.1	The display shall be easily viewed from several angles Mktg Req 6.B, 6.E, 7.F	The LCD shall have a wide viewing angle > 45° all 4 angles The LCD display shall have anti-glare characteristic Numerics shall be readable from 12 feet away	21-07-0338 Gemini Software V&V History
4.1.2.2	There shall be a AC indicator located on the front panel Mktg Req 7.D	The AC indicator shall be illuminated whenever the Device is connected to AC (regardless of battery state)	21-07-0338 Gemini Software V&V History
4.1.2.3	The display shall present patient and equipment information Mktg Req 6.C, 6.D, 6.E, 7.B.a-j	The display shall use a 10.4" (diagonally measured) Color, VGA display (640 x 480 pixels) using 256 color palette The background color for normal operations shall be black	21-07-0338 Gemini Software V&V History
4.1.2.4	There shall be a brightness adjustment for the display Mktg Req 6.B	There shall be a minimum of 4 levels of user selectable brightness adjustments for the LCD	21-07-0338 Gemini Software V&V History
4.1.2.5	The display shall present the current battery state Mktg Req 7.E	There shall be on screen icon to indicate the state of the battery: • Not present • Charging • Discharging, possibly various states of discharge • Low Battery condition • Depleted Battery condition	21-07-0338 Gemini Software V&V History
4.1.2.6	There shall be an area to display the current time & date Mktg Req 6.A	The device shall incorporate the use of a battery-backed, non-volatile Real Time Clock (RTC), settable by the User The time shall be displayed in 24-hour format: 2-digit hours and 2 digit minutes (e.g., 11:34, leading zeros) The date shall be displayed as a 2-digit day, 3-letter abbreviated month and 2-digit year (e.g., 02-Jun-11, leading zeros)	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.1.2.7	There shall be an area to display the Patient ID Mktg Req 6.A	The device shall allow the user to enter a Patient ID via a QWERTY keyboard. The keyboard shall include A-Z, 0-9 & _ Patient ID shall be optional - not needed to save data Patient ID shall be used to help define Patient data file name	21-07-0338 Gemini Software V&V History
4.1.2.8	The Device shall be have an area to display numerics that are easily read at a distance of up to 15' Mktg Req 6.E, 7.B.a,e,i,j	The Device shall be able to display a maximum of four (4) numeric values: 1 numeric for each channel (①, ②, ③, ④) along the right side of the display Each numeric shall be 2-digits (leading space), 2 dashes "- -" if the value is invalid (no Sensor, Sensor off patient, etc.) The Numeric digits shall be 0.5" minimum in height (15' readable) The numeric for each channel shall have an associated color representing the location of the Sensor The color of the numerics (and traces) shall be the same color as the primary color of the Sensor location icons Each numeric shall have an associated Trace There shall be an area in each numeric to display a choice of Left/Right indicator (near body icon) Area in each numeric section to display a reference saturation value Numeric field shall include icons for the channel number Numeric field shall include the alarm limit values and icons for the TPI for channels with valid body locations Sensor location icons shall be displayed in the Numeric field: **Phase 1.0:** **Left** **Right** Cerebral/Brain **Phase 1.5** Tissue under Sensor Arm Flank Legs	21-07-0338 Gemini Software V&V History
4.1.2.9	The Device shall be have an area to display the signal strength for each channel Mktg Req 7.B.e	A Tissue Perfusion Index (TPI) consisting of 4 ascending height bars shall be visible near the channel Numeric TPI Bars shall be white (outlines/filled in) on black background Low/no bars indicates poor tissue perfusion, while higher bars indicates better tissue perfusion	21-07-0338 Gemini Software V&V History
4.1.2.10	There shall be an area to display the trace for each value Mktg Req 6.C	Traces shall have fixed scales with reference marks/values along the left side of the traces All traces shall have the same sweep speed (View) When one preamp is installed 2 overlapping traces and 2 individual numerics may be displayed When two preamps are installed 2 pairs of overlapping traces and 4 individual numerics may be displayed When a numeric is invalid, the trace shall be the same color as the background (blank)	21-07-0338 Gemini Software V&V History
4.1.2.11	There shall be an area to display each channel's Patient and Channel conditions Mktg Req 6.A	Patient and Channel conditions shall be displayed in a message area associated with each channel's numeric at all times (normal mode) Patient and Channel conditions shall have priority alarms status based on Risk Analysis Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN[4]
4.1.2.12	There shall be an area to display the System Status Mktg Req 6.A	The System status shall be displayed in a dedicated area, visible on screen at all times (normal mode) System status shall have priority alarms status based on Risk Analysis High Priority System conditions shall be displayed as white text on a red background Medium Priority System conditions shall be displayed black text on yellow background Low Priority System conditions shall be displayed yellow text on black background Informational System conditions shall be displayed white text on black background Mixed priority conditions (High, Medium, Low & information) shall only display the highest Priority System condition Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History
4.1.2.13	Icons should be used where possible Mktg Req 7.B.a,e	Icons should be used in place of text where possible to limit translations Icons should be of sufficient size and should be designed so that their interpretation is intuitive	21-07-0338 Gemini Software V&V History
4.1.3	**Audible Indicators**		
4.1.3.1	Audible tones shall be generated to indicate various conditions Mktg Req 7.B.f,g	The Device shall generate High Priority tones for High Priority conditions The Device shall generate Medium Priority tones for Medium Priority conditions The Device shall generate Low Priority tones for Low Priority conditions Mixed priority conditions (High, Medium & Low) shall only generate the High Priority tones Mixed priority conditions (Medium & Low) shall only generate the Medium Priority tones User selectable Volume Adjustments – User is not allowed to turn volume to OFF Audio Silence capabilities shall be implemented to allow for temporary suspension of Audio tone generations Audio tones shall meet IEC 60601-1-8 requirements Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History
4.1.4	**Device Patient Connector Receptacles**		
4.1.4.1	Device Patient connectors shall be located for ease of use Mktg Req 5.A	Device Patient connector(s) shall be on the left side of the Device (looking at front of Device) The Device Patient connectors will be identified with the associated Channel number (e.g., ①, ②, ③, ④) near the connections	21-07-0338 Gemini Software V&V History
4.1.4.2	Device Patient connections shall connect to the Preamp Cable Mktg Req 14	Device Patient connectors shall withstand a minimum of (b) Preamp Cable insertions	21-07-0338 Gemini Software V&V History
4.1.4.3	The Device Patient connection should be unique Mktg Req 14	Mechanical keying may be used to avoid accidental connection of other cables using the Device Patient connector	21-07-0338 Gemini Software V&V History
4.1.5	**External Interfaces**		
4.1.5.1	The Device may be powered by AC Mktg Req 9.F, 9.G, 9.H	The Device shall use a universal power supply to allow voltage input from 100 to 240 VAC, 50 or 60 Hz without any user selection The fuses are accessible without opening the housing, but are not accessible w/o first removing the AC power cord. (Per IEC 65)	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
		AC Power input shall be by means of EN60320 (IEC320) C14 connector on rear of Device, suitable for attachment of medical grade power cord equipped with EN60320 C13 receptacle and a plug suitable for the country of destination	
4.1.5.2	The Device shall provide two (2) RS-232 serial Interface connections Mktg Req 10.D	Two (2) dedicated bi-directional RS-232 connections shall be located on the rear panel of the Device The RS232 interfaces will be DTE connections using DB9 plugs. Each connector will provide 4-40 threaded standoffs for jackscrew retention	21-07-0338 Gemini Software V&V History
4.1.5.3	The Device shall provide basic serial protocols Mktg Req 8.C, 10.E, 10.Fa-d	The Device shall provide a Philips VueLink protocol selection on either RS-232 port (refer to 4.1.5.2) The Device shall provide a Comma Separated Valve (CSV) protocol selection on either RS-232 port (refer to 4.1.5.2) The Device shall provide a CAS ATE protocol selection on either RS-232 port (refer to 4.1.5.2) The Device shall provide support for printing STS and FS Data	21-07-0338 Gemini Software V&V History
4.1.5.4	The Device shall provide 1 Ethernet connection Mktg Req 10.A	The Device shall have the capability for a 10Base-T/100Base-T Ethernet connection The Ethernet connection shall be a RJ45 jack located on the rear panel	21-07-0338 Gemini Software V&V History
4.1.5.5	The Device shall provide connection to USB Memory devices Mktg Req 10.B	The Device shall provide a primary USB Host port ("A" connector) for use only with Flash Memory 'sticks' having no power or data connection other than the Host Port. The Primary USB connection shall be located on front of Device The Device shall provide a Secondary USB Host port ("A" connector) for use only with devices requiring having no power or data connection other than the Host Port. A Secondary USB connection shall be located on rear of Device	21-07-0338 Gemini Software V&V History
4.1.5.6	The Device shall provide a Video output Mktg Req 10.C	The Device shall provide an VGA standard video output port (DE15) DFU shall stipulate connection to Video output shall be to a Medical Grade display or video device	21-07-0338 Gemini Software V&V History
4.1.5.7	The Device shall provide an optional wireless feature Mktg Req, Beyond Phase 1	The Device may be configured with a factory-installed optional Bluetooth capability. The Device may be configured with a factory-installed optional WiFi (802.11 b/g/n) capability.	21-07-0338 Gemini Software V&V History
4.2	**USER INTERFACE**		
4.2.1	The user interface shall use a touchscreen Mktg Req 7.A	The touchscreen interface shall allow the user to touch images on the LCD and perform an action A minimum number of touches shall be used to navigate and alter any user selectable feature	21-07-0338 Gemini Software V&V History
4.2.2	The user interface shall allow the user to configure the Device Mktg Req 7.Bb-k, 8.B	The User Interface software shall use the following features (similar to Microsoft 'Windows"), including but not limited to • Patient – Patient Setup, Patient ID • Limits – High, low and differential limits • View – Horizontal time scale, TUT threshold and display • Events – Place and manage list of events • Data – Patient Data transfer to USB • Setup – Time/Date, brightness, etc.	21-07-0338 Gemini Software V&V History
4.2.3	There shall be a "Silence / Reset" touchscreen target area always available on the screen Mktg Req 7.B.g	The "Silence / Reset" target shall have an audio silence symbol (e.g., speaker with single/dual dashed or solid diagonal line on it) Touching the target shall disable or enable the temporary (2-Min) audio silence function	21-07-0338 Gemini Software V&V History
4.2.4	The Device shall have a Normal Mode of operations	The Device shall display 2 channels and waveforms, as well as associated channel information	21-07-0338 Gemini Software V&V

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Mktg Req 4.A, 6.E	The Device shall display 4 channels (when monitoring more than 2 channels) and waveforms, as well as associated channel information	History
4.2.5	The Device shall have an Engineering (Eng) Menu Mktg Req, Appendix II	Engineering personnel can access an Eng Menu by use of a specific password or USB Key The Eng Menu shall allow the Device to be examined for Eng related issues	21-07-0338 Gemini Software V&V History
4.2.6	The Device shall have a Manufacturing (Mfg) Menu Mktg Req, Appendix II	Engineering personnel can access an Mfg Menu by use of a specific password or USB Key The Mfg Menu shall allow the Device to be examined for manufacturing related issues	21-07-0338 Gemini Software V&V History
4.2.7	The Device shall have a Service (Srv) Menu Mktg Req, Appendix II	Engineering personnel can access an Srv Menu by use of a specific password or USB Key The Service Menu shall allow the Device to be examined for service related issues	21-07-0338 Gemini Software V&V History
4.2.8	The Device shall have a Demo Mode(s) Mktg Req, Appendix II	The text "Demo" shall be shown prominently on the display while the Device is in Demo Mode The Device shall enter the Demo Mode and remain in Demo Mode until one of the following occurs: • Power is cycled • Demo exited by de-selecting "Demo Mode" • Preamp connected w/non-Demo sensors connected	21-07-0338 Gemini Software V&V History
4.2.9	The display text in Normal Mode user shall be easily understood Mktg Req 7.F, 12.A Mktg Reg, Appendix I	Normal Modes of operation shall present text that is concise and appropriate for the intended audience Text shall be multi-language selectable with provisions for multiple Language to be stored in the device – The following languages shall be available (both for GUI and IFUs)	21-07-0338 Gemini Software V&V History
	Phase 1.0 & 1.5 Mandatory:	English, Spanish, French, Italian, German, Dutch, Russian (1.5)	
	Desired:	Polish, Finnish, Swedish, Norwegian, Danish, Portuguese, Turkish, Arabic	
	Phase 2.0 Mandatory:	Polish, Finnish, Swedish, Norwegian, Danish, Portuguese, Turkish, Arabic	
	Desired:	Japanese, Chinese, Korean	
	Phase 3.0 Mandatory:	Japanese, Chinese, Korean	
4.2.10	The display text seen by Service / Mfg / Eng Menu user shall be easily understood menus Mktg Req, Appendix II	Srv, Mfg & Eng Menus shall present text that is concise and appropriate for the intended audience Srv, Mfg & Eng Menu text shall be in English only	21-07-0338 Gemini Software V&V History
4.3	**LABELING**		
4.3.1	**Labeling Requirements for IEC 60601-1 Section six**		
4.3.1.1	There shall present any required markings on the outside of the Device and also in Device DFU[8] Regulatory Standards Requirement	Markings on the outside of the Equipment and also referenced in the Device DFU shall meet IEC 60601-1 Section Six a) Indication of Origin: **CAS Medical Systems, Inc.** **Branford, CT, USA 06405** b) Connection to the supply rated supply voltage(s) or range(s) **100-240 VAC** c) Supply frequency **50/60 Hz** d) Power input **1.5A RMS (max) @ 115 VAC**	21-07-0338 Gemini Software V&V History

[8] DFU – Refers to Directions For Use, e.g., could be single page or multi-page User Manual

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
		e) Symbols for Device classification from IEC 60601-1 Section Five Degree of Protection against Electrical Shock **Input - Type BF** BF defib symbol, IEC 60417 - 5334 f) Type and rating of fuses accessible **listed in Device DFU and next to fuses** g) Symbol of Equipotentiality, IEC 60417-5021	
4.3.1.2	There shall be markings for European Deviations Product Profile	Warnings and instructions for use should be printed in all languages prior to shipping to the corresponding country	Marketing planning and strategy
4.3.1.3	There shall be markings for Korean Deviations Product Profile	Accompanying documents shall be in Korean as well as DFUs and appliance marking related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417, prior to shipping units to Korean	Marketing planning and strategy
4.3.1.4	There shall be markings on the inside of the equipment and also referenced in the Device DFU Regulatory Standards Requirement	Markings on the inside of the Device and also referenced in the Device DFU shall meet IEC 60601-1 Section Six a) Presence of high voltage accessible parts IEC Symbol IEC 60417 - 5036 located on or around power supply (if required) b) Battery type (if required) c) Protective earth terminal (if required)	21-07-0338 Gemini Software V&V History
4.3.2	**Labeling Requirements for the Medical Device Directive (for CE marked devices)**		
4.3.2.1	The Device shall provide Labeling associated with Medical Device Directive (Reference Annex 1, Section 13.3) Regulatory Standards Requirement	(a) The name or trade name and address of the manufacturer and the name and address of the authorized representative of the manufacturer established within the EC Community • Manufacturer: **CAS Medical Systems, Inc.** **44 East Industrial Road** **Branford, Connecticut 06405** **USA** (b) The details strictly necessary for the user to identify the Device and the contents of the packaging (c) Where appropriate, an indication that the Device is for single use (ISO 7000-1051) (d) Any special storage and/or handling conditions: • Storage / Transport Temperature: -20°C to +60°C (-4°F to +140°F) • Storage / Transport Humidity: 15%RH to 90%RH (non-condensing) (e) Any special operating instructions (f) Any warnings and/or precautions (g) Year of manufacture (can be part of a SN) – Symbol for "DATE OF MANUFACTURING" to be put in Device DFU to explain SN format (h) The CE mark and control number (i) Detachable components shall be identified with "CAS" PN (j) The symbol for "attention" ISO 7000-0434 shall be placed wherever the User should see directions for use (k) The symbol "REF" shall be placed wherever a re-order number appears (l) The word "LOT" within a box shall be placed wherever a lot number is indicated (m) The symbol "SN" proceeding any serial number	21-07-0338 Gemini Software V&V History
4.3.3	**Labeling Requirements General**		
4.3.3.1	The Device shall use Special Labels when required	Devices intended for clinical investigation will be clearly labeled and will comply with all applicable standards and requirements	21-07-0338 Gemini Software V&V

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Regulatory Standards Requirement		History
4.3.3.2	Labels should be easy to read / understand, legible and durable Regulatory Standards Requirement	Labels shall be made with as large a font possible, using permanent ink, whenever possible; label ink shall not easily be removed by common cleaning	21-07-0338 Gemini Software V&V History
4.3.3.3	The Device shall have labels for the Patient Connectors Mktg Req 4.A	Label contains channel number dark text on light background Label is located on side panel of Device, near patient connectors	21-07-0338 Gemini Software V&V History
4.3.3.4	The Device shall have a label[9] for the FORE-SIGHT ELITE™ brand name Standard CAS product Labeling	The image contains FORE-SIGHT ELITE™ logo - dark text w/4 green ascending size circles on light background The image is located on the top front area of Device	21-07-0338 Gemini Software V&V History
4.3.3.5	The Device shall have a label for the CASMED© brand name Standard CAS product Labeling	The image contains CASMED© logo – Dark text on light background The image is located on the top front area of Device	21-07-0338 Gemini Software V&V History
4.3.3.6	The Device shall have a Serial Number label Regulatory Standards Requirement	Label contains part number, serial number, and barcode(s) information using standard CAS SN Labels & colors Label is located on the rear panel of the Device The serial number will contain information on date of manufacture and be assigned in accordance with QSP1007	21-07-0338 Gemini Software V&V History
4.3.3.7	The Device shall have a NRTL label Regulatory Standards Requirement	Label contains part NRTL symbol & a control number Label is located on the rear panel of the Device	21-07-0338 Gemini Software V&V History
4.3.3.8	The Device shall have the required Non Equipotential, Warning and Caution labels Regulatory Standards Requirement	A label contains BF defib symbol IEC 60417–5334, example: A label containing the symbol for "Caution" ISO 7000-0434 - dark icon on light background, example: A Label shall be located on the front of Device, near the USB connection A Label shall be located on the rear panel of Device, near the USB connection A label containing the symbol for "Warning" ISO 7010:2003-W001 - dark icon on Yellow background, example: A Label shall be located on the left side of Device, near the Patient connection	21-07-0338 Gemini Software V&V History
4.3.3.9	The Device shall have the required refer to User Manual (DFU) label(s) Regulatory Standards Requirement	A label contains the IEC 7010-M002 "Follow Instructions for use" – Blue background with white icon, Example: A label shall be located on the rear of the monitor A label shall be located on the bottom of the preamp A label contains the IEC 7010-M002 "Follow Instructions for use" – Black background with white icon, Example: A label shall be located on the Sensor pouch	21-07-0338 Gemini Software V&V History
4.3.3.10	The Device shall have a label for the AC Rating Regulatory Standards Requirement	Label contains correct AC ratings per 4.3.1.1- dark icon/text on light background Label is located on rear panel of the Device near the power entry module	21-07-0338 Gemini Software V&V History
4.3.3.11	The Device shall use a Warranty Void label to indicate when unauthorized service was done Standard CAS product Labeling	Label contains text "WARRANTY VOID IF DAMAGED" – Standard CAS label Label is located on an overlapping enclosure seam The label may be underneath a plastic cover.	21-07-0338 Gemini Software V&V History

[9] The term "Label" refers to a physical applied label or an image imprinted on a physical surface

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.3.3.12	There shall be a Device User Manual Regulatory Standards Requirement Mktg Reg , 12.A	The User Manual for the device shall include the following: • Provide a brief troubleshooting guide for selected conditions • Use the standard CAS electronic CD manual format • Be made available electronically via the Internet at a later time • Contain section with all warnings and cautions identified in this specification and associated project documentation • Shall be included with the Device (shipping container)	21-07-0338 Gemini Software V&V History
4.3.3.13	There shall be a Device Quick Reference Guide Mktg Reg , 12.A	A Quick Reference Guide may instruct the user with the basic operation of the device and may be included with the Device	21-07-0338 Gemini Software V&V History
4.3.3.14	Sensor cartons shall include a Sensor Directions for Use Regulatory Standards Requirement Mktg Reg , 12.A	A Direction for Use for each size Sensor, shall be included with the Sensor Cartons	21-07-0338 Gemini Software V&V History
4.3.3.15	The Preamp Cable shall have the required labels Regulatory Standards Requirement	Label contains Manufacturers name and reorder PN	21-07-0338 Gemini Software V&V History
4.3.3.16	The Preamp cable shall indicate that it is multiple use (do not discard) Regulatory Standards Requirement Mktg Req 17.C	Label contains "Do not throw away" text with waste basket in circle w/single slash - dark text on light background, example: Label shall be located on the cable	21-07-0338 Gemini Software V&V History
4.3.3.17	The Device shipping container shall have the required labels Regulatory Standards Requirement	These labels will be identified by product type A Serial Number label shall be available on outside of sealed box The shipping container will have a contents label on outside of the sealed box containing: Company name, transport & storage conditions and CE & Authorized Representative label Label(s) will have dark text on light background	21-07-0338 Gemini Software V&V History
4.3.3.18	The Device shall have the required WEEE (waste) label Regulatory Standards Requirement	Label contains the "crossed-out wheeled bin" WEEE symbol - dark text on light background, example: Located on rear panel of the Device	21-07-0338 Gemini Software V&V History
4.3.3.19	The Device shall have the required warning and caution labels Regulatory Standards Requirement	All appropriate Warning and Caution labels shall meet UL requirements for character height (7/64th), durability, adhesion and visibility.	21-07-0338 Gemini Software V&V History
4.3.3.20	The Device shall have the required EC Rep symbol Regulatory Standards Requirement	Located on the shipping carton and in Device DFU EC Rep label shall be dark text on light background	21-07-0338 Gemini Software V&V History
4.4	**LANGUAGES**		
4.4.1	**Labels (markings) and printed text**		
4.4.2	Device DFU shall be available in various languages Standard CAS product Labeling Mktg 12.A, Appendix II	Device DFU shall be available in multi-languages – Initial Languages to be defined by Mktg prior to release Additional translations of the Device DFU shall be completed as required after the initial release	21-07-0338 Gemini Software V&V History
4.4.3	Sensor DFU shall be available in various languages Standard CAS product Labeling Mktg 12.A, Appendix II	Sensor DFU shall be available in multi-languages – Initial Languages to be defined by Mktg prior to release Additional translations of the Sensor DFU shall be completed as required after the initial release	21-07-0338 Gemini Software V&V History
4.5	**SYSTEM REQUIREMENTS**		
4.5.1	**Sensors**		
4.5.1.1	The Device shall use be able to monitor Cerebral sites for Adult patients	Standard CAS disposable Large Sensor will be used to monitor Adult Cerebral sites for Adult patients Refer to 21-07-0314, Large Sensor Specifications	21-07-0338 Gemini Software V&V History

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Mktg Req 17.A, 2.A, PRD release Phase 1.0 Release	Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	
4.5.1.2	The Device shall use be able to monitor Tissue under Sensor in Adult patients Mktg Req 17.A, 2.A, PRD release Phase 1.5 Release	Standard CAS disposable Large Sensor will be used to monitor Adult Tissue under Sensor sites for Adult patients Refer to 21-07-0314, Large Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.3	The Device shall use be able to monitor Cerebral and Tissue under Sensor in Pediatric patients Mktg Req 17.A, 2.A, PRD release Phase 2.0 Release	Standard CAS disposable Medium Sensor will be used to monitor Cerebral and Tissue under Sensor sites for Pediatric patients Refer to 21-07-0315, Medium Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.4	The Device shall use be able to monitor Intestine sites on Pediatric patients Mktg Req 17.A, 2.A, PRD release Phase 2.0 Release	Standard CAS disposable Medium Sensor will be used to monitor Intestine sites on Pediatric patients Refer to 21-07-0315, Medium Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.5	The Device shall use be able to monitor Cerebral sites for Neonatal and small Pediatric patients Mktg Req 17.A, 2.A, PRD release Phase 3.0 Release	Standard CAS disposable Small Sensor will be used to monitor Cerebral sites for Neonatal and small Pediatric patients Refer to 21-07-0316, Small Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.6	The Device shall use be able to monitor Abdominal sites on Neonatal patients Mktg Req 17.A, 2.A, PRD release Phase 3.0 Release	Standard CAS disposable Small Sensor will be used to monitor Abdominal sites on Neonatal patients Refer to 21-07-0316, Small Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.7	The Device shall use be able to monitor Intestine sites on Pediatric patients Mktg Req 17.A, 2.A, PRD release Phase 3.0 Release	Standard CAS disposable Medium Sensor will be used to monitor Intestine sites on Pediatric patients Refer to 21-07-0315, Medium Sensor Specifications Refer to the current IFU submitted in the FDA 510(k) for specific patient applications	21-07-0338 Gemini Software V&V History
4.5.1.8	The System shall be optimized for various patient groups Mktg Req 7.B.c, 17.D-O	The System requires only the entry of the patient's body location of the Sensor (non-unused body location = valid location) Sensors shall have a unique ID readable by the Device	21-07-0338 Gemini Software V&V History
4.5.1.9	The Sensors shall be packaged for sale and distribution Mktg Reg 17.C, 17.M	The Sensors shall be packaged for individual use The Sensors shall be packaged as non-sterile The Sensor size coding on the Sensor top and pack-outs use FORE-SIGHT G1 size color scheme	21-07-0338 Gemini Software V&V History
4.5.1.10	The Sensors shall have noise immunity Mktg Reg 16.A, 16.B	The Sensors shall have the same level of noise immunity as the FORE-SIGHT G1 product The Sensors shall have the same level of protection from ESU "Bovie Interference"	21-07-0338 Gemini Software V&V History
4.5.1.11	The Sensors shall be as small and flexible as possible Mktg Reg 17.F, 17.G, 17.K, 17.N	The Sensor shall present a low profile to minimize pressure points if Sensor is positioned under the weight of the patient Sensor construction should conform to the attachment site without applying excessive force and the construction should not cause the part to lift from the patient The Sensor shall be able to conform to curved surfaces of patient The attachment area shall be no larger than FORE-SIGHT G1 Sensors; could be smaller and more flexible if possible The lead exit for Large and Medium Sensors preferred in-line with Sensor pad The release liner shall be required to be removed from the Sensor to apply the Sensor to the patient	21-07-0338 Gemini Software V&V History
4.5.1.12	The Sensors shall have a long shelf life	The Sensor shall have a minimum 24 month shelf life	21-07-0338 Gemini Software V&V

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

[redacted]

SECTION	Functional Requirements	SPECIFICATION	PLAN[4]
	Mktg Req 17.O		History
4.5.1.13	(b)(4) [redacted]		21-07-0338 Gemini Software V&V History
	Mktg Req 17.N		
4.5.1.14	Ability to identify channel near each Sensor Mktg Req 17.N	Label on preamp cable near Senor connection allows User to easily identify preamp channel	21-07-0338 Gemini Software V&V History
4.5.2	**Preamp Cable**		
4.5.2.1	The Preamp Cable shall connect to the Device Mktg Req 14.A-E, 15.A-D	The Preamp Cable shall be 4m ±3.175% in length An optional longer Preamp Cable may be made available (~6.5m) The Preamp Cable shall have a unique ID readable by the Device The Device shall require 2 Preamp Cables, each Preamp Cable supplies input for 2 channels The Preamp Cable (box and cables) shall be grayish/off-white in color The Preamp Cable shall be able to withstand a 300lb roll-over (on the cable only) while being as flexible as possible The Preamp Cable may have provisions to limit the number/time of monitor connections The Preamp Cable to Device connection shall provide a positive locking mechanism that is easily connected and disconnected Each Preamp Cable Device connectors shall withstand at least (b)(4) insertions	21-07-0338 Gemini Software V&V History
4.5.2.2	The Preamp Cable shall connect to the Sensor Mktg Req 14.J, 15.D	The Preamp Cable to Sensor connection shall be as small or smaller that the FORE-SIGHT G1 connection The Preamp Cable to Sensor connection shall provide a positive locking mechanism that is easily connected and disconnected The Sensor connector shall disconnect from the preamp cable with a maximum 8 lb inline pull/breakaway force The Preamp Sensor connection shall be able to withstand a fluid cleaning (wipe down) The Preamp Cable connectors shall withstand at least (b)(4) insertions w/Sensors (b)(4) [redacted] The Preamp Sensor Cable shall have a means for identifying the active channel	21-07-0338 Gemini Software V&V History
4.5.2.3	The Preamp Cable should be able to lie on a bed without falling off Mktg Req 14.H-I, 14.K, 15.A-B	The Preamp Cable shall provide a means to attach to a fixed object (bed, sheets, etc.)	21-07-0338 Gemini Software V&V History
4.5.3	**Characterized**		
4.5.3.1	The Sensors shall be characterized for all known sizes Mktg Req 17.N	Sensors shall be characterized in the manufacturing process; wavelengths, power etc. The Device requires no factory or field calibration Functional verification procedure to be provided in Device DFU	21-07-0338 Gemini Software V&V History
4.5.3.2	Internal Printed Circuit Boards (PCBs) should be able easily serviced Mktg Req 13.A	Device PCBs shall have Manufacturing and Service information stored on the board	21-07-0338 Gemini Software V&V History
4.5.4	**Power Interfaces**		
4.5.4.1	The Device shall have the ability to operate from a battery Mktg Req 9.A-E	The Device shall operate on the fully changed battery for approximately ½ hour (4-channels) In the event of AC power failure, the Device shall switch to battery operations without interruption A fully discharged battery shall take no more than 5 hours to become > 90 % charged with the Device connected to AC	21-07-0338 Gemini Software V&V History

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SECTION	Functional Requirements	SPECIFICATION	PLAN[4]
		The Device will be installed with a Battery Cut-off feature that will disconnect the Battery from the system when the battery voltage falls below a set threshold - This will reduce the possibility of deep discharge of the battery The batteries shall be user accessible via a tool (screwdriver) The Device may be operated (on AC) without a battery installed	
4.5.5	**Transportability**		
4.5.5.1	The System shall be transportable (as well as being stationary) Mktg Req. 1.C, 3.A-B	The Device is designed to be placed on a shelf, or affixed to wall or pole mount The Device may also be mounted on a roll stand	21-07-0338 Gemini Software V&V History NRTL results located in Project DHF[10]
4.5.5.2	The System shall have a handle Mktg Req 1.C	Design & position to be selected such as to encourage proper carrying with natural and comfortable wrist position	21-07-0338 Gemini Software V&V History
4.5.6	**Cleaning**		
4.5.6.1	The Device shall be capable of being easily cleaned Mktg Req 1.E-F	The Device may be disinfected with a cleaning solution (e.g., 70% isopropyl alcohol, 10% bleach & water or CaviCide-like solutions) Wipe down with cloth dampened with clean water There shall be a caution statement to not immerse or sterilize Complete cleaning information provided in Device DFU Also refer to section 4.14.1.4	21-07-0338 Gemini Software V&V History
4.5.6.2	The Preamp Cable(s) shall be capable of being easily cleaned Mktg Req 14.I, 15.C	The Preamp Cable may be disinfected with a cleaning solution (e.g., 70% isopropyl alcohol, 10% bleach & water or CaviCide-like solutions) Wipe down with cloth dampened with clean water There shall be a caution statement to not immerse or sterilize Complete cleaning information provided in Device DFU Also refer to section 4.14.1.4	21-07-0338 Gemini Software V&V History
4.5.7	**Audible Noise**		
4.5.7.1	The Device should generate minimal sounds Mktg Req 9.I	The Device may generate low-level sounds inherent with its operation due to the function of internal components such as inductors, relays, and fan(s) The maximum allowable inherent sounds shall be < 38 dBA, at 1 meter, TWA	21-07-0338 Gemini Software V&V History
4.6	**MESSAGES**		
4.6.1	**Alarm Limit Messages**		
4.6.1.1	The Device shall have the ability to set generate messages for High/Low Limit violations Mktg Req Appendix II	Alarm Limit violation shall have priority alarms status based on Risk Analysis Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History
4.6.1.2	The Device shall have factory default Alarm limits Mktg Req 7.B.f	The default Low Alarm Limits shall be 50% The default High Alarm Limits shall be 90% The default Alarm delay shall be 0 sec	21-07-0338 Gemini Software V&V History
4.6.1.3	The Device shall allow for setting of limits within a set range Mktg Req 7.B.f	Low Limit range shall be 2 to 93 % in 1% increments High Limit range shall be 7 to 98 % in 1 % increments There always be 5% difference between channel High & Low limits	21-07-0338 Gemini Software V&V History
4.6.1.4	The Device shall present equipment statuses Mktg Req 6.A, 6.D	Equipment status Alarms shall have priority alarms status based on Risk Analysis Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History

[10] DHF – Design History File for Project Gemini retained by the Regulatory Affairs/Quality Assurance group

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.6.1.5	The Device shall present channel status Mktg Req 6.A, 6.D	Channel status Alarms shall have priority alarms status based on Risk Analysis Refer to 21-07-0343 Gemini Displayed Message Priority Assignment Document	21-07-0338 Gemini Software V&V History
4.6.1.6	The Device shall present High priority system messages Mktg Req 6.A	The product shall display an appropriate High Priority messages in the Equipment and/or Channel message area A front panel LEDs shall flash red when a high priority condition is present High Priority messages may be output to all external communications ports configured for protocols supporting alarm codes (CSV, ATE, Philips VueLink, Philips IntelliBridge)	21-07-0338 Gemini Software V&V History
4.6.1.7	The Device shall present Medium priority system messages Mktg Req 6.A	The product shall display an appropriate Medium Priority messages in the Equipment and/or Channel message area A front panel LEDs shall flash yellow when a Medium priority condition is present (unless a High priority condition) Medium Priority messages may be output to all external communications ports configured for protocols supporting alarm codes (CSV, ATE, Philips VueLink, Philips IntelliBridge)	21-07-0338 Gemini Software V&V History
4.6.1.8	The Device shall present Low priority system messages Mktg Req 6.A	The product shall display an appropriate Low Priority messages in the Equipment and/or Channel message area A front panel LEDs shall indicate yellow when a low priority condition is present (unless a High or Medium priority condition) Low Priority messages may be output to all external communications ports configured for protocols supporting alarm codes (CSV, ATE, Philips VueLink, Philips IntelliBridge)	21-07-0338 Gemini Software V&V History
4.6.1.9	The Device shall present Informational system messages Mktg Req 6.A	The product shall display an appropriate Informational messages in the Equipment and/or Channel message area Informational messages may be output to all external communications ports configured for protocols supporting alarm codes (CSV, ATE, Philips VueLink, Philips IntelliBridge)	21-07-0338 Gemini Software V&V History
4.6.1.10	The Device labeling shall make available troubleshooting advice Regulatory Standards Requirement	There shall be a section in the Device DFU that has a brief section dedicated to common troubleshooting	21-07-0338 Gemini Software V&V History
4.7	**MONITORING**		
4.7.1	**Measurement**		
4.7.1.1	The Device shall provide a means to measure absolute tissue blood oxygen saturation values Mktg Req 4.A	The Device shall employ a modified Beer-Lambert Near Infrared Spectroscopy (NIRS) algorithm	21-07-0338 Gemini Software V&V History
4.7.1.2	The Device shall display a computed value Mktg Req 4.A	The computed value shall be the absolute tissue oxygen saturation (StO_2)	21-07-0338 Gemini Software V&V History
4.7.1.3	The Device shall have a specified measurement range Mktg Req 4.A	The measurement range shall be: 0 to 99 %	21-07-0338 Gemini Software V&V History
4.7.1.4	The System shall have a specified accuracy Mktg Req 4.A	The accuracy shall be specified for each Sensor and IFU combination (refer to FDA 510(k) clinical data for stated accuracy)	21-07-0338 Gemini Software V&V History
4.7.1.5	The Device shall have a specific numeric resolution Mktg Req 4.A	The numeric resolution of the Device shall be: 1%	21-07-0338 Gemini Software V&V History
4.7.1.6	The Device shall have a specific data rate Mktg Req 4.A	The Device acquisition rate: ≥ 1.0 Hz The Device numeric update rate: minimum 0.5 Hz	21-07-0338 Gemini Software V&V History
4.7.1.7	The Device shall be able to present Collected Data	The Device shall be capable of starting and stopping Data collection	21-07-0338 Gemini Software V&V

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Mktg Req 7.B.h, 8.B	The Device shall be capable of storing patient data to USB for review with graphing PC application tool	History
4.7.1.8	The Device shall be able to present STS Collected Data Mktg Req 7.B.h, 10.E	STS data collection accumulates the amount & time for values between 1 and 99% - Collection shall be automatic The minimum supported database output formats shall be Congenital Heart Surgery (v3.0), General Thoracic Surgery (v. 2.2), and Adult Cardiac Surgery (v2.73) The Device shall be capable of displaying and printing the collected STS Data	21-07-0338 Gemini Software V&V History
4.7.1.9	The Device shall be able to present FS Collected Data Mktg Req 7.B.h, 10.E	FS Data collection accumulates the amount & time for values between 1 and 99% The Device shall be capable of displaying and printing the FS Collected data	21-07-0338 Gemini Software V&V History
4.7.1.10	The Device shall be able capture data from multiple patients and store through power cycles Mktg Req 8.A, 9.D	The Device shall be capable of storing the equivalent ~20 days of patient data (assuming 0.5 Hz rate) into internal, non-volatile memory. The number of files shall be limited only by the amount of available memory for Patient data. Stored data shall be capable of exporting individual Patient files to USB memory stick	21-07-0338 Gemini Software V&V History
4.8	**ENVIRONMENTAL CONDITIONS** (Refer to Reference Section 2 for latest standard revisions/dates)		
4.8.1	**System Operating Environment**		
4.8.1.1	The System shall have a specified: High Operating temperature Low Operating temperature Regulatory Standards Requirement	 IEC 60601-1 §10.2, +40°C (+104°F) continuous IEC 60601-1 §10.2, +10°C (+50°F) continuous	NRTL results located in Project DHF
4.8.1.2	The System shall have a specified Operating humidity, non-condensing Regulatory Standards Requirement	IEC 60601-1 §10.2, 30 to 75% RH, non-condensing	NRTL results located in Project DHF
4.8.2	**Device Operating Environment**		
4.8.2.1	The Device shall have a specified: Level of Fluid ingress Regulatory Standards Requirement	IEC 60529 IPX0 min Phase 1, IPX1 by Phase 2	NRTL results located in Project DHF
4.8.2.2	The Device shall have a specified: Solid foreign object ingress Regulatory Standards Requirement	IEC 60529 IPX0 min Phase 1, IPX1 by Phase 2	NRTL results located in Project DHF
4.8.3	**Device Storage Environment**		
4.8.3.1	The Device shall have a specified: High Storage temperature Low Storage temperature Regulatory Standards Requirement	 IEC 60601-1 §10.1, +60°C (+140°F) IEC 60601-1 §10.1, -20°C (-4°F)	NRTL results located in Project DHF
4.8.3.2	The Device shall have a specified Storage humidity, non-condensing Regulatory Standards Requirement	IEC 60601-1 §10.1, 15%RH to 90%RH, non-condensing	NRTL results located in Project DHF
4.8.4	**Sensor Storage Environment**		
4.8.4.1	The Sensor shall have a specified: High Storage Temperature Low Storage Temperature Regulatory Standards Requirement	 IEC 60601-1 §10.1, +32°C (+90°F) IEC 60601-1 §10.1, +10°C (+50°F)	NRTL results located in Project DHF
4.8.4.2	The Sensor shall have a specified Storage humidity, non-condensing	IEC 60601-1 §10.1, 15%RH to 90%RH, non-condensing	NRTL results located in Project DHF

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
	Regulatory Standards Requirement		
4.8.5	**System Mechanical Environment**		
4.8.5.1	The Device and Sensor shall have a specified Immunity to mechanical shock Regulatory Standards Requirement	IEC 60068-2-27:2008 Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	NRTL results located in Project DHF
4.8.5.2	The Device and Sensor shall have a specified Immunity to mechanical random vibration Regulatory Standards Requirement	IEC 60068-2-68:2008 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	NRTL results located in Project DHF
4.8.5.3	The Device shall have a specified flammability Regulatory Standards Requirement	The Device shall meet at IEC 60601-1 standard	NRTL results located in Project DHF
4.9	**ELECTROMAGNETIC COMPATIBILITY**		
4.9.1.1	The System shall have a specified immunity to Radiated emissions Regulatory Standards Requirement	IEC 60601-1-2, BS EN 55011 – CISPR 11 Class A	NRTL results located in Project DHF
4.9.1.2	The System shall have a specified immunity to Conducted emissions Regulatory Standards Requirement	IEC 60601-1-2, BS EN 55011 – CISPR 11 Class A	NRTL results located in Project DHF
4.9.1.3	The System shall have a specified immunity to ESD Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-2, Level 3 6kV contact, 8kV air discharge	NRTL results located in Project DHF
4.9.1.4	The System shall have a specified immunity to Radiated immunity Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-3, 3 V/m for 26 to 1000 MHz	NRTL results located in Project DHF
4.9.1.5	The System shall have a specified immunity to Fast Transients Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-4, 2 kV power lines, 1 kV I/O lines > 3 meters	NRTL results located in Project DHF
4.9.1.6	The System shall have a specified immunity to Fast Surges Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-5, 0.5 kV (differential), 2 kV (common mode)	NRTL results located in Project DHF
4.9.1.7	The System shall have a specified immunity to Conducted signals Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-6 10 kHz – 100 MHz, curve #3, modulated; 3 V, 150 kHz to 80 MHz, modulated	NRTL results located in Project DHF
4.9.1.8	The System shall have a specified immunity to Magnetic fields Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-4-8 5 cm for 30 Hz to 100 kHz; 3 A/m at 50/60 Hz	NRTL results located in Project DHF
4.9.1.9	The System shall have a specified immunity to Voltage dropout	IEC 60601-1-2, IEC 61000-4-11 10 ms, 100 ms, 500 ms, 2 s; 0%,40%, and 70% of input voltage	NRTL results located in Project DHF
	Regulatory Standards Requirement		
4.9.1.10	The System shall have a specified immunity to Harmonics Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-3-2	NRTL results located in Project DHF
4.9.1.11	The System shall have a specified immunity to Flicker Regulatory Standards Requirement	IEC 60601-1-2, IEC 61000-3-3	NRTL results located in Project DHF
4.9.1.12	The System shall have a specified immunity to Quasi static fields Regulatory Standards Requirement	Determination made that above testing is equivalent / exceeds requirements of this test 2 kVaP/VaR $_{,p}$ at 0.5 Hz sine-wave modulation	NRTL results located in Project DHF
4.10	**ELECTRICAL AND MECHANICAL SAFETY REQUIREMENTS**		
4.10.1	The System shall have a specified Enclosure leakage current Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.10.2	The System shall have a specified Patient risk current Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF
4.10.3	The System shall have a specified Patient defibrillator withstand Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF
4.10.4	The System shall have a specified Enclosure surface temperature Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF
4.10.5	The System shall have a specified Construction Regulatory Standards Requirement	IEC 60601-1, UL 60601-1	NRTL results located in Project DHF
4.11	**PHYSICAL**		
4.11.1	**Size and Weight** (Device only)		
4.11.1.1	The Device should be light weight Mktg Req 1.B	The Device should weigh ≤ 15 lbs (7kg)	21-07-0338 Gemini Software V&V History
4.11.1.2	The Device should be <10" in height Mktg Req 1.A	The Device should be ≤ 10 in (26 cm) tall (excluding handle)	21-07-0338 Gemini Software V&V History
4.11.1.3	The Device should be <13" in width Mktg Req 1.A	The Device should be ≤ 13 in (33 cm) wide	21-07-0338 Gemini Software V&V History
4.11.1.4	The Device should be <9" in depth Mktg Req 1.A	The Device should be ≤ 9 in (23 cm) deep	21-07-0338 Gemini Software V&V History
4.11.2	**Cooling** (Device only)		
4.11.2.1	The Device should be able to dissipate Heat generated by internal components Regulatory Standards Requirement Mktg Req 9.I	The Device shall have venting holes as well as an internal fan(s) Adequate clearance shall be maintained above and alongside the Device to allow sufficient airflow for cooling The Device shall be able to effectively dissipate at least 60 watts (205 BTU/hrs) using forced air cooling (fan(s)) and 10 watts (35 BTU/hrs) using passive cooling (no fan(s) operating)	21-07-0338 Gemini Software V&V History
4.11.3	**Stability** (Device only)		
4.11.3.1	Device shall not move easily when the user controls are operated Mktg Req 7.A	The Device shall be equipment with non-skid feet	21-07-0338 Gemini Software V&V History
4.11.4	**Shipping** (Device only)		
4.11.4.1	The System shall be packaged for shipping Standard CAS product Labeling	Simple, low-cost, logical shipping package with as few pieces as possible	21-07-0338 Gemini Software V&V History
4.11.5	**Styling** (all)		
4.11.5.1	The Device shall have a forgiving texture Mktg Req 1.E, 15.C, 17.I	The Device shall present a surface that hides minor imperfections and signs of normal use The surface of the device shall be smooth and present seams or gaps as narrow as possible for easy cleaning	21-07-0338 Gemini Software V&V History
4.11.5.2	The Device should be durable Mktg Req 1.E, 14.G-H, 15.C-D, 17.I	The Device chassis and case shall be constructed to provide the maximum strength throughout the life of the product The User Control components shall be chosen to provide the maximum number of operations throughout the life of the product	21-07-0338 Gemini Software V&V History
4.11.6	**Color** (all)		
4.11.6.1	The Device and Cables shall be light in color Mktg Req 1.D, 14.B, 17.I	The front & rear of the Device case shall be white The Preamp Cable and Sensors should be white or Cool Gray Cable connections colors should blend and not contrast with the Device, Preamp Cable and Sensors	21-07-0338 Gemini Software V&V History
4.12	**ACCESSORIES**		

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.12.1	**Device Accessories**		
4.12.1.1	The System shall provide a means to verify proper operation Mktg Req 13.B	The Device shall be capable of connecting each channel to a CAS designed Sensor Simulator The Sensor Simulator shall present signals similar in magnitude to those generated by actual Sensors applied to a patient's tissue that produce a known and stable StO_2 value	21-07-0338 Gemini Software V&V History
4.12.1.2	The System shall provide a means for mounting on standard hospital equipment Mktg Req 3.A	The device shall provide GCX-compatible mounting features for securing to roll stands, articulating arms, etc.	21-07-0338 Gemini Software V&V History
4.12.1.3	The System shall provide a means to generate analog signals Mktg Req 10.F.d	The device shall interface to FORE-SIGHT G1 Analog Output device Configured to accept FORE-SIGHT G1 or Gemini CSV protocol	21-07-0338 Gemini Software V&V History
4.13	**REGULATORY APPROVAL AND STANDARDS REQUIREMENTS** (Refer to Reference Section 2 for latest standard revisions/dates)		
4.13.1	**United States of America**		
4.13.1.1	The System must meet FDA clearance to market substantially equivalent Device Regulatory Standards Requirement	Code of Federal Regulation – 21 CFR part 807 (refer to CAS QSP1017)	Refer to FDA 510k clearance letter
4.13.1.2	The System must meet Underwriters Laboratory or equivalent Regulatory Standards Requirement	UL 60601-1 Listed, USA/Canada	NRTL results located in Project DHF
4.13.1.3	The System must meet the General Principal of Software Validation – Final Guidance for Industry and FDA staff Regulatory Standards Requirement	CDRH	NRTL results located in Project DHF
4.13.2	**European Union**		
4.13.2.1	The System shall have the CE Mark Regulatory Standards Requirement	93/42/EEC Medical Device Directive (MDD)	NRTL results located in Project DHF
4.13.2.2	The System shall meet the European Standard – General requirements for safety Part 1 Regulatory Standards Requirement	IEC 60601-1	NRTL results located in Project DHF
4.13.2.3	The System shall meet the European Standard – Part 1-2 Collateral std: electro-magnetic compatibility. Regulatory Standards Requirement	IEC 60601-1-2	NRTL results located in Project DHF
4.13.2.4	The system shall meet European Standard – Part 1-6 Collateral std: Usability Regulatory Standards Requirement	IEC 60601-1-6	NRTL results located in Project DHF
4.13.2.5	The System shall meet the European Standard – Part 1-8 General requirements, tests and guidance for Alarm systems in medical Electrical Equipment and Medical Electrical Systems Regulatory Standards Requirement	IEC 60601-1-8	NRTL results located in Project DHF
4.13.2.6	The Sensor patient contact surface shall meet the Biological testing of medical and dental materials and devices Regulatory Standards Requirement	ISO 10993-1	Biocompatibilities results located in Project DHF

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SECTION	Functional Requirements	SPECIFICATION	PLAN[4]
4.13.2.7	The System shall meet the International Organization for Standardization – Application of Risk management to Medical Devices Regulatory Standards Requirement	ISO 14971	NRTL results located in Project DHF
4.13.2.8	The System shall meet the use of non-hazardous materials in the Device, cables and accessories Mktg Req 19.A Regulatory Standards Requirement	Directive 2002/95/EC of the European Parliament and of the Council RoHS directive	NRTL results located in Project DHF
4.13.2.9	The System shall meet the proper disposal of the Device, cables and accessories Regulatory Standards Requirement	Directive 2002/96/EC of the European Parliament and of the Council WEEE directive	NRTL results located in Project DHF
4.13.3	**Canada**		
4.13.3.1	The System shall meet the Medical Device safety Regulatory Standards Requirement	Product licensing CMDR	Refer to appropriate Country's documentation
4.13.3.2	The System shall meet the Health Canada license Bureau Regulatory Standards Requirement	Product licensing CMDR	
4.14	**CLASSIFICATIONS** (Refer to Reference Section 2 for latest standard revisions/dates)		
4.14.1	**IEC 60601-1** (reference clause)		
4.14.1.1	The System shall meet the Type of protection against electrical shock (5.1) Regulatory Standards Requirement	Equipment energized from an external power source Class I / Internal Power Source	NRTL results located in Project DHF
4.14.1.2	The System shall meet the Type of protection against electrical shock (5.2) Regulatory Standards Requirement	Type BF Equipment, Type B protection against Electric Shock with Floating Applied Part	NRTL results located in Project DHF
4.14.1.3	The Device shall meet the Degree of protection against harmful ingress of water (5.3) Regulatory Standards Requirement	Drip proof equipment, IPX1 protection against the harmful ingress of water (IPX0 min Phase 1, IPX1 by Phase 2)	NRTL results located in Project DHF
4.14.1.4	The System shall have Methods of disinfection (5.4) Regulatory Standards Requirement	The Device and Preamp Cable may be disinfected with a cleaning solution such as 70% isopropyl alcohol or 10% bleach. Wipe down with cloth dampened with clean water or commercial disinfecting solutions including but not limited to: • Aspeti-Wipe™ • 3M™ Quat #25 • Metrix CaviCide® • Phenolic germicidal detergent solution (per manufacturer's recommendations) • Quaternary ammonium germicidal detergent solution (per manufacturer's recommendations) Device DFU shall indicate not to immerse or sterilize the Device or the Preamp Cable The device cleaning instructions may include the following statement "*Follow recommended cleaning and disinfecting procedures per your institution's guidelines, with use of methods such as those outlined by the Association for Professionals in Infection Control & Epidemiology (APIC) or the World Health Organization (WHO).*"	21-07-0338 Gemini Software V&V History

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SECTION	Functional Requirements	SPECIFICATION	PLAN [4]
4.14.1.5	The System shall meet the Degree of safety of application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide Regulatory Standards Requirement	The Device DFU indicates the equipment is not suitable for use in the presence of a flammable anesthetic gas mixture with air, oxygen, or nitrous oxide	21-07-0338 Gemini Software V&V History
4.14.1.6	The System shall have a Mode of operation (6.1) Regulatory Standards Requirement	Continuous Operation	NRTL results located in Project DHF
4.15	**FIELD SERVICE / TECHNICAL SUPPORT FUNCTIONS**		
4.15.1	**Documentation**		
4.15.1.1	The System may provide a Service Manual Standard CAS product Labeling	Available prior to the expiration of the warranty on the first production units (available after initial release) Shall contain at a minimum, the following sections – • Installation procedure • Preventative maintenance procedure • Safety test procedure • Technical specifications • Schematics and detailed drawings • Troubleshooting procedure • Replacement parts list • Service accessory parts list • RMA return/Shipping information	21-07-0338 Gemini Software V&V History
4.15.1.2	The System shall be field repairable Standard CAS product Labeling	The Device will be field repairable down to an FRU level by Authorized CAS trained personnel The Preamp Cable shall not be repairable in the field – except by authorized CAS Service centers	21-07-0338 Gemini Software V&V History
4.15.2	**Installation**		
4.15.2.1	The System does not need calibration when installed Mktg Req 17.N	No calibration is required at installation Any written installation procedure shall be provided to verify proper operation in the Device User Manual	21-07-0338 Gemini Software V&V History
4.15.3	**Troubleshooting**		
4.15.3.1	The System shall provide field troubleshooting procedure Mktg Req 13.C	Shall be provided in the Device User manual to attempt to identify failing or faulted FRD (Field Replaceable Device) The system will be field repairable down to an FRU level by Authorized CAS trained personnel	21-07-0338 Gemini Software V&V History
4.15.3.2	The System shall provide visual reporting of any failure Mktg Req 13.C,	If any power-up test, or any periodic test fails, a failure message shall be displayed stating the Device needs service	21-07-0338 Gemini Software V&V History
4.15.4	**Preventative Maintenance**		
4.15.4.1	The System shall provide procedures for Preventative Maintenance Mktg Req 13.A, 13.B, 13.C	The Device DFU shall provide procedures for Safety tests The Device DFU shall indicate the interval and procedure for periodic Device functional verification The Device DFU & Service Manuals shall indicate the interval and procedure for periodic Device and Preamp Cable cleaning Software Service reminders may be enabled to remind Users about Service intervals (beyond Phase 1)	21-07-0338 Gemini Software V&V History
4.16	**WARRANTY**		
4.16.1.1	The System shall have a warranty Standard CAS product Labeling	The following CAS Warranty apply – 2 year minimum on the Device 6 months on batteries 90 days on Preamp cable	21-07-0338 Gemini Software V&V History

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5 PRODUCT ARCHITECTURE

5.1 SYSTEM ARCHITECTURE

Project Gemini architecture uses the following components:

- Project Gemini Device consists of:
  - Chassis: internal metal cage and Plastic enclosure
  - Main Ctrl Board: Main app – GUI, Threshold detection, communications, USB
  - NSAM Board: NSAM App, signal acquisition and processing
- Dual Preamp Cable: up to 2 per System, 1 Preamp Cable for 2 channels
- Sensors: 2 per Dual Preamp Cable (1 per channel)

5.2 PRODUCT INTERFACES

5.2.1 Patient Interfaces

Project Gemini will allow connection only to Gemini Preamp Cable and Sensors.

Project Gemini will not be backwards compatible with the FORE-SIGHT G1 Preamp Cable or Sensors

5.2.2 Serial Interfaces

- Serial interfaces are RS232 DTE through DB9 plugs.
- Project Gemini will connect to a Philip's Vital Signs device using their proprietary interface protocol (VueLink or IntelliBridge).
- Project Gemini will communicate with other devices using Comma Separated Values (CSV) or CAS ATE Protocols.

5.2.3 USB Interfaces

Project Gemini shall provide storage and retrieval of patient information and system software and parameters.

5.2.4 Ethernet Interface

Project Gemini shall provide an interface for patient information exchange.

5.3 PREDICATE DEVICE(s)

Predicate devices include the following monitors:

CAS FORE-SIGHT - Tissue Oximeter, Model MC-2000 Series

Somanetics INVOS - 2 wavelength LED NIRS monitor

Nonin EQUANOX – 3 and 4-wavelength LED NIRS monitors

***Hamamatsu NIRO 200, 200*-NX, and 300** - 3 wavelength laser and LED Oximeters

Spectros T-Stat VLS 303 - Microvascular Tissue Oximeter

Hutchinson Technologies InSpectra - *StO_2 Tissue Oxygenation Monitor*

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6 DESIGN AND CONSTRUCTION

Project Gemini will be designed to meet or exceed the standards referenced in Section 2.1 of this document regarding the safe use for medical instrumentation when the Device is used in a manner that is consistent with the operation and environment according to its intended use.

6.1 WORKMANSHIP

Production units will be built to the exact specifications as dictated by the assembly documentation using quality components, the cGMP and the QSR.

6.2 INTERCHANGEABILITY

All replaceable major components of Project Gemini shall be identified with a CAS part or assembly number. All parts or assemblies with the same assembly number shall be interchangeable, independent of the revision of the assembly.

Once the product is released, any change to a part or assembly that makes it no longer backward compatible with existing assemblies will require generation of a new part number for the affected assembly.

7 CONSTRAINTS AND LIMITATIONS

The following factors constrain or limit the latitude of the product development described by this specification.

(b)(4) [redacted]

7.2 COMPONENT AND CONDUCTOR SPACING

The spacing for each component and conductor will be in accordance with the manufacturers recommended guidelines and satisfying all safety creepage and clearance requirements. Consideration will also be given to components requiring room for heat dissipation of power devices, separation of analog and digital signals and power planes to maintain as high a signal to noise ratio as possible, and other layout guidelines as recommended by the Device manufactures.

7.3 DIAGNOSTIC TECHNIQUES

Project Gemini shall use the following diagnostic techniques:

(a) Checksums in ROM (startup self-test)

(b) Verification of SRAM integrity (startup self-test)

(c) Checksums on all packets transmitted via the serial interface between host microprocessor and the individual modules (whenever available)

(d) Automated test software to allow control of many Device functions

(e) Performing periodic system checks ensure circuit integrity

(f) Electronic and physical of all PC boards shall include provision for ATE

7.4 INDUSTRIAL DESIGN

The industrial design of Project Gemini shall provide for the functional, operational and human engineering requirements of this specification and conform to the standards referenced in Section 2 of this document.

7.5 TECHNOLOGICAL

No technological constraints exist for the design and manufacture of this product.

7.6 FIELD SERVICE

No field serviceable parts - other than replacement of the battery (within a pack).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8 PARTS, MATERIALS AND PROCESSES

8.1 ELECTRONIC AND ELECTRICAL PARTS

Wherever possible, the electrical parts used shall be UL-listed and CE-marked for the intended application. All electronic parts shall be consistent with conservative derating values. Guidelines for derating are as follows:

(b)(4) [redacted]

Wherever practical, the electronic parts shall be selected from the CAS standard parts and from associated lists of preferred or high usage parts.

8.2 MECHANICAL PARTS

Mechanical parts such as connectors shall be evaluated for suitability and reliability. All components shall be constructed of materials known to be suitable for the application and specified environments of use.

8.3 LABELS

All labels on the devices should be clear and easy to read. All labels and adhesives thereof shall be constructed of materials known to be suitable for the application and specified environments of use. Caution and Warning labels shall meet UL requirements for character height, durability, adhesion and visibility.

8.4 MATERIALS

The Device and Preamp Cable shall be constructed of materials known to be suitable for the application and expected environments. Materials shall meet the requirements of the following specifications:

IEC 60601-1	Safety of Medical Electronic Equipment - General Requirements Part 1
UL 60601-1	Medical Electrical Equipment Part 1: General Requirements for Safety
UL 94	Test for Flammability of Plastic Materials for parts in Devices and Appliances

The Sensor shall be constructed of materials known to be suitable for prolonged patient contact.

8.5 PROCESSES

All special processes will be detailed by specifications and procedures included in the product documentation package. These specifications and procedures shall contain or reference QA and inspection requirements.

8.6 MANUFACTURING PROCESS

Project Gemini shall be manufactured in accordance with standard CAS manufacturing process procedures.

The Sensor may be manufactured outside CAS, but in accordance with standard CAS manufacturing procedures.

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9 PRODUCT ASSURANCE

9.1 General

Each requirement shall be verified, either by analysis, inspection or test(s) as outlined in this document or referenced documents.

9.2 Verification and Validation

Verification procedures are to be conducted in accordance with applicable QSPs.

Testing and validation requirements are to be defined in applicable QSP specification and protocols.

9.3 Documentation

9.3.1 Drawings

Drawings will be produced using available drafting capabilities in a manner appropriate with their intended use.

Drawings may be available in either paper or machine readable formats.

Drawings will be maintained as released documents under formal change control per QSP1005: Engineering Change Procedure.

There shall be a Device Master Record (DMR), which shall list all applicable assemblies and their subassemblies, reference drawings, schematics, source control drawings and specifications.

9.3.2 Software

The software shall be documented in accordance with the appropriate CAS Engineering Software Standards as set forth in QSP4002. After release, revisions shall be under formal change control.

9.3.3 Instruction Manuals

All DFUs (e.g., Device & Sensor) shall comply with applicable QSP procedures concerning instrument manuals. The manuals will address the requirements set forth in the Medical Device Directive and in IEC 60601-1.

DFUs shall be designed to be understood by the personnel at the level of training at which the equipment are to be used.

9.3.3.1 IEC 60601-1, General Requirements for Safety, (6.8) Accompanying Documents

a) General Requirements

- Instructions for use
- Technical description
- Company name and address
- Classifications (type of protection against shock, degree of protection against shock, degree of protection against ingress of water, disinfection method, degree of safety of application in presence of flammable gases, and mode of operation)
- Meaning of all figures, symbols and warning statements and abbreviations used.

b) Instructions for use – General information (as applicable)

- Device function and intended application
- How to operate
- Explanation of the function of controls, displays, signals, sequence of operation, connection and disconnection of detachable parts and accessories and replacement of consumables.
- Information regarding potential electromagnetic or other interference between Device and other devices and advice on avoidance.
- An indication on recognized accessories, and parts or materials if they can degrade safety.
- Instruction and frequency for cleaning, preventive maintenance, maintenance and safe performance of routine maintenance.
- Instruction and frequency of preventive maintenance (where it can be performed by others).
- Explanation of the meaning of symbols, warning statements and abbreviations shown on the Device.

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- Signal outputs and input connections intended for specific equipment shall be called out
- Details about cleaning, disinfecting, and sterilizing patient contact equipment parts
- Identify any risks, and advice on minimizing risks associated with disposal of waste products, residues, etc. and of Device and its accessories at end of useful life.

c) Technical description (as applicable)

- Describes all data which are essential for safe operation
- Data mentioned in IEC 60601-1 sub clause 6.1
- Describe characteristics of equipment such as ranges, accuracy, precision of displayed values (or where that information can be found)
- Any particular measures or conditions for installation or start up.
- Where types and ratings of fuses, external to Device, are not apparent, they will be included
- Instructions for replacement of interchangeable or detachable parts subject to deterioration during normal use.
- For repairable parts of equipment, a statement that supplier will make available (on request) circuit diagrams, parts list, descriptions, calibration information, etc. for the benefit of qualified technical users.
- Explain permissible environmental conditions for transport and storage as stated on package labeling

9.3.3.2 IEC 60601-1-2, Electromagnetic Compatibility Requirements and Tests, (6.8.201) Instructions for Use

Note: Only the requirements not already called out in 8.3.3.1 are here.

a) Instructions for use (as applicable)

- Include a statement that the Device needs special precautions regarding EMC and ESD and needs to be installed and put into service according to EMC information provided
- Include a statement that portable and mobile RF comm. equipment can affect the Device

b) Technical description (as applicable)

- Include a list of cables, transducers and other accessories that are specified for compliance with EMC requirements
- Include a warning that the use of accessories, transducers and cables other than those specified, may result in increased emissions or decreased immunity of the Device
- Include a declaration of conformity (table 201) showing compliance with electromagnetic emissions
- Include a declaration of conformity (table 202) showing compliance with electromagnetic immunity
- Include a warning that the Device and Device system should not be used adjacent or stacked with other equipment, and should that be unavoidable, the Device and system configuration should be observed verifying normal operation. If a safe configuration has been predetermined, a description or list of configurations may be provided
- Include a justification for each compliance level lower than 60601 test level
- Include a declaration of conformity (table 204) showing compliance with electromagnetic conducted and radiated immunity
- Include an informational (table 206) showing separation distances between Device and mobile and portable RF comm. devices
- Include each frequency or frequency band of reception; the preferred frequency or frequency band, if applicable; and the bandwidth of the receiving section of the Device in those bands
- Include a warning that other equipment may interfere with the Device or system even if the other equipment complies with CISPR emissions requirements
- Include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the effective radiated power

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9.3.3.3 Labeling – Regulatory Requirements for Medical Devices (par. 1040.10)

Note: Only the requirements not already called out in 8.3.3.1 and 8.3.3.2 are here.

a) General requirements

9.3.3.4 Other FDA general instructions for labeling

Note: Only the requirements not already called out in 8.3.3.1, 8.3.3.2 and 8.3.3.3 are here.

a) Instructions for use

- Include the Rx statement for prescription devices – "Federal law restricts this Device to sale by or on the order of a health care professional";

10 HANDLING AND SHIPPING

Handling and shipping shall be in accordance with CAS Manufacturing department SOPs.

Prior to FDA clearance, domestic shipments shall contain proper labeling for Investigational Devices.

Special environmental requirements for the safe transport and handling, including temperature and humidity limits, will be clearly indicated on the external Device packaging. The shipping carton labeling will also include a description of the package contents.

11 TECHNOLOGICAL RISKS

11.1 PRODUCT PERFORMANCE & DEVELOPMENT RISKS

The following performance & development risks[11] have been identified at this time:

1. **Clinical Data** - Time frame to acquire and verify all clinical patient data (Adult, Pedi & Neo with Large, Medium and Small Sensors) for requested indications is challenging. Clinical results may also demonstrate inferior performance to FORE-SIGHT G1. Use of FORE-SIGHT G1 as validation reference versus invasive blood measurements may not satisfy requirements of the FDA. Pre-IDE submission with protocol and validation plans to reduce risk but may delay start of clinical work.
2. **Usability** - IEC60601-1 3rd Edition requires a Validated Usability Process. There may be a risk that the UI interface is unacceptable to the majority of Users and require UI modifications, which may not be accomplished within the timeframe.
3. **Sensor Construction** - Flex circuit (not hand wired) to emitter and detector components may pose a challenge to be manufactured reliability, consistently and economically.
4. **Touchscreen Interface** - Size of on-screen targets for touchscreen will need to be large enough to touch with an adult finger; may limit amount of info on screen; interface with PEG unknown for touchscreen but should be able to emulate a mouse click.
5. **Screen Size** - Larger screen (assumed 10.4" diagonal) will need to display 4 channels of info as well as equipment, Sensor, patient info.
6. **Screen Resolution** - Same resolution as FORE-SIGHT G1; proposed (640 x 480) should be capable of displaying CJK and Cyrillic characters; may have char memory limitations, even with expanded memory to achieve 20K of CJK char in multiple fonts.
7. **SW Development Tools** - The FORE-SIGHT G1 SW development tools (CodeWarrior, MQX and PEG) have gone through several upgrades and revisions to improve performance and add new features so may not be totally compatible with FORE-SIGHT G1 code. Porting of FORE-SIGHT G1 code may take longer than anticipated.

[11] Risks are not listed in any particular order or priority.

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8. **USB** - Using MQX USB driver may pose a challenge; desire to allow increase use of different size and Mfg of USB memory devices; changing releases of development environment and changes to and automatic to Microsoft operating systems may cause delays to determine fixes or workarounds.
9. **Physical Characteristics** - Keeping the outside dimensions of the monitor to a minimum while creating a full metal enclosure inside.
10. **Preamp** - Smaller electrical Sensor connections will need to be custom; reduction in preamp weight size (to minimum) may be a challenge; moving of some preamp components back to monitor may pose some risk.
11. **LED Array** - 5 LED array may pose some design risk to get a small geometry. Broad spectral output and uncertainty in wavelength may limit precision of system, preventing equivalent performance with the FORE-SIGHT G1 monitor. (b)(4) [redacted] (b)(4) [redacted]
12. **Sensor Construction** - The success of high throughput sensor manufacture depends on a robust high throughput test fixture. This is uncharted territory for us and could take longer to complete or be more difficult than anticipated. The flex circuit (not hand wired) to emitter and detector components may pose a challenge to be manufactured reliability, consistently and economically. Large number of electrical connections to sensor may complicate cable design and impact mechanical or electrical performance. High-current signals used to drive LEDs introduce crosstalk with sensitive photodiode circuits in sensor, cabling, and preamp and may increase cost, complexity, and limit sensitivity of sensor for patients with high absorption.
13. **Cable Connections** - Preamp cable to monitor and preamp cable to Sensor connections as well as preamp cable length need to be acceptable in real clinical scenarios. Verifying acceptability of the cable retention mechanism (i.e., clip) could be done simultaneously.
14. **Connectivity** - Selecting and implementing the correct methods to communicate with other devices and the inter system connectivity landscape can change quickly.
15. **Market Risk** - Acceptance of LED-based design may require additional clinical preference testing or delay sales of system until experience base established.
16. **Signal Generation and Acquisition Design** - Edge-detection design susceptible to coherent crosstalk from high-current LED transitions. Design places tighter constraints on performance of components such as sensor, cabling, and PCB layout within the signal path.

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14. Proposed Labeling

Note – Some Elite labeling refers to the "project" name Gemini. They are one and the same.

Part number and name
21-22-3000 FORE-SIGHT Elite Absolute Tissue Oximeter User Manual (DRAFT 01Xa)
21-05-0240 FORE-SIGHT Elite Sales Sheet and Specification rev.02 (2- pages front and back)
21-01-1978 FORE-SIGHT Gemini Rear Panel label (has Rx symbol) rev.02
21-01-1979 Gemini Patient Connection Label rev. 01
21-01-2017 FORE-SIGHT Elite 01-06-3000 US Serial Number Label rev.01
21-01-2018 FORE-SIGHT Elite 01-06-3005 OUS Serial Number Label rev.01
21-01-1981 FORE-SIGHT Elite US Monitor Contents Label rev.0
21-01-2020 FORE-SIGHT Elite OUS Monitor Contents Label rev.0
21-01-1980 FORE-SIGHT Elite Battery Contents Label rev.0
21-01-1982 Gemini Battery Label rev.0
21-01-2003 FORE-SIGHT Elite Battery Pack Mfg. Label rev.01
05-02-0194 FORE-SIGHT Elite Large Sensor Directions For Use (DRAFT rev.03)
05-02-0188 FORE-SIGHT Printed Pouch Stock FORE-SIGHT Elite Large Sensor rev.02
05-02-0190 Carton Label FORE-SIGHT Elite Large Carton of 20 rev.02
01-06-3100 13 Elite Dual Pre Amp Bottom Label
21-01-2008 Dual Pre Amp Label, FORE-SIGHT Elite rev. 02
21-01-1801 Pre Amp Box Serial No. Label rev. 01
21-01-1966 Do Not Discard Label for Pre-Amp monitor cable rev. 0
01-06-3100 22 Contents Label, FORE-SIGHT Elite Absolute Tissue Oximeter Dual Pre Amp rev.A

(See examples in Attachment C)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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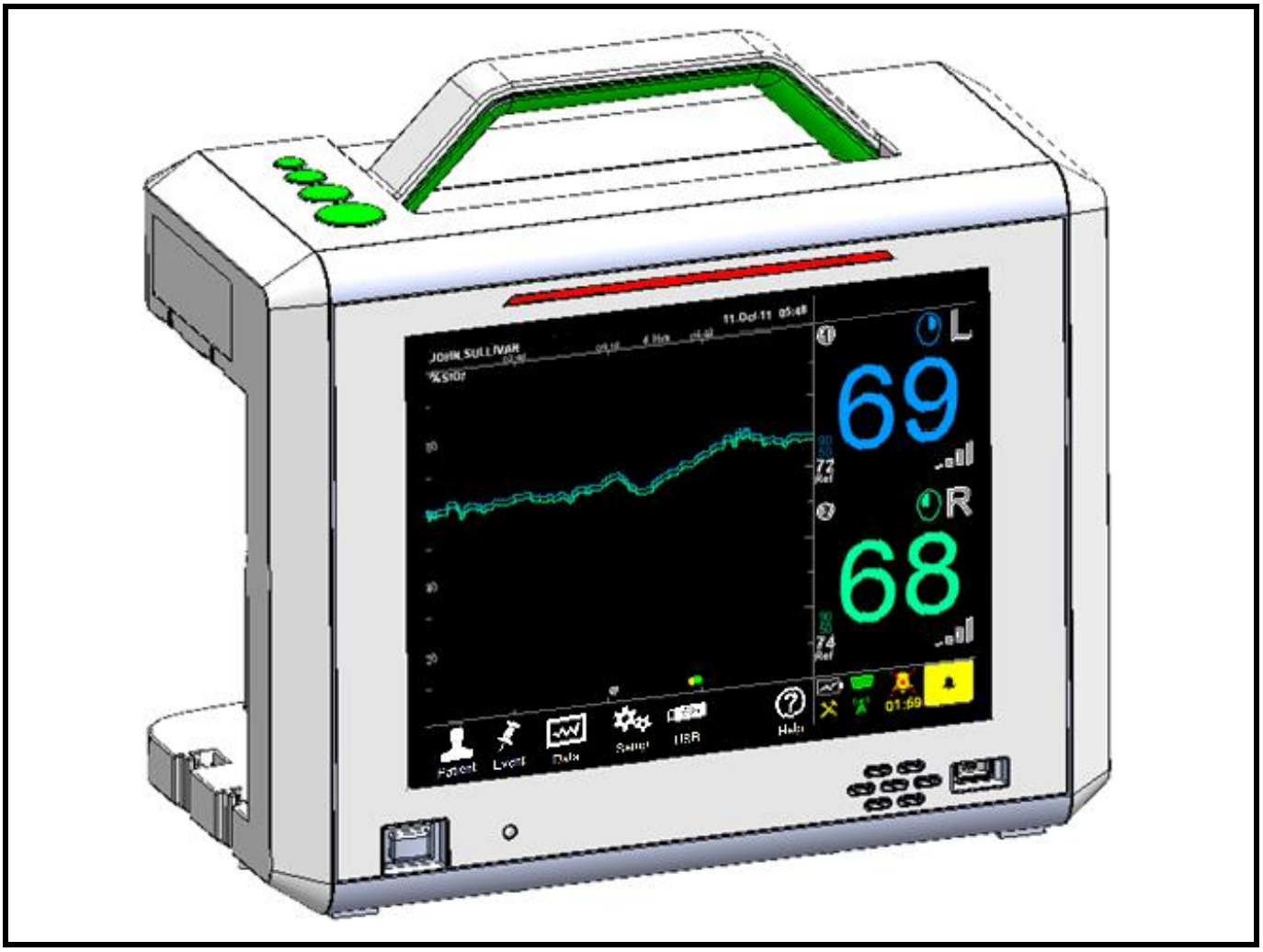
FORE-SIGHT ELITE™
Absolute Tissue Oximetry



User Manual

CE 0086

CASMED®
FOR WHAT'S VITAL

This User Manual describes the features and operations of FORE-SIGHT ELITE Oximeter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Overview

Trademarks

Trademarked names appear throughout this document. Instead of inserting a trademark symbol with each mention of the trademarked name, the publisher states that it is using the names only for editorial purposes and to the benefit of the trademark owner with no intention of improperly using that trademark.

CASMED® is a registered trademark of CAS Medical Systems, Inc.

FORE-SIGHT ELITE™ is a trademark of CAS Medical Systems, Inc.

Contact Addresses

CAS Medical Systems, Inc. 44 East Industrial Road Branford, CT 06405 U.S.A. Phone: in the US: (800) 227-4414 +1 (203) 488-6056 Fax: +1 (203) 488-9438 E-Mail: custsrv@casmed.com sales@casmed.com techsrv@casmed.com Web: www.casmed.com	**EC REP** MediMark® Europe 11 rue E. Zola 38100 Grenoble. France

Please contact the distributor in the country of purchase if product information or service should be required.

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Manufacturer's Declaration of Conformity

Manufacturers Declaration of Conformity
Electronic Emissions and Immunity

The FORE-SIGHT ELITE Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Oximeter should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment
RF emissions – CISPR 11	Group 1	The Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions – CISPR 11	Class A	The Oximeter is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions	Complies	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Level 3	Level 3	The Oximeter is designed for use in controlled environments only. Per OSHA guidelines for operating rooms, the area must employ adequate static electricity controls. The relative humidity should be maintained at about 50%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	The Oximeter is designed for use in controlled environments only. Per OSHA guidelines for operating rooms, the Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) mode ±2 kV line(s) to earth mode	±0.5 kV line(s) to line(s) mode ±2 kV line(s) to earth mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If user of the Oximeter requires continued operation during power mains interruptions, it is recommended that the Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the A.C. mains voltage prior to application of the test level.

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FORE-SIGHT Elite Oximeter

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The FORE-SIGHT ELITE Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Oximeter should insure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. ***Recommended separation distance:*** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and *d* is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1 At 80 MHz and 800MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is effected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Oximeter is used exceeds the applicable RF compliance level above, the Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Oximeter.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Oximeter

The Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	Separation distance according to frequency of transmitter (Meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters operating at a maximum output power not listed above, the recommended separation distance *d* in meters can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.
Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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CE Marking Information

Compliance The FORE-SIGHT ELITE Oximeter bears the CE mark CE-0086 indicating conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive.

Exceptions None

Conventions Used in this Manual

Warning: Directions that warn of conditions that put the patient or the caregiver at risk.

Caution: Directions that help to avoid damaging the Oximeter or losing data.

Note: Directions that make it easier to use the Oximeter, something not readily apparent.

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General Information

This manual is an integral part of the product and describes its intended use. Compliance with the manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety. Refer to Symbols starting on page 43 for additional information.

The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers.

CAS Medical Systems, Inc., (CASMED) is responsible for the effects on safety, reliability, and performance of the product only if:

- Assembly, operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by CASMED.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The device is used in accordance with the instructions for use.
- All publications conform to the product specifications and applicable IEC publications on safety and essential performance of electro-medical equipment as well as with applicable UL requirements and AHA recommendations valid at the time of printing.

For complete warranty information, refer to the Warranty Policy located on page 48.

The CASMED quality management system complies with the international standards ISO 13485 and the Council Directive on Medical Devices 93/42/EEC.

The parts of the Oximeter include the Oximeter, Preamp cable(s), Battery Pack, AC power Cord and Sensor(s). Refer to Oximeter on page 52.

The accessories for the Oximeter include, but are not limited to: USB Flash Drive, $St0_2$ Simulator and mounting hardware. Refer to Accessories on page 52

Note: Due to continuing product innovation, specifications in this manual are subject to change without notice.

Warning: Before using the Sensors and Oximeter for the first time, please read the information given in Safety section, starting on page 12 and the directions for use provided with the Sensors.

In the U.S. the following **Caution** applies: Rx only

Caution: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

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About This Manual

This User Manual describes the features and operation of the FORE-SIGHT ELITE Oximeter.

Manual Purpose

This manual contains the instructions necessary to operate the Oximeter safely and in accordance with its functions and intended use.

Note: All illustrations in this manual are provided as examples only. They may not necessarily reflect your monitoring setup or data displayed on your Oximeter.

Intended Audience

This manual is written for clinical professionals. Clinical professionals are expected to have working knowledge of medical procedures, practices, and terminology as required for monitoring of critically ill patients.

Warning: For continued safe use of this equipment, it is necessary that the listed instructions be followed. Nothing in this user guide is intended to override procedures and regulations imposed at the institutional level or above. Hospital's quality system, privacy rules, or other legal or policy requirements may govern whether and how to implement any specific procedure in this manual.

Training

Training on this Oximeter for the safe and effective use of the primary operating functions can be provided through CAS Medical Systems. Refer to Contact Addresses on page 2 for e-mail and phone number information.

CAS Medical Systems recommends in-service training on the Oximeter after the initial installation or whenever a new User intends to operate the device. No periodic retraining should be required. Training can also be provided when updates to the system are provided or whenever a User may be unfamiliar with the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Revision History

This manual has a revision number located at the bottom of each page. It changes whenever the manual is updated.

Rev-00-Xi	Oct/2013
Rev 01-Xa	Nov/2013

Read this manual carefully before patient use of the Oximeter

CASMED reserves the right to make changes to this manual and improvements to the product it describes at any time without notice or obligation.

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Contents

Overview **2**
Trademarks 2
Contact Addresses 2

Manufacturer's Declaration of Conformity **3**
CE Marking Information 5
Conventions Used in this Manual 5
General Information 6
About This Manual 7
Manual Purpose 7
Intended Audience 7
Training 7
Revision History 8

Safety **12**
Indications for Use 12
Contraindications 12
Installation and Setup 13
Device Handling 15
Safety Checks 15
Monitoring 16
Initial Inspection 17
Oximeter Checklist 17
Patient Environment 18
Oximeter Classifications of Electrical Insulation 18

Basic Operations **19**
Introduction 19
Getting Started 19
Physical Configuration 20
Front View 20
Rear View 21
Side View 22
Oximeter Controls 23
On / Off Button 23
Touchscreen 23
Oximeter Display 24
Parts of the Display Screen 24
Starting the Oximeter 25
Turning the Oximeter On 25
Touchscreen Navigation 25
Patient/Case Menu 25
Alarm Limit Menu 25
Start Patient Monitoring 26
Connecting Preamp Cable 26
Connecting Sensor to Preamp Cable 27
Preparing Patient 28
Applying Sensor 28
Sensor Selection Guide 29
TPI Indicator 29
Stop Patient Monitoring 30
Removing Sensor 30
Disconnecting Sensor from Preamp Cable 30
Disconnecting Preamp Cable (Optional) 30

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Monitoring the Patient 31
Controlling Alarm Volume & Limits 31
Adjusting Alarm Volume & Limits 31
Alarm Volume 31
High & Low Limits 31
Saving Alarm Volume and Limits 32
Responding to Alarms 33
Alarm LEDs 33
System Messages 33
Channel Messages 35
Philips IntelliVue Messages 37

Cleaning 38
Cleaning the Oximeter 38
Cleaning Preamp Cables 38
Cleaning Sensors 38

Maintenance 39
Maintenance Intervals 39
Waste Electrical and Electronics Equipment (WEEE) 39
Fuse Replacement 40
AC Fuse Replacement 40
PC Board Fuse Replacement 41
Battery Maintenance 42
Installing/Removing the Battery Pack 42

Appendix 43
Symbols 43
Symbols on Front of Oximeter 43
Symbols on Left Side of Oximeter 43
Symbols on Rear of Oximeter 43
Symbols on Display of Oximeter 44
Symbols on Battery Pack 46
Symbols on Oximeter Packaging 46
Symbols on Preamp 46
Symbols on Preamp Packaging 46
Symbols on Sensor Packaging 47
Warranty Policy 48
Oximeter Configuration Record 49
Specifications 49
Parts 52
Oximeter 52
Accessories, Detachable Parts and Materials 52
Philips IntelliVue/VueLink Accessories and Options 53

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Figures

Figure 1: Patient Environment 18
Figure 2: Front View 20
Figure 3: Rear View 21
Figure 4: Side View 22
Figure 5: Major Areas of Display 24
Figure 6: 1st Level buttons 25
Figure 7: Connecting Preamp Cable 26
Figure 8: Preamp top label, Ch1 & Ch2 Preamp connected 27
Figure 9: Preamp top label, Sensor connected to Ch1 27
Figure 10: Sensor Selection Guide 29
Figure 11: AC Fuse Placement 40
Figure 12: System Control Board Fuse Locations & Ratings 41
Figure 13: NSAM Board Fuse Placement 41

Tables

Table 1: System Messages 34
Table 2: Channel Messages 36
Table 3: Oximeter Messages on Philips IntelliVue 37

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Safety

The operator must comply with the following **Warnings**, **Cautions**, and **Notes** to guarantee safe operation of the Oximeter.

Additional **Warnings**, **Cautions**, and **Notes**, which apply to specific parameters, are listed in the sections that pertain to each parameter.

Indications for Use

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced-flow or no-flow ischemic states and is indicated for use as follows:

When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescent's ≥40 Kg.

Contraindications

- The FORE-SIGHT ELITE sensor is contraindicated for use on patients with physical site area too limited for proper sensor placement.
- The FORE-SIGHT ELITE sensor is contraindicated for use on patients with allergic reactions to sensor adhesive.
- The sensor site must be checked at least every eight hours; and if the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.
- Do not adhere sensors to underdeveloped, immature, compromised, or healing skin.
- No other contraindications are known at this time.

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Installation and Setup

Warning: The Oximeter is to be operated by qualified personnel only. Failure to read this manual, accessory direction for use, all precautionary information, and specifications could result in injury.

Warning: The Oximeter needs special precautions if it is placed close to a strong EMC transmitter such as X-ray, ESU or MRI devices. There is a risk that these signals could interfere with the Oximeter resulting in disruption of performance of this device. For continued protection against this risk, replace the AC power cord only with one provide by CASMED. Authorized CASMED or biomedical engineering personnel should replace the AC power cord.

Warning: To reduce the risk of injury, do not move or place the Oximeter in any position that might cause it to fall on patient, bystander or operator.

Warning: As with all medical equipment, carefully route and secure all cables to reduce the risk of patient entanglement or strangulation.

Warning: Do not lift or pull the Oximeter by any cable, or place the Oximeter or accessories in any position that might present a risk that the Oximeter may fall on the patient, bystander or operator.

Warning: The proper assembly of the various mounting solutions cannot be assured for structural integrity. There is risk that a damaged or improperly assembled Oximeter mounting solution may fall on patient, bystander or operator.

Warning: Do not come into contact with patients during defibrillation otherwise serious injury or death could result.

Warning: To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

Warning: The Oximeter is defibrillator-proof. It may remain attached to the patient during defibrillation, but the readings may be inaccurate during use and up to twenty (20) seconds thereafter. For proper protection against the effects of a cardiac defibrillator only CASMED supplied Preamp cables and Sensors shall be used.

Warning: Do not come into contact with patients during defibrillation. Otherwise serious injury or death could result.

Warning: Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

Warning: Avoid placing anything in front of the Oximeter that will cause the speaker output to be muffled.

Warning: Avoid placing the Oximeter where the controls can be changed by the patient.

Warning: Do not use the Oximeter for any purpose other than specified in this manual. Doing so will invalidate the Oximeter's warranty.

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Warning: Do not connect more than one patient to an Oximeter.

Warning: *Leakage Current Test* - When interfacing with other equipment, qualified biomedical engineering personnel must perform a test for leakage current before using it with patients. Serious injury or death could result if the leakage current exceeds applicable standards.

Warning: Patient Safety – If a Sensor is damaged in any way, discontinue use immediately.

Warning: The Oximeter is not "Category AP or APG Equipment."

Warning: Isolation of product from mains can only be achieved by removal of external AC power cord. If the integrity of the protective earth conductor is in doubt, the Oximeter may be operated from the internal batteries by disconnecting the AC power cord completely from the Oximeter. Do not position the Oximeter in a position that makes it difficult to remove the external AC power cord.

Warning: Do not place Sensor over poorly perfused tissues. Avoid uneven skin surfaces for best adhesion. Do not place sensor over sites with ascites, cellulitis or edema.

Warning: Do not position Sensor under the weight of the patient. Prolonged periods of pressure (such as taping over the Sensor or the patient lying on a Sensor) transfers weight from the Sensor to the skin, which can injure skin and reduce Sensor performance.

Warning: Measurements may be affected in the presence of strong electromagnetic sources such as electro-surgery equipment and measurements may be inaccurate during use of such equipment.

Caution: The USB connector accommodates a CASMED USB Flash Drive; do not connect any other USB type device or cable.

Caution: Qualified biomedical engineering personnel only must interface monitoring equipment with other types of medical equipment. Be certain to consult manufacturers' specifications to maintain safe operation.

Caution: Avoid placing either side of the Oximeter against objects that would restrict air flow through the air intakes and exhausts (other side).

Note: In the event that the location of the selected tissues cannot be palpated or visualized, confirmation by ultrasound or x-ray is recommended.

Note: The Oximeter is designed for continuous operation.

Note: The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

The Oximeter can remain connected to the patient during cardiac defibrillation. All applied parts are "Type BF Defibrillation Proof."

The Oximeter has been designed to promote patient safety. All equipment parts are protected against the effects of the discharge of a defibrillator. No separate actions are required when using this equipment with a defibrillator.

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Device Handling

Warning: Do not, under any circumstances, perform any liquid cleaning while the Oximeter or AC power cord while the Oximeter is being used to monitor a patient. The Oximeter must be turned off, Sensors removed from the patient and the AC power cord disconnected before servicing or cleaning the Oximeter. There is a risk of serious injury or death if this procedure is not followed.

Warning: If the Preamp Cable should become grossly contaminated with blood or other bodily fluids, it should be discarded to reduce the risk of contamination and cross infection.

Caution: Pressing the front display touchscreen with a sharp or pointed instrument may permanently damage the membrane. Press the touchscreen using only your finger.

Caution: Do not attempt to sterilize, gas sterilize or autoclave the Oximeter or accessories.

Note: There are no known risks with common disposal of equipment or accessories; however, the disposing of accessories should follow in accordance with local hospital policies. The user should ensure these policies do not conflict with any local, state, or federal guidelines.

Safety Checks

Warning: There is a risk of an explosion hazard if a damaged Oximeter or accessory is used in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

Warning: Inspect the cables and Sensors for damage prior to operation. If any damage is noted, the cables or Sensor should not be used until it has been serviced or replaced. There is a risk that these damaged parts could reduce the performance of the Oximeter or present a safety hazard.

Warning: Liquids must not be allowed to enter the device. There is a risk of electric shock or device malfunction if liquids enter a device. If the Oximeter or Preamp is accidentally wetted, take it out of operation. It should be thoroughly dried (minimum 1 hour) and have it checked by a service technician before it is used again.

Warning: The operator should not perform any servicing except as specifically stated in this manual.

Warning: If the accuracy of any value displayed on the Oximeter is questionable, determine the patient's vital signs by alternative means. The functions of the Alarm system for monitoring of the patient must be verified at regular intervals and whenever the integrity of the product is in doubt, periodically test all functions.

Warning: Only use CASMED-supplied accessories with this Oximeter. CASMED-supplied accessories ensure patient safety and preserve the integrity, accuracy, and electromagnetic compatibility of the Oximeter.

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Caution: If the Oximeter fails to respond, do not use it until the situation has been corrected by authorized CASMED personnel.

Caution: Inspect the Oximeter and accessories for damage prior to operation. If any damage is noted, the Oximeter or accessory should not be used until it has been serviced. Only personnel authorized to do so by CASMED should repair the Oximeter. Refer to Contact Addresses on page 2 for e-mail and phone number information.

Monitoring

Warning: If the accuracy of any value displayed on the Oximeter is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly. Failure to comply may lead to injury.

Warning: The Sensor site must be inspected at least every eight hours; to reduce the risk of inadequate adhesion, circulation, and skin integrity. If the circulatory condition or skin integrity has deteriorated, the Sensor should be applied to a different site.

Warning: The Sensor is designed for single patient use, and is not to be reprocessed. There is risk of contamination and cross infection from used sensors. The disposing of accessories should follow in accordance with local hospital and institution policies.

Warning: *Conductive Connections* - Extreme care must be exercised when applying Sensors. Sensor circuits are conductive and it is very important that the Sensor does not come into contact with other grounded, conductive parts. Such contact would bridge the patient's isolation and cancel the protection provided by the Sensor.

Warning: Interfering substances: Elevated levels of Carboxyhemoglobin (COHb) or methemoglobin (MetHb) may lead to inaccurate measurements. Intravascular dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings. Other factors that may affect the accuracy of measurement include: myoglobin, hemoglobinopathies, anemia, pooled blood under the skin, interference from foreign objects in Sensor path, Bilirubinemia, externally applied coloring (tattoos) or birthmarks.

Warning: Sensors are not sterile and therefore should not be applied to sites with compromised skin integrity. Exercise caution when applying Sensors to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.

Warning: Failure to apply Sensors properly may cause incorrect measurements. Misapplied Sensors or Sensors that become partially dislodged may cause either over- or under-reading of oxygen saturation.

Warning: Do not modify or alter the Oximeter or Sensor in any way. Alterations or modification may affect performance and/or accuracy.

Warning: *Electrocautery* – To prevent unwanted skin burns; apply electrocautery electrodes as far as possible from all other Sensors, a distance of at least 15 cm (6 in.) is recommended.

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Note: For patients experiencing complete bilateral ECA occlusion, measurements may be lower than expected.

Note: Body location does not change any settings for output of the Oximeter, but is used to improve measurement accuracy.

Initial Inspection

Before unpacking the Oximeter, inspect the packaging for damage. If there are any signs of damage to the package, a claim should be filed immediately with the shipping agent. It is the receiver's responsibility to notify the carrier's local office to arrange for the pickup of the damaged items. Save the damaged shipping carton as evidence.

Contact your distributor, CASMED sales representative, or CASMED to report external damage and to arrange for repair or replacement of damaged equipment.

The shipping carton should contain the items listed below. Unpack the Oximeter and account for each item. Inspect each item for signs of external damage, dents, cracks, scratches, etc. If an item is missing or damaged, contact your distributor, CASMED sales representative, or CASMED.

Refer to Contact Addresses on page 2 for e-mail and phone number information.

Record the serial number and date of purchase at the back of this manual.

Oximeter Checklist

- 1 FORE-SIGHT ELITE Oximeter
- 1 FORE-SIGHT ELITE Preamp Cable
- 1 FORE-SIGHT ELITE User Manual
- 1 Hospital Grade AC power cord

Warning: Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Grade".

Note: The Oximeter is shipped with the appropriate line cord for the country and voltage being used.

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Patient Environment

The Oximeter has been tested with specific parts of the system used within the patient environment (see Figure 1 below).

These parts are:

- The Oximeter
- Appropriate accessories as listed under Parts, on page 52, at the back of this manual.
- AC power cord

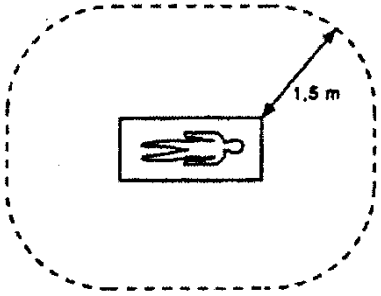

Figure 1: Patient Environment

Oximeter Classifications of Electrical Insulation

The Oximeter (with integrated AC power supply) is a Class I device.

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Basic Operations

Introduction

The Oximeter is pre-configured to measure absolute tissue oxygen saturation.

The Oximeter detects oxygenation changes in biological tissue mainly at the microcirculation level (capillary, arteriole, and venula) based on different absorption characteristics of the chromophores oxyhemoglobin (HbO_2) and deoxyhemoglobin (Hb) in the near-infrared spectrum. A biological spectroscopic window exists at the wavelength range 660–940 nm in which Hb and HbO_2 can be differentiated and measured. Tissue oxygen saturation (StO_2) is determined from the ratio

$$((HbO_2)/(HbO_2 + Hb)) \times 100\%$$

The Oximeter uses LED Technology to project light into tissue to measure oxygen saturation.

The Oximeter is equipped with a rechargeable backup battery pack that allows the Oximeter to be used independently from an external power source.

Refer to the Battery Maintenance section on page 42.

Getting Started

Before operating the Oximeter, the user should be thoroughly familiar with the following:

- **Warnings** and **Cautions** in the Safety section starting on page 12.
- Physical configuration of the Oximeter, page 20.
- Content and use of the Oximeter display, page 24.
- Procedures described in this guide, pages 26 and following,
- Use the Oximeter, starting on page 23.
    1. Set up the Oximeter for the patient (optional). See page 26.
    2. Connect the Preamp Cable(s) to the Oximeter. See page 26.
    3. Connect the Sensors(s) to the Preamp Cable(s). See page 26.
    4. Affix the Sensor(s) to the patient. See page 27.
    5. Begin monitoring. See page 26.

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Physical Configuration

Front View

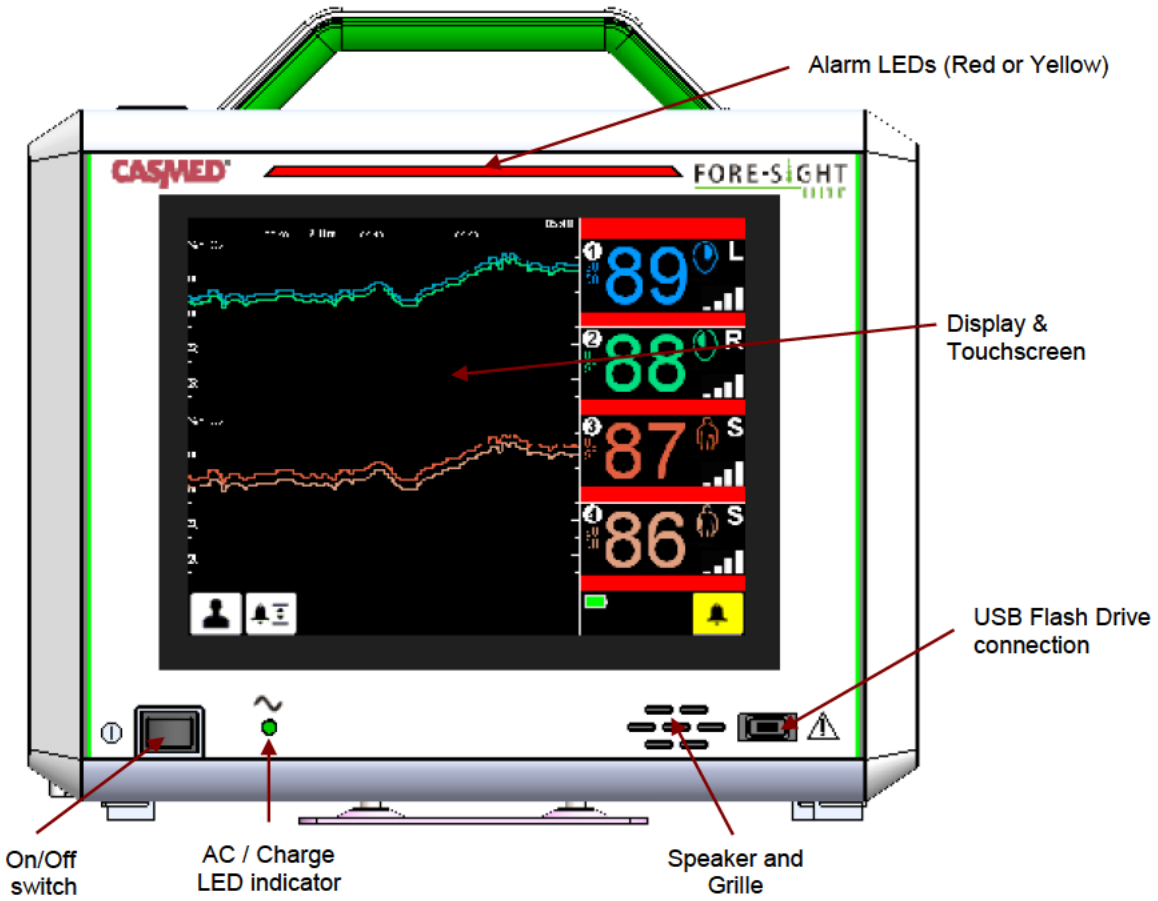

Figure 2: Front View

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Rear View

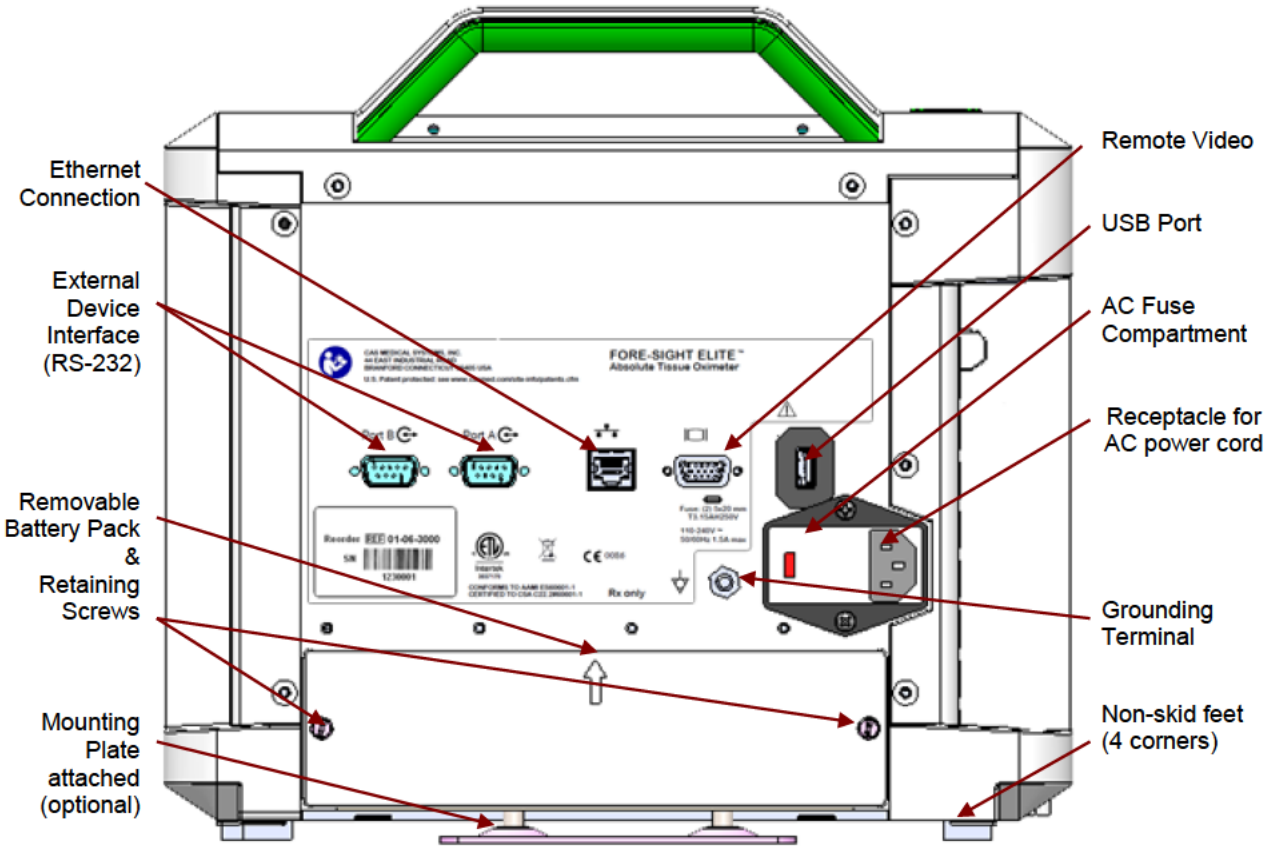

Figure 3: Rear View

Note: The Ethernet connection is for the use of CASMED service personnel only.

Note: The 4 non-skip feet may be removed (feet are attached with sticky tape) to make installation with the various mounting solutions easier.

Note: The Grounding Terminal can provide a connection between the Oximeter and the potential equalization bus-bar of the electrical installation.

When using the Grounding Terminal, the line cord shall not incorporate a potential equalization conductor.

Refer to IEC 60601-1 for additional information.

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Side View

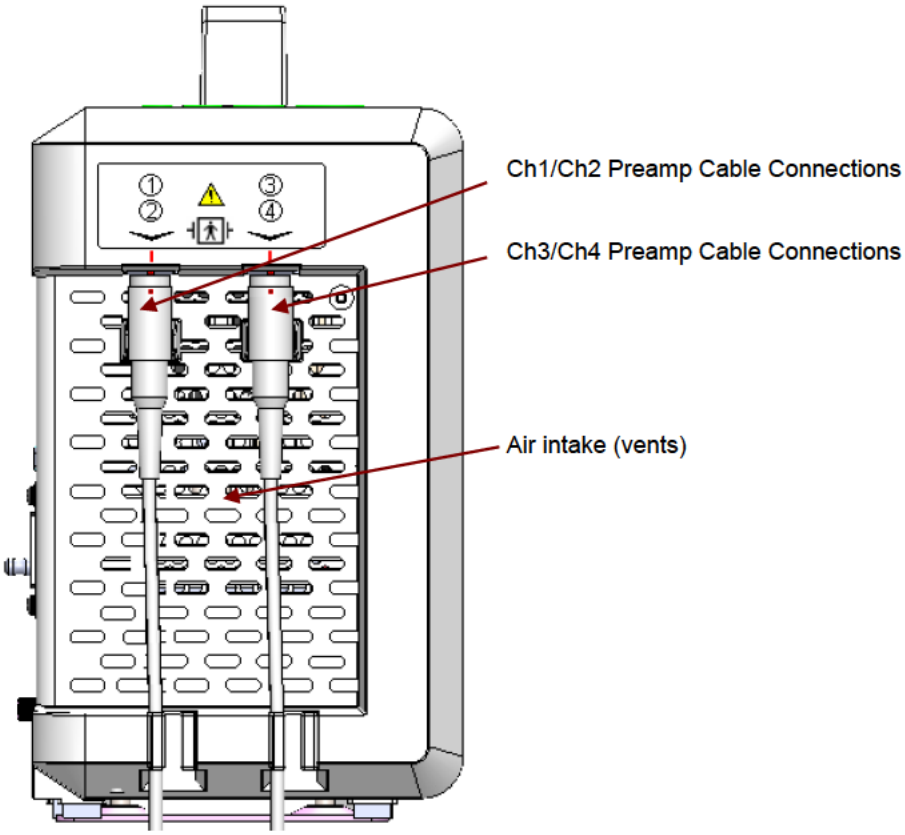

Figure 4: Side View

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Oximeter Controls

On / Off Button

Press the On / Off button to switch from Off to On.

Press the On / Off button to switch from On to Off.

The Oximeter will remain Off when connected to AC power and the On / Off button is not pressed

Touchscreen

The touchscreen gives the user access to on-screen Oximeter functions.

The user can:

- Silence Audio Alarms
- Navigate through all menu selections
- Choose optional settings
- Enter data

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Oximeter Display

Parts of the Display Screen

The major indicators on the Oximeter display are shown in Figure 5 below.

Note: The Major Areas of the Oximeter display illustrate all the areas of the display and certain settings presented may not represent actual display configurations.

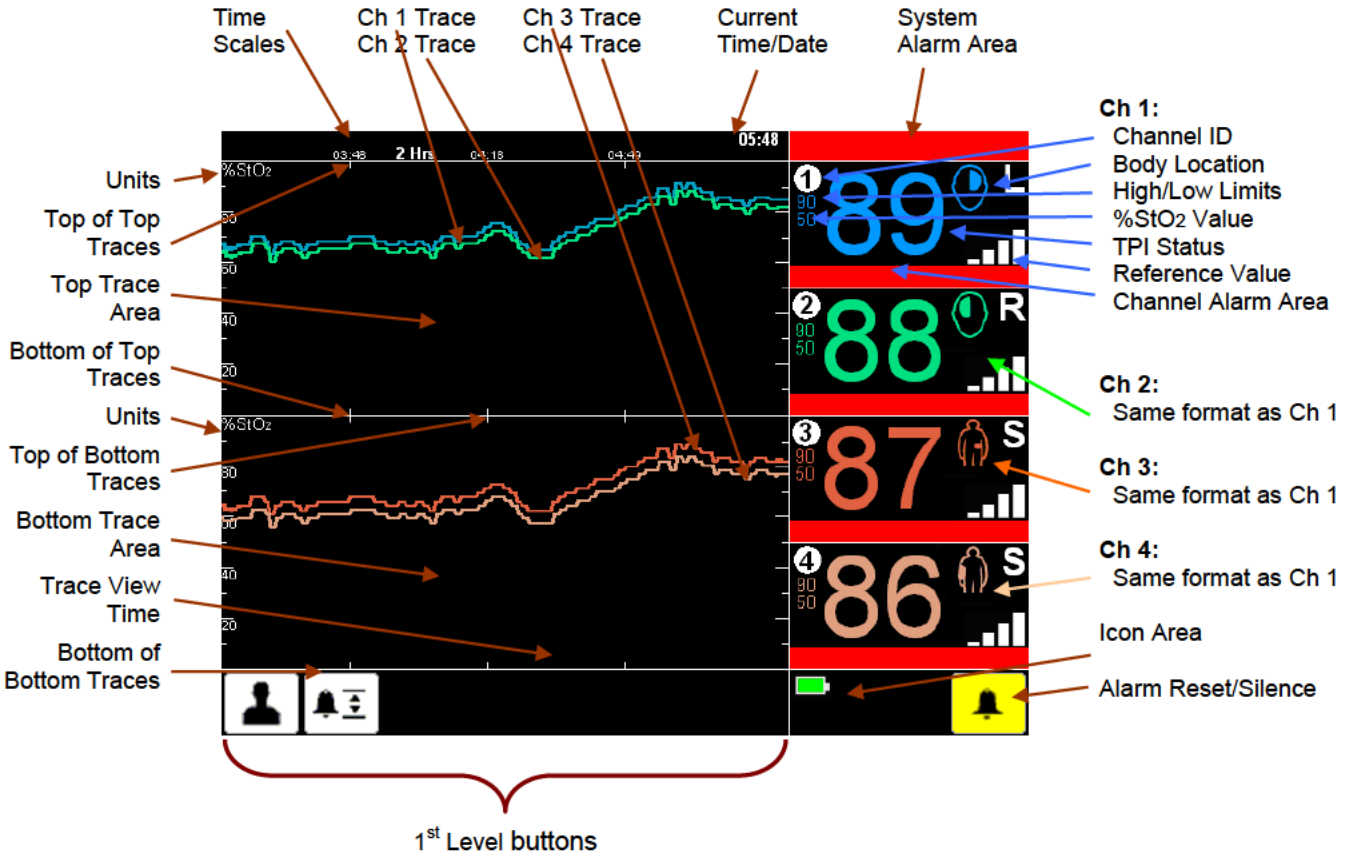

Figure 5: Major Areas of Display

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Starting the Oximeter

Turning the Oximeter On

Note: The Oximeter may be turned on before or after connecting cables and Sensors.

To turn the Oximeter on:

1. Plug the AC power cord into a power outlet.

Note: The Oximeter is equipped with a removal battery pack that allows the user to turn the Oximeter on without plugging it into an outlet. The battery status indicator shows the state of charge in the form of a colored battery icon on the display. Refer to the Battery Maintenance section on page 42.

2. Push the On / Off switch on the front of the Oximeter. The Oximeter will power on within a few seconds.

While the software initializes, a splash screen and a set of diagnostic tests are displayed. When the diagnostic tests are done the Oximeter will switch to the main screen, and is ready to begin normal operation.

Touchscreen Navigation

The user can control the operations of the Oximeter through the touchscreen system (see Figure 6 below). The procedures in this manual make frequent reference to the touchscreen system. This section explains how to navigate through it.

Figure 6: 1st Level buttons

The following paragraphs briefly describe what can be done from the various menus.

This section serves as an orientation to the touchscreen system.

Specific procedures making use of the touchscreen system are found in later sections of this manual.

Patient/Case Menu

The Patient/Case menu lets the user select the body locations of the sensors on the Patient.

Alarm Limit Menu

Touching the Alarm Limit icon allows user change each Channel's High & Low Alarm Limit.

Note: Powering the Oximeter off and on (for any period of time) will retain the last saved High & Low Limits.

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Start Patient Monitoring

Connecting Preamp Cable

Preamp Cables (see Figure 7, below) connect the Oximeter to the Sensors. Preamp Cables are reusable.

Note: Preamp Cables can remain connected to the Oximeter between uses.

Note: Preamp Cables should be replaced when they no longer properly functioning. Keep track of cable installation date and usage. See Parts on page 52 for reorder information.

To connect the Preamp Cables to the Oximeter:

1. Remove the Preamp Cable from the packaging.
2. Position the Preamp connector under the desired Oximeter Preamp connector (1&2 or 3&4). The Preamp connector housing may rest on the Guides under each Oximeter connection.
3. Line-up the alignment marks (red dots) on the Preamp Cable and Oximeter Preamp Receptacle. The Preamp Connector may be placed in the Oximeter Receptacle and rotated until the Preamp connectors inserts further.
4. Gently push the Preamp Cable Connector straight up into the Oximeter Preamp Receptacle, the Preamp Connector should snap into place.
5. Pull down gently on the Preamp cable to make sure the Preamp Connector has fully snapped into place.

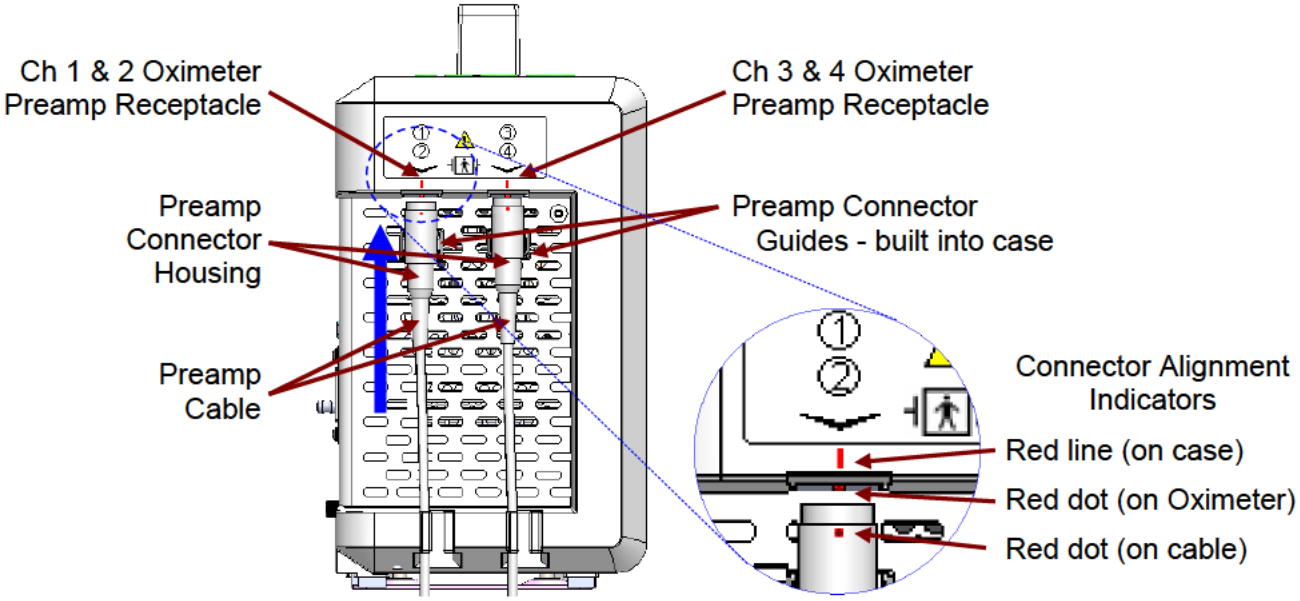

Figure 7: Connecting Preamp Cable

6. The small box at the far end of the Preamp cable contains indicators that will illuminate when the Preamp and Sensors are connected. The indicators will denote Preamp channel assignment 1, 2, 3 or 4.

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The Preamp plastic housing has a top label (refer to Figure 8) to indicate Channel Identification as well as Sensor connection status. Each Channel identification contains 2 LEDS; 1 green, 1 white

When a Preamp cable is connected to the Oximeter, the appropriate pair of white Channel ID LEDs (① ② or ③ ④) will be lit.

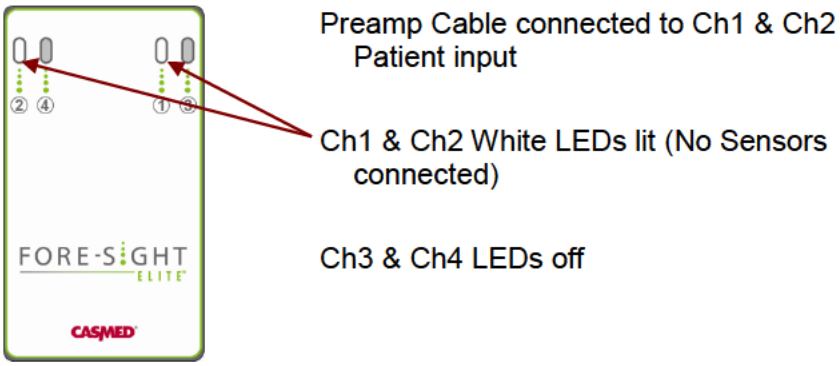

Figure 8: Preamp top label, Ch1 & Ch2 Preamp connected

Connecting Sensor to Preamp Cable

Sensors connect the Preamp Cables to the patient.

Caution: The Sensor is designed for single patient use, and is not to be reprocessed. Use a new Sensor for every patient and discard after use.

To connect a Sensor to the Preamp Cable:

1. Remove Sensor from its packaging.
2. Position the Sensor connector in front of the Preamp Sensor connector.
3. Line-up the alignment marks on the Sensor and Preamp Sensor connector.
4. Gently push the Sensor connector straight into the Preamp Sensor connector, the connector should snap into place.

The Channel ID LED on the preamp housing will change to green when a Sensor is connected (refer to Figure 9).

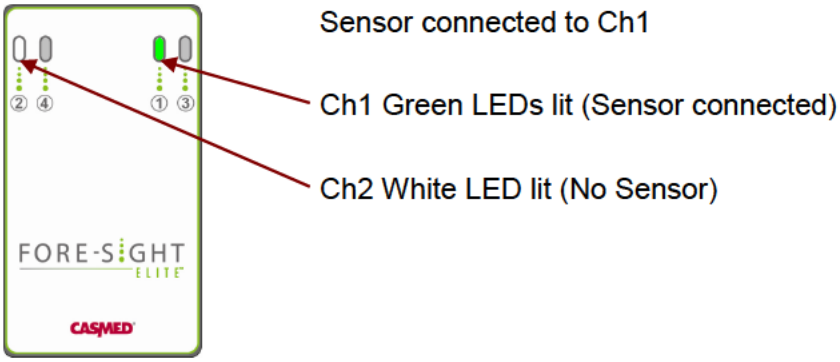

Figure 9: Preamp top label, Sensor connected to Ch1

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Preparing Patient

To prepare the patient's skin for placement of the Sensor:

1. Make sure the skin area where the Sensor is to be placed is clean, dry, intact and free of powder, oil or lotion.
2. If necessary, shave hair from skin at chosen site.
3. Use an appropriate cleanser to gently clean the intended Sensor site. Allow the skin to dry completely before applying the Sensors.

Applying Sensor

Caution: Sensors should not to be placed on high density hair areas.

Caution: The Sensor must be flush with clean, dry skin. Any debris, lotion, oil, powder, perspiration, or hair that prevents good contact between the Sensor and the skin will affect the validity of the data collected and may result in an alarm message.

Note: Skin pigmentation does not affect the validity of collected data. The Oximeter compensates automatically for skin pigmentation.

Note: For cerebral applications, If possible, locate the Sensor away from the midline of the forehead or over a sinus cavity.

Note: Refer to Figure 10: Sensor Selection Guide below to help select the proper Sensor for the patient.

Apply Sensor using the instructions provided in the Sensor kit package.

1. Be sure that all cables are fully connected and Sensors are placed correctly on the patient's skin.
2. Use the clip/hook near the Preamp to secure the cable to prevent the cable from being pulled away from the patient.

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Sensor Selection Guide

Cerebral & Skeletal Muscle Applications

kg	40-60	>60
10-18 yrs		L
> 18 yrs	L	L
lbs	88-132	>132

Figure 10: Sensor Selection Guide

L – Large Sensor

TPI Indicator

A 4-bar indicator of the Tissue Perfusion Index (TPI) represents the amount of hemoglobin in the tissue under a Sensor and is displayed near the $St0_2$ value (see Symbols on Display of Oximeter on page 44).

The TPI level is useful for the initial placement of a Sensor or for assessing an existing Sensor site:

Initial Placement:

- Without removing the white protective paper, hold the Sensor on the selected monitoring site.
- Slide the Sensor over the target sensing area until the highest TPI level is achieved.
- Visually note the Sensor position and remove & discard the protective paper prior to affixing the Sensor.

Routine Assessment:

- In normal operation, the TPI level should be 3 to 4 bars.
- If the TPI level changes to 2 bars, the user should verify proper Sensor contact and assess the site for reliability (e.g., edema is more present).
- For subjects that become hemodiluted during monitoring, a decrease in the TPI level is likely (e.g., during initiation of cardiopulmonary bypass).
- If 1 bar is present, the Sensor must be moved to a location with a higher TPI level. After 10 seconds this condition may trigger a warning message and $St0_2$ values will become dashes.

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Stop Patient Monitoring

Removing Sensor

Carefully peel the Sensor from the patient to avoid damaging the skin.

Discard the adhesive Sensors.

Disconnecting Sensor from Preamp Cable

To remove a Sensor from the Preamp Cable:

1. Grasp the Sensor connector of desired Preamp Cable to be disconnected.
2. Gently pull the Sensor connector straight out until the Sensor connector disengages from the Preamp Sensor connector.

When the Sensor is disconnected from the Preamp, the associated Channel ID LED on the Preamp housing will change back to white (refer to Figure 8).

3. Discard the Sensor.

Disconnecting Preamp Cable (Optional)

To remove a Preamp Cable from the Oximeter (see Figure 7 on page 18):

1. Grasp the housing of the connector (near The Oximeter Preamp Receptacle) of desired Preamp Cable to be disconnected.
2. Gently pull straight down on the Preamp Cable connector housing until the Preamp Cable connector disengages from the Oximeter Preamp Receptacle.

When the Preamp cable is disconnected from the Oximeter, all Channel ID LEDs on the Preamp housing will turn off.

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Monitoring the Patient

This section assumes that you are familiar with the front panel controls (see Figure 2: Front View on page 20) and the parts of the display screen (see Figure 5: Major Areas of Display on page 24).

Controlling Alarm Volume & Limits

The user can disable audible alarms by pressing the Alarm Silence / Reset button on the Oximeter front panel. Pressing the button disables the audio associated with all alarms for two (2) minutes. This does not affect the visual alarms. See Responding to on page 33 for a list of alarm conditions.

One the two minute audio disable time reaches zero, the audio will be re-enabled, assuming an alarm condition is still present.

The user can re-enable the audible alarms by pressing the Alarm Silence / Reset button on the Oximeter front panel when the audio is currently being disabled.

The user can set the High and Low Alarm limits of acceptable percentages on each channel independently.

The Oximeter shall annunciate an alarm when the Numeric value is below the Low limit or above the High limit. The Oximeter shall generate an alarm sound at the selected volume, indicate an alarm limit violation (text) in the Numeric field as well as flashed the Alarm LEDs at the top of the front display.

Adjusting Alarm Volume & Limits

To view or change the Alarm Volume or Alarm Limits:

1. Touch the Alarm Limit icon on the Main menu (see Figure 6 on page 25).
2. Touch the High/Low Limit icon and the High/Low Limit screen should appear

Alarm Volume

To adjust the Alarm Volume perform the following:

1. Touch the target area entitled “Volume”.
2. A selection of available Alarm Volumes will appear.
3. Touch the desired Alarm Volume, the selection shall be outlined for as long as the selection is touched.
4. Release the selection. The selected Volume shall be updated in the Volume target area.

High & Low Limits

To adjust the Alarm Limits perform the following:

1. Touch the target area entitled “High Limit” to adjust the High limit or “Low Limit” to adjust the Low limit

Note: Each High & Low limit selections shall be adjacent (to the left) of the corresponding channel Numeric

2. Numeric buttons (0-9, accept & backspace) will appear.
3. Enter a 2-digit limit

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The Backspace button may be used to delete the last entered digit

4. After the 2nd digit is entered, the Accept icon should be available, touch to accept.

   If the value entered is valid, the value shall be updated as the appropriate High or Low Alarm Limit (depending on which selection was made) and the numeric buttons shall disappear.

   OR

   If the value entered is invalid, the value shall be displayed as red and the numeric buttons shall remain. The value must be deleted and re-entered as a valid value before proceeding.

Caution: Setting the High Alarm limit to an extreme high value can render the High Limit detection ineffective.

Caution: Setting the Low Alarm limit to an extreme low value can render the Low Limit detection ineffective.

Note: The alarm delay for High and Low limits remains constant during any alarm condition. The alarm delay High and Low limits are factory set to 0 and cannot be altered.

Note: The High Limit cannot be set less than the Low Limit (for the same channel). The Low Limit cannot be set greater than the High Limit (for the same channel). There is always 5% difference between the Low and High limits (same channel).

Saving Alarm Volume and Limits

Once the Alarm Volume and High/Low limits have been entered, perform the following to save them:

Touch Accept icon to accept this Alarm Limit changes.

OR

Touch Cancel icon to discard this channel's Alarm Limit changes.

Note: For proper identification of the Alarm signals generated by the Oximeter, the operator should be positioned directly in the front of the Oximeter, facing the front panel.

Note: To test the Alarm operation, connect a $St0_2$ simulator (available through CASMED) to the patient connection of the Oximeter. Set the High Alarm limits to at least 1% less than the current displayed value and verify the activation of the High limit detection. Reset the High Alarm limits to the desired level. Set the Low Alarm limits to at least 1% more than the current displayed value and verify the activation of the Low limit detection. Reset the Low Alarm limits to the desired level. Testing of the Alarm operation should be done at least once every 6 months.

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Responding to Alarms

Alarm LEDs

High Priority Alarms will flash the Red Alarm LEDs, refer to Figure 2.

High Priority Alarms will be generated over any Medium Priority alarms.

Medium Priority Alarms will flash the Yellow Alarm LEDs.

Medium Priority Alarms will be generated over any Low Priority alarms.

Low Priority Alarms will also turn on the Yellow Alarm LEDs.

Low Priority Alarms will be generated over any Informational alarms.

All Alarm Messages are displayed in the following order:

- High Priority messages will be displayed before any Medium Priority message.
- Medium Priority messages will be displayed before any Low Priority message.
- Low Priority messages will be displayed before any Informational message.

System Messages

Table 1 lists the System Messages in order of priority, the conditions they signify, and the recommended action you should take.

System condition message appear in the System Alarm area, refer to Figure 5 for additional information.

Message	*Condition*	*Recommended Actions*
Medium Priority Alarms (Black on Yellow) - listed highest to lowest		
System Error E##	Internal component failure E##, ## indicates type of Error	If condition persists, contact CASMED customer service
Depleted Battery	Battery needs to be recharged	Plug Oximeter into AC outlet
Internal Temp	Unit is above upper operating temperature	If condition persists, contact CASMED customer service
Low Priority Alarms (Yellow on Black) - listed highest to lowest		
Low Battery	Battery needs to be recharged	Plug Oximeter into AC outlet
Port *X* Comm Lost	Communications problem with bi-directional wired device *X* indicates Port A or B	Inspect the Serial cable connections Make sure the Serial cable connectors are properly engaged Verify the Serial settings are correct Verify target device is turned on and actively displaying information
Informational Alarms (White on Black) - listed highest to lowest		
Connect to AC	AC power loss, Oximeter operating on Battery power	Plug Oximeter into AC outlet Make sure outlet is powered

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Message	Condition	Recommended Actions
Faulty System Fan	Operation of fan faulty	Check for free flow of temperate air around Oximeter Move Oximeter away from wall or other obstruction Move it to a cooler area If condition persists, contact CASMED customer service
Faulty Battery	Battery Pack is incapable of operating unit w/o AC	If condition persists, contact CASMED customer service to replace Battery Pack
Unknown Battery	Problem with Battery Pack Memory or Temp device	If condition persists, contact CASMED customer service to replace Battery Pack
Set Time/Date	Time & Date not set Clock Battery not capable of retaining Time & Date values	Enter Setup screen and set correct Time & Date If condition persists, contact CASMED customer service to replace Clock Battery
Faulty USB/VGA	Problem with VGA and USB Ports	If condition persists, contact CASMED customer service
Faulty Serial Port	Problem with RS-232 ports	If condition persists, contact CASMED customer service
Faulty Front USB	Problem with Front USB Port	If condition persists, contact CASMED customer service
Faulty Rear USB	Problem with Rear USB Port	
Faulty Clock Battery	RTC Battery not capable of storing Time & Date values	If condition persists, contact CASMED customer service

Table 1: System Messages

Note: Priorities of these Alarm Conditions are Factory configured and cannot be altered by the user.

A High Priority auditory signal is characterized by 10 audio pulses repeated every 10 seconds at a frequency of 970 Hz.

A Medium Priority auditory signal is characterized by 3 audio pulses, repeated every 20 seconds at a frequency of 575 Hz.

The Low Priority auditory signal is characterized by 1 pulse at a frequency of 575 Hz.

There is no auditory signal associated with Informational messages, only visual.

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Channel Messages

The message area at the bottom of each Numeric field and are associated with that Channel. Table 2 lists the Channel Messages in order of priority, the conditions they signify, and the recommended action you should take.

Channel condition message appear in the Channel Alarm area(s), refer to Figure 5 for additional information.

Message	*Condition*	*Recommended Actions*
High Priority Alarms (White on Red)		
High StO^2	Reading exceeds user-selected High alarm limit	Assess the patient and physiologic Oximeter to verify the condition and then respond accordingly
Low StO^2	Reading is below user-selected Low alarm limit	Assess the patient and physiologic Oximeter to verify the condition and then respond accordingly
Medium Priority Alarm (Black on Yellow) - listed highest to lowest		
Faulty Preamp	Preamp Cable is defective	If condition persists, contact CASMED customer service to replace Preamp Cable
Preamp Disconnected	Preamp cable has become disconnected	Connect Preamp cable to Oximeter
Faulty Sensor	Sensor is defective	Replace disposable Sensor if necessary
Sensor Disconnected	Sensor has become disconnected	Connect Sensor to Preamp
Sensor Over Temp	Temperature under Sensor is > 41°C	Cooling of patient or environment may be required
Signal out of Range	Sensor on inappropriate object	Remove Sensor from inappropriate object and place on patient
Check under Sensor	Tissue under Sensor may have fluid accumulation/edema	Check patient for edema under Sensor When tissue condition returns to normal range (e.g. patient is no longer edematous)
High Ambient Light	Sensor is not in correct contact with patient	Check that Sensor is in direct contact with skin
Low Priority Alarm (Yellow on Black) - listed highest to lowest		
Incorrect Sensor Size	Sensor is not compatible with the specified Body Location	Use the Sensor recommended for the specified Body Location
External Interference	Interference from outside source	Move Sensor away from interfering source
Sensor Under Temp	Temperature under Sensor < 8 °C	Warming of patient or environment may be required
Informational Alarms (White on Black) - listed highest to lowest		
Ambient Light	Ambient light approaching maximum value	Check that the Sensor is in direct contact with skin
Set Body Location	Sensor connected with no body location assigned	Set Body location for channel

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Message	*Condition*	*Recommended Actions*
Connect Preamp	Connect Preamp to start monitoring channels	Connect Preamp to Oximeter
Connect Sensor	Connect Sensor to start monitoring channel	Connect Sensor to Preamp
Acquiring Data	Channel is acquiring data	Normal operation Wait for message to clear

Table 2: Channel Messages

Note: Priorities of these Alarm Conditions are Factory configured and cannot be altered by the user.

A High Priority auditory signal is characterized by 10 audio pulses repeated every 10 seconds at a frequency of 970 Hz.

A Medium Priority auditory signal is characterized by 3 audio pulses, repeated every 20 seconds at a frequency of 575 Hz.

The Low Priority auditory signal is characterized by 1 pulse at a frequency of 575 Hz.

There is no auditory signal associated with Informational messages only visual.

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Philips IntelliVue Messages

Table 3 below lists the conversion of High, Medium and Low Priority System and Channel Alarm Messages displayed on the Oximeter to the Alarm Message displayed on the Philips IntelliVue:

Oximeter Message	Philips IntelliVue Message
High StO_2	High rSO_2-# [1]
Low StO_2	Low rSO_2-# [1]
System Error Exx Internal Temp Depleted Battery Low Battery	FS Sys Warning
Diff Ch *x* & Ch *y* [2]	Diff StO_2
Faulty Preamp [3] Faulty Sensor	FS-# [1] Error
Preamp Disconnected [3] Sensor Disconnected Sensor Over Temp Signal out of Range Check under Sensor High Ambient Light	FS-# [1] Warning
Incorrect Sensor Size External Interference Sensor Under Temp	FS-# [1] Chk Sensor

Table 3: Oximeter Messages displayed on Philips IntelliVue

Note: Only High, Medium and Low Priority System and Channel Alarm Messages are displayed on the Philips IntelliVue.

Note: Alarm messages displayed the Oximeter may appear different on the Philips IntelliVue due to text length limitations.

[1] # Represents the corresponding Patient Data Channel 1, 2, 3 or 4
[2] Differential Alarm message Ch *x* & Ch *y*, where *x* & *y* represent Patient Data Channel 1, 2, 3 or 4, e.g., ***Diff Ch1 & Ch 2***
[3] Preamp messages will present 2 VueLink messages, 1 for each Preamp channel: 1 & 2 or 3 & 4

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Cleaning

Warning: The Oximeter is designed to be cleaned with soft cloths dampened with cleaning solutions. If the Oximeter or Preamp is accidentally wetted, take it out of operation. It should be thoroughly dried (minimum 1 hour) and have it checked by a service technician before it is used again.

Caution: Do not open the Oximeter to clean it.

Caution: Do not use abrasive cleaners, isopropyl alcohol or organic solvent for cleaning. Use of these cleaners can cause damage, stiffness and brittleness to the Oximeter's surface and to cables and wires.

Cleaning the Oximeter

Examine the Oximeter's case for damage and check the AC power cord for bent or broken prongs, cracks or fraying. Neither the Oximeter nor the AC power cord should be used if damaged. If any damage is noted, contact the appropriate service personnel. Refer to Contact Addresses on page 2 for e-mail and phone number information.

- **Housing:** The Oximeter surfaces may be disinfected using a soft cloth dampened with a 10% (1:10) solution of chlorine bleach in tap water. When all of the surfaces have been disinfected, wipe the entire surface of the Oximeter using a soft cloth dampened with fresh water to remove any trace amounts of residue and/or fumes.
- **Display:** Clean the display window using a soft, lint-free cloth sprayed with an alcohol free glass cleaner. The use of paper towels is not recommended as it may scratch the surface.

Thoroughly wipe off any excess cleaning solutions

Cleaning Preamp Cables

Clean the Preamp Cable using a soft cloth dampened with a 10% (1:10) solution of chlorine bleach in tap water. Do not use alcohol.

Cleaning Sensors

Sensors are not design to be cleaned and/or re-used.

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Maintenance

Warning: No modification of this equipment is allowed.

Caution: Service performed by unauthorized personnel could be damaging to the Oximeter and may void the warranty. For service, contact your CASMED Representative. Refer to Contact Addresses on page 2 for e-mail and phone number information.

The only Oximeter parts requiring preventive inspection and maintenance are the AC Fuse Replacement on page 40 and the Battery Maintenance on page 42.

CASMED will make available on request circuit diagrams, component parts lists, to assist CAS Authorized Service personnel.

Maintenance Intervals

Preventive maintenance of the Oximeter is an important function that should be performed routinely to ensure safe and efficient Oximeter operation. The following maintenance intervals are recommended:

- **Oximeter:** No user calibration is required
- **Battery Pack:** Should be replaced every 2 years

Caution: To maintain proper battery charge, plug the Oximeter into mains power when not in use. Failure to do so may diminish the service life and function of the battery.

Waste Electrical and Electronics Equipment (WEEE)

To facilitate the sound treatment of WEEE, information will be made available for current CASMED products upon request. EU distributors and treatment facility personnel may contact techsrv@casmed.com to obtain relevant information.

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Fuse Replacement

Warning: Before changing any fuse, turn power off, remove battery pack and unplug the AC power cord.

Warning: For continued protection against fire hazard, replace only with identically rated fuses.

Warning: The Oximeter has multiple fuses located inside the Oximeter and Battery Pack. These fuses are not user replaceable. These fuses should only be replaced by CAS Authorized Service personnel.

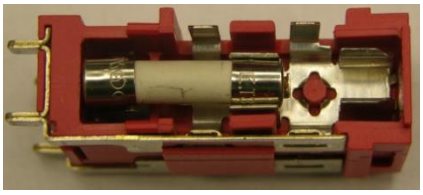
AC Fuse Replacement

The Oximeter has a dual fuse AC power input receptacle. Both AC lines are fused.

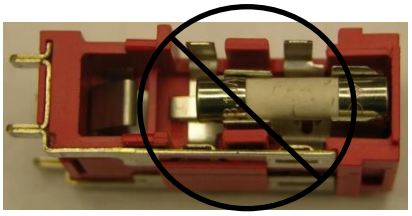
A fuse may need to be replaced if the Oximeter is plugged into an electrical outlet but the AC Power indicator is not illuminated.

To replace the AC power fuses, proceed as follows:

- Turn the Oximeter off and disconnect the AC power cord.
- Using a small screw driver, open the fuse cover on the AC Fuse Compartment (see Figure 3 on page 21).
- Using a small screw driver, pull out the red fuse holder from the AC Fuse compartment.
- Remove the suspect fuse.
- Place the new fuse into the fuse holder as indicated by the orientation (see Figure 11 below).
- Repeat this process for the fuse on the other side of holder.
- Insert the fuse holder back into the power input receptacle (the fuse holder can be inserted in either orientation).
- Close the fuse cover on the AC Fuse Compartment.
- There should be an audible click when it is secured.
- Reconnect the AC power cord back to the Oximeter.



Correct Placement



Incorrect Placement

Figure 11: AC Fuse Placement

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PC Board Fuse Replacement

The Oximeter has fuses located inside the Oximeter.

Below are the locations and ratings for the fuses on the System Control Printed Circuit Board Assembly, CAS PN 03-59-0402:

Ref Des	Rating
F3	F5.00A/125V
F2	F5.00A/125V
F1	F5.00A/125V
F4	F2.00A/125V
F5	F250mA/125V

Figure 12: System Control Board Fuse Locations & Ratings

Below are the locations and ratings for the fuses on the NSAM Printed Circuit Board Assembly, CAS PN 03-50-0450:

Ref Des	Rating
F2	F250mA/125V
F4	F250mA/125V
F1	F2.00A/125V
F3	F125mA/125V
F5	F125mA/125V

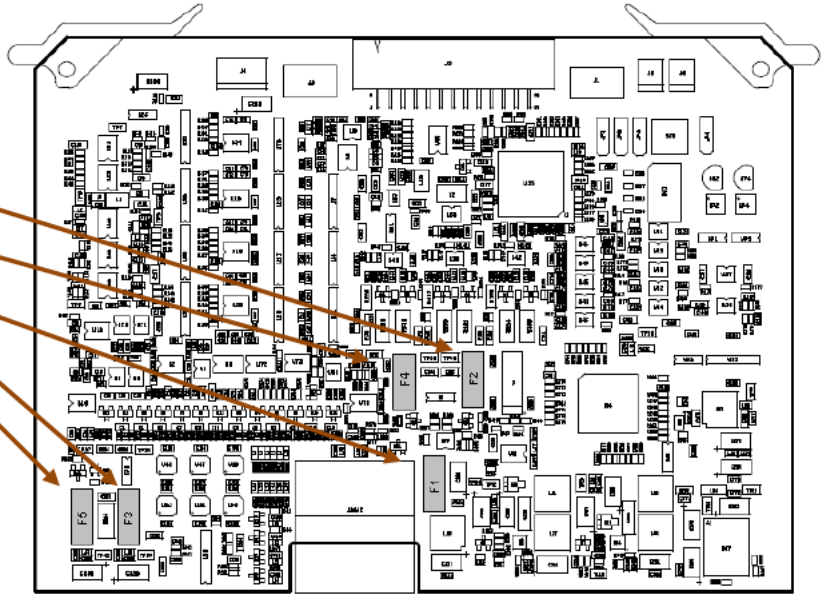

Figure 13: NSAM Board Fuse Placement

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Battery Maintenance

The Battery Pack provides power to operate the Oximeter for up to a half hour (on a new, fully charged battery).

To properly maintain the battery charge level and prolong battery life, the Oximeter should be connected to AC power at all times.

As with all batteries, the capacity will diminish over time. It is recommended that properly maintained batteries be replaced by CASMED service every 2 years.

If Oximeter will not operate for more than 10 minutes on battery power prior to the 2 year replacement interval, then the Oximeter should be returned to CASMED for service and battery replacement.

Installing/Removing the Battery Pack

Warning: Use only the battery pack that is listed in the Accessories, Detachable Parts and Materials section on page 52.

The Battery Pack in the Oximeter is designed to be easily replaced. Turn the Oximeter Off and remove the AC power cord whenever removing or installing a battery pack.

To remove a Battery Pack:

1. Locate the Battery Pack – bottom area of rear of Oximeter (see Figure 3).
2. Loosen the retaining screws on either side of the Battery Pack.
3. Grasp the retaining screws of the battery pack and pull the Battery Pack slightly out of the Oximeter - this will disconnect the Battery pack electrically from the Oximeter.
4. Gently slide the Battery pack out of the remainder of the Battery compartment of the Oximeter.

To reinstall a Battery Pack:

1. Position the Battery Pack with the arrow on outside cover facing up and the two side tabs towards the top of the pack.
2. Gently slide the Battery pack in to the Battery compartment of the Oximeter until a slight resistance if encountered.
3. With equal force on both sides of the Battery Pack, push the Battery Pack into the Battery compartment until the outside of the Battery Pack is flush with the rear of the Oximeter.

Caution: If significant resistance in encountered, do not force the Battery Pack into the Battery compartment. Ensure the arrow on outside cover facing up and the two side tabs towards the top of the pack.

4. Tighten the retaining screws on either side of the Battery Pack. Do not over tighten the screws.
5. With the AC power cord disconnected, press the front panel power button and verify the Oximeter will power on with the Battery Pack installed
6. Reconnect the AC power cord back to the Oximeter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Appendix

Symbols

The following is a summary of all symbols used on the Oximeter and accessories. Symbols may occur on the product or on its packaging. Symbols shall be black unless otherwise indicated.

Symbols on Front of Oximeter

AC power indicator / Charge mode enabled (Green circle)

On / Off

Caution

Symbols on Left Side of Oximeter

(Near the Oximeter Patient Connections)

Patient connections are Type BF

Warning (Yellow background)

Symbols on Rear of Oximeter

Caution

Potential Equalization Post (Grounding Terminal)

This symbol appears here instead of on the Oximeter. The first two digits of the Oximeter's serial number indicate the year of manufacture in the 21st century.

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Indicates this Oximeter is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

Alternating current

Communication port, RS-232 Connector

Video port, VGA Connector

Follow instructions for use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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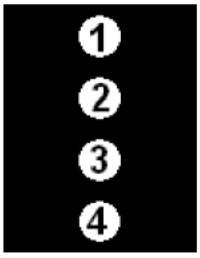
Symbols on Display of Oximeter

Audio Disable State

Temporary Audio Disabled (Yellow bell w/red dotted X) - Indication the Alarm Audio is temporarily disabled

Channel Indicators



Channel 1 (Black number on White circle background)

Channel 2 (Black number on White circle background)

Channel 3 (Black number on White circle background)

Channel 4 (Black number on White circle background)

Body Locations

Left Brain - Frontal lobe (Blue). Position over the left eyebrow, but below the hairline (higher up is best to avoid air sinus).

Left Arm Muscle - (Tan). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

Left Flank Muscle - (Tan). Position over the lateral abdominal wall below the rib cage (rib margins should be palpable or too much adipose or edema maybe present).

Left Leg Muscle - (Tan). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

Right Brain - Frontal lobe (Green). Position over the right eyebrow, but below the hairline (higher up is best to avoid air sinus).

Right Arm Muscle - (Orange). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

Right Flank Muscle - (Orange). Position over the lateral abdominal wall below the rib cage (rib margins should be palpable or too much adipose or edema maybe present).

Right Leg Muscle - (Orange). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

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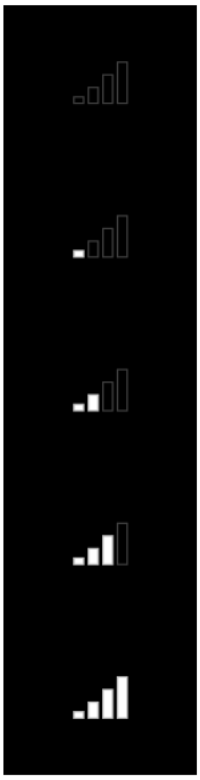
TPI Indicators



NONE (four empty Gray bars) No Sensor or Preamp connected or Sensor and Preamps connected, but Sensor off patient.

POOR (one White-filled bar & three empty Gray bars) Indicates that the Sensor should be moved as monitoring will soon stop. After 10 seconds, this condition triggers the "Check tissue under Sensor" message and $St0_2$ values become two dashes, "--".

FAIR (two White-filled bars & two empty Gray bars) If seen when first placing the Sensor, reposition to achieve a GOOD or EXCELLENT level. If TPI reduces to FAIR during monitoring, verify that the Sensor is well adhered and assess the site for reliability, e.g., edema.

GOOD (three White-filled bars & one empty Gray bar) For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site.

EXCELLENT (four White-filled bars) Ideal monitoring state. For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site.

Actions

Accept (Green) - Accepts changes and return to previous menu.

Cancel (Red) - Discards changes and return to previous menu.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Symbols on Battery Pack

Caution

Recycling suggested

Indicates this Battery pack contains lead (Pb) and is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

Symbols on Oximeter Packaging

Symbol used to indicate the minimum and maximum storage and transport Temperatures.

Refer to Storage/Transport Environment on page 50.

Symbol used to indicate the minimum and maximum relative humidity for storage and transport.

Refer to Storage/Transport Environment on page 50.

Symbol used to indicate the minimum and maximum atmospheric pressure for storage and transport.

Refer to Storage/Transport Environment on page 50.

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Fragile, handle with care

This end up

Symbols on Preamp

Follow instructions for use

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Indicates this Preamp is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

Do not Discard
Intended for Multiple use

Found on the Preamp cable
(Black text & symbol on Green background)

Symbols on Preamp Packaging

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Indicates this Preamp is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

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Symbols on Sensor Packaging

Rx only	In the U.S. the following **Caution** applies
NON STERILE	Non-Sterile
	Storage and transport temperatures
	Use only once
PVC	PVC Free
	Follow instructions for use
Latex	Latex free
	Do not cut or trim Sensor
	Do not apply prolonged pressure to the Sensor
	Manufacturer
LOT	Lot number
CE 0086	The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

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Warranty Policy

All products are sold by CASMED, under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this product directly from CASMED or CASMED's Authorized Distributors as new merchandise and are extended to the first buyer thereof, other than for resale.

The CASMED FORE-SIGHT ELITE Oximeter is warranted for a period of twelve (12) months. All products, if applicable, are warranted to be free from functional defects in materials and workmanship and to conform to the description of the product contained in the User Guide, published specifications, and accompanying labels and/or inserts, provided that the same is properly operated under conditions of normal use in accordance with applicable safety and regulatory requirements, and that replacements and repairs are made in accordance with the instructions provided by CASMED.

The same warranty conditions are made for a period of twelve (12) months with respect to the battery. A ninety (90) days warranty is provided for non-disposable accessories such as reusable Preamp Cables and other accessories provided by CASMED as part of the original purchase. CASMED warrants disposable or single-patient-use products, including Sensors for out-of-box failure only. Where the accessory is not a CASMED manufactured product, the manufacturer's own warranty applies. Warranty of accessories purchased separately from listed suppliers will be the responsibility of such listed suppliers. Damage to any part through misuse, neglect, or accident, or by affixing any accessories or attachments other than CASMED manufactured accessories or attachments, is not covered by this warranty.

The foregoing warranties shall not apply if the product has been configured, modified, adjusted or repaired other than by CASMED or by persons expressly authorized by CASMED, or not in accordance with written instructions provided by CASMED, or if the product has been subjected to misuse, negligence, or accident.

CASMED reserves the right to perform warranty service operations in its own factory, at an authorized repair facility, or at the customers' site. The sole and exclusive obligation of CASMED and Buyer's sole and exclusive remedy under the above warranties, is limited to repairing or replacing, free of charge, a product which is reported in writing or via telephone to CASMED has a Return Material Authorization (RMA) number assigned and which is returned during normal business hours, transporting charges prepaid to:

CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405 USA

Telephone:	+1 203 488 6056
Fax:	+1 203 488 9438
E-mail:	custsrv@casmed.com

CASMED SHALL NOT BE OTHERWISE LIABLE FOR ANY DAMAGES INCLUDING, BUT NOT LIMITED TO, INCIDENTAL DAMAGES, CONSEQUENTIAL DAMAGES OR SPECIAL DAMAGES.

THERE ARE NO EXPRESS OR IMPLIED WARRANTIES WHICH EXTEND BEYOND THE WARRANTIES HEREINABOVE SET FORTH. CASMED MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCT OR PARTS THEREOF.

DRAFT COPY

Oximeter Configuration Record

Serial Number: _____

Date of Purchase: _____

Specifications

Physical Dimensions and Weight

H × W × D: (without feet)	10 in (25.4 cm) × 12 in (30.5 cm) × 9 in (22.9 cm)
Weight:	13.2 lbs (5.9 kg)

Operating Environment

Operating temperature:	10°C (50°F) to 40°C (104°F)
Humidity:	30 to 90% RH, non-condensing
Altitude:	-1,000 ft (106 kPa) to 10,000 ft (68 kPa)

Oximeters may not meet performance specifications if stored or used outside temperature and humidity ranges. When moving an Oximeter from a storage location, wait at least one hour prior to use to allow it to adjust to room temperature.

Measurement

Method:		Modified Beer-Lambert Law Near Infrared Spectroscopy (NIRS)
Information output:		Absolute saturation of tissue oxygenation (StO_2)
Measurement range:		0 to 100%
Display resolution:		1%
Data rates:		Acquisition ≤ 100 Hz, numeric display = .5 Hz
Accuracy:	**Cerebral**	Accuracy not determined < 45%. Oximeter may not be accurate at saturations below 45%.
	Large Sensors	45% to 95%: ±3.05% to 1 standard deviation
	Skeletal Muscle	Accuracy not determined < 45%. Oximeter may not be accurate at saturations below 45%.
	Large Sensors	45% to 95%: ±5.17% to 1 standard deviation

DRAFT COPY

Patient Alarms

Adjustable alarms:	High, Low limits for Ch1, Ch2, Ch3 & Ch4
Alarm indicators:	• Visual • Audible • Text in Channel alarm message window
Audible sound pressure @ 100% Volume	High Priority Alarms: >56db (Fast A) @ 1m in front of Oximeter Medium Priority Alarms: <56db (Fast A) @ 1m in front of Oximeter

Patient Parameter	**Low (Default 40%)**	**High (Default 90%)**
Range: Ch1, Ch2, Ch3, Ch 4	5 to 90%	10 to 95%

Low limits cannot be set above the associated high limit.
High limits cannot be set lower than the associated low limit.
There is a min of 5% difference between the Low and High limit values at any time.

Display

Display:	LCD display of measurement results, instructions, troubleshooting messages, waveforms, and signal strength bar.
Numerics:	1 corresponding to each channel

Storage/Transport Environment

Storage Temperature:	-20°C (-4°F) to 60°C (149°F)
Transport Temperature:	-20°C (-4°F) to 60°C (149°F)
Humidity:	15 to 90% RH, non-condensing
Altitude:	-1,000 ft (106 kPa) to 10,000 ft (68 kPa)

Power

External AC power:	100 to 240 VAC, 50/60 Hz, 1.5A Max (1.5A to 0.75A) Fuse rating: T3.15AH250V (two provided)
Chassis leakage current:	100 µA (maximum)
Heat dissipation:	60 watts (205 BTU/hr)
Battery:	Sealed lead-acid battery
Charge Time:	6 hours
Operating Time:	0.5 hour (minimum with new and properly maintained battery)

Note: The life of batteries is influenced by actual use, temperature, charging & discharging cycles, and mechanical abuse.

DRAFT COPY

Serial Interface

Interface type:	Bi-directional serial communication
Speed:	User-programmable
Signal level:	RS-232C
Data length:	8 bits
Start bit:	1 bit
Stop bit:	1 bit
Parity:	None
Flow control:	None

Standards

Oximeter comply with the following requirements:

CE marking according to Directive 93/42/EEC
IEC 60601-1:2005
IEC 60601-1-2:2007
IEC 60601-1-6:2010
IEC 60601-1-8:2006
ANSI/AAMI ES 60601:2005
ANSI/AAMI IEC 62366:2007
CAN/CSA C22.2 #60601-1

U.S. Patent protected: see www.casmed.com/site-info/patents.cfm

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Parts

Contact our Customer Service department or see our website for the latest product information. Refer to Contact Addresses on page 2 for e-mail and phone number information.

Oximeter

Catalog No.	Description
01-06-3000	(1) FORE-SIGHT ELITE Oximeter
Provided With:	(1) FORE-SIGHT ELITE Dual Preamp (1) FORE-SIGHT ELITE Battery Pack (1) FORE-SIGHT ELITE User Manual (on CD) (1) Hospital Grade AC power cord (country specific) (1) Service Card & Sleeve

Accessories, Detachable Parts and Materials

Catalog No.	Description
01-02-0395	Replacement power cord, North America
01-02-0384	Replacement power cord, U.K.
01-02-0385	Replacement power cord, Australian
01-02-0386	Replacement power cord, European
01-06-3100	FORE-SIGHT ELITE Dual Preamp
01-06-3011	FORE-SIGHT ELITE USB Flash Drive
01-06-3014	FORE-SIGHT ELITE Battery Pack
01-06-3036	FORE-SIGHT ELITE User Manual on CD
01-07-1110	FORE-SIGHT ELITE $St0_2$ Simulator
01-07-2103	FORE-SIGHT ELITE Large Sensor Carton (20 sensors)
01-06-0231	Giraffe®[4] Dovetail Attachment
01-06-0232	FORE-SIGHT 3 inch Utility Basket for 01-06-0234, 01-06-0235 or 01-06-0236 Arms
01-06-0233	FORE-SIGHT 6 inch Utility Basket for 01-06-0234, 01-06-0235 or 01-06-0236 Arms
01-06-0234	FORE-SIGHT 16 inch Arm Wall Mount
01-06-0236	FORE-SIGHT 16 inch Arm Pole Mount
01-06-0238	FORE-SIGHT Roll Stand, with basket & Handle
01-06-0239	FORE-SIGHT ELITE GCX Mounting Plate Kit
The following part require the 01-06-0231 Giraffe Dovetail Attachment:	
01-06-0235	8 inch Arm Giraffe Bed Mount

[4] Giraffe® is a registered trademark of GE Healthcare

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Philips IntelliVue/VueLink Accessories and Options

Description - Purchased directly from Philips:

Philips VueLink Module AUXPLUS PN: M1032A #A05

Philips Interface Cable PN: M1032A #K6C, M1032-61699

Philips contact information:

www.medicalphilips.com	Web
medical@philips.com	E-Mail

Catalog No.	Description
01-06-2133	**FORE-SIGHT** VueLink Extension Cable

Warning: Connection of the Oximeter to a Philips Patient Monitor could result in previously unidentified risks to Patients, or Operators and the User should identify, analyze, and control such risks.

Warning: Changes in the Oximeter to a Philips Patient Monitor connection including changes to configuration, additional or deletion of items and updating or upgrading of equipment could introduce new risks that may require new analysis.

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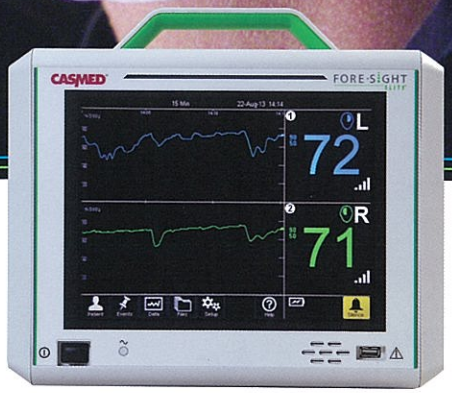
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

"It doesn't make sense, every other parameter indicates good cerebral oxygenation."

Logic dictates that acceptable blood pressure and pulse oximetry readings correlate to adequate oxygenation in the brain. But logic doesn't apply to desaturation events. The only way to be truly certain and avoid the risks associated with these events is accurate cerebral oximetry.



INTRODUCING FORE-SIGHT ELITE™

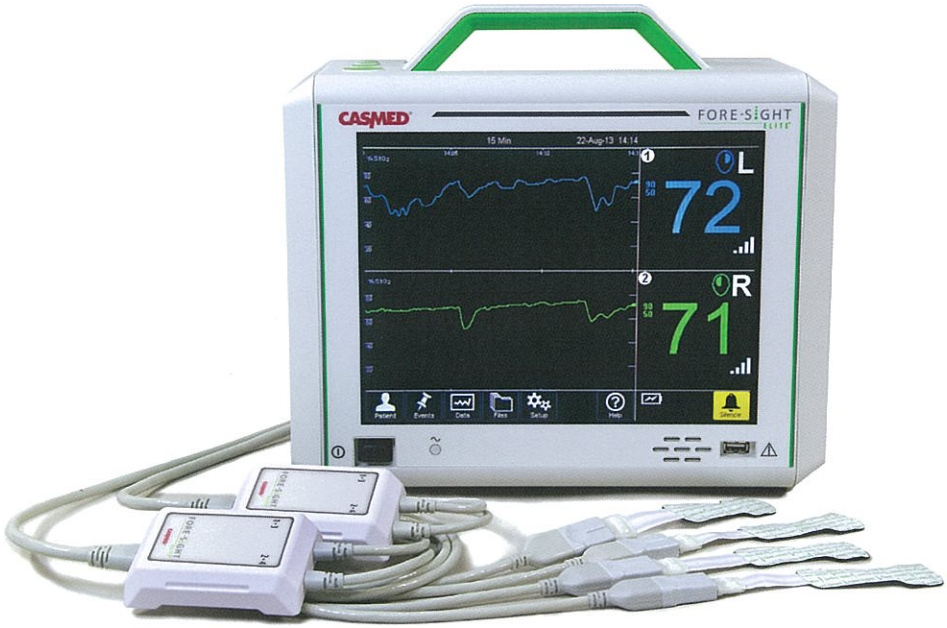
With the introduction of ELITE, CASMED has taken tissue oximetry to the next level and is making it easier than ever to get the kind of accurate and actionable readings you can trust. Building upon the proven accuracy of the FORE-SIGHT algorithm, the ELITE is the first and only FDA cleared tissue oximeter featuring 5 wavelengths of near-infrared light for greater accuracy and enhanced tissue recognition. ELITE is next generation technology designed to deliver a level of confidence that other conventional parameters can not match.

FORE-SIGHT ELITE™
Absolute Tissue Oximetry
from CASMED®

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Desaturation events may defy logic, they don't have to defy detection.



Experience the enhanced performance and ease of use with FORE-SIGHT ELITE to optimize brain protection

- First and only FDA cleared tissue oximeter utilizing a 5th wavelength of near-infrared light to reduce patient variability
- Enhanced FORE-SIGHT algorithm improves accuracy to unprecedented levels (3.05% A_{rms})[1]
- Eliminates the need for pre-induction baseline reading
- Detects otherwise unnoticed cerebral desaturation events
- Wide range of connectivity options with VGA output, Philips IntelliBridge, and EMR Systems

Preamp Cable

P/N: 01-06-3100

Large Sensor

P/N: 01-07-2103 (20 sensors/case)
Adult Cerebral: ≥ 40kg

Monitor Specifications

Absolute Tissue Oxygen Saturation
Range: 0 to 99%
Dimensions: 30.5 cm (12 in) X 25.4 cm (10 in) X 22.9 cm (9 in)
Weight: 5.9 kg (13.2 lbs)

Call our Customer Service toll-free number (800) 227-4414 to contact your local sales representative.

BSI Product is CE Marked

ISO 13485 Certificate Number FM 72259

44 East Industrial Road, Branford, CT 06405 USA
800.227.4414 | www.casmed.com

FORE-SIGHT Absolute Tissue Oximetry ELITE™ from CASMED®

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All other trademarks belong to the companies indicated. U.S. Patents information at www.casmed.com/patents

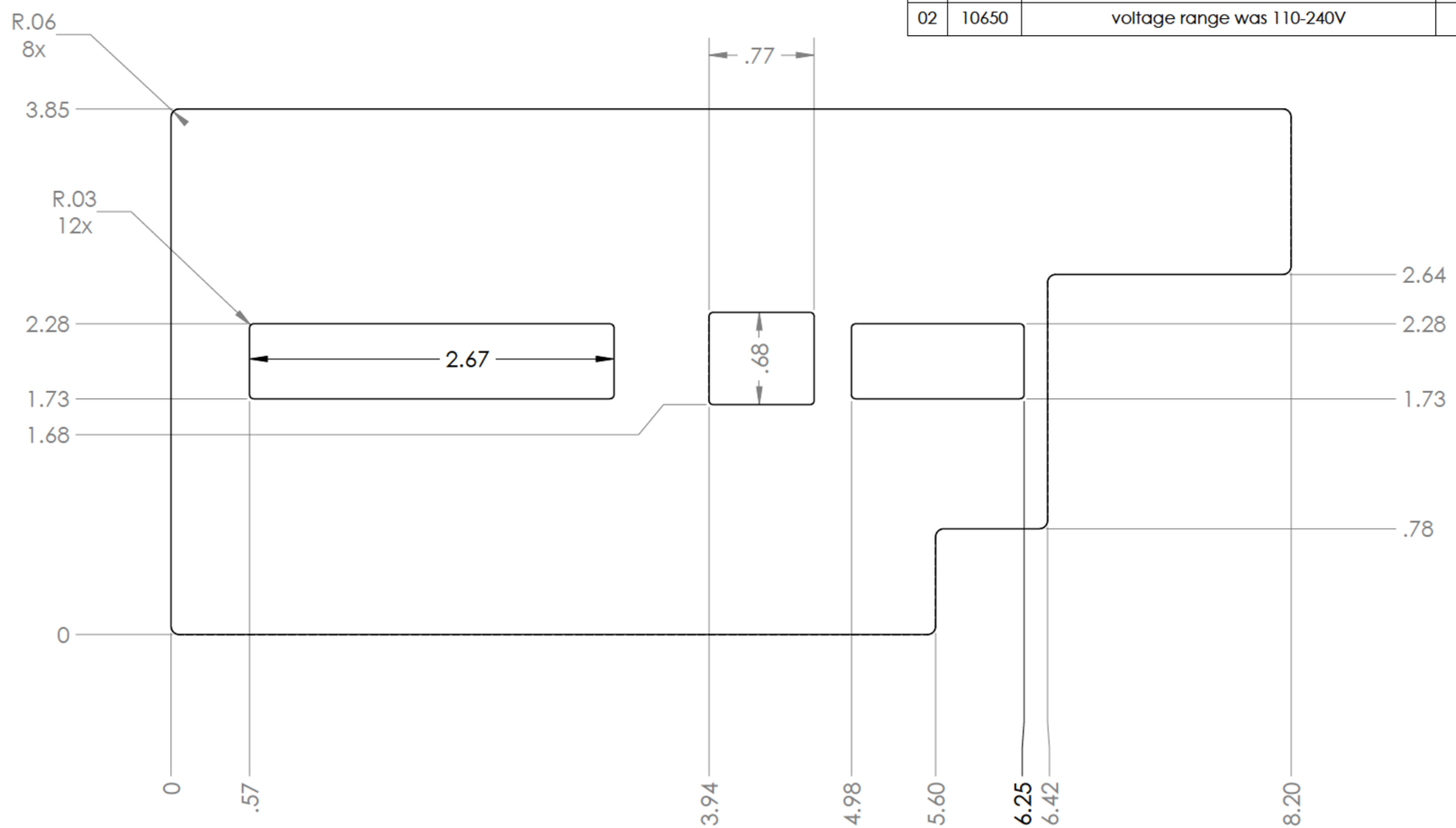
1) Validated accuracy for cerebral measurements on adults ≥40kg

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

21-05-0240 Rev 02

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN #	DESCRIPTION OF CHANGE	BY	DATE	APPROVED
00	10425	INITIAL RELEASE . WAS REV XB	MCC	9-4-2012	HT
01	10497	Interchanged position of "Port A" & "Port B	MCC	2-28-2013	mcc
02	10650	voltage range was 110-240V			



NOTES:

1. MATERIAL: 7MIL LEXAN, VELVET, #8B35
2. ADHESIVE WITH BACKING 3M 468MP
3. GRAPHIC COLORS:
   BACKGROUND OPAQUE PMS WHITE
   GRAPHICS IN BLACK COLOR EXCEPT FOR
   PERSON READING BOOK IN PMS BLUE 287

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—	FS–ELITE
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	±	N/A
2 PLACE DECIMALS	±	.01
3 PLACE DECIMALS	±	.005
ANGLES	±	1°0'

DRAWN	MCC	DATE	4-10-2012
CHECKED	M.Mancini	DATE	9-4-2012
ENGINEER	H.Triebel	DATE	9-4-2012

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTES
FINISH: —

CASMED® FOR WHAT'S VITAL

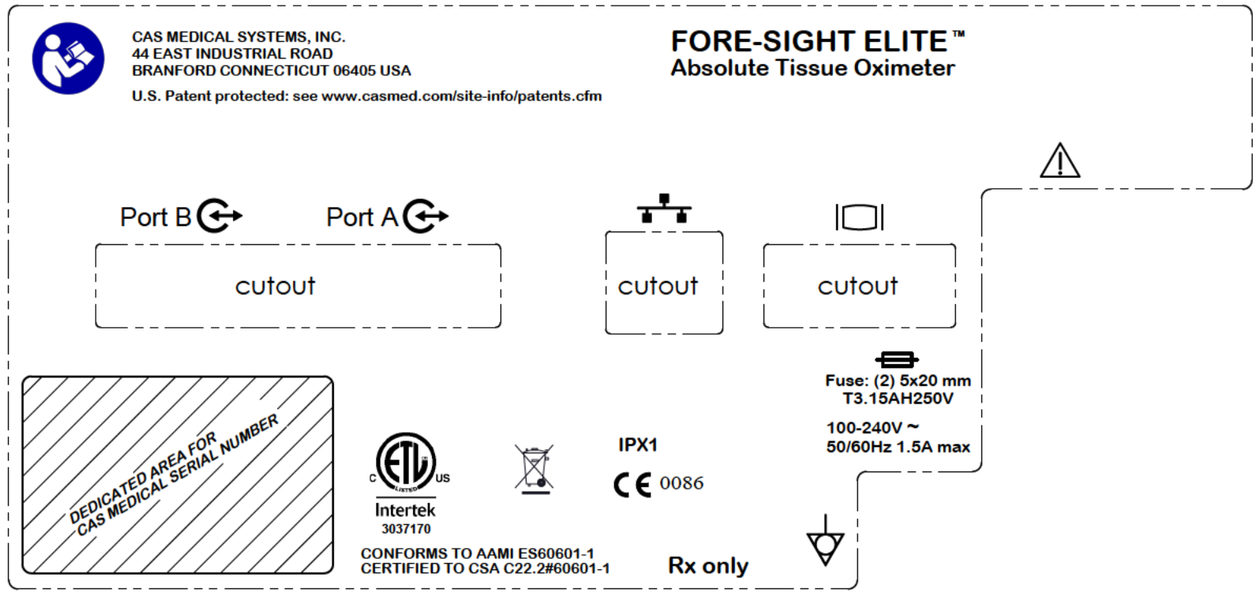
TITLE: **GEMINI REAR PANEL LABEL**

SIZE	DWG. NO.	REV
B	21-01-1978	02

SCALE: 1:1 | DO NOT SCALE DRAWING | SHEET 1 OF 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015



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—	FS–ELITE
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	±	N/A
2 PLACE DECIMALS	±	.01
3 PLACE DECIMALS	±	.005
ANGLES	±	1°0'

DRAWN	DATE
CHECKED	DATE
ENGINEER	DATE

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH

CASMED® FOR WHAT'S VITAL

TITLE: **GEMINI REAR PANEL LABEL**

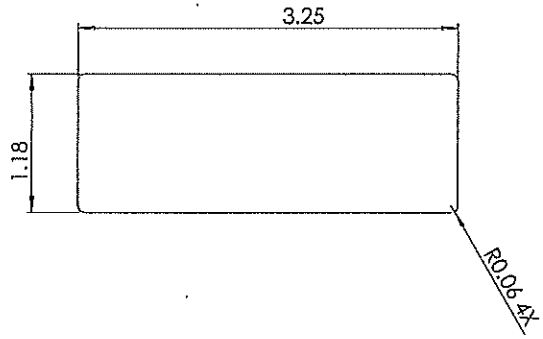
SIZE	DWG. NO.	REV
B	21-01-1978	02

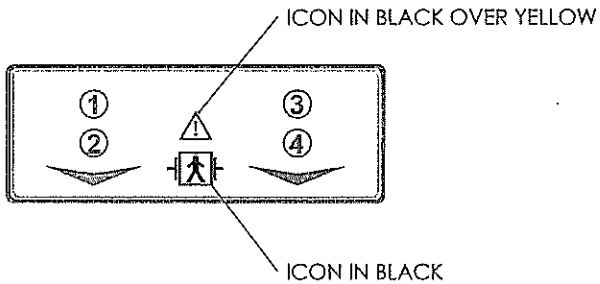
SCALE: 1:1 | DO NOT SCALE DRAWING | SHEET 2 OF 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	BY	DATE	APPROVED
01	10437	INITIAL RELEASE ADDS CAUTION ICON, DEFIB.-PROOF ICON WAS IN COOL GREY 11U			





NOTES:

1. MATERIAL: AUTOTEX V-150, 6 MILS TEXTURED, VELVET POLYESTER
2. ADHESIVE WITH BACKING 3M 468MP
3. GRAPHIC COLORS:
   BACKGROUND OPAQUE PMS WHITE
   GRAPHICS BLACK, YELLOW, PMS GREEN 368U, & PMS COOL GREY 11U

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NEXT ASSY	USED ON
—	

APPLICATION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	±	N/A
2 PLACE DECIMALS	±	.01
3 PLACE DECIMALS	±	.005
ANGLES	±	1°0'

DRAWN Michael Chenoli DATE 10-5-12
CHECKED [illegible] DATE 10/5/12
ENGINEER Michael Chenoli DATE 10-5-12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL | FINISH

CASMED® FOR WHAT'S VITAL

TITLE: GEMINI PATIENT CONN LABEL

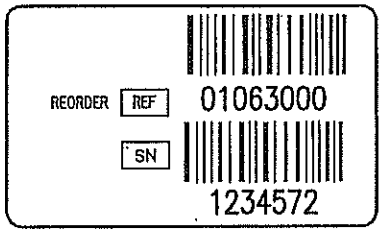
SIZE	DWG. NO.	REV
B	21-01-1979	01

SCALE: 1:1 | DO NOT SCALE DRAWING | SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE		11/12	HMT
01	10479	ADD PN BAR CODE		4/13	4/10/13



EXAMPLE ONLY

NOTES:

1. MATERIAL: METALIZED POLYESTER, 1.2" x 2.0"
2. PRINT COLOR: Black using 21-01-1814 Ribbon
3. ARTWORK: 21-01-2017.btw
4. Make labels using BarTender Software and ZEBRA printer
5. Annotate label if required

Dwg Filename: 21012017-R01

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01-06-3000	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN	MARK MANCINI	DATE	10/11/12
CHECKED	MARK MANCINI	DATE	10/11/12
ENGINEER	HARRY TRIEBEL	DATE	10/15/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTES	SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE: FS ELITE US 01-06-3000 SN Label

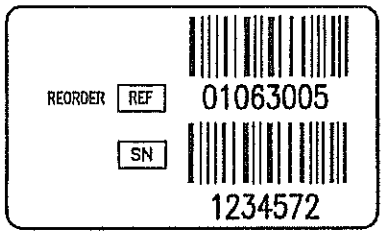
SIZE	DWG NUMBER	REV
A	21-01-2017	01

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE		11/12	HMT
01	10479	ADD PN BAR CODE		4/13	4/10/13



EXAMPLE ONLY

NOTES:

1. MATERIAL: METALIZED POLYESTER, 1.2" x 2.0"
2. PRINT COLOR: Black using 21-01-1814 Ribbon
3. ARTWORK: 21-01-2018.btw
4. Make labels using BarTender Software and ZEBRA printer
5. Annotate label if required

Dwg Filename: 21012018-R01

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01-06-3005	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN	MARK MANCINI	DATE	10/11/12
CHECKED	MARK MANCINI	DATE	10/11/12
ENGINEER	HARRY TRIEBEL	DATE	10/15/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTES	SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE: FS ELITE OUS 01-06-3005 SN Label

SIZE	DWG NUMBER	REV
A	21-01-2018	01

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE			

MANUFACTURED BY: CAS MEDICAL SYSTEMS, INC.
44 EAST INDUSTRIAL ROAD
BRANFORD, CT 06405 USA
(800) 227-4414 (203) 488-6056

REORDER REF 01-06-3000

FORE-SIGHT ELITE
TISSUE OXIMETER - US

CONTENTS	QUANTITY
MONITOR	1 EA.
ACCESSORY KIT	1 EA.

CE 0086

NOTES:

MATERIAL: Direct Thermal Label
Radist 4x3 Perf (179)

PRINT COLOR: BLACK

ARTWORK: 21-01-1981.btw

Make labels using BarTender Software and ZEBRA printer

Annotate label if required

Dwg Filename: 21011981-R00

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01-06-3000	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± 1/16
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN DATE 10/12/12
CHECKED DATE 10/12/12
ENGINEER DATE 10/15/12

DO NOT SCALE - WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTES
FINISH: SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE: FS ELITE US 01-06-3000 Contents Label

SIZE	DWG NUMBER	REV
A	21-01-1981	00

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE			

MANUFACTURED BY:
CAS MEDICAL SYSTEMS, INC.
44 EAST INDUSTRIAL ROAD
BRANFORD, CT 06405 USA
(800) 227-4414 (203) 488-6056

REORDER REF 01-06-3005

FORE-SIGHT ELITE
TISSUE OXIMETER – OUS

CONTENTS	QUANTITY
MONITOR	1 EA.
ACCESSORY KIT	1 EA.

CE 0086

NOTES:

MATERIAL: Direct Thermal Label
Radist 4x3 Perf (179)

PRINT COLOR: BLACK

ARTWORK: 21-01-2020.btw

Make labels using BarTender Software and ZEBRA printer

Annotate label if required

Dwg Filename: 21012020-R00

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NEXT ASSY	USED ON
01-06-3005	FS

APPLICATION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± 1/16
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN DATE 10/12/12
CHECKED DATE 10/12/12
ENGINEER DATE 10/12/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTES
FINISH: SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE: FS ELITE OUS 01-06-3005 Contents Label

SIZE: A | DWG NUMBER: 21-01-2020 | REV: 00

SCALE: 1:1 | SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE			

MANUFACTURED BY: CAS MEDICAL SYSTEMS, INC.
44 EAST INDUSTRIAL ROAD
BRANFORD, CT 06405 USA
(800) 227-4414 (203) 488-6056

REORDER REF 01-06-3014

FORE-SIGHT ELITE BATTERY PACK

CONTENTS	QUANTITY
BATTERY	1 EA.

CE 0086

NOTES:

MATERIAL: Direct Thermal Label
Radist 4x3 Perf (179)

PRINT COLOR: BLACK

ARTWORK: 21-01-1980.btw

Make labels using BarTender Software and ZEBRA printer

Annotate label if required

Dwg Filename: 21011980-R00

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01-06-3000	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± 1/16
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN DATE 10/12/12
CHECKED DATE 10/12/12
ENGINEER DATE 10/12/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTES
FINISH: SEE NOTES

CASMED® FOR WHAT'S VITAL

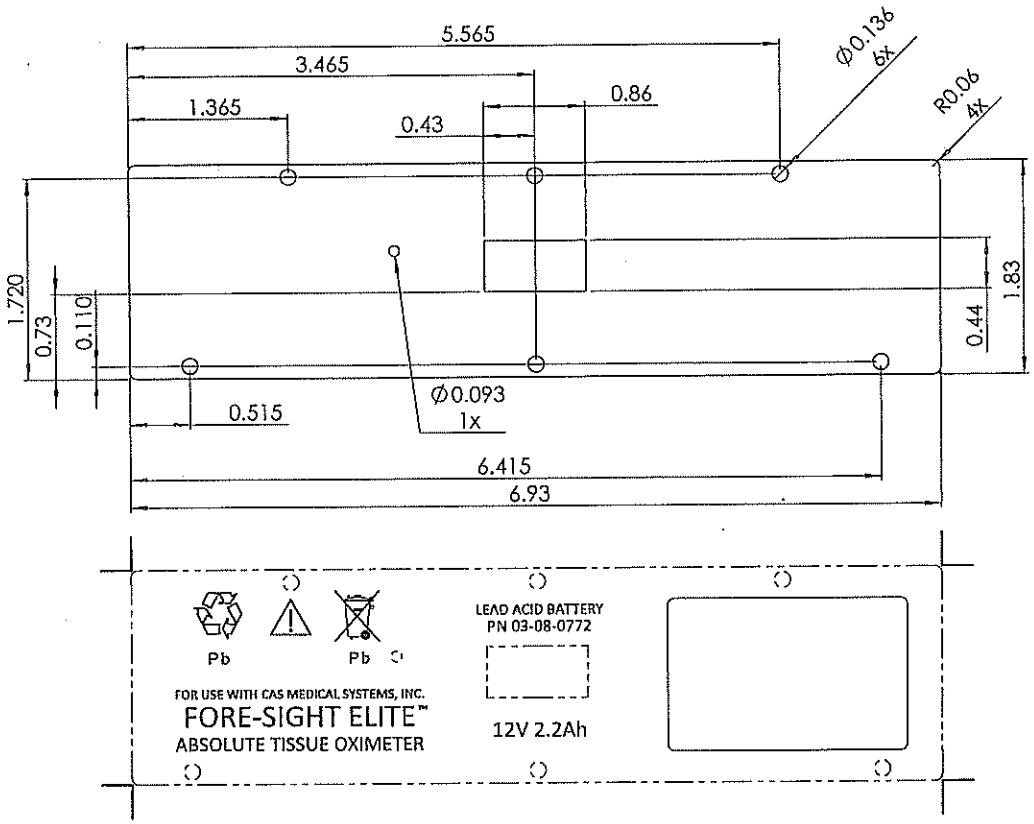
TITLE: FORE-SIGHT ELITE Battery Contents Label

SIZE	DWG NUMBER	REV
A	21-01-1980	00

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015



NOTES:

1. MATERIAL: AUTOTEX V-150, 6 MILS TEXTURED, VELVET POLYESTER
2. ADHESIVE WITH BACKING 3M 468MP
3. GRAPHIC COLORS:
   BACKGROUND OPAQUE PMS WHITE
   GRAPHICS IN PMS COOL GREY 11U

REV	ECN #	DESCRIPTION OF CHANGE	BY	DATE	APPROVED
00	10425	INITIAL RELEASE. WAS REV XD			

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NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	±	N/A
2 PLACE DECIMALS	±	.01
3 PLACE DECIMALS	±	.005
ANGLES	±	1°0'

DRAWN MGC DATE 9/4/2012
CHECKED DATE 9/4/2012
ENGINEER DATE 9/4/2012

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL | FINISH

CASMED. FOR WHAT'S VITAL

TITLE: GEMINI BATTERY LABEL

SIZE	DWG. NO.	REV
B	21-01-1982	00

SCALE: 1:1 | DO NOT SCALE DRAWING | SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10445	NEW RELEASE			
01	10517	ADD BATTERY MFG DATE TO LABEL		4/13	4/4/13

BATTERY–PACK MFG DATE XX/XX/XX
(mm/dd/yy)

WARNING – Use of unapproved batteries will invalidate the product's warranty and may result in serious safety consequences for the patient and user

BATTERY MFG DATE XX/XX/XX
(mm/dd/yy)

NOTES:

1. MATERIAL: 8200S METALIZED POLYESTER
   44A–UN1978 Cils International, 1.2" x 2.0"
2. PRINT COLOR: Black using 21–01–1814 Ribbon
3. ARTWORK: 21–01–2003.btw
4. Make labels using BarTender Software and ZEBRA printer
5. Annotate label if required

Dwg Filename: 21012003–R01

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03–08–0772	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN	M.A. Mancini	DATE	10/11/12
CHECKED	M.A. Mancini	DATE	10/11/12
ENGINEER	H. Triebel	DATE	10/12/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTES	SEE NOTES

CASMED® FOR WHAT'S VITAL

TITLE
FS ELITE Battery Pack Mfg Label

SIZE	DWG NUMBER	REV
A	21–01–2003	01

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Large Sensor - Directions for Use

Warnings

Assess the Sensor site at least every 8 hours, or more often as required by the institution's protocol.
Remove Sensor if the circulatory condition or skin integrity has deteriorated.
Do not lay patient on Sensor or cable.
Do not attach Sensor to skin with unapproved devices, such as headbands, tapes, hats, etc.
Do not place Sensor or accessories over eyes, nose, or mouth.
Do not cut the Sensor. Cutting the Sensor will result in risk of injury to the patient.
Do not use in an MRI environment.

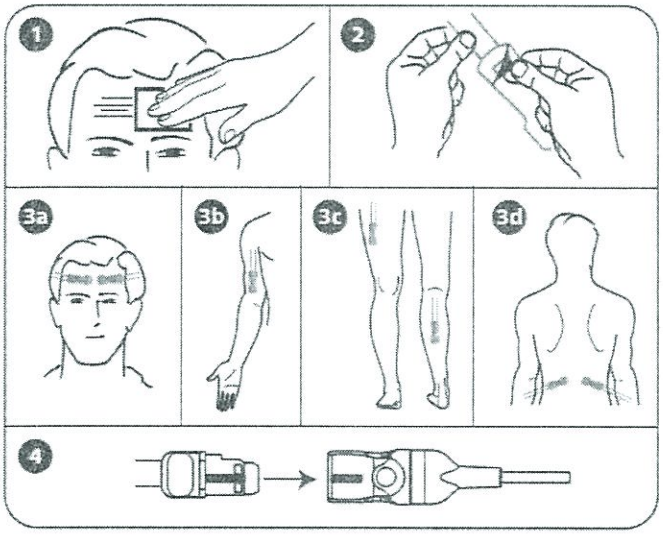
Cautions

Avoid positioning Sensor over hair or air sinus.
Avoid attaching Sensor to sites with excess adipose, ascites, or edema.
The materials used in the manufacture of the Sensor were not designed for reuse. Reuse may cause the Sensor not to perform as intended.

Instructions

1. Remove the Sensor from the package. Carefully inspect the Sensor for damage. Discard and replace Sensor if damage is found.
2. Select Sensor location on the monitor and patient.
   - Cerebral Use: Select the site on the forehead above the eyebrow and just below the hairline where the Sensors will be linearly aligned.
   - Somatic Use: Select the site that provides the ideal access to the desire skeletal muscle tissue (over biceps, brachioradialis, deltoid, quadriceps, tibialis, soleus, external oblique or latissimus dorsi, below the rib cage).
3. Clean and dry Sensor site. (1)
4. Remove white backing from the Sensor. (2)
5. Apply Sensor to patient. (3a,3b,3c,3d)
6. Insert the connector straight into the Preamp Sensor connector until it snaps into place. (4)
7. For further instructions on how to begin monitoring, consult the User Manual.

For use with FORE-SIGHT ELITE Absolute Tissue Oximeter. Refer to FORE-SIGHT ELITE User Manual for additional instructions



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

PRINTER NOTES:
Purple, orange and yellow keylines
DO NOT PRINT

PMS 368C

FORE-SIGHT ELITE™

Absolute Tissue Oximetry

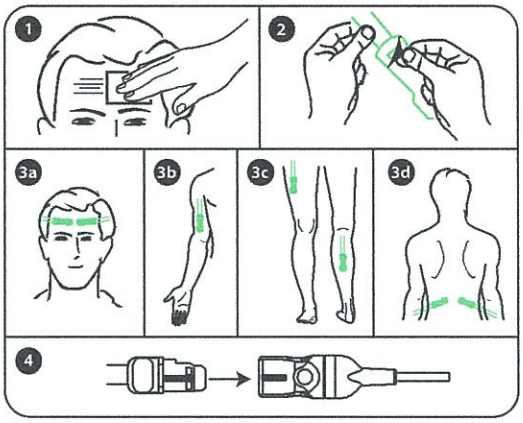
LARGE SENSOR

x1

REF 01-07-2103

≥ 40 kg

SP: Sensor Grande
FR: Capteur Grand
PT: Sensor Grande
IT: Sensore Grande
TR: Büyük Sensör
NL: Grote Sensor
DE: Großer Sensor
RU: Большой Сенсор
DA: Stor Sensor
EL: Μεγάλου Μεγέθους
PL: Duży Czujnik
FI: Suuri Anturi
NO: Stor Sensor
CS: Velký snímač
SV: Stor Sensor
SK: Návod na použitie
HU: Kis méretű érzékelő
AR: مستشعرات كبيرة
CN: 大号探头
JP: 大型センサー



Rx only NON STERILE 50°F 10°C 90°F 32°C CE 0086

PVC Latex

Notice: This kit is sold under the following U.S. Patents and foreign equivalents for single patient use only: 6,456,862; 7,047,054; 7,072,701; 7,313,427. U.S. Patents Pending.

(01) 1 0609538 72103 5

CASMED®
44 East Industrial Road,
Branford, CT 06405 USA
www.casmed.com
800.227.4414

05-02-0188 REV03
04-02-0194

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

FORE-SIGHT ELITE™

Absolute Tissue Oximetry

x20

LARGE SENSORS

REF 01-07-2103

≥ 40 kg

SP: Sensor Grande	NL: Grote Sensor	PL: Duży Czujnik	SK: Návod na použitie
FR: Capteur Grand	DE: Großer Sensor	FI: Suuri Anturi	HU: Kis méretű érzékelő
PT: Sensor Grande	RU: Большой Сенсор	NO: Stor Sensor	AR: مستشعرات كبيرة
IT: Sensore Grande	DA: Stor Sensor	CS: Velký snímač	CN: 大号探头
TR: Büyük Sensör	EL: Μεγάλου Μεγέθους	SV: Stor Sensor	JP: 大型センサー

EC REP

MediMark® Europe.
11 rue E. Zola 38100
Grenoble. France

90°F 32°C
50°F 10°C

Rx only

CE 0086

(01) 1 0609538 72103 5

CASMED®

44 East Industrial Road,
Branford, CT 06405 USA
www.casmed.com
800.227.4414

05-02-0190 REV02
21-01-2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

MW P/N: LB1059

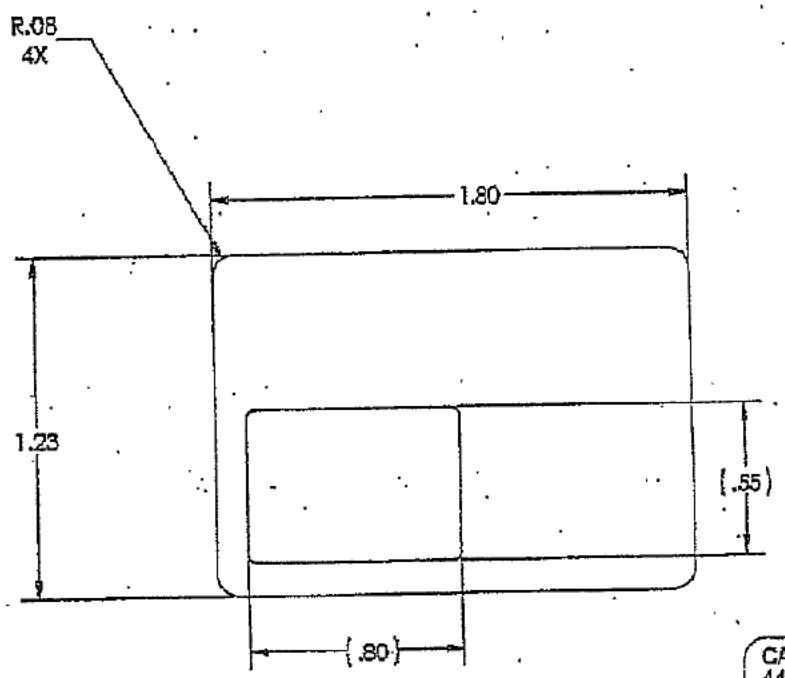
PART NAME: LABEL REV: B

DATE INITIATED: 7/3/12 BY: H. SCHNOBRICH CHK BY: BILL WHELAN

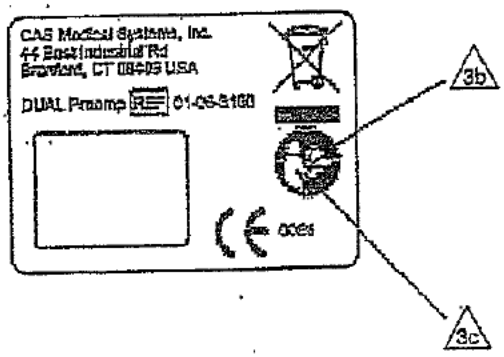
DESCRIPTION: DUAL PREAMP BTM LABEL

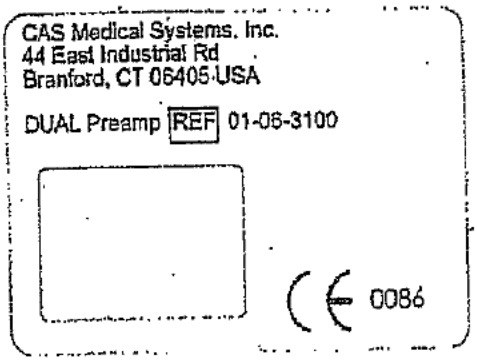
M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
ST.PAUL STAMP WORKS	M	MINNE065-33047-2



9 of 25





NOTES:

1. MATERIAL: .002" MATTE SILVER MYLAR
2. ADHESIVE: .001" ACRYLIC FLEXCON V-23
3. COLOR:
   a. TEXT BLACK
   b. BACKGROUND, "INST. FOR USE" SYMBOL (ISO-7010-M002): BLUE, PMS 287
   c. ICON, "INST. FOR USE" SYMBOL: WHITE

REV	DATE	INITIALS	DESCRIPTION
B	10/17/12	BW/JS	SEE ECN #2135
A	7/27/12	BN	RELEASED

REVISIONS

1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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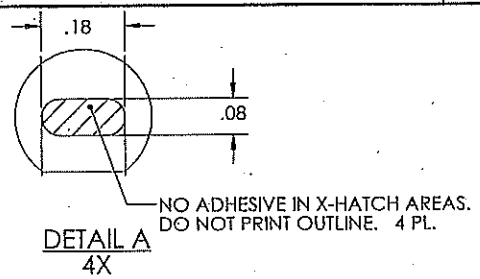
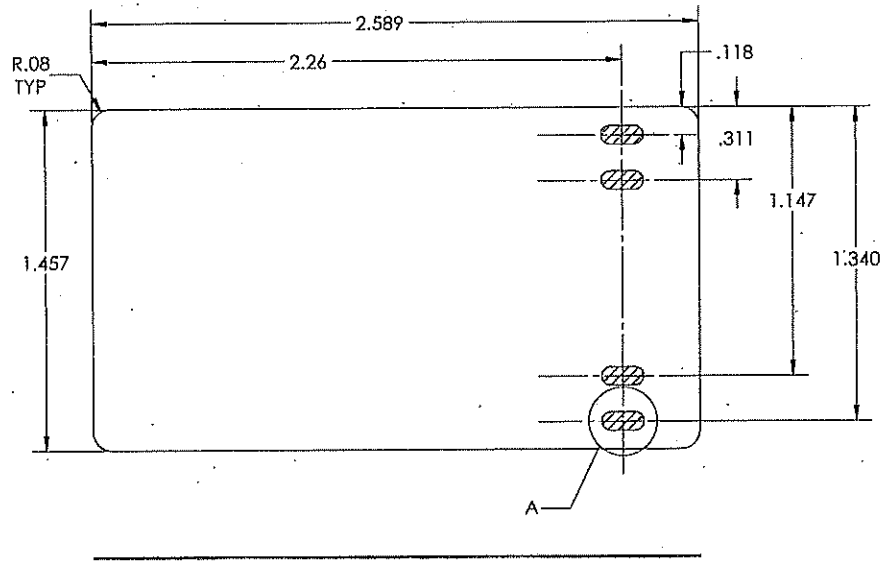
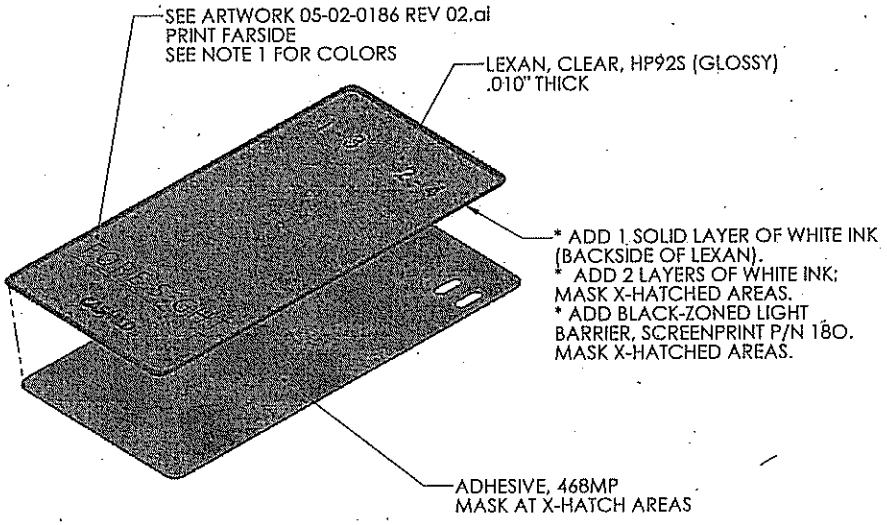
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

REVISIONS

REV.	ECN #	DESCRIPTION	DRAFTER	DATE	APPROVED
00	10408	NEW RELEASE			
01	10429	CHANGE ARTWORK TO MOVE CHANNEL DESIGNATIONS; REMOVE 'NO BORDER AROUND WINDOWS' NOTE			
02	10515	CHANGE SEQUENCE OF NUMBERS. CHANGE ARTWORK AND CONSTRUCTION TO IMPROVE AESTHETICS; ELIMINATE GREEN BORDER	RA	4/10/13	







NOTES:

1. GRAPHICS COLORS:
   - BACKGROUND COLOR: OPAQUE WHITE.
   - NUMBERS: BLACK
   - GREEN DOTS AND 'ELITE': PMS 368 U
   - RED 'CASMED' LOGO: PMS 193 U
   - OTHER TEXT AND BORDER: PMS COOL GREY 11U
2. FINAL PRODUCT TO BE RoHS COMPLIANT.
3. ARTWORK REGISTRATION TO LABEL: +/- .015"

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NEXT ASSY	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .010
ANGLES	± 1°0'

DRAWN	RABRAMS	DATE	09/30/11
CHECKED	K.DUFFY	DATE	6/15/12
ENGINEER	RABRAMS	DATE	6/15/12

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTES	SEE NOTES

CASMED® FOR WHAT'S VITAL

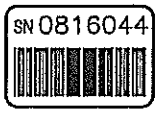
TITLE PREAMP. TOP LABEL WITH DEADFRONT

SIZE	DWG NUMBER	REV
B	21-01-2008	02

SCALE 4:1 SHEET 1 OF 1

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	8137	NEW RELEASE			
01	9337	ADDITION OF BARCODE TO LABEL	LD	11/14/08	[illegible]



LASER PRINTER
(EXAMPLE ONLY)

NOTES:

1. MATERIAL: 1/2 x 3/4" METALIZED POLYESTER LASER LABEL
   # AL4-9200-5
2. PRINT COLOR: BLACK
3. ARTWORK: 21-01-1801.btw
4. FOLLOW LABEL PROCEDURE WP2054
   * FOUND IN "BARTENDER" IN THE FORE-SIGHT FOLDER
   * LABEL IS PRINTED ON A LASER PRINTER ON MATERIAL SPECIFIED ABOVE.
   * 8 DIGIT SERIAL NUMBER USED IN FORMAT: YYMMXXXX WHERE "XXXX" IS A SEQUENTIAL NUMBER.
   * BAR CODE REQUIREMENTS

Dwg Filename: 21011801-R01

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03-08-0695F	FS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN	Donna LeMontague	DATE	01/22/07
CHECKED	Ron Jeffrey	DATE	01/26/07
ENGINEER	Gus Lopez	DATE	01/26/07

DO NOT SCALE – WORK TO DIMENSIONS SHOWN.
REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL	FINISH
SEE NOTE #1	N/A

CASMED® FOR WHAT'S VITAL

TITLE
PREAMP BOX SERIAL NUMBER

SIZE	DWG NUMBER	REV
A	21-01-1801	01

SCALE 1:1 SHEET 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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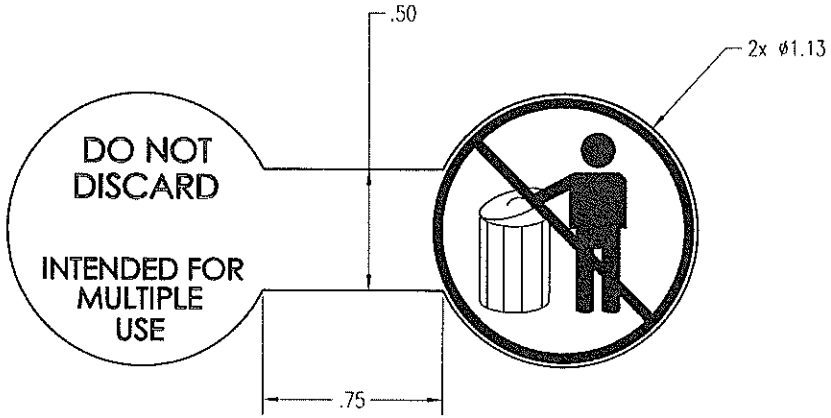
REV	ECN	DESCRIPTION	DRFT	DATE	APPV'D
00	10050	NEW RELEASE			



NOTES:
1.MATERIAL:3M 7908 LABEL MATERIAL
2.COLORS:TEXT AND GRAPHICS–BLACK
BACKGROUND–PMS 368 GREEN

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NEXT ASSY	USED ON
03-08-0760CF	FS
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES. DIMENSIONS IN BRACKETS ARE MILLIMETERS

FRACTIONS	± N/A
2 PLACE DECIMALS	± .01
3 PLACE DECIMALS	± .005
ANGLES	± 1°0'

DRAWN R.ABRAMS DATE 07/20/2010
CHECKED DATE 7/30/10
ENGINEER DATE 7/30/10

DO NOT SCALE – WORK TO DIMENSIONS SHOWN. REMOVE BURRS, BREAK SHARP EDGES & CORNERS.

MATERIAL: SEE NOTE
FINISH: N/A

CASMED® FOR WHAT'S VITAL

TITLE: NEUROSAT DO NOT DISCARD LABEL
MONITOR CABLE LABEL

SIZE: B | DWG NUMBER: 21-01-1966 | REV: 00
SCALE: 1:1 | SHEET 1 OF 1

Dwg Filename: 21011966-R00

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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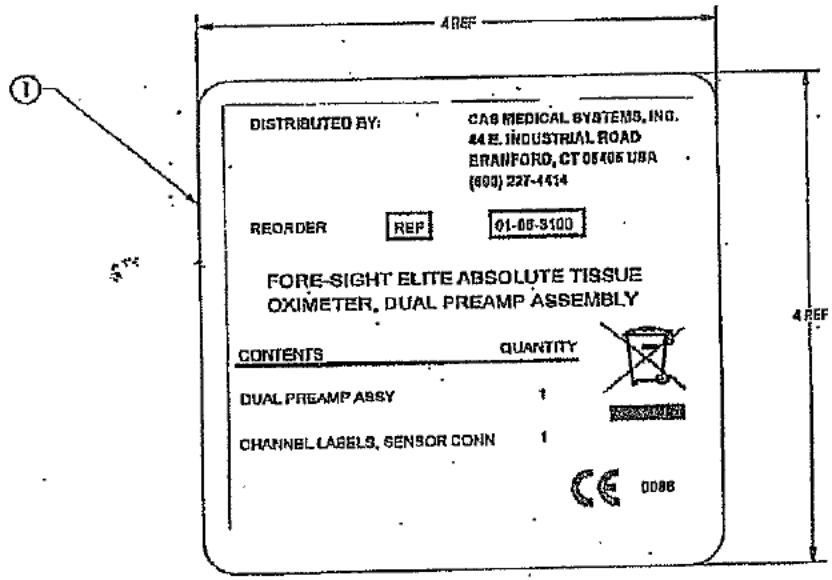
REVISIONS			
REV	DATE	INITIALS	DESCRIPTION
A	10/9/12	SS	RELEASED FOR PRODUCTION

PARTS LIST						
ITEM	QTY	DESCRIPTION	SERIES	PART NO	COLOR	MATERIAL
1	1	BLANK LABEL		LB471	WHITE	



NOTES:

1) BLACK TEXT ON WHITE BACKGROUND

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PROJECTION

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO

DRAWN BY B.WHELAN	DATE 10/1/12	TITLE LABEL, BAG FOR C726	N/A
APPROVED BY S. SOUTE	DATE 10/9/12		REV A
MANUFACTURING	DATE 10/9/12		
QUALITY	DATE 10/9/12	NAMECO CASMED	SHEET 1 OF 1
			DWG NO LB1076

(b)(4) [redacted]

18 OF 25

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

15. Sterilization and Shelf Life

No part of the FORE-SIGHT Elite™ Absolute Tissue Oximeter system or its accessories is sterilized.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

16. Biocompatibility

SENSOR BIOCOMPATIBILITY DATA

Note: Conditions of contact per ISO 10993-1: Intact skin for a prolonged period.

All sensor assemblies have been used on subjects during clinical trials. There are no reported incidents of adverse reaction. The information below represents the large Elite sensor.

Sensor Component	Testing	Pass / Fail	Documentation Enclosed & Comment
Clear (b)(4) [redacted] sensor optical components	- CAS arranged lab testing May 2012	Pass	Cytotoxicity Report # SDWH-2012-20304; Skin Sensitization Report # SDWH-2012-20305 and 6; Skin Irritation Report # SDWH-2012-20307.
Sensor bottom surface foam adhesive	Complete skin safety testing done by adhesive manufacturer 3M	Pass	3M Product Clinical Data Summary – Product Number (b)(4) [redacted]. Two page summary of positive testing results. In addition, this material has been used on CAS predicate devices for 6-years without incident.
Sensor bottom foam (b)(4) [redacted]	Manufacturer Lab testing and CASMED Lab testing for Cytotoxicity	Pass	(b)(4) [redacted] – Specification # 17-038 pg. 2 – Primary Skin Irritation; CAS Medical Systems, Inc. – Cytotoxicity Test Report #05-02163. In addition, this exact material has been used on CAS predicate devices for 6-years without incident.
Sensor top cover (b)(4) [redacted]	Complete skin safety testing done by vendor DuPont	Pass	DuPont Medical Packaging – Technical Reference Guide. Pg. 14 Biocompatibility.
Sensor tail laminate (b)(4) [redacted]	Complete skin safety testing done by vendor (b)(4) [redacted]	Pass	(b)(4) [redacted] Company – Biocompatibility Data Summary.
Molded connector housing – (b)(4) [redacted] c (b)(4) [redacted] - (b)(4) [redacted]	Complete skin safety testing done by vendor (b) [redacted] c	Pass	(b)(4) [redacted] Biocompatibility Statement and Test Reports
Sensor Gasket	Complete skin safety testing done by foam manufacturer 3M	Pass	(b)(4) [redacted] (b)(4) [redacted] Biocompatibility Report

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

证书编号：2010100305S

TESTING
CNAS L2954

Testing Center of Sanitation & Environment technic Institute, Soochow University, Test Report

Report Number: SDWH-2012-20304

Sample Name: (b)(4) [redacted]

Test Performed: Cytotoxicity Test

Sample Supplier: (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

TABLE OF CONTENTS

Page number

Title Page....1

Table of Contents....2

Supplementary Explanation....3

Signature Page....4

1.0 Summary....5

2.0 Introduction....5

3.0 Test System and Test System Management....5

4.0 Justification for Selection of Test System....5

5.0 Materials....5

6.0 Test Method....6

7.0 Results....7

8.0 Conclusion....9

9.0 Record Storage....9

10.0 Confidentiality Agreement....9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUPPLEMENTARY EXPLANATION

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Testing Center of Sanitation & Environment Technic Institute

Soochow University

Test Report

Sample name	(b)(4) [redacted]
Sample supplier	[redacted]
Model No./Size	Not Supplied
Lot No	Not Supplied
Part Number	P/N：52-0560
The information above is provided by sample supplier.	
Test Performed	Cytotoxicity Test
Receiving Date	Feb 10, 2012
Technical Initiation Date	Feb 14, 2012
Technical Completion Date	Feb 17, 2012
Sample Image	[redacted]

Edited by: Gu Yunlan

Checked by: [illegible]

Approved by: Zhang Tongcheng

Testing Center of Sanitation & Environment technic Institute, Soochow University

Date: [illegible] 2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.0 Summary

The test article (b)(4) [redacted] was evaluated in a cytotoxicity test in accordance with the ISO 10993-5:2009: Tests for In Vitro Cytotoxicity The testing test article extract was added to growth media containing L-929 cells, and then incubated in 96 well plates for 24h at 37℃ in 5% CO_2. Intracytoplasmic granulation and cell lysis were observed in the test article extract-treated cells. The MTT method was used to determine the potential cytotoxicity. The results showed that the cytotoxicity ratio of the 100 % extract of the test article extract was 88.9%, the 50 % extract of the test article extract was 90.5% the negative control was 96.1%, and the positive control cytotoxicity ratio was 1.9%.This meant that the cytotoxicity test was valid and the test article extract had no toxicity to L-929 cells in this study.

2.0 Introduction

The test article was evaluated for cytotoxicity in accordance with ISO 10993-5:2009: Tests for In vitro Cytotoxicity. The purpose of this study was to determine the potential cytotoxicity of the test article extract to L-929 cells.

3.0 Test System and Test System Management

L-929 mouse fibroblast cells, (American Type Culture Collection CCLI (NCTC clone 929), were obtained from American. The cells were grown in Minimal Essential Media (MEM) with 10% fetal bovine serum (10% FBS). Cells were seeded into the 96-well cell culture plates, and incubated at 37℃ in a humidified incubator with 5% CO_2 to obtain a confluent monolayer of cells prior to use. Aseptic procedures were used in the handling of cell cultures.
Personnel: Associates involved were appropriately qualified and trained.

4.0 Justification for Selection of Test System and Route of Administration

Mammalian cell culture monolayer, L-929 mouse fibroblast cells (American Type Culture Collection CCLI (NCTC clone 929), were used. In vitro mammalian cell culture studies have been used to historically evaluate the cytotoxicity of biomaterials of medical device.
The test article was extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system. This was the optimal route of administration available in this test system as recommended in the ISO 10993-5 guidelines.

5.0 Materials

5.1 Control Articles
5.1.1 Negative Control:
Name: High density polyethylene
Lot No: H0F046
Physical State: Solid

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Color: White
Stability: Stable at room temperature
Storage Conditions: Room temperature

5.1.2 Positive Control:
Name: MEM medium, with addition 10% FBS and 0.5 % phenol (Lot No: 862839)
Physical State: Liquid
Color: Red/Pink
Stability: Stable
Storage Conditions: 4 ± 2 ℃

5.1.3 Blank Control:
Name: MEM medium (Lot No: 862839), with addition 10% FBS
Physical State: Liquid
Color: Red/Pink
Stability: Stable
Storage Conditions: 4 ± 2 ℃

5.2 Equipments
Autoclaves (SDWH-327)
CO_2 Incubator (SDWH-021)
Inverted microscope (SDWH-037)
Super clean working desk (SDWH-047)
Refrigerator (SDWH-448)
Power Wave XS Microplate Reader (SDWH-312).

5.3 Reagents
MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide) (Lot No: 0793)
FBS (Lot No: 8143029)
Trypsinase (Lot No: 774748)
Penicilline, Streptomycin sulfate (Lot No: 773135)
MEM (Lot No: 862839)
99.9%Isoopropanol (Lot No: T20101123).

5.4 Cell Strain
L-929 mouse fibroblast cells, American Type Culture Collection CCLI (NCTC clone 929).. L929 mammalian fibroblast cells are storaged at -80℃ by SDWH.

6.0 Test Method

6.1 The test article Extracts Preparation
The sterilized test article was put into a culture flask, and MEM medium (10%FBS) was then added, finally the flask was sealed, and the sample was extracted at 37℃ and 5% CO_2 for 24h to obtain the

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sample extract. The blank control, negative control and positive control were prepared simultaneously by the same extraction method.

Extraction ratio	Actual sampling	Extraction conditions	The pH value of the final extract	Whether the extract is clear or not
$6cm^2$: 1ml	$42cm^2$: 7.0ml	37℃, 5% CO_2,24 h	7.0	Clear

6.2 Control Preparation

Negative control: High density polyethylene +MEM medium, with10% FBS and 37℃,5% CO_2 for 24 hours.

Positive control: MEM medium, with 10%FBS and 0.5 % phenol and 37℃,5% CO_2 for 24 hours.

Blank control: MEM medium, with 10% FBS and 37℃,5% CO_2 for 24 hours.

6.3 Cell Culture

L929 cells were cultured in MEM medium, supplemented with 10% FBS at 37℃ in a humidified atmosphere of 5% CO_2. L929 cells were digested by using 0.5% trypsin containing EDTA.The single-cell suspension was diluted to 1×10^5 cells/ml. The suspended cells were dispensed at 100μl per well in 96-well plates. After the cells grew to form a monolayer, the original culture medium was discarded, The 96 well plates were then treated with 100μl of the test article extract. Control wells were treated with , positive control solution and negative control solution. Five replicates of each test and control article were tested.

6.4 Cell Morphological Observation and Evaluation of Cytotoxicity

The test article and control article treated plates were incubated for 24 hours at 37℃ in a humidified atmosphere of 5% CO_2. Cell morphology was evaluated to verify that the monolayer was satisfactory. A 50μl aliquot of MTT (1mg/mL) was added to each well. The cells were incubated for 2 hours at 37℃ in a humidified atmosphere of 5% CO_2. The liquid in each well was tipped out and 100 μl 99.9% isopropanol was added to each well to suspend the cell layer.

Test article extract suspensions were evaluated with a dual-wavelength spectrophotometer, with the measurement wavelength at 570 nm and reference wavelength at 650 nm. The blank controls, negative controls and positive controls were tested as described in the above method.

The cell cytotoxicity ratio of the negative control group, positive control group and sample group were determined by the following formula:

The cell cytotoxicity ratio=[$\bar{O}D570$-$\bar{O}D650$] of sample group(or [$\bar{O}D570$-$\bar{O}D650$] of positive control group)/ [$\bar{O}D570$-$\bar{O}D650$] of blank control group×100%.

7.0 Results

The observation of the morphology in this experiment are showed Table 1.

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Table 1 Observation of the Cell morphology

Group	Before inoculation	Before exposed to the test group in 96-well plates	24h after exposed to the test group in 96-well plates
blank	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
negative control			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
positive control			Nearly complete or complete destruction of the cell layers.
100% test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
75% test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
50% test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
25% test article extract			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.

Results in this experiment are showed Table 2.

Table2 : Results of the Cell Vitality

Group	$\bar{OD}$570±SD	Viability.%
blank	0.589±0.013	100%
negative control	0.575±0.009	96.1%
positive control	0.011±0.001	1.9%
100% test article extract	0.531±0.007	88.9%
75% test article extract	0.536±0.009	89.6%
50% test article extract	0.542±0.014	90.6%
25% test article extract	0.562±0.016	93.9%

According to ISO 10993-5:2009, if viability is reduced to < 70 % of the blank, it has a cytotoxic potential. The 50 % extract of the test sample should have at least the same or a higher viability than

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the 100 % extract, otherwise the test should be repeated.
The test article extract was mixed a suspension of L-929 cells, and then incubated for 24 hours at 37℃ in a humidified atmosphere of 5% CO_2.The MTT method was used to measure the cytotoxicity ratio, and the result for the 100 % test article extract was 88.9%.

8.0 Conclusion

Under the conditions of this study, the results showed the test article extract had no toxicity to L-929 cells.

9.0 Record Storage

All raw data pertaining to this study and a copy of the final report are retained in designated SDWH archive.

10.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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证书编号：2010100305S

TESTING
CNAS L2954

Testing Center of Sanitation & Environment technic Institute, Soochow University, Test Report

Report Number: SDWH-2012-20305

Sample Name: (b)(4) [redacted]

Test performed: Skin Sensitization Test (the Guinea Pig Maximization Test)

Sample Supplier: (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

TABLE OF CONTENTS

Page number

Title Page....1

Table of Contents....2

Supplementary Explanation....3

Signature Page....4

1.0 Summary....5

2.0 Purpose....5

3.0 Materials....5

4.0 Test System....6

5.0 Justification of Test System....6

6.0 Animal Management....6

7.0 Experimental Procedure....6

8.0 Results....8

9.0 Conclusion....8

10.0 Record Storage....9

11.0 Confidentiality Agreement....9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Testing Center of Sanitation & Environment technic Institute

Soochow University

Test Report

Sample name	(b)(4) [redacted]
Sample supplier	[redacted]
Size	Not supplied
Lot No	Not supplied
Part Number	P/N: 52-0560
	The information above was provided by sample supplier.
Test performed	Skin Sensitization Test (the Guinea Pig Maximization Test)
Receiving Date	2012-02-10
Technical Initiation Date	2012-02-20
Technical Completion Date	2012-03-16
Sample Image	[redacted]

Edited by: _____

Checked by: _____

Approved by: Zhang Tongcheng

Testing Center of Sanitation & Environment technic Institute, Soochow University

Date: Mar 2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.0 Summary

A guinea pig maximization test (ISO 10993-10:2010) of sample (b)(4) [redacted] was conducted to evaluate the potential for delayed dermal contact sensitization. The method of Magusson and Kligman (1970) was adapted for 0.9% sodium chloride solution test article extract.

The extract of the test article was intradermally injected and occlusively patched to ten guinea pigs in an attempt to induce sensitization. Following a recovery period, the original ten test and five control animals received a challenge absorbent gauze patch (2.5 cm×2.5 cm) of the test article extract and the control vehicle. In addition the test article was applied to the same animals. All sites were scored at 24h and 48h after patch removal.

Under the conditions of this study, the test article extract and the test article showed no signification evidence of causing delayed dermal contact sensitization in the guinea pig.

2.0 Purpose

A guinea pig maximization test identified below was conducted to evaluate the potential to cause delayed dermal contact sensitization.

3.0 Materials

3.1 Sample and Control Preparation

For each phase of this test, a ratio according to the table below (test article to volume of vehicle) was used for the test extract. The test article was extracted in 0.9% sodium chloride.

Extraction ratio	Actual sampling	Extraction conditions	The pH value of the final extract	Whether the extract is clear or not
$6cm^2$: 1ml	$60cm^2$: 10ml	37 ℃,72 h	6.2	Clear

The vehicle (without the test article) was similarly prepared to serve as the control.

3.2 Equipments

Electric-heated thermostatic water bath (SDWH-418),Autoclave (SDWH-048),Balance (SDWH-306), Electronic scale (SDWH-442).

3.3 Regents

0.9% sodium chloride (SC) (Lot No: 111022 3-1)
Freund's Adjuvant,Complete liquid (Lot No: 021M8728)
10% sodium dodecyl sulfate (10%SDS) (Lot No: F20090922)

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4.0 Test System

Species: Healthy young adult albino guinea pigs of either sex form a single outbred strain, weighing 300g to 500g at the start of the test shall be used. If female animals are used, they shall be nulliparous and not pregnant.
Source: Provided by Wuxi Huishan Jiangnan Experimental Animal Center <Permit Code: SCXK (SU) 2009-0005>.
Acclimation Period: 7 days .
Number of Animals: 15.

5.0 Justification of Test System

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, 1-chloro-2,4-dinitrobenzene (DNCB) has been substantiated at SDWH with this method. The average dermal scoring for the Positive controls was 1.9, see SDWH-2011-22434, completed on Jan 6, 2012.

6.0 Animal Management

Husbandry: Refer to ISO 10993-2:2006.
Food: Animal foods were provided by Wuxi Huishan Jiangnan Experimental Animal Center.
Water: Drinking water met the sanitary standard.
Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date.
Environment: The room Temp will be monitored daily. The temperature will be controlled within 20-26℃. The room humidity will be controlled within 30%-70%.The light cycle is controlled for 12hours' light and 12hours' dark.
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.

7.0 Experimental Procedure

7.1 Intradermal induction phase I

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.
Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.
Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%) was injected into the control animals with an emulsion of the blank liquid with adjuvant.

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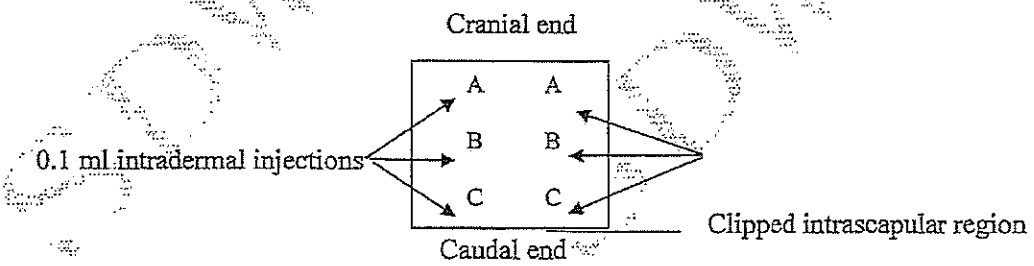

Figure 1 Location of intradermal injection sites

7.2 Topical induction phase Ⅱ

Seven days after completion of the intradermal induction phase, the test sample was administered by topical application to the intrascapular region of each animal, using a patch of area approximately 8cm^2 (filter paper or absorbent gauze), so as to cover the intradermal injection sites. The concentration selected in intradermal induction phase Ⅰ for Site B was used. The patches were secured with an occlusive dressing. The dressings and patches were removed after 48h.
The control animals were treated similarly, using the blank liquid alone.

7.3 Challenge phase

At 14 days after completion of the topical induction phase, all test and control animals were challenged with the test sample. The test sample and a vehicle control were administered by topical application to sites that were not treated during the induction stage, such as the upper flank of each animal, using appropriate patches soaked in the test sample at the concentration selected in the intradermal induction phase Ⅰ for site C. Dilutions of this concentration were also applied to other untreated sites in a similar manner. Occlusive dressings were used to secure areas treated. The dressings and patches were removed after 24h.

7.4 Observation of animal

The appearance of the challenge skin sites of the test and control animal were observed after 24h and 48h removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions.
The skin reactions for erythema and oedema were observed and graded according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval .It is highly recommended that reading be done without knowledge of the treatment, in order to minimize bias in the evaluation of the results.

7.5 Evaluation of results

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animal. If grades of 1 or greater are noted in control animal, then the reactions of test animal which exceed the most severe reaction in control animals are presumed to be due to sensitization. If the response is equivocal, re-challenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in the test and control animal.

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Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

8.0 Results

Individual results of dermal scoring for the challenge appear in Table 2. Clinical Observations: All animals appeared clinically normal throughout the study.

Table 2 Guinea pig Sensitization Dermal Reactions – Challenge

Animal Number/ Group	Topical induction phase II		Hours following patch removal (h)		Weight (g)	
	Left	Right	24	48	Before injection	After experiment
1 Test	0	0	0	0	329	373
2 Test	0	0	0	0	318	384
3 Test	0	0	0	0	306	370
4 Test	0	0	0	0	322	377
5 Test	0	0	0	0	323	377
6 Test	0	0	0	0	315	381
7 Test	0	0	0	0	304	370
8 Test	0	0	0	0	327	382
9 Test	0	0	0	0	319	369
10Test	0	0	0	0	330	385
11Negative control	0	0	0	0	322	388
12Negative control	0	0	0	0	306	372
13Negative control	0	0	0	0	300	368
14Negative control	0	0	0	0	308	358
15Negative control	0	0	0	0	323	377
16 Positive control	3	3	2	2	304	369
17 Positive control	3	3	2	2	326	384
18 Positive control	3	3	2	2	311	372
19 Positive control	3	3	1	2	314	377
20 Positive control	3	3	2	2	303	365

Note: The data of positive control come from SDWH 2011-22434.

9.0 Conclusion

Under the conditions of this study, the test article extract and the test article showed no significant evidence of causing delayed dermal contact sensitization in the guinea pig.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

11.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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证书编号：2010100305S

TESTING
CNAS L2954

Testing Center of Sanitation & Environment technic Institute, Soochow University, Test Report

Report Number: SDWH-2012-20307

Sample Name: (b)(4) [redacted]

Test performed: Skin irritation Test

Sample Supplier: (b)(4) [redacted]

Testing Center of Sanitation & Environment technic Institute, Soochow University
Add: No.199 Ren'ai Road, Suzhou Industrial Park, China Tel: 0512-65880038
Fax: 0512-65880038 PC: 215123

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TABLE OF CONTENTS

Page number

Title Page....1

Table of Contents....2

Supplementary Explanation....3

Signature Page....4

1.0 Summary....5

2.0 Introduction....5

3.0 Test System....5

4.0 Justification of Test System....5

5.0 Animal Management....5

6.0 Experimental Procedure....6

7.0 Result....7

8.0 Conclusion....8

9.0 Record Storage....8

10.0 Confidentiality Agreement....8

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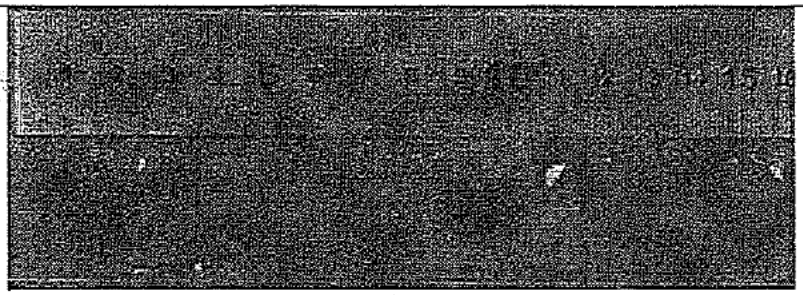
Testing Center of Sanitation & Environment technic Institute
Soochow University
Test Report

Sample name	(b)(4) [redacted]
Sample supplier	[redacted]
Size	Not supplied
Lot No	Not supplied
Part Number	P/N: 52-0560
The information above was provided by sample supplier.	
Test performed	Skin irritation Test
Receiving Date	Feb 10, 2012
Technical Initiation Date	Feb 20, 2012
Technical Completion Date	Feb 26, 2012
Sample Image	

Edited by: Tang Yu.

Checked by: [illegible]

Approved by: Zhang Tongchang

Testing Center of Sanitation & Environment technic Institute, Soochow University

Date: [illegible], 2012

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1.0 Summary

The test article, (b)(4) [redacted] was evaluated for skin irritation in accordance with the ISO 10993-10:2010 Tests for irritation and skin sensitization. The skin responses on application sites in 1h, 24h, 48h and 72h respectively after removal the patches were observed and recorded. The tissue reaction was graded for erythema and oedema according to the classification system given in Table 1. According to what was observed, the response of skin on testing side does not exceed that on the control side. The primary irritation index for the test article was calculated to be 0 (The positive irritation index was 6.1; see SDWH-2012-20205, regent is 20% sodium dodecyl sulfate). The test result showed that the applied sample does not induce irritation to rabbit skin.

2.0 Introduction

The test article was evaluated for skin irritation in accordance with the guidelines of the ISO 10993-10:2010 Tests for irritation and skin sensitization. This study was to determine the potential skin irritation after the sample applied to the animal back.

3.0 Test System

Species: Healthy young adult albino rabbits of either sex form a single strain.
Breed: New Zealand white (single strain).
Source: Provided by Animal Center, SDWH <Permit Code: SYXK (SU) 2007-0035>.
Body Weight Range: Not less than 2 kg.
Age: Young adult.
Acclimation Period: 7 days.
Number of Animals: Three.

4.0 Justification of Test System

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current ISO 10993-10:2010 testing standards. The rabbit is widely used for this purpose and relative ranking of irritant scores can be determined.

5.0 Animal Management

Husbandry: Refer to ISO 10993-2:2006.
Food: Animal foods were provided by Wuxi Huishan Jiangnan Experimental Animal Center.
Water: Provided by Sanitary Standard for drinking water.
Housing: Animals were individually housed in stainless steel suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environment: The room Temp will be monitored daily. The temperature will be controlled within 20-26℃. The room humidity will be controlled within 30%-70%.The light cycle is controlled for

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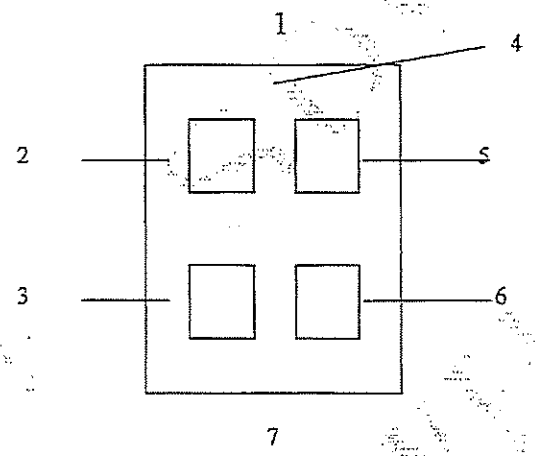
12hours' light and 12hours' dark.
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused, animals free from irritation or other dermatological lesions that could interfere with the test were selected.

6.0 Experimental Procedure

6.1 Sample and Control Preparation: Clip the test and control sample (gauze) into 2.5cm×2.5cm.

6.2 Use only animals with healthy intact skin. Fur is generally clipped within 24h of testing on the backs of the animals a sufficient distance on both sides of the spine for application and observation of all test sites(approximately 10×15cm)



1- Cranial end, 2- Test site, 3- Control sits, 4- Clipped dorsal region, 5- Control area, 6- Test area, 7- Caudal end

Figure1 Location of skin application sites

Apply the samples of the test material directly to the skin on each side of each rabbit as shown in Figure 1.Similarly, apply the control samples to each rabbit, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4h. At the end of the contact time, remove the dressing.

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 and Table 2 for each application site at each time interval. Record the appearance of each application site at 1h, 24h, 48h and 72h following removal of the patches. Use only 24h, 48h, and 72h observations for calculation. For each animal add together the primary irritation scores for the test material for both erythema and oedema at each time point and divide the total number of observations. Add together the irritation scores of all animals and divide by the total number of animals. This value is the cumulative irritation index.

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7.0 Results

According to what observed, the response of skin on testing side does not exceed that on the control side. Thus, it is identified as grade 0. See table 2.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Total possible score for irritation	8
Irritation Response Categories in the Rabbit	
Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

NOTE: Other adverse changes at the skin sites were recorded and are reported

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Table 2 Dermal Observations

Rabbit No.	Group		Interval (hours)			
			1	24	48	72
1	Test	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
2	Test	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
3	Test	Erythema	0	0	0	0
		Oedema	0	0	0	0
	Control	Erythema	0	0	0	0
		Oedema	0	0	0	0
4	Positive control	Erythema	2.0	3.0	3.0	3.0
		Oedema	2.0	4.0	4.0	2.0
5	Positive control	Erythema	2.0	3.0	3.0	3.0
		Oedema	2.0	4.0	3.0	2.0
6	Positive control	Erythema	2.0	3.5	3.0	3.0
		Oedema	2.0	3.5	3.0	2.0

Note: Positive control performed once every six months, the positive irritation index was 6.1; see SDWH-2012- 20205.

8.0 Conclusion

The test result shows that of the applied sample does not induce irritation to skin.

9.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

10.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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证书编号：2010100305S

TESTING
CNAS L2954

Testing Center of Sanitation & Environment technic Institute, Soochow University, Test Report

Report Number: SDWH-2012-20306

Sample Name: (b)(4) [redacted]

Test performed: Skin Sensitization Test (the Guinea Pig Maximization Test)

Sample Supplier: (b)(4) [redacted]

Testing Center of Sanitation & Environment technic Institute, Soochow University
Add: No.199 Ren'ai Road, Suzhou Industrial Park, China Tel: 0512-65880038
Fax: 0512-65880058 PC: 215123

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TABLE OF CONTENTS

		Page number
Title Page		1
Table of Contents		2
Supplementary Explanation		3
Quality Assurance Statement		4
Verification of Study Process		5
Signature Page		6
1.0	Summary	7
2.0	Purpose	7
3.0	Materials	7
4.0	Test System	8
5.0	Justification of Test System	8
6.0	Animal Management	8
7.0	Experimental Procedure	8
8.0	Results	10
9.0	Conclusion	11
10.0	Record Storage	11
11.0	Confidentiality Agreement	11

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SUPPLEMENTARY EXPLANATION

1. If the analysis report requires modification please raise the matter within 15 days of receiving the report, otherwise the request will not be accepted.
2. The test report is void without test center's seal.
3. The test report is only valid when signed by the persons who edited, checked and approved it.
4. Any erasure renders the report null and void.
5. The test result is only valid for the sample provided.
6. The copyright of analysis report is reserved by the analysis center. If a copy is required, please get permission from the center first. Only complete copies of the test report may be made.

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Testing Center of Sanitation & Environment technic Institute

Soochow University

Test Report

Sample name	(b)(4) [redacted]
Sample supplier	[redacted]
Size	Not supplied
Lot No	Not supplied
Part Number	P/N: 52-0560
	The information above was provided by sample supplier.
Test performed	Skin Sensitization Test (the Guinea Pig Maximization Test)
Receiving Date	2012-02-10
Technical Initiation Date	2012-02-20
Technical Completion Date	2012-03-16
Sample Image	[redacted]

Edited by: _____

Checked by: _____

Approved by: Zhang Tongcheng

Testing Center of Sanitation & Environment technic Institute, Soochow University

苏州大学卫生与环境技术研究所 检测中心

Date: Mar 9 2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.0 Summary

A guinea pig maximization test (ISO 10993-10:2010) of sample (b)(4) [redacted] was conducted to evaluate the potential for delayed dermal contact sensitization. The method of Magusson and Kligman (1970) was adapted for SO solution test article extract.

The extract of the test article was intradermally injected and occlusively patched to ten guinea pigs in an attempt to induce sensitization. Following a recovery period, the original ten test and five control animals received a challenge absorbent gauze patch (2.5 cm×2.5 cm) of the test article extract and the control vehicle. In addition the test article was applied to the same animals. All sites were scored at 24h and 48h after patch removal.

Under the conditions of this study, the test article extract and the test article showed no signification evidence of causing delayed dermal contact sensitization in the guinea pig.

2.0 Purpose

A guinea pig maximization test identified below was conducted to evaluate the potential to cause delayed dermal contact sensitization.

3.0 Materials

3.1 Sample and Control Preparation

For each phase of this test, a ratio according to the table below (test article to volume of vehicle) was used for the test extract. The test article was extracted in SO.

Extraction ratio	Actual sampling	Extraction conditions	The pH value of the final extract	Whether the extract is clear or not
$6cm^2$: 1ml	$60cm^2$: 10ml	37 ℃,72 h	5.8	Clear

The vehicle (without the test article) was similarly prepared to serve as the control.

3.2 Equipments

Electric-heated thermostatic water bath (SDWH-418),Autoclave (SDWH-048),Balance (SDWH-306), Electronic scale (SDWH-442)

3.3 Regents

100%Sesame oil (SO) (Lot No: 2010/07/26 TZH)
Freund's Adjuvant,Complete liquid (Lot No: 021M8728)
10% sodium dodecyl sulfate (10%SDS) (Lot No: F20090922)

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4.0 Test System

Species: Healthy young adult albino guinea pigs of either sex form a single outbred strain, weighing 300g to 500g at the start of the test shall be used, If female animals are used, they shall be nulliparous and not pregnant.
Source: Provided by Wuxi Huishan Jiangnan Experimental Animal Center <Permit Code: SCXK (SU) 2009-0005>.
Acclimation Period: 7 days.
Number of Animals: 15.

5.0 Justification of Test System

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, 1-chloro-2,4-dinitrobenzene (DNCB) has been substantiated at SDWH with this method, The average dermal scoring for the Positive controls was 1.7, see SDWH-2011-22435, completed on Jan 6, 2012.

6.0 Animal Management

Husbandry: Refer to ISO 10993-2:2006.
Food: Animal foods were provided by Wuxi Huishan Jiangnan Experimental Animal Center.
Water: Drinking water met the sanitary standard.
Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date.
Environment: The room Temp will be monitored daily. The temperature will be controlled within 20-26℃. The room humidity will be controlled within 30%-70%.The light cycle is controlled for 12hours' light and 12hours' dark.
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.

7.0 Experimental Procedure

7.1 Intradermal induction phase I

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.
Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.
Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%) was injected into the control animals

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with an emulsion of the blank liquid with adjuvant.

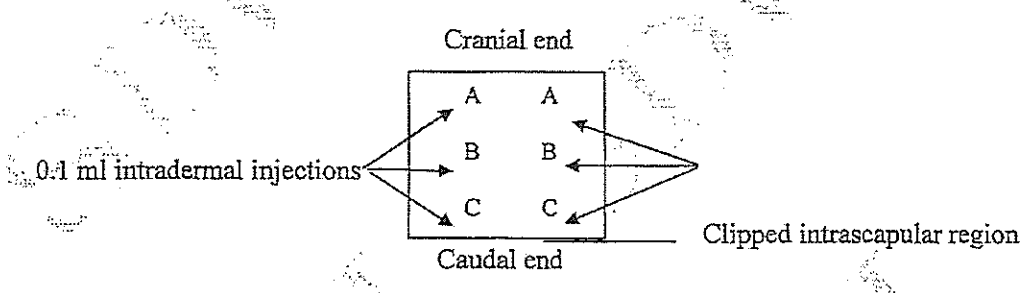

Figure 1 Location of intradermal injection sites

7.2 Topical induction phase II

Seven days after completion of the intradermal induction phase, the test sample was administered by topical application to the intrascapular region of each animal, using a patch of area approximately 8cm^2 (filter paper or absorbent gauze), so as to cover the intradermal injection sites. The concentration selected in intradermal induction phase I for Site B was used. The maximum concentration that could be achieved in intradermal induction phase I did not produce irritation, when the area was pretreated with 10% sodium dodecyl sulfate massaged into the skin 24h before the patch was applied. The patches were secured with an occlusive dressing. The dressings and patches were removed after 48h.

The control animals were treated similarly, using the blank liquid alone.

7.3 Challenge phase

At 14 days after completion of the topical induction phase, all test and control animals were challenged with the test sample. The test sample and a vehicle control were administered by topical application to sites that were not treated during the induction stage, such as the upper flank of each animal, using appropriate patches soaked in the test sample at the concentration selected in the intradermal induction phase I for site C. Dilutions of this concentration were also applied to other untreated sites in a similar manner. Occlusive dressings were used to secure areas treated. The dressings and patches were removed after 24h.

7.4 Observation of animal

The appearance of the challenge skin sites of the test and control animal were observed after 24h and 48h removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions.

The skin reactions for erythema and oedema were observed and graded according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval .It is highly recommended that reading be done without knowledge of the treatment, in order to minimize bias in the evaluation of the results.

7.5 Evaluation of results

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization,

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provided grades of less than 1 are seen in control animal. If grades of 1 or greater are noted in control animal, then the reactions of test animal which exceed the most severe reaction in control animals are presumed to be due to sensitization. If the response is equivocal, re-challenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in the test and control animal.

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

8.0 Results

Individual results of dermal scoring for the challenge appear in Table 2. Clinical Observations: All animals appeared clinically normal throughout the study.

Table 2 Guinea pig Sensitization Dermal Reactions – Challenge

Animal Number/ Group	Topical induction phase II		Hours following patch removal (h)		Weight (g)	
	Left	Right	24	48	Before injection	After experiment
1 Test	0	0	0	0	318	378
2 Test	0	0	0	0	309	375
3 Test	0	0	0	0	324	390
4 Test	0	0	0	0	313	367
5 Test	0	0	0	0	305	366
6 Test	0	0	0	0	307	357
7 Test	0	0	0	0	322	377
8 Test	0	0	0	0	316	370
9 Test	0	0	0	0	304	364
10Test	0	0	0	0	323	378
11Negative control	0	0	0	0	318	378
12Negative control	0	0	0	0	325	380
13Negative control	0	0	0	0	313	367
14Negative control	0	0	0	0	310	370
15Negative control	0	0	0	0	311	377
16 Positive control	3	3	1	2	321	385
17 Positive control	3	3	2	2	305	367
18 Positive control	3	3	2	2	314	373
19 Positive control	3	3	1	1	328	391
20 Positive control	3	3	2	2	310	369

Note: The data of positive control came from SDWH 2011-22435.

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9.0 Conclusion

Under the conditions of this study, the test article extract and the test article showed no significant evidence of causing delayed dermal contact sensitization in the guinea pig.

10.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

11.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

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3M

PRODUCT CLINICAL DATA SUMMARY

(b)(4) [redacted]

Effective: September 2010

The adhesive used on this tape has been subjected to the following safety evaluations:

In Vitro Cytotoxicity

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO_2 for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis.
The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

MEM Elution

An additional *in vitro* study was conducted to evaluate for potential cytotoxic effects following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37 degrees C for 24 hours. The negative control, reagent control and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37 degrees C in the presence of 5% CO_2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25mm x 25mm sections of the test article and control article were topically applies to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application
There was very slight to well defined erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.9. The response of the test article was categorized as slight.

Guinea Pig Sensitization

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig based on the requirements of ISO 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was occlusively patched to the intact skin of ten animals for 6-8 hours, three times a week over a 3 week period. The control article was similarly patched to 5 animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test and control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. 3M Study 011346 (all)

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In addition, earlier studies using a similar adhesive have shown the following results:

Repeated Insult Patch Test (Draize) in Humans
Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. 3M Study # MRFE 03009.
Results: No evidence of induced contact sensitization.

21-day Cumulative Irritation in Humans
Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. 3M Study # 01789.
Results: Consistent with responses characteristic of adhesive materials; within historically acceptable levels for surgical tapes.

The use of the term "hypoallergenic" has come to indicate a product that is non-sensitizing to the general public. The hypoallergenic claim for this product is supported by clinical evaluation using the repeated insult patch test in humans, commonly known as the Draize test. This protocol involves repeated application of samples on 200 healthy volunteers for a 2- to 3-week induction period, followed by a 2-week rest period and a challenge application. To be termed hypoallergenic, 3M Medical Specialties products are required to show no evidence of sensitization potential under these test conditions.

It is the responsibility of our customers to determine the final suitability of our products for their application.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

Typical Product Properties

(b)(4) [redacted]

PROPERTY	TEST METHOD	VALUE
PHYSICAL		
Density, lb. / ft³ (kg /m³)	ASTM D 3574-95, Test A	15 (240)
Tolerance, %		± 10
Thickness, inches (mm)		0.125 - 0.500 (3,18 - 12,70)
Tolerance, %		± 10
Standard Color (Code)		Black (04)
Compression Force Deflection, psi (kPa) Typical psi (kPa)	0.2" / min. Strain Rate Force Measured @ 25% Deflection	0.3 - 3.5 (2 - 24) 2 (14)
Hardness, Durometer, Shore "O", Shore "A"	ASTM D 2240-97	2 -
Compression Set, % max.	ASTM D 1667-90 Test D @ 73°F (23°C) ASTM D 3574-95 Test D @ 158°F (70°C) ASTM D 3574-95 Test J/Test D autoclaved 5 hrs @ 250°F (121°C)	2 10 5
Resilience by Vertical Rebound, %	ASTM D 2632-96	4
Dimensional Stability, % max. change	22 hrs @ 176°F (80°C) in a forced-air oven	± 5
Tensile Strength, Min. psi (kPa), Typical psi (kPa)	ASTM D 3574-75 Test E	15 (103) 30 (207)
Tensile Elongation, % min., Typical	ASTM D 3574-75 Test E	120 205
Tear Strength, Min. pli (kN/m), Typical pli (kN/m)	ASTM D 264-91 Die C	4 (0.7) 5 (0.9)
ELECTRICAL AND THERMAL		
Dielectric Constant, K' ("DK")	ASTM D 150 measurements at 72°F (22°C) relative humidity 50% for 24 hrs.	1.48
Dielectric Strength, volts/mil	ASTM D 149-97a	50
Dissipation Factor, tan D ("DF")	ASTM D 150-98	0.04
Volume Resistivity, ohm-cm	ASTM D 257-99	8×10^{11}
Surface Resistivity, ohm/sq.	ASTM D 257-99	10×10^{11}
Thermal Conductivity, W/m-C (BTU-in./hr/ft²-F)	ASTM C 518-98	-
Coefficient of Thermal Expansion		$2.3 - 3.1 \times 10^{-4}$ in./in./°C

Please see reverse side for additional data.

The world runs better with (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted] Continued

PROPERTY	TEST METHOD	VALUE
Density, lb. / ft^3 (kg /m^3)	ASTM D 3574-95, Test A	15 (240)
TEMPERATURE RESISTANCE		
Recommended Constant Use, max.	SAE J-2236	194°F (90°C)
Recommended Intermittent Use, max.	ASTM D 746-98	250°F (121°C)
Embrittlement	ASTM D 746-98	-4°F (-20°C)
Cold Flexibility	MIL-P-12420D 1991 @ -40°F (40°C)	-
FLAMMABILITY AND OUTGASSING		
Flammability	UL 94HBF (File E20305) (Pass ≥) MVSS 302 (Pass ≥) CSA Comp HBF (File 188149) (Pass ≥)	- - -
Fogging	SAE J-1756 3 hrs @ 212°F (100°C)	Pass
Outgassing, Total Mass Loss (TML) %	ASTM E 595-93 24 hrs @ 257°F (125°C) @ <7x10^{-3} Pa	1.73
Outgassing, Collected Volatile Condensable Materials (CVCM) %		0.14
Outgassing, Water Vapor Regain (WVR) %		0.71
ENVIRONMENTAL		
Gasketing and Sealing	UL JMST2 (Consisting of UL50 and UL508) CAN/CSA – C22.2 No. 94-M91	File MH15464
Water Absorption, High Humidity Exposure, % weight gain, typical	AMS 3568-95	2
Water Absorption, Immersion Testing, % weight gain, typical	ASTM D 570-95	34
UV Resistance	ASTM G 53-95	-
Ozone Resistance	GM 4485P-95	-
Corrosion Resistance	AMS 3568-91	-
Mildew/Bacteria Resistance	ASTM G 21	Good
Staining	ASTM D 925	No Stain
Skin Contact Irritation	Primary Skin Irritation Test (FHSA)	Pass

The information contained in this data sheet is intended to assist you in designing with (b)(4) [redacted] *It is not intended to and does not create any warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose or that the results shown on the data sheet will be achieved by a user for a particular purpose. The user should determine the suitability of* (b)(4) [redacted] *for each application.*

Notes:
1. All metric conversions are approximate.
2. Additional technical information is available.

(b)(4) [redacted]

3049-0503-0.6C, Publication # 17-036

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Micro Laboratories, Inc.

World Cla *ing Services*

ISO 9001: 2000 an 7025: 1999 Certified

AGAR OVERLAY CYTOTC
TEST REPORT

Client: CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405

: #: 05-02163
028944
eived: 04/18/05

Report to: Ron Jeffrey

Sample Description: (2) Sample #3 NIRS Probe Material – Foam

Cell Line: L929 (L-008) **Pass #:** 6 **Date Plated:** 04/15/05 **Plate Size:** 60 X 15mm
Cell Density: Monolayer **Plated By:** JEG **MTL SOP#:** 2020IL rev 004
Extract Ratio: 1cm^2 agar surface **2X MEM:** Lot #: 05-342, exp. Date 6/10/05, e: 04/19/05, exp. date: 4/26/05

Sample Applied By: SSK **Date:** 04/20/05 **Time:** 4:20pm
Dye Applied By: MAC **Date:** 04/21/05 **Time:** 4:30pm
Plates Graded By: MAC **Date:** 04/21/05 **Time:** 5:35pm

Results:

Sample	Reactivity Grade		
24 Hour Reading:	Pl	Plate 2	Plate 3
Sample #3 NIRS Probe Material – Foam pad		2	2
Positive Control: Latex Rubber Lot #04-1140		4	4
Negative Control: USP Plastic Lot #05-302		0	0
Test Blank: All normal, healthy cells		0	0

Comments: The sample meets the requirements of the test if none of monolayer exposed to the sample shows greater than a mild reactivity (Grade 2).

Conclusion: The sample tested "mildly induced" cytotoxicity after 24 . The results as stated on this report are exclusive to the product defined in the "Sample Descriptio n. This report may not be reproduced, except in full, without the expressed written consent of M st Laboratories, Inc.

Reserve: The remaining sample(s) will be held at MicroTest Lab ories for 30 days following the final report completion date and then discarded, unless ed in writing by the client.

Analyst: Sheida Kouzehkanani D 05/05

Sheida S. Kouzehkanani, B.S.
Group Leader, Laboratory Technician II

NOTE: All service Undertaken Subject to the following General Policy: MICROTEST LABORATORIES, INC. Reports are Submitted For Exclusive Use of The Clients to Whom they are addressed. Their Significance is Subject to the Adequacy and Representative Character of the samples and to the Comprehensiveness of the Tests, Examination or Surveys Made. No Quotations from MICROTEST LABORATORIES, INC., Reports or use of MICROTEST LABORATORIES, INC., Name is Permitted Except as Expressly Authorized in writing. The liability of MICROTEST LABORATORIES, INC., with respect to services rendered shall in no event exceed the amount of the invoice.

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TEST REPORT

Sample #05-02163

Analyst: Michelle Coach — 25Apr05

Michelle Coach, M.B.A., B.S., RM (NRM)
Senior Supervisor, Microbiology Laboratory

Approved by: Dennis Champagne — 26Apr05

Dennis Champagne, RM (NRM)
Director of Laboratory Services

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DuPont Medical Packaging

TECHNICAL REFERENCE GUIDE

DUPONT

The miracles of science™

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1 Introduction 1

2 Why DuPont™ Tyvek® is unique 3

3 DuPont™ Tyvek® vs. medical-grade papers: a comparison of properties 5

4 Compatibility with sterilization methods 9

Aging studies 15

6 Guidelines for printing on DuPont™ Tyvek® 21

Processing/troubleshooting guidelines 24

Glossary of medical packaging terms 27

9 Guide to some common industry acronyms 31

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INTRODUCTION

1

DuPont™ Tyvek® for medical packaging delivers trusted protection

Since its introduction to the industry more than 40 years ago, DuPont™ Tyvek® brand protective material has been recognized as a standard of excellence for medical packaging. Tyvek® earned this distinction because it provides a higher degree of protection for medical devices and supplies than any other porous material used for sterile packaging applications.

The unique structure of Tyvek® gives it inherent advantages over other materials. Specifically, Tyvek® offers:

Outstanding resistance to microbial penetration

In test after test, Tyvek® held out bacterial spores and test particles better than other porous packaging materials—even under the most rigorous conditions. What's more, a long-term shelf-life study proved conclusively that Tyvek® can maintain sterility for at least five years if package integrity is not compromised. The photomicrographs shown here illustrate how bacteria are trapped on the fiber surfaces of Tyvek®.

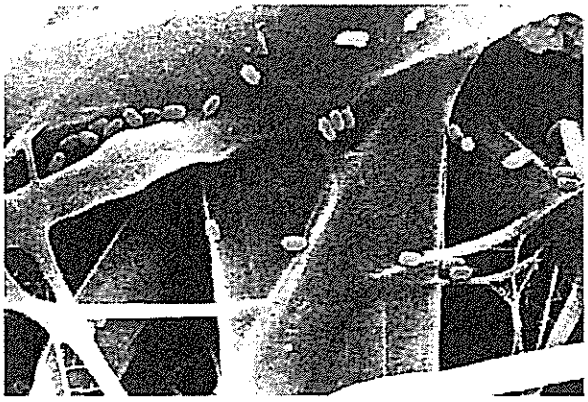
Superior tear strength and puncture resistance

The tough, continuous fibers of Tyvek® protect package integrity from both product breakthrough inside and rough handling outside. Tyvek® is so tough, it resists punctures—even from the irregular or sharp edges of many surgical devices.

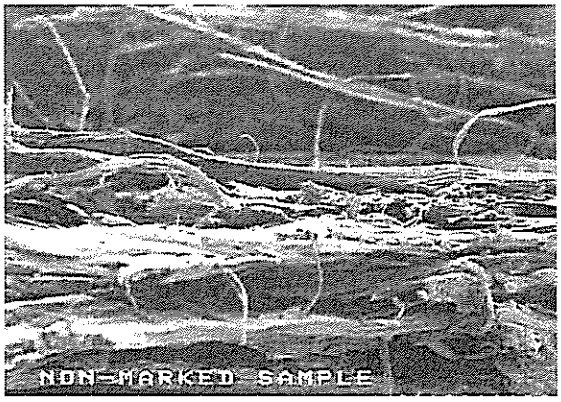
Clean peel

Because the structure of Tyvek® makes it low-linting, virtually no airborne particles are generated when packages are opened. This clean peel minimizes the risk of introducing particulates into a clean environment.

Figure 1. Scanning electron micrographs (SEMs) of Tyvek®.
The unique structure of Tyvek®, which creates a tortuous path with substantial lateral movement, results in superior microbial barrier properties.



Microbes trapped on fiber surfaces of Tyvek®
(500x magnification)



Cross-sectional view of Tyvek®
(500x magnification)

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1

Compatibility with a broad range of sterilization methods

Only DuPont™ Tyvek® is compatible with all of the most commonly used sterilization methods. No matter which process you use: ethylene oxide (EtO), gamma, electron-beam, steam (under controlled conditions) or newer methods, such as the Sterrad® Sterilization System, Tyvek® will retain its protective properties, color and flexibility.

Bioburden

The process of manufacturing Tyvek® allows only short periods of time when the sheet is subject to airborne particulates and microbes; therefore, the bioburden on the surface of Tyvek® is very low. This low bioburden does not add significantly to the required sterilization time. Measured as colony forming units (cfu) per ft^2, the typical bioburden for Tyvek® 2FS™ is 62; for Tyvek® 1059B is 93; and for Tyvek® 1073B is 80.

Ideal fit with environmental goals

As for ecological responsibility, Tyvek® is an excellent choice. This lightweight, durable material is an effective way to conserve resources and demonstrate environmental stewardship. It is lightweight for the performance delivered and is recyclable. It can also be cleanly incinerated or easily landfilled. Due to its porous structure, if compressed, Tyvek® would have less than half its thickness. In the United States, Tyvek® can be recycled at more than 70 facilities nationwide that accept flexible high-density polyethylene (HDPE) with the SPI #2 symbol. In Europe, Tyvek® is produced on a site under verified environmental management policy according to ISO 14000 (EMAS). It can be recycled at local recycling facilities that accept polyethylene waste according to local legislation. The items sent for recycling must not have been in contact with any hazardous substance. There are also several facilities in Asia Pacific that will accept Tyvek® for recycling. For more information, visit **www.MedicalPackaging.DuPont.com**. Visit **www.MSDS.DuPont.com** for a copy of the Material Safety Data Sheet (MSDS).

An industry and technology leader

The DuPont Medical Packaging Team, backed by the vast resources of DuPont, is committed to developing new, cost-effective solutions and providing the support you need to ensure that end-users receive the highest quality medical packaging available. As leaders in the industry, we are dedicated to sharing information and expertise on topics ranging from industry standards and regulatory compliance to technical issues and quality.

We developed a seminar series to help the industry stay on top of standards, regulations and new technologies. In addition, members of our team regularly participate on American Society for Testing and Materials (ASTM-International), International Organization for Standardization (ISO), European Committee for Standardization (CEN), as well as in industry activities, such as the Sterile Barrier Association (SBA, formerly known as ESPA), Association of periOperative Registered Nurses (AORN) Congress, Institute of Packaging Professionals (IoPP), European Medical Devices and Technology Industry Association (EUCOMED) and International Safe Transit Association (ISTA). And, because we want to help future packaging engineers, we established a scholarship program at some of the top packaging science schools.

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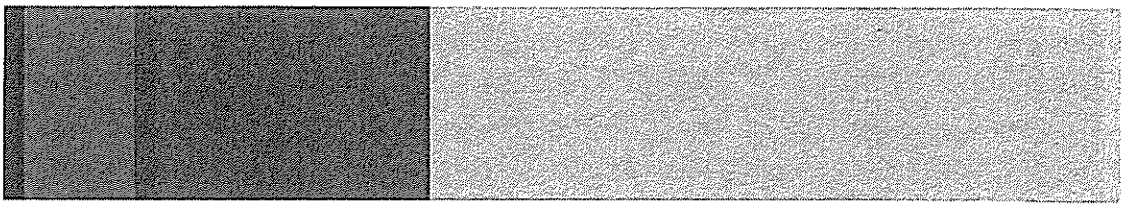

Biocompatibility

Biocompatibility testing using industry accepted test methods was performed on samples of DuPont™ Tyvek® 1073B, 1059B and 2FS™ before and after exposure to sterilization. Methods included: ethylene oxide (EtO), gamma irradiation, electron beam irradiation and STERRAD®. The results of the testing indicate that all of the styles of Tyvek® are biocompatible.

Table VI. Sample exposure results for Tyvek® 1073B, 1059B and 2FS™.

Test Performed	Unsterilized	Ethylene oxide (EtO)	Gamma Irradiation (25-35 kGy)	Electron Beam Irradiation (25-35 kGy)	STERRAD
Determination of Extractives from Olefin Polymers[3]			Below maximum allowable percentage		
Hemolysis-Rabbit Blood-ISO[2,4]			Non-hemolytic		
L929 MEM Elution Test-USP[8]			Non-cytotoxic		
ISO-Rabbit Pyrogen Test (Material Mediated)[1,2]			Non-pyrogenic		
Kligman Maximization Test-ISO (CSO and NaCl extracts)[2,7]			Non-allergenic		
Systemic Injection Test-ISO[1,2]			No biological reaction		
Primary Skin Irritation Test-ISO[7]			Non-irritant		
Short Term Intramuscular Implantation Test-ISO (14 and 28 days)[5,6]			Non-irritant		
USP Class VI Test[9]			0% sensitization		

Note: Biocompatability tests are currently underway for Tyvek® Asuron®.

Tests were based on the following references:

1. Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity, *EN/ISO 10993-1995*
2. Biological Evaluation of Medical Devices-Part 12: Sample Preparation and Reference Materials. *EN/ISO 10993-12, 1997*
3. *21 CFR 177. 1520, Olefin Polymers, Federal Register, Title 21, Chapter 1, 1997.*
4. Biological Evaluation of Medical Devices-Part 4: Selection of Tests for Interactions with Blood, *ISO 10993-4, 1992*
5. Biological Evaluation of Medical Devices-Part 6. Tests for Local Effects After Implantation, *ISO 10993-6, 1995*
6. *ASTM Section 13, Volume 13.01 Medical Devices, Designation: F 981-93, 1994*
7. Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Sensitization, *EN/ISO 10993-10, 1996*
8. *United States Pharmacopoeia 25, National Formulary 20, 2002, <87>* Biological Reactivity Tests, In Vitro.
9. *United States Pharmacopoeia 25, National Formulary 20, 2002, <88>* Biological Reactivity Tests, In Vivo.

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(b)(4) [redacted]

(Summary of Biocompatibility data for the adhesive used in (b)(4) [redacted]

Cytotoxicity study– The method used was the ISO Agarose Overlay Method (Solid); the study does comply with ISO 10993-5. The test article was a dry acrylic pressure sensitive adhesive made from the liquid resin. The adhesive (1 cm x 1 cm portions) was dosed as provided (no extraction). The results of this study showed no cell lysis or toxicity.

Skin Irritation Study – The test guidelines met FIFRA/TSCA requirements. The test article was the liquid resin (not dry adhesive). Therefore, no extraction was necessary. The results of this study showed minimal indication of skin irritation.

Dermal Sensitization Study – The test guideline was the Buehler method (closed-patch repeated insult study in guinea pigs). The test article was the liquid resin (not dry adhesive). The adhesive (1 in x 1 in portions) was applied as provided (no extraction). The study was conducted under EPA TSCA Good Laboratory Practices. The result of this study showed that the tape did not cause dermal sensitization. Statistically the results indicated that it is likely to state with 95% confidence it will be tolerated by no less than 98.29% and by as much as 100% of the population at risk.

**This data is provided by our supplier.*

This toxicology summary is intended only as a guide and should not be construed as a warranty. All implied warranties are expressly disclaimed, including without limitation any warranty of merchantability and fitness for use. All users of the material are responsible for assuring that it is suitable for their need, environment and end use. As such, final approval must be confirmed in an appropriate manner on the end use product. All data is subject to change, as DermaMed deems appropriate.

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Tel: 330-633-8216 * Fax: 330-633-2461

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(b)(4) [redacted]

DermaMed Coatings Company, LLC
Product Specification UNCONTROLLED COPY
Product No: (b)(4) [redacted]
Issue Date: September 6, 2005
Revision Date: May 9, 2006

5.0 TRACEABILITY

Material traceability must comply with current Good Manufacturing Practices. Each shipment of material will contain a lot number, which is traceable through production records. Certification will accompany each shipment.

6.0 PRODUCT SAFETY:

Product safety data sheets are contained on file regarding adhesives.

7.0 STORAGE CONDITIONS:

Product should be stored at temperatures between 50-80°F.

8.0 STANDARD LABELING:

Materials will have core labeling stating part number, roll number, lot number, width, and linear feet per roll. *Note: Any additional labeling requirements by customer should be noted at time of order entry.*

9.0 BIOCOMPATIBILITY/SAFETY INFORMATION

9.1 Cytotoxicity-Pass

9.2 Primary Dermal-Pass

9.3 Buehler Sensitization-Pass

All biocompatibility testing performed is required to satisfy FDA/GMP requirements.

It is the responsibility of the consumer to determine that the product is safe, lawful and technically suitable for the intended.

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(b)(4) [redacted]

DermaMed Coatings Company, LLC
Product Specification UNCONTROLLED COPY
Product No: (b)(4) [redacted]
Issue Date: September 6, 2005
Revision Date: May 9, 2006

1.0 MATERIAL DESCRIPTION:

Single coated 1 mil white pearlized BOPP film with a medical grade acrylic pressure-sensitive, adhesive supported by a 54# release liner.

2.0 PRODUCT CONTENTS:

2.1 (b)(4) [redacted]

2.2

2.3 Backing –Coated one side having a basis weight of 54 lb.

3.0 ROLL DIMENSIONS:

3.1 Length – 2,000 linear feet

3.2 Width - Maximum 59 inch

3.3 Core - 3 inch inside diameter

4.0 PRODUCT REQUIREMENTS:

4.1 Physical Properties:

PEEL (PSTC-1): > 900 gm/inch average
(Preliminary data of initial samples submitted.)

4.2 Splices:

Splices are "functional", meaning that the splice on the tape and liner is intended for continuous process conditions.

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(b)(4) [redacted]

Biocompatibility Statement for (b)(4) [redacted]

This letter is provided as a response to your request for information on the biocompatibility of (b)(4) [redacted]

While biocompatibility tests have not been performed for all available colors in this grade, (b)(4) [redacted] has subjected samples of (b)(4) [redacted] from typical production lots of (b)(4) [redacted] natural") molded within the processing guidelines to certain biocompatibility tests specified by the United States Pharmacopeia (USP) or described by ISO 10993, "Biological Evaluation of Medical Devices", which is the guideline for biocompatibility developed by the International Organization for Standardization (ISO). The ISO 10993 tests were also consistent with the guidance provided by the US Food and Drug Administration (FDA) regarding use of the ISO 10993 standard. These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity test, 7. Sensitization test, and 8. Physico-chemical test. The purpose of these tests is to provide our customers with data to help them determine the suitability of the subject resin, for use as containers or accessories for parenteral preparations. The samples of (b)(4) [redacted] subjected to the ISO 10993 tests passed each of these tests and met the criteria for USP Class VI / ISO 10993.

Although the specific color of interest to you has not been subjected to these tests, we believe that if tested, the results of such tests would yield results similar to those described above. The basis for this belief is that it seems unlikely that the presence of small amounts of colorants, in a tightly bound form in the inert resin matrix, would cause any change in the results of these tests.

The medical device manufacturer and the drug packager are in the best position to know the details of the intended conditions of use. It is incumbent upon the device manufacturer or drug packager to carry out the appropriate biocompatibility tests to assure safety, efficacy, and regulatory compliance. (b)(4) [redacted] considers the determination of suitability of (b)(4) [redacted] for a medical device to be the responsibility of the device manufacturer and the drug packager. (b)(4) [redacted] **does not recommend and will not support the use of any** (b)(4) [redacted] **products in medical devices intended to remain continuously in the human body for longer than 29 days.**

Because of the potential for chemical incompatibility between (b)(4) [redacted] and materials used in components comprising the application or present in the end-use environment, it is recommended that appropriate chemical compatibility be conducted with all components under intended conditions of use and reasonably foreseeable misuse.

To assist in the review of the use of (b)(4) [redacted] for medical devices and drug packages with the appropriate FDA regulatory personnel, we maintain both a Device Master File (MAF-1575) and Drug Master File (b)(4) [redacted] with the FDA. The DMF contains detailed formulation information and test data on certain (b)(4) [redacted] Plastics considers this information proprietary and does not divulge it without a properly executed secrecy agreement. The FDA holds this information in confidence, but with our specific authorization will review it on behalf of a specific company's application or submittal for the purpose of rendering an opinion about the safety and suitability of the proposed usage.

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(b)(4) [redacted]

I trust that this information will adequately satisfy your needs. Should you have questions, or require additional information, please contact me via e-mail: patrick.rodgers (b)(4) [redacted]

In the name of the manufacturer,

(b)(4) [redacted]

(b)(4) [redacted]

Patrick A Rodgers

Patrick A. Rodgers

(b)(4) [redacted]

Washington, WV 26181
United States

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(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted] continues to strive for excellence in customer support. As part of ongoing efforts to address increasing customer requirements, we are further aligning our "healthcare product" portfolio to meet these needs. This alignment will also simplify product identification of "healthcare products" for our customers. These "healthcare products" are subject to formula lock and a stringent management of change process.

As part of this effort, the following current products (Old Names) have been changed to the corresponding new product names (New Names). This is a grade-name and color-name change only – the formulation, specification and manufacturing process remains unchanged:

(b)(4) [redacted]

(b)(4) [redacted] when it was

The "healthcare product" nomenclatures, specified below, contain the letter "H" in both grade names and color names to signify their inclusion in the (b)(4) [redacted] Healthcare product" portfolio. As such, these resin products are subject to the following (b)(4) [redacted] Plastics' "Healthcare Product" Policy:

- Easily identifiable "healthcare product" nomenclature: (b)(4) [redacted]
- Biocompatibility assessed (according to ISO10993 or USP Class VI)
- Food Contact compliance for most "healthcare products"
- FDA Drug Master File and/or Device Master File listing (Letter Of Authorization provided as needed)
- (b)(4) [redacted] "healthcare products" are subject to formula lock and stringent management of change process (ask your (b)(4) [redacted] representative for more details)

These processes support typical healthcare customer needs and regulatory requirements regarding change management for plastic materials used in medical devices or drug packaging.

Please be advised that (b)(4) [redacted] will no longer provide biocompatibility information for the old product names. Biocompatibility information will only be available for the new product nomenclature.

Please do not hesitate to contact (b)(4) [redacted] if you have any further questions.

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(b)(4) [redacted]

In the name of the manufacturer,
(b)(4) [redacted]

Patrick A. Rodgers

Patrick A. Rodgers

(b)(4) [redacted]

Washington, WV 26181
United States

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Technical Information Sheet

(b)(4) [redacted]

Effective: February 2007
Supersedes all previous specifications

Features and Benefits:

- Hypoallergenic Pressure Sensitive Adhesive
- Soft & Cushioning
- Highly Conformable
- ETO & Gamma Compatible
- Good Adhesion to Skin
- Opaque Ivory Color

Composition:

Tape Caliper	22.5 mils (0.6 mm) Polyvinyl Chloride Foam Tape
Backing	20 mils (0.5 mm) Ivory PVC Closed-cell Foam
Adhesive	Acrylate, designed for medical/surgical applications
Release Liner	65 lb. Super-calendered Kraft paper, silicone on one side (4.0 mil/0.1 mm)

Typical Properties+:

Adhesion to Steel, 180° Peel	8 ounces/inch width (2.2 N/25 mm width) (227 gm/25 mm width)
Liner Release	17 gm/inch width (17 gm/25 mm width)
Visual Defects	May include pock marks and pinholes (maximum 0.063 inch /1.6 mm diameter) - allowed up to 10 per square yard

+3M test methods are available upon request.

Roll Description: Tape supplied on 3 inch (76 mm) diameter cores.

Length, Maximum	210 yards (192 m) ± 2%
Width, Maximum	48 inch (122 cm) ± 1/16 in (1.5 mm)

Splices: Splices on the tape are intended for continuous processing.

Roll Width	**Maximum Number of Splices per Roll**
≤ 8 inch (20 cm)	3 per 72 yd (66 m)
	4 per 150 yd (137 m)
	5 per 210 yd (192 m)

Information on the splice frequency in roll widths greater than 8 inch (20 cm) is available upon request.

Packaging and Recommended Storage:
Product as supplied in original packaging will maintain stated properties for a period of two years from date stamped on shipping container when stored at temperatures between 50-80°F (10-27°C) and a relative humidity between 40-60 percent.

Please see reverse side for important product, safety and warranty information.

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Product and Safety Information: User is solely responsible for determining the suitability of 3M samples and products for the intended use including any necessary safety or toxicity assessment. 3M will provide Material Safety Data Sheets and results of toxicity testing upon request. In every case before using any product in full scale production users should conduct their own tests to determine to their own satisfaction whether the product is of acceptable quality and is suitable for their particular purposes under their own operating conditions.

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Limitation of Remedies: If products are proven not to meet 3M's specifications, the sole and exclusive remedy available and 3M's only obligation shall be, at 3M's option, to replace such quantity of Products which are proven out of specification or to refund the purchase price paid for Products.

Limitations of Liabilities: The remedies provided herein are exclusive remedies against 3M for any alleged or actual nonconformance to specifications or defect or other failure in products or for 3M's performance of its supply obligations. Under no circumstances is 3M liable for any direct, indirect, incidental, special or consequential damages (including lost profits) in any way related to the product under any theory of law including, but not limited to, negligence and strict liability.

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Fax: 86-21-5208-2205

Colombia
3M Colombia S.A.
Tel: 57-1 4108585
Fax: 57-1 4161677

Czech Republic
3M Cesko s.r.o.
Tel: +420-261 380 111
Fax: +420-261 380 110

Denmark
3M a/s
Tel: 45-43-48-0100
Fax: 45-43-96-8596

Dominican Republic
3M Dominicana
Tel: (809) 530-6560 X499
Fax: (809) 530-2960

Finland
Suomen 3M Oy
Tel.: 358-9-52-521
Fax: 358-9-512-29-44

France
Laboratoires 3M Santé
Tel: 33-1-3031-8376
Fax: 33-1-3031-8378

Germany
3M Medica
Tel: 49 2131 14 40 00
Fax: 49 2131 14 49 99

Hong Kong
3M Hong Kong Ltd.
Tel: (852) 2806 6111
Fax: (852) 2234 6044

Hungary
3M Hungária Kft.
Tel: (36-1) 270-7777
Fax: (36-1) 320-0951

India
3M India Ltd.
Tel: 0091-80-2223 1414
Fax: 0091-80-22231450

Indonesia
PT 3M Indonesia
Tel: (62-21) 520 3401
Fax: (62-21) 520 3106

Italy
3M Italia SPA
Tel: +39 2 7035-2406
Fax: +39 2 7035-2484

Japan
3M Health Care Ltd.
Tel: 81-3-3709-8289
Fax: 81-3-3709-8754

Kazakhstan
3M Representation Office
Tel: +7 3272 509 944
Fax: +7 3272 509 573

Korea
3M Korea Ltd.
Tel: 82-2-3771-4286
Fax: 82-2-786-2825

Malaysia
3M Malaysia Sdn. Bhd.
Tel: 6-03-7806 2888
Fax: 6-03-7806 2902

Mexico
3M México, S.A. de C.V.
Tel: +52-55-5270-0400
Fax: +52-55-5270-0433

Middle East
3M Gulf Ltd.
Tel: 971-4-3670-777
Fax: 971-4-3670-699

The Netherlands
3M Nederland B.V.
Tel: 31-715-450-450
Fax: 31-715-450-212

New Zealand
3M New Zealand
Tel: 64-9-444 4760
Fax: 64-9-443 7885

Peru
3M Peru S.A.
Tel: 511-224-2728
Fax: 511-224-3171

Philippines
3M Philippines
Tel: (632) 8133781 to 95
Fax: (632) 8145873 to 74

Poland
3M Poland Sp.z o.o.
Tel: (48 22) 739 60 00
Fax: (48 22) 739 60 01

Portugal
3M Portugal
Tel: 351-21-3134500
Fax: 351-21-3134680

Russia
3M Russia
Tel: 7 (495) 784-74-74
Fax: 7 (495) 784-74-75

Singapore
3M Technologies (S) Pte. Ltd.
Tel: 65-6450-8866
Fax: 65-6455-2130

Sri Lanka
3M Lanka (Pvt.) Ltd.
Tel: (94) 11 2785701
Fax: (94) 11 4410083-4

Spain
3M España, S.A.
Tel: 34-91-321-6000
Fax: 34-91-321-6002

Sweden
3M Svenska AB
Tel: +46-8-92 21 00
Fax: +46-8-92 24 22

Switzerland & Eastern Europe
3M (Schweiz) AG
Tel: +41 44 724 92 44
Fax: +41 44 724 94 80

Thailand
3M Thailand Ltd.
Tel: (66)2 260 8577 Ext 175
Fax: (66)2 261 7535

Taiwan
3M Taiwan Ltd.
Tel: 886-2-2704-9011
Fax: 886-2-2706-0355

Turkey
3M Turkey
Tel: 9 (0212) 3507777
Fax: 9 (0212) 2821742

Ukraine
3M Ukraine
Tel: +380 44 490 57 77
Fax: +380 44 490 57 75

United Kingdom & Ireland
3M Health Care Ltd.
Tel: 44-1509-611-611
Fax: 44-1509-237-288

Venezuela
3M Manufacturera Venezuela
Tel: 58-241-8391911
Fax: 58-241-8391928

Viet Nam
3M Viet Nam Ltd.
Tel: 84 8 640986
Fax: 84 8 641024

3M

3M Medical Specialties
3M Center, Building 275-5W-05
St. Paul, MN 55144-1000 USA
Tel.: 800 228-3957

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FM 14552

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Medical Specialties
3M Skin and Wound Care Division
3M Center
St. Paul, MN 55144-1000
651 733 1110

PRODUCT CLINICAL DATA SUMMARY
(b)(4) [redacted]

Effective: September 2010

The adhesive used on (b)(4) [redacted], as part of another tape construction, has been subjected to the following safety evaluations:

In Vitro Cytotoxicity

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO_2 for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis.
The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

MEM Elution

An additional *in vitro* study was conducted to evaluate for potential cytotoxic effects following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37 degrees C for 24 hours. The negative control, reagent control and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37 degrees C in the presence of 5% CO_2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25mm x 25mm sections of the test article and control article were topically applies to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application
There was no erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

Guinea Pig Sensitization

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig based on the requirements of ISO 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was occlusively patched to the intact skin of ten animals for 6-8 hours, three times a week over a 3 week period. The control article was similarly patched to 5 animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test and control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. 3M Study 011344 (all)

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3M Skin and Wound Care Division
3M Center
St. Paul, MN 55144-1000
651 733 1110

TA SUMMARY

(b)(4) [redacted]

In addition, earlier studies using the same adhesive have shown the following results:

Repeated Insult Patch Test (Draize) in Humans
Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States.
Results: No allergic contact dermatitis observed.

21-day Cumulative Irritation in Humans
Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States.
Results: Consistent with responses characteristic of adhesive materials.

The adhesive used in this product has been shown to be hypoallergenic. The use of the term "hypoallergenic" has come to indicate a product that is non-sensitizing to the general public. The hypoallergenic claim for this product is supported by clinical evaluation using the repeated insult patch test in humans, commonly known as the Draize test. This protocol involves repeated application of samples on 200 healthy volunteers for a 2- to 3-week induction period, followed by a 2-week rest period and a challenge application. To be termed hypoallergenic, 3M Medical Specialties products are required to show no evidence of sensitization potential under these test conditions.

It is the responsibility of our customers to determine final suitability of our products for their application.

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17. Software

In accordance with FDA's Guidance for the content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005, the FORE-SIGHT Elite Absolute Tissue Oximeter is categorized as a Moderate Level of Concern. This designation is appropriate because failures or latent design flaws in this adjunct monitor could lead to an erroneous diagnosis or a delayed or unnecessary medical treatment.

The FORE-SIGHT ELITE Oximeter firmware is comprised of (b)(4) [redacted] The Main Application processor and the NIRS Signal Acquisition Module (NSAM) Application processor. The Main Application processor is responsible for displaying the acquired absolute tissue oxygen saturation value (as a numeric & trace), generating alarm signals based on current conditions, interfacing with the remote equipment and the User via a touchscreen to configure the Oximeter (refer to CAS Document 21-07-0325). The NSAM Application processor is responsible for controlling the LEDs on the sensor at the patient site, acquiring the corresponding signals and computing an absolute tissue oxygen saturation value (refer to CAS Document 21-07-0327).

The software has undergone validation to verify the software functions and the data algorithm supporting the large sensor somatic tissue capability. All verification and validation testing was successfully completed and no new hazards were identified. The software requirements and report for the validation are:

- Gemini Main Application Software Requirements 21-07-0325
- Gemini NSAM Application Software Requirements 21-07-0327
- Gemini Main Application Software Architecture 21-07-0329
- Gemini NSAM Application Software architecture 21-07-0331
- Gemini Main Application Software (Life Cycle) 21-07-0334
- Gemini NSAM Application Software (Life cycle) 21-07-0336
- FORE-SIGHT Elite Software Validation Report with Plan VaR 120019
- Project Gemini Product Specification 21-07-0302.

These documents may be found in Attachment A (Product Specification) and E.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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090026218173a0fd.pdf
System attempted to attach the file. Please look at attachments to open this file manually.

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Author: P. Swanke, H. Triebel **Date:**[1] 05-Feb-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

2/6/13 Project Leader Date	2/6/13 Software Eng[2] Date
2/6/13 Regulatory Affairs Date	

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Form Revision History

00 – Initial release

Document Revision History

00 – Initial release
01 – Update Hazard/Risk Section numbers – Age/Weight feature/risks removed from RMF docs, Update list of Main Bootloader Verification plans

PURPOSE

The following Software Life Cycle Worksheet[3] shall be completed by the Project Leader early in Stage 4 with information obtained from Design Inputs (Product Specifications, Marketing Requirements or SPRs) and information gathered from Software Eng(s) involved in the design. A final review of this Software Life Cycle Worksheet shall be performed in Stage 7 prior to the Product Release.

1. Introduction – Describe the Project/Product

This document covers the Software Life Cycle of the Project Gemini's Main Application software. The Main Application will perform Graphical User Interface (GUI), obtain and display computed values from the NSAM for all channels, provide Serial communications with external devices and allow for upgrading of the NSAM Bootloader and Application.

[1] Date: Refers to date the Information on this form was last fully updated and **not** the revision of the form itself (see footer)

[2] The Form may be altered to include approvals for additional Software Engs

[3] This form may be modified by the addition of other fields. Fields should **not** be removed, and unused fields should be indicated as Not Applicable (NA) along with a justification if necessary.

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Overall Software System Safety Class[4]:	☐ Class A: No injury or damage to health is possible
	☒ **Class B: Non-serious injury is possible**
	☐ Class C: Death or serious injury is possible

Rational: IFU: The prospective clinical value of data from the FORE-SIGHT Oximeter has not been demonstrated in disease states and these data should not be used as a sole basis for diagnosis or therapy. Warning in the User manual: The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. High/Low Alarm Limit violations are High priority alarms.

Software items with lower Safely Class than Overall Software System (see above): **None**

Software Item: **Auxiliary / Debug port functionality** Class: A

Rationale: Does not affect safety / data collection, it is used for debugging purposes only Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

[4] Software System Safety Class is defined in ANSI/AAMI/IEC 62304 Standard

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Other Software Development processes used and not described in 21-07-0017 - Software Style Guidelines:	**None**

Design Input: Documents:	☒ Product Specifications:	**21-07-0302, Gemini Product Specifications**
	☐ Marketing Requirements:	
	☐ SPRs:	
	☐ Other:	

Design Outputs Software Documents:	**21-07-0325, Gemini Main App SW Requirements**
	21-07-0329, Gemini Main App SW Architecture
	Details the requirements of the Main Application to perform basic GUI
	functions, obtain and display computed values from the NSAM for all
	channels, provide Serial communications with external devices and allow for
	upgrading of the Main Bootloader and Application

Verification Documents:	Gemini Main App - System Verification Plan
	Gemini Main App - Integration Verification Plan:
	Gemini Main App: Main & Task Creation Integration Plan
	Gemini Main App: MQX Related/Common Drivers Integration Plan
	Gemini Main App: 1-Wire Integration Plan
	Gemini Main App: Shell & Debug Integration Plan
	Gemini Main App: Utilities Integration Plan
	Gemini Main App: Peg Integration Plan
	Gemini Main App - Main Screen Verification Plan
	Gemini Main App - Medium & Low Priority Alarm Annunciation Verification Plan
	Gemini Main App - Alarm Silence Verification Plan
	Gemini Main App - System Message Verification Plan
	Gemini Main App - Alarm Limit Layout Verification Plan
	Gemini Main App - Alarm Volume Verification Plan
	Gemini Main App - Hi/Lo Alarm Limits Verification Plan

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	Gemini Main App - Alarm Limit Delays Verification Plan
	Gemini Main App - Alarm Annunciation Verification Plan
	Gemini Main App - Numeric field Verification Plan
	Gemini Main App - Trace Area Verification Plan
	Gemini Main App - Patient menu Verification Plan
	Gemini Main App - Date/Time Menu Verification Plan
	Gemini Main App - Battery Condition Verification Plan
	VaP 120018, Gemini / FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan
	VaP 120019, Gemini / FORE-SIGHT ELITE Software PEMS Validation

Config Management:	☒ New Project & Files ☐ Use Concurrent Versions System (CVS) files: From Build _____ Rev: _____ ☐ Use DocControl Archive files: From Build Rev:

For each Software build, describe the Tools and Environment (Mfg, Name, Rev, etc.):

Software	Tools & Environment Used to Build Software
(b)(4) [redacted]	

Complete the following if the Overall Software System is Class C ☐ or N/A ☒

Standards: **N/A**

Method: **N/A**

Other Problem Resolving processes not used or described in QSP4004 - System Performance Reports (SPR), Product Request (PR): **Yes** - (b)(4) [redacted] (Source Configuration and Management) solution, Software Version: 4.0, Database Version: 4.0

Complete the following if the Overall Software Systems is Class B ☒, C ☐ or N/A☐:

Integration Test Plan: 1) Main App: Main & Task Creation Integration Plan

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2) Main App: MQX Related/Common Drivers Integration Plan
3) Main App: 1-Wire Integration Plan
4) Main App: Shell & Debug Integration Plan
5) Main App: Utilities Integration Plan
6) Main App: Peg Integration Plan

Project Risk Management:	Risk Management Plan:	**21-07-0303, Gemini Risk Management Plan**
	Hazard Identification:	**21-07-0304, Gemini Hazard Identification**
	dFMEA Analysis:	**21-07-0305, Gemini Monitor dFMEA Analysis**
	Risk Analysis:	**21-07-0306, Gemini Risk Analysis**
	Risk Management Summary:	**21-07-0307, Gemini Risk Management Summary**
	Other:	

SW Risk[5]	Control Measures / VeR Plan [6]
4.1.2.1 Poorly assembled or damaged monitor creates a broken electrical connection causing heat to be generated in Medical Device resulting in thermal injury (burns) at contact site	Error message is indicated on display when excessive power is attempted to be delivered to LEDs output & LEDs turned off Gemini Main App - System Message Verification Plan
4.1.2.5 Thermal failure of plastic bezel before end of expected service life of Medical Device creates an exposed electrical connection allowing for personal contact resulting in electrical shock	Medical Device monitors internal temperature and shuts down when max temp reached Gemini Main App - System Message Verification Plan
4.1.2.7 Batteries are subjected to over-charging that produces excessive heat that increases the ambient temperature causing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Medical Device monitors internal temperature and shuts down when max temp reached Gemini Main App - System Message Verification Plan
4.1.3.6 Patient moves/turns or loss of adhesion due to perspiration or inadequate placement causing Sensor to move from original position causing sensor to cover nose or mouth resulting in suffocation or injury	Ambient light detection to alert User Gemini Main App - Alarm Annunciation Verification Plan

[5] Refer to 21-07-0304 Gemini Hazard Identification & 21-07-0306 Gemini Risk Analysis for additional information

[6] All Control Measures are verified by specific Verification Plans as well as VaP 120018, Gemini / FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan

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SW Risk[5]	Control Measures / VeR Plan [6]
4.3.1.1 Medical Device is inoperable due to susceptibility of electromagnetic fields (EMC) from other devices causing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Sustained noisy conditions will blank numeric & recover when noise is removed Gemini Main App - Numeric field Verification Plan
4.3.4.1 Medical Device is inoperable due to extreme temperature, humidity or atmospheric pressure causing device readings to be incorrect resulting in a lack, delay or over treatment of patient	SW monitors internal temp & adjusts fan speed accordingly Detects inoperable fan Shut device down if max temp exceeded Gemini Main App - System Message Verification Plan
4.5.1.1 Medical device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Body location for Sensor prominently indicated on display Sensor body location saved Gemini Main App - Numeric field Verification Plan Gemini Main App - Patient menu Verification Plan
4.5.1.2 Poorly designed medical device labeling leads to an incorrect interpretation and lack of understanding resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display Tissue Perfusion Index (TPI) shall be displayed on the main screen for each channel and values described under a Help menu Any icons or abbreviations used are consistence with medical industry standards Gemini Main App - Numeric field Verification Plan
4.5.2.1 Medical Device used with inappropriate accessory allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Software detection of connection to an approved accessory or external medical device Gemini Main App - Main Screen Verification Plan
4.5.3.1 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display Sensor body location saved Gemini Main App - Numeric field Verification Plan Gemini Main App - Patient menu Verification Plan
4.5.4.1 Medical Device used by unskilled/ untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & values Gemini Main App - Numeric field Verification Plan
4.5.4.2 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Body location of Sensor prominently indicated on display Sensor body location saved Gemini Main App - Numeric field Verification Plan Gemini Main App - Patient menu Verification Plan

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SW Risk[5]	Control Measures / VeR Plan [6]
4.5.5.1 Medical Device used by unskilled/ untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & value Gemini Main App - Numeric field Verification Plan
4.5.5.2 Medical Device used with an inappropriate Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display Sensor body location saved Gemini Main App - Numeric field Verification Plan Gemini Main App - Patient menu Verification Plan
4.5.6.2 Medical Device used with an inappropriate size Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Error messages displayed Gemini Main App - System Message Verification Plan
4.5.6.3 Software performance issue in Medical Device allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Periodic system checks Gemini Main App - System Message Verification Plan
4.5.7.1 Medical Device used in an inappropriate manner with incompatible consumables/accessories allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Software recognition application for detection of connection to an approved medical device Gemini Main App - System Message Verification Plan
4.5.10.1 Alarm Volume altered to lowest setting, allowing user to miss the Alarm tones resulting in a lack, delay or over treatment of patient	Alarm Volume cannot be turned off Lowest Alarm volume setting still audible in normal use environment Alarm message and alarm icons visible on screen Always visible Alarm LED Gemini Main App - Alarm Volume Verification Plan Gemini Main App - Alarm Silence Verification Plan Gemini Main App - Alarm Annunciation Verification Plan
4.5.10.2 Display brightness altered to lowest setting, allowing user to not see Alarm message resulting in a lack, delay or over treatment of patient	Always visible Alarm LED Alarm annunciation always includes audio tones regardless of display brightness Brightness cannot be turned off Lowest brightness setting still allows viewing of screen in normal use environment Gemini Main App - Alarm Silence Verification Plan Gemini Main App - Alarm Annunciation Verification Plan

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SW Risk[5]	Control Measures / VeR Plan [6]
4.6.1.1 Medical Device presents information that are mistaken/ misinterpreted for actual values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Parameter name & units displayed adjacent to Numeric value TPI displayed on the main screen for each channel & values Gemini Main App - Main Screen Verification Plan Gemini Main App - Numeric field Verification Plan
4.6.1.2 Arrangement of front panel controls allows user to incorrectly configure Medical Device for current type patient leading to incorrect readings and inaccurate diagnoses resulting in a lack, delay or over treatment of patient	User interface uses touchscreen with icons Menu interface driven by touchscreen allow for navigation & selection Current selections on screen are highlighted to indicate location Feature state indicated by checkbox, numeric value or outline Gemini Main App - Main Screen Verification Plan Gemini Main App - Patient menu Verification Plan Gemini Main App - Date/Time Menu Verification Plan
4.6.2.1 Abbreviations used with the Medical Device allow for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Parameter name & units displayed adjacent to Numeric value Gemini Main App - Numeric field Verification Plan
4.6.3.1 Medical Device displays ambiguous or unclear states that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid information shall be presented as dashes & messages Limit violation & Equipment alarm messages displayed TPI displayed on main screen for each channel & values Gemini Main App - Numeric field Verification Plan Gemini Main App - Hi/Lo Alarm Limits Verification Plan Gemini Main App - Numeric field Verification Plan
4.6.3.2 Wrong size Sensor used on an inappropriate type/size patient allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display Sensor body location saved TPI displayed on the main screen for each channel & value Gemini Main App - Numeric field Verification Plan

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SW Risk[5]	Control Measures / VeR Plan [6]
4.6.4.1 Medical Device displays ambiguous or unclear settings that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid information shall be presented as dashes & messages Limit violation & Equipment alarm messages displayed TPI displayed on main screen for each channel & values Gemini Main App - System Message Verification Plan Gemini Main App - Numeric field Verification Plan
4.6.5.1 Erroneous or lack of visual information (e.g., limited viewing angle of display) on Medical Device that allows for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Unit provides brightness adjustments for improved visibility in varying light conditions Periodic Power Supply checks Highly visible numerics & traces due to high contrast of color Gemini Main App - System Message Verification Plan Gemini Main App - Numeric field Verification Plan Gemini Main App - Trace Area Verification Plan
4.6.6.1 Lack of audible feedback on Medical Device that allows for missing Alarm conditions causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Audible output may be allowed to be turned down, and not turned off Visual indicators remain even if audio is muted/silenced Gemini Main App - Alarm Volume Verification Plan Gemini Main App - Alarm Annunciation Verification Plan
4.7.1.1 Internal data transfer is erroneous allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Periodic RS232 checks – packet checksum Communications between NSAM & Main ctrl board uses checksum'ed information Invalid received data not used/displayed Lack of continuous missing data will cause system alarm Gemini Main App - System Message Verification Plan
4.7.1.2 Calculated FS Data is collected erroneous due to a software performance issue allowing FS Data readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Software calculations for FS Data Collection are based on simple algorithms FS Data transfer to USB Patient data file or snapshot/print feature Gemini Main App - System Message Verification Plan

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SW Risk[5]	Control Measures / VeR Plan [6]
4.7.1.3 Medical Device readings are transmitted erroneously due to a software performance issue or faulty connection allowing remote readings to be incorrect causing inaccurate diagnoses resulting in wrong course of patient treatment leading to ischemic or hypoxic injury	Periodic RS232 checks – Protocol check Serial output protocol based on documented format Gemini Main App - System Message Verification Plan
4.7.2.1 Medical Device readings are displayed erroneously due to lack/delay of specifications of maintenance checks allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Periodic hardware checks (Power Supply, Memory, USB, VGA & RS232) Gemini Main App - System Message Verification Plan
4.7.4.1 Re-use of disposable, single-use Sensor (e.g., by user reprocessing, or non-removal of release liner on adhesive type Sensors) allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Software recognition software for detection of connection to an approved medical device Gemini Main App - System Message Verification Plan
4.7.5.1 Medical Device controls become inoperable due to age/use & not allowing user to enter proper patient data or forced to use existing patient case allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Periodic power supply checks TPI displayed on the main screen for each channel & values Gemini Main App - System Message Verification Plan Gemini Main App - Numeric field Verification Plan
4.7.5.2 Medical Device LCD become partially inoperable due to age/use & not allowing user to fully view patient data & causes inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Periodic power supply checks Gemini Main App - System Message Verification Plan
4.7.5.4 Patient connectors become inoperable due to age/use & mechanical insertion/extraction allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid computed information shall either present as dashes or a warning message Gemini Main App - Numeric field Verification Plan
4.7.5.7 Fans become inoperable due to age/use leading to an internal temp above stated environmental limits allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	If fan stops and the internal device temp reaches a maximum threshold device will perform auto-shut off Gemini Main App - System Message Verification Plan

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SW Risk[5]	Control Measures / VeR Plan [6]
4.8.1.1 User does not have access to view provided electronic copy of DFU safety instructions, that allows for improper use of device & causes delay of treatment of patient	Ambient light detection message and alarm Gemini Main App - System Message Verification Plan
4.11.1.1 Disconnected, faulty Sensor, preamp or device causes the Medical Device to be inoperable resulting in a lack, delay or over treatment of patient	Periodic device hardware fault testing Fault conditions indicated & annunciated Always visible Alarm LED Gemini Main App - System Message Verification Plan Gemini Main App - Alarm Annunciation Verification Plan Gemini Main App - Alarm Silence Verification Plan
4.11.1.2 Lack of notification by Medical Device of the decrease in a patient's StO_2 values resulting in a lack, delay or over treatment of patient	Low Alarm limits available to alert user of decrease in StO_2 value Visual & audible annunciation of Low StO_2 Alarm Gemini Main App - Hi/Lo Alarm Limits Verification Plan Gemini Main App - Alarm Annunciation Verification Plan Gemini Main App - Alarm Silence Verification Plan
4.11.1.3 Lack of notification by Medical Device of the increase in a patient's StO_2 values resulting in a lack, delay or over treatment of patient	High Alarm limits available to alert user of increase in StO_2 value Visual & audible annunciation of High StO_2 Alarm Gemini Main App - Hi/Lo Alarm Limits Verification Plan Gemini Main App - Alarm Annunciation Verification Plan Gemini Main App - Alarm Silence Verification Plan
4.11.1.4 Annunciation of flashing visual Alarm conditions on screen may cause spasms and/or convulsions in people prone to seizures (e.g., epilepsy)	Visual Alarm Flashing conforms to IEC 60601-1-8 flash rates of alarm LEDs Gemini Main App - Alarm Annunciation Verification Plan Gemini Main App - Alarm Silence Verification Plan

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SW Risk[5]	Control Measures / VeR Plan [6]
4.11.2.1 StO_2 High/Low Alarm Limit selection cannot be accurately tested against the actual Patient StO_2 value allowing a possible undetected change in physiological condition to exist resulting in circulatory injury	StO_2 computed value & StO_2 High & Low Alarm Limits have resolution of 1% High Alarm: StO_2 value > High StO_2 Limit Low Alarm: StO_2 value < Low StO_2 Limit Gemini Main App - Alarm Limit Layout Verification Plan Gemini Main App - Hi/Lo Alarm Limits Verification Plan

Software includes or uses SOUP[7]: ☐ Yes ☒ No

Description/Mfg: **N/A**

SOUP included in Risk Management review: ☐ Yes ☒ No

SOUP Risks: **N/A**

Control Measures: **N/A**

[7] SOUP = Software Of Unknown Provenance, refer to ANSI/AAMI/IEC 62304 Standard

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Author: M. Kenigsztein **Date:**[1] 05-Feb-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Project Leader	2/6/13 Date	Software Eng[2]	02/06/13 Date
Regulatory Affairs	2/6/13 Date		

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Form Revision History

00 – Initial release

Document Revision History

00 – Initial release
01 – Update Hazard/Risk Section numbers – Age/Weight feature/risks removed from RMF docs, Update list of Main Bootloader Verification plans

PURPOSE

The following Software Life Cycle Worksheet[3] shall be completed by the Project Leader early in Stage 4 with information obtained from Design Inputs (Product Specifications, Marketing Requirements or SPRs) and information gathered from Software Eng(s) involved in the design. A final review of this Software Life Cycle Worksheet shall be performed in Stage 7 prior to the Product Release.

1. Introduction – Describe the Project/Product

This document covers the Software Life Cycle of the Project Gemini's NSAM Application software. The NSAM Application will perform computation of the NIRS Algorithm based on Sensor Body locations and sensor types as well as allowing for upgrading of the NSAM Bootloader via serial code/file transfer from the Gemini Main Application

[1] Date: Refers to date the Information on this form was last fully updated and **not** the revision of the form itself (see footer)

[2] The Form may be altered to include approvals for additional Software Engs

[3] This form may be modified by the addition of other fields. Fields should **not** be removed, and unused fields should be indicated as Not Applicable (NA) along with a justification if necessary.

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Overall Software System Safety Class[4]:	
	☐ Class A: No injury or damage to health is possible
	☒ **Class B: Non-serious injury is possible**
	☐ Class C: Death or serious injury is possible

Rational: IFU: The prospective clinical value of data from the FORE-SIGHT Oximeter has not been demonstrated in disease states and these data should not be used as a sole basis for diagnosis or therapy. Warning in the User manual: The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. The calculations of the %StO2 values are performed within the NSAM algorithm.

Software items with lower Safely Class than Overall Software System (see above):

Software Item: **Boot loader update functionality** Class: A

Rationale: Does not affect safety / data collection, it is done offline by a biomed Documented in RM file: ☐

Software Item: **Auxiliary / Debug port functionality** Class: A

Rationale: Does not affect safety / data collection, it is used for debugging purposes only Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

Software Item: Class:

Rationale: Documented in RM file: ☐

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[4] Software System Safety Class is defined in ANSI/AAMI/IEC 62304 Standard

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Other Software Development processes used and not described in 21-07-0017 -

Software Style Guidelines: **None**

Design Input: Documents:		
	☒ Product Specifications:	**21-07-0302, Gemini Product Specifications**
	☐ Marketing Requirements:	
	☐ SPRs:	
	☐ Other:	

Design Outputs Software Documents:	
	21-07-0327, Gemini NSAM Application SW Requirements
	21-07-0331, Gemini NSAM Application SW Architecture
	Details the architecture and requirements of the NSAM Application to perform computation of the NIRS algorithm based on Sensor Body locations and allows for upgrading of the NSAM Bootloader

Verification Documents:	
	Gemini NSAM Application Power On Self-Test (POSTs) Verification Plan
	Gemini NSAM Application Algorithm Verification Plan
	VaP 120018, Gemini / FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan
	VaP 120019, Gemini / FORE-SIGHT ELITE Software PEMS Validation

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Config Management:

☒ **New Project & Files**

☐ Use Concurrent Versions System (CVS) files:

From Build _____ Rev: _____

☐ Use DocControl Archive files:

From Build Rev:

For each Software build, describe the Tools and Environment (Mfg, Name, Rev, etc.):

Software	Tools & Environment Used to Build Software
(b)(4) [redacted]	

Complete the following if the Overall Software System is Class C ☐ or N/A ☒

Standards: **N/A**

Method: **N/A**

Other Problem Resolving processes not used or described in QSP4004 - System Performance Reports (SPR), Product Request (PR): **Yes -** (b)(4) [redacted] **(Source Configuration and Management) solution, Software Version: 4.0, Database Version: 4.0**

Complete the following if the Overall Software Systems is Class B ☒, C☐ or N/A ☐

Integration Test Plans: 1) NSAM App: Main - Initialization & Task Creation Integration Plan

2) NSAM App: MQX Related/Common Drivers Integration Plan

3) NSAM App: 1-Wire Integration Plan

4) NSAM App: NIRS Algorithm Integration Plan

5) NSAM App: Shell and Debug Integration Plan

6) NSAM App: Utilities Integration Plan

7) NSAM App: Bootloader Upgrade Integration Plan

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Project Risk Management:	Risk Management Plan:	21-07-0303, Gemini Risk Management Plan
	Hazard Identification:	21-07-0304, Gemini Hazard Identification
	dFMEA Analysis:	21-07-0305, Gemini Monitor dFMEA Analysis
	Risk Analysis:	21-07-0306, Gemini Risk Analysis
	Risk Management Summary:	21-07-0307, Gemini Risk Management Summary
	Other:	N/A

SW Risks:[5]	Control Measures / VeR Plan:[6]
4.1.2.3 Sensor LED design, damaged monitor or Software issue that allows excessive current to drive LEDs causing localized tissue injury (burn)	Power to LEDs output is limited (current & duty cycle) Temp measurement in Sensor will shut off LEDs if max Temp exceeded Gemini NSAM Application Algorithm Verification Plan
4.1.2.6 Applied Sensor raises the temperature under the Sensor to > 41.0℃ resulting in thermal tissue injury (heat) at Sensor site	Temp measurement in Sensor will shut off LEDs if max Temp exceeded Gemini NSAM Application Algorithm Verification Plan
4.1.3.6 Patient moves/turns or loss of adhesion due to perspiration or inadequate placement causing Sensor to move from original position causing sensor to cover nose or mouth resulting in suffocation or injury	Ambient light detection to alert User Gemini NSAM Application Algorithm Verification Plan
4.3.1.1 Medical Device is inoperable due to susceptibility of electromagnetic fields (EMC) from other devices causing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Data filter attempts to eliminate noise signals Value captured & not updated during noisy periods Sustained noisy conditions will blank numeric & recover when noise is removed Gemini NSAM Application Algorithm Verification Plan
4.4.1.2 Sensor LEDs calibration values invalid allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Cal values stored within Sensor memory, Values need to inputted by NSAM, Checksum of Cal values must be correct in order for Sensors to be used and error message generated Gemini NSAM Application Algorithm Verification Plan
4.5.4.1 Medical Device used by unskilled/untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & values Gemini NSAM Application Algorithm Verification Plan
4.5.5.2 Medical Device used with an inappropriate Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	Sensor on body location prominently indicated on display LEDs will not turn on if incorrect Sensor attached Gemini NSAM Application Algorithm Verification Plan
4.5.6.2 Medical Device used with an inappropriate size Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient	LEDs will not turn on if incorrect Sensor attached Gemini NSAM Application Algorithm Verification Plan

[5] Refer to 21-07-0304 Gemini Hazard Identification & 21-07-0306 Gemini Risk Analysis for additional information

[6] All Control Measures are verified by specific Verification Plans as well as VaP 120018, Gemini / FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan

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SW Risks:[5]	Control Measures / VeR Plan:[6]
4.5.6.3 Software performance issue in Medical Device allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient Some examples of mitigating know SW issues:	Power On Self-Test (POST) & periodic system checks Software algorithm output verified against development SW (used to obtain clinical data) output for all Sensor sizes based on body locations Gemini NSAM Application Power On Self-Test (POSTs) Verification Plan Gemini NSAM Application Algorithm Verification Plan
Communication integrity between the NSAM and Host (SCB)	Checksum for every command Gemini NSAM Application Power On Self-Test (POSTs) Verification Plan Gemini NSAM Application Algorithm Verification Plan
Communication's port to Host not responding	Flag a critical system error on the host Gemini NSAM Application Algorithm Verification Plan
Un-normal input signals causing unpredicted calculations	Check signal levels to be appropriate, check for divide by zero and Log(0), avoid calculation and flag it to the host Gemini NSAM Application Algorithm Verification Plan
Memory fragmentation	Avoid excessive run time dynamic memory allocations Gemini NSAM Application Algorithm Verification Plan
Memory leaks	Code review, prolonged testing Gemini NSAM Application Algorithm Verification Plan
Data corruption while writing to a non-volatile memory	Use Checksums, redundant data storage, avoid /delay as possible power loss Gemini NSAM Application Algorithm Verification Plan
4.5.9.1 Continuous LED output to patient Sensor site causes increase of temperature at Sensor site resulting in tissue injury	Power to LED output is limited Gemini NSAM Application Algorithm Verification Plan
4.6.1.1 Medical Device presents information that are mistaken/ misinterpreted for actual values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & values Gemini NSAM Application Algorithm Verification Plan
4.6.3.1 Medical Device displays ambiguous or unclear states that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid information shall be presented as dashes & messages TPI displayed on main screen for each channel & values Gemini NSAM Application Algorithm Verification Plan
4.6.3.2 Wrong size Sensor used on an inappropriate type/size patient allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	TPI displayed on the main screen for each channel & value Gemini NSAM Application Algorithm Verification Plan
4.7.5.3 Medical Device calibration data incorrect that allows device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Sensor Flash R/W check Redundant checksum storage of critical calibration data Gemini NSAM Application Algorithm Verification Plan

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SW Risks:[5]	Control Measures / VeR Plan:[6]
4.7.5.6 Patient connectors become inoperable due to age/use and mechanical insertion/extraction allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient	Invalid computed information shall either presented as dashes with warning message Gemini NSAM Application Algorithm Verification Plan
4.11.1.1 Disconnected, faulty Sensor, preamp or device causes the Medical Device to be inoperable resulting in a lack, delay or over treatment of patient	Sensing of Sensor & Preamp connect & disconnect Periodic Sensors & Preamp fault testing Periodic device hardware fault testing Fault conditions indicated & annunciated Gemini NSAM Application Algorithm Verification Plan

Software includes or uses SOUP[7]: ☐ Yes ☒ No

Description/Mfg: **N/A**

SOUP included in Risk Management review: ☐ Yes ☒ No

SOUP Risks: **N/A**

Control Measures: **N/A**

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[7] SOUP = Software Of Unknown Provenance, refer to ANSI/AAMI/IEC 62304 Standard

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CASMED®	Part Number: VaP 120019	Rev: 9.0
Title: Gemini / FORE-SIGHT ELITE Software PEMS Validation Plan		

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals:

Validation Engineer	P. Tala	12.10.13 Date
Project Engineer	R. Bystrianyk	12/12/13 Date
Eng Project Leader	H. Triebel	11-Dec-13 Date
VP R & D	J. Gamelin	11-Dec-2013 Date
Mktg Product Manager	M. Aceves	12/11/13 Date
Quality Assurance Regulatory Affairs	R. Jeffrey	12/11/13 Date

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Document Revision History		
Rev	Author(s)	Description
1.0	P. Tala	Initial release, Software Rev 0.2.0 Test Plan
2.0	P. Tala	Update plan to include changes for Rev 0.3.3 Test Plan
3.0	P. Tala	Update plan to include changes for Rev 0.3.5 Test Plan
4.0	P. Tala	Update plan to include changes for Rev 0.3.6 Test Plan
5.0	P. Tala	Update plan to include changes for Rev 1.0.0 Test Plan
6.0	P. Tala	Update plan to include changes for Rev 1.0.1 Test Plan
7.0	P. Tala	Update plan to include changes for Rev 1.0.2 Test Plan
8.0	P. Tala	Update plan to include changes for Rev 1.1.0 Test Plan
9.0	P. Tala	Update plan to include changes for Rev 1.1.1 Test Plan

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Table of Contents

1 Introduction 7

2 Scope 7

3 Reference Documents 9

4 List of Equipment 10

5 Initial Setup 10

6 Regression Validation Justification 10

7 Data Sheets - Pass/Fail Criteria 11

8 Test Procedure 12

8.1 SCB & NSAM Software Code Upload & System Configuration 12
8.1.1 SCB & NSAM Package and Software Upload 12
8.1.2 System Configuration 13
8.1.3 Touch Screen Calibration 13

8.2 Oximeter Start Up 14
8.2.1 Standard Start Up 14
8.2.2 Start Up With Failed Power-On Self-Test 14

8.3 Visual & Display Indicators 15
8.3.1 Main Screen Display 15
8.3.1.1 Title Bar/Line Area 16
8.3.1.2 System Message Area 16
8.3.1.3 Trace Area 16
8.3.1.4 Numeric Field 17
8.3.1.5 1ST , 2nd Levels Touch button 18
8.3.1.6 Alarm Silence button 19

8.4 User Controls 20
8.4.1 Patient Menu 20
8.4.1.1 Patient Menu Selections 20
8.4.1.2 Body Location Settings 20
8.4.1.2.1 US Configuration 20
8.4.1.2.2 OUS Configuration 22
8.4.1.3 Alarm Limits Settings 23
8.4.1.4 Alarm Limit Range 24
8.4.1.5 Patient ID 25
8.4.1.6 New Patient 25
8.4.2 Event Marks 25
8.4.2.1 Events Menu Selection 25
8.4.2.2 Events from List Addition 26
8.4.2.3 Removing placed Events 28
8.4.2.4 Auto Events 29
8.4.3 Data Menu 30
8.4.3.1 Data Menu Selection 30
8.4.3.2 STS View Menu 31
8.4.3.3 STS Data Collection and Verification 32
8.4.3.4 Reference Value REF 35

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.4.4 Patient Data Management ... 36
8.4.4.1 Multiple Patients Storage ... 36
8.4.4.2 Saving Selected Files to the USB ... 37
8.4.4.3 Reviewing Data Saved to the USB ... 37
8.4.4.4 Deleting Selected Files to the USB ... 40
8.4.5 Setup Menu ... 40
8.4.5.1 Setup Menu Selection ... 40
8.4.5.2 View Settings ... 41
8.4.5.3 Volume Settings ... 41
8.4.5.4 Brightness Settings ... 42
8.4.5.5 Ports Settings ... 42
8.4.5.6 Time and Date Settings ... 43
8.4.5.7 Language Settings ... 45
8.4.5.8 Alarm Delay ... 46
8.4.5.9 Factory Defaults Settings ... 46
8.4.5.10 Help Menu ... 48

8.5 Connection Status & StO2 Data Collection ... 50
8.5.1 Patient & Monitor Cable Status ... 50
8.5.1.1 Connection Status at Power on ... 50
8.5.1.2 Disconnection Status after Power on ... 51
8.5.2 Sensor Connection and StO2 Data Acquisition ... 51
8.5.3 New /Continue Patient Timer & Prompting ... 52
8.5.4 TPI Status Indicator ... 53
8.5.5 Adult TOP Calibration Rule ... 55
8.5.6 NSAM Application Adult Cerebral Algorithm Verification ... 56
8.5.7 NSAM Application Adult Somatic Tissues Algorithm Verification ... 57

8.6 Data Communication ... 57
8.6.1 2-CH Comma Separated Value (CSV) ... 57
8.6.2 4-CH Comma Separated Value (CSV) ... 57
8.6.3 2-CH CAS Protocol (ATE) ... 58
8.6.4 4-CH CAS Protocol (ATE) ... 59
8.6.5 Philips VueLink and IntelliBridge Communication ... 61
8.6.6 Scientific Communication ... 61

8.7 Alarms Handling & Management ... 61
8.7.1 System LEDs ... 61
8.7.2 Parameter Alarms ... 61
8.7.2.1 2-Min Audio Disable Inactive ... 61
8.7.2.2 2-Min Audio Disable Active ... 62
8.7.3 Equipment Alarm ... 62
8.7.3.1 Ambient Light Condition ... 62
8.7.3.2 Sensor Temperature Monitoring ... 63
8.7.3.3 ESU Disturbance Condition ... 65
8.7.3.4 2-Min Audio Disable Inactive ... 65
8.7.3.5 2-Min Audio Disable Active ... 67
8.7.4 System Alarms ... 68
8.7.4.1 Battery Status ... 68
8.7.4.2 System Fan Status ... 68
8.7.4.3 System Temperature ... 69
8.7.4.4 2-Min Audio Disable Inactive ... 70
8.7.4.5 2-Min Audio Disable Active ... 71
8.7.5 Alarm Interference & Priority ... 72
8.7.5.1 Parameter and Equipment Alarms ... 72
8.7.5.2 Parameter and System Alarms ... 72

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.7.5.3 Equipment and System Alarms 73
8.7.5.4 Parameter, Equipment and System Alarms 74

9 Summary 75

FIGURES

Figure 1 – Initial Power On Screen (e.g. 2 Channels Mode) 15
Figure 2 – Numeric Field Organization 18
Figure 3 – Examples of button's Activation State 19
Figure 4 – Adult Cerebral (US) Body Location Menu 21
Figure 5 – Adult Tissue (OUS) Body Location Menu 22
Figure 6 – STS View Menu content 31
Figure 7 – Time & Date Menu 44
Figure 8 – Russian (Cyrillic) Alphabet keyboard 45
Figure 9 – About Help Menu 48
Figure 10 – Sensor Selection Help Screen 49
Figure 11 – Start Monitoring Help Screen 49
Figure 12 – Applying Sensors Help Screen 49
Figure 13 – Numeric Field Help Screen 50

TABLES

Table 1 – Alarm Silence Activation Access availability 20
Table 2 – Alarm Limit Range 24
Table 3 – OR Event Marks List 27
Table 4 – ICU Event Marks List 28
Table 5 – Vascular Event Marks List 28
Table 6 – NSAM Conditions Auto Events 30
Table 7 – STS View Data Record 33
Table 8 – STS DATA Calculation Data Sheet 34
Table 9 – Regional Oxygen Saturation Percentile Ranges Calculation 35
Table 10 – Calculated STS Data 35
Table 11 – Alarm Index Table 39
Table 12 – Password Protected Menu Screen 40
Table 13 – View Settings 41
Table 14 – Brightness Settings 42
Table 15 – Serial Protocols Baud Rates Selections 43
Table 16 – Simultaneous Serial Output Table 43
Table 17 – Time and Date setting 44
Table 18 – Alarm Delay 46
Table 19 - Factory Default Settings 48
Table 20 – Power On Connection Status 51
Table 21 – Connection Status during Monitoring. 51
Table 22 – Sensor Selection and StO2 Data Acquisition 52
Table 23 – TPI Symbol Status – Cerebral Monitoring 54
Table 24 – TPI Symbol Status – Somatic Tissues Monitoring 55
Table 25 – NSAM TOP Calculation Rule 56
Table 26 - ATE Serial Output Commands 60
Table 27 – Parameter Alarms Control (2-Min Audio Disable inactive) 62
Table 28 – Parameter Alarms Control (2-Min Audio Disable active) 62

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Table 29 – Equipment Alarms Control (2-Min Audio Disable inactive) 66
Table 30 – Equipment Alarms Control (2-Min Audio Disable active) 67
Table 31 – System Alarms Control (2-Min Audio Disable inactive) 71
Table 32 – System Alarms Control (2-Min Audio Disable active) 71
Table 33 – Parameter and Equipment Alarm condition Interference. 72
Table 34 – Parameter and System Alarm condition Interference. 73
Table 35 – Equipment and System Alarm condition Interference. 73
Table 36 – Parameter, Equipment and System Alarm condition Interference. 74

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

1 Introduction

The purpose of this document is to detail the validation of the design requirements for the Gemini / FORE-SIGHT ELITE Oximeter Software. The Oximeter is a medical device comprised of a Color 10.4" display, user interface controls (Touchscreen) and hardware to support the acquisition of a patient's tissue oxygen concentration. The Validation Plan will validate that the performance output meets the design input requirements set out in Gemini Product Specification documents (refer to Section 0 below).

NOTE: The term Gemini refers to the Eng Project, while FORE-SIGHT ELITE refers to the product name. They may be used interchangeably.

2 Scope

The Oximeter Software shall include the following components:

1. Oximeter SCB Bootloader Software
2. Oximeter SCB Application Software
3. Oximeter NSAM Bootloader Software
4. Oximeter NSAM Application Software

The Software Package version to be verified is Rev 1.1.1

The plan shall include validation of the safety of PEMS of installed SW listed above and detailed in Section 4 List of Equipment.

Following are the Fixes (SPRs) to the SCB & NSAM Main Application and Boot Loader Software (15-06-0285, 15-06-0284, 15-06-0283 & 15-06-0282) to be validated within this Validation Plan. Refer to the appropriate sections in the Validation Plan:

Software	New Features, Improvements and Fixes
Main Boot 15-06-0284	• Touch screen calibration range check. (1026) • Adjust Ambient light upper threshold for NSAM test (1030)
Main App 15-06-0285	• Sensor Off Tissue and StO2 Value (928) • Addition of languages including Russian (multiple CRs) • Russian Cyrillic keyboard. (1029) • Implement adaptive fan speed based on internal temperatures. (1021, 1080) • Channel ATE and CSV (1008) • Ports no longer require a system reset (827) • Special file on the USB stick "eng1984.cas" automatically starts the network (1047) • Shell - 1-wire serial memory tests (command "serm") (1045) • Create secondary level of reporting NSAM issues to the user (1052, 1053) • Entering Biomed password will display Button bar with Language and defaults (1054) • Add confirm dialog to Stop STS data (1058) • Adjust priorities and error messages (1062) • Change Brightness settings scale (1064) • CAS/ATE Remap Unstable Signal status (1071) • Add Patient ID to USB File Name (1073) • Add one decimal digit to Cumulative Sat Below Thresh & Reg O2 % Ranges (1067) • Add scientific mode to all users. (1075) • Different body locations available in OUS (1077) • Add translation for Ports -> scientific (1081) • Add automatically generated events based on special NSAM conditions (1061) • Add languages to USB patient file (1095) • Add toggling bitmap Checkbox to Engineering settings dialog (1142)

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Software	New Features, Improvements and Fixes
	• Add klog tools to Engineering Dialog (1163) • Bug Fix - Correct redraw speed of numeric fields after display of events - Still may occur but is vastly improved (746) • Bug Fix - Rapid changes in Settings-View causes crash (1038) • Bug Fix - External Interference causes the Numeric field to go blank instead of dashes (1041) • Bug Fix - Monitor reset if Factory Defaults activated (1003, 827) • Bug Fix - Correct underlying alarm led and audio problems. (1057) • Bug Fix - Pressed Events, then OR then screen froze showing just bottom 3 options (949) • Bug Fix - Rapid switching between Event button and Undo button causes crash (965) • Bug Fix - Possibility to delete more than the last Event entered (1000) • Bug Fix - USB File - need to add a decimal digit precision to STS data (1094) • Bug Fix - ICU Event list "Reposition Patient" should be Green Event after "Prostaglandin" (1096) • Bug Fix - Caution - Investigational Device not displayed when engineering body locations are enabled (SPR 765)(1129) • Bug Fix - In Italian "View" 24 Hour selection is 1Ore, should be 24 Ore (SPR 762-2) (1136) • Bug Fix - In 4 CH CAS protocol, crash when baud rate is selected (SPR 761)(1145) • Bug Fix - Numeric Field "Current Value" sometimes blank after fast boot (SPR 764)(1147) • Bug Fix - Remove active case from USB save list (SPR 758 & 760) (1148) • Bug Fix - Change STS statistics to match CSV (SPR 756)(1149) • Bug Fix - Text for sensor over/under temperature not appearing in CSV event. (755)(1150) • Bug Fix - Clicking the Ref value does not toggle the Ref line on graph (757)(1151) • Bug Fix - Event Mark vertical dotted line (SPR 754) (1153) • Bug Fix - Dutch under STS & other string fixes(SPR 762-1 & 763) (1158)
NSAM App 15-06-0283	• (b)(4) [redacted] • Account for the 1 wire temperature NSAM offsets & Code Cleanup (1043) • Enable the Enhanced AGC, allow higher dynamic range for the gains (1044) • Adjust high Ambient Light Threshold (1048) • Enhance the Bovie Filter (1049) • (b)(4) [redacted] (b)(4) [redacted] • Add Adult Somatic IFU, adjust Adult Cerebral TPI Levels (1079) • Adjust Sensor Off Temp, Adjust Low Thb levels, High Ambient Light (1093) • Ignore Low brain 690nm values & do not include in spectral window calculation of "Sensor Off" (1140)

New Features, Improvements and Fixes	Section
SPR # 741 - Possibility to delete more than the last Event entered (CR 1000)	8.4.2.3
SPR # 747 - System Reset after Factory Defaults activation (CR 1003)	8.4.5.9
SPR # 754 - Event Mark vertical dotted line (CR 1153)	8.4.2.2
SPR # 755 - NSAM Auto Event Mark on USB (CR 1150 & 1154)	8.4.2.4
SPR # 756 - STS Data Calculation (SPR 1149 & 1155)	8.4.3.3
SPR # 757 - Reference Value: Horizontal dotted line not toggling (CR 1151 & 1156)	8.4.3.4
SPR # 758 - Active case total duration time. (CR 1148)	8.4.4.1
SPR # 760 - Active cases saved to the USB (CR 1148)	8.4.4.2
SPR # 761 - Ports Settings & Baud Rate (CR 1145)	8.4.5.5

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New Features, Improvements and Fixes	Section
SPR # 762 - Dutch & Italian Strings under STS & View Menus (CR 1136 & 1158)	8.4.5.7
SPR # 763 - GUI Strings Translation (CR 1158 & 1159)	8.4.5.7
SPR # 764 - System Reset & StO2 Numerics on Display (CR 1147)	8.3
SPR # 765 - OUS Configuration & Body Location (CR 1129 & 1160)	8.4.1.2.2

3 Reference Documents

- IEC 60601-1-8 Alarm Sounds
- CAS QSP1026, Risk Management
- CAS QSP4001, Product Design Procedure
- CAS QSP4002, Software Life Cycle Procedure
- CAS QSP4004, System Performance Report (SPR), Product Request (PR)
- CAS QSP4007, Design Verification and Validation
- 21-07-0302, Gemini Product Specification
- 21-07-0312, Gemini GUI Specifications
- 21-07-0322, Gemini Philips VueLink Translation Document
- 21-07-0323, Gemini Software Icons Specifications
- 21-07-0324, Gemini Main Bootloader Software Requirements
- 21-07-0325, Gemini Main Application Software Requirements
- 21-07-0326, Gemini NSAM Bootloader Software Requirements
- 21-07-0327, Gemini NSAM Application Software Requirements
- 21-07-0328, Gemini Main Bootloader Software Architecture & Specification
- 21-07-0329, Gemini Main Application Software Architecture & Specification
- 21-07-0330, Gemini NSAM Bootloader Software Architecture & Specification
- 21-07-0331, Gemini NSAM Application Software Architecture & Specification
- 21-07-0333, Gemini Main Bootloader Software Life Cycle Worksheet
- 21-07-0334, Gemini Main Application Software Life Cycle Worksheet
- 21-07-0335, Gemini NSAM Bootloader Software Life Cycle Worksheet
- 21-07-0336, Gemini NSAM Application Software Life Cycle Worksheet
- 21-07-0337, Gemini Software Level of Concern Document
- 21-07-0339, Gemini Software Revision History
- 21-07-0342, Gemini USB Patient Data File Storage Format
- 21-07-0343, Gemini Displayed Message Priority Assignment Document
- 21-07-0344, Gemini Help Screen Specifications
- 21-07-0345, Gemini Scientific Data Serial Output Protocol
- 21-07-0346, Gemini 4-Ch Comma Separated Value Serial Output Format
- 21-07-0355, Gemini/FORE-SIGHT ELITE GUI Text Translations (Fre, Spa, Dut, Ger, Ita, Rus)
- 21-07-0360, Gemini USB Patient Data File Storage Format - Scientific Debug Events
- FS ATE, FORE-SIGHT ATE SERIAL PROTOCOL
- IntelliVue Patient Monitor- Instructions For Use – Rev H.0
- VaP/VaR 120010 – FORE-SIGHT ELITE Philips IntelliBridge/VueLink Connectivity Validation
- VeP/VeR 130033 – FORE-SIGHT ELITE Main App Research Mode Verification

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4 List of Equipment

- Gemini Tissue Oximeter: SN 1315182 1315183 referred to as Unit Under Test (UUT)
  - NSAM Bootloader software 15-06-0282 Ver 1.0.0
  - NSAM Application software 15-06-0283 Ver 2.0.0a
  - Main Bootloader software 15-06-0284 Ver 1.1.0A
  - Main Application software 15-06-0285 Ver 1.1.1A
- 1 Hospital Grade AC Power Cord.
- Gemini Large & Medium Sensors w/ & w/o optical phantoms
- Gemini Dual Preamp Cables
- PC running XP or higher with an available USB, Ethernet, and serial port
- Windows Telnet program
- FS-Elite Large Sensor (03-05-0511)
- Gemini Large optical phantoms
- FORE-SIGHT Elite Dual Preamp Cable (01-06-3100)
- VueLink & IntelliBridge compatible Patient Monitor: INTELLIVUE MP50
  SW. Rev: J.10.26 SN: DE820A9121
- Philips VueLink® Interface Module Auxiliary Plus (M1032A, Type B)
- Philips VueLink® connection cable with D-SUB 9 connector (M1032A #K6C)
- DB9 M/M Null Modem Interconnect Cable
- Philips IntelliBridge EC10 Module: PN 865115 #A01 101
- Philips IntelliBridge EC5 Module: PN 865114 #104
- Max 10 m, CAT5, Straight wired Cable (to connect EC5 to EC10 modules)
- Assorted USB Sticks

5 Initial Setup

None required

6 Regression Validation Justification

None required. Full validation of the currently available features of the Oximeter Software shall be completed.

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7 Data Sheets - Pass/Fail Criteria

This Validation Plan will be considered completed when all Test Procedure steps referenced on the following pages have been completed. The following rules shall be followed for the Data Sheets:

- Checking and signing the Data Sheets results will be done in **blue** or **black** ink only.
- The word **PASS** in the associated _____ will be used to identify when a Data Sheet step was successfully been validated.
- The word **FAIL** in the associated _____ will be used to identify when a Data Sheet step was unsuccessfully been validated.
- All Data Sheet steps must be filled in w/ Pass or Fail.
- Data Sheet step failures shall be marked in red ink and shall be initialed and dated.
- Data Sheet step discrepancies shall be marked in red ink, be lined out with the correction inserted next to the error and shall be initialed and dated.
- All performance reports and Plan discrepancies will be reviewed and their resolution approved prior to releasing the product or accessory.

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8 Test Procedure

8.1 SCB & NSAM Software Code Upload & System Configuration

8.1.1 SCB & NSAM Package and Software Upload

a) Plug the power cord into a power outlet and in to the UUT and make sure the battery pack is installed

b) **Starting with a UUT that has the Software Package version 1.0.2 installed.**

c) Connect a USB that has the Software package folder "15-06-0339_FSElite_1.1.1" (**without new Bootloader Rev 1.1.0 included**) installed to the UUT.

d) Power on the UUT to validate the Bootloader automatically enters the **Package update** menu PASS

e) Validate the Bootloader application compares the Software update file on the USB to the currently installed on the UUT PASS

f) Validate files that needs to be upgraded are properly marked red. PASS

g) Wait for the "**Update System**" key to become available then start the package update.

h) Validate all software package are updated without any further user intervention. PASS

i) Exit the Bootloader menu once done with the package installation to enter the Main menu.

j) Connect appropriate Preamps, Sensors and optical simulators to validate the system starts to report valid StO2 data. PASS

k) Validate the UUT is operating properly. PASS (Note any encountered issues below)

l) Enter the Help\About menu to validate the Package version and date do match the Package version and installation date PASS

m) Cycle powers to the UUT and reenter the Bootloader menu.

n) Enter the "**About**" menu to validate the installed software versions do match the versions within the software package installed on the UUT. PASS

o) Cycle power to the UUT to reenter the Bootloader menu

p) Connect a USB that has the **Bootloader version 1.1.0** to the UUT and start to upload the Bootloader software into the UUT using the individual software download menu to validate the update is performed without any issues. PASS (Note any encountered difficulties below)

q) Enter the Engineering Menu and validate there is the possibility to either perform a Package or an individual Software Download.

   a. Engineering PASS
   b. Manufacturing PASS
   c. Service PASS
   d. Biomed PASS (Package Up date only)

r) Exit the Bootloader to enter Main menu.

s) Connect appropriate Preamps, Sensors and optical simulators to validate the system starts to report valid StO2 data. PASS

t) Validate the UUT is operating properly. PASS (Note any encountered issues below)

u) Enter the Help\About menu to validate the Package version and date do match the Package version and installation date PASS (An "*" appears next to the Package Version)

v) Turn off the UUT

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.

Test Performed By (signature): Proton Tola Date of Test: 12.12.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.1.2 System Configuration

a) Turn On the UUT and apply the Three finger while the Monitor is displaying the splash screen to validate the UUT enters the Bootloader menu. PASS

b) Enter the special Menus below and validate there is the possibility to change the system **IP Address.** (same IP address reported on the Splash screen at system start)
   a. Engineering PASS
   b. Manufacturing PASS
   c. Service PASS

c) Enter the **Biomed** Menu to validate there is **no** possibility to Change the **IP Address** PASS

d) Enter the **View Logs\Audit Log** and **View Logs\Error Log** to validate all recently recorded events are accessible. PASS

e) Cycle power to the UUT and wait to enter the Main menu before entering the **Setup** menu.

f) Validate the same System **Serial-** & **Asset Number** reported in the Bootloader Menu are also reported in the Main **Help\About** menu and on the last line of the Splash screen. PASS

g) Enter the appropriate password to enter the Menus below and validate there is no possibility to change the Monitor type from **"US"** to **"OUS"**
   a. Engineering PASS
   b. Biomed PASS

h) Enter the **Manufacturing** Menu to validate there is the possibility to Change the Monitor Type from **"US"** to **"OUS"** PASS

i) Enter the About menu to validate the Monitor Model Number for **US** is **01-06-3000** PASS and **01-06-3005** for **OUS** PASS

j) Set the UUT for **US** before cycling powers to validate the Monitor configuration is kept PASS

k) Set the UUT for **OUS** before cycling powers to validate the Monitor configuration is kept PASS

l) Turn off the UUT

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.1.3 Touch Screen Calibration

a) Turn On the UUT and wait for the UUT to display the splash screen.

b) Press and hold the power key for at least 30 seconds while the UUT is still displaying the splash screen to validate the UUT turns off. PASS

c) Turn On the UUT and validate the UUT does not enter the usual splash screen but the touch screen Calibration menu. PASS

Test Performed By (signature): [signature] Date of Test: 12.12.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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d) Follow the indication up to the second touch but touch the opposite corners for the last two indications to validate the calibration menu is not exited and the user is redirected to beginning of the calibration procedure. PASS.

e) Cycle power to the UUT and wait to enter the Splash screen to validate the UUT does instead enter the touch screen calibration menu. PASS

f) Wait for at least three minutes to validate the screen is not exited and remains in the Calibration menu. PASS

g) Follow the indication on the calibration menu to validate that this time the calibration routine is completed and the menu exited. PASS

h) Cycle power to the UUT to validate the UUT enters the splash screen then the main menu. PASS

i) Turn off the UUT

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.2 Oximeter Start Up

8.2.1 Standard Start Up

a) Turn on the UUT

b) Validate UUT first enter the Bootloader screen PASS

c) Validate Bootloader displays a splash screen image after the LCD screen has been initialized PASS

d) Validate Bootloader generates 2 short duration "beeps"; one with the High Priority and the second with Medium Priority tone during the POST sequence PASS

e) Validate Bootloader turns on all the Yellow and then all the Red Alarm LEDs during the POST sequence PASS

f) Validate during the Diagnostics, the system displays the version of the SCB Bootloader Software PASS

g) Validate the UUT enter Main Screen PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.2.2 Start Up With Failed Power-On Self-Test

a) Turn off the UUT

b) Disconnect the NSAM Board from the UUT

c) Turn on the UUT

d) Validate the UUT enters the Bootloader Menu and starts the POSTs sequence PASS

e) Validate the UUT displays **"E009-1" Error message** PASS

f) Validate the UUT generates a High Priority Alarm tone sequence and the Alarm LEDs are flashing Red PASS

Test Performed By (signature): Protais Tala Date of Test: 12.12.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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g) Validate the UUT does not enter the Main application menu and stays in the High Priority Alarm condition PASS (Red LEDs and High Priority alarm tone)

h) Turn off the UUT

i) Reinstall the NSAM Board into the UUT

j) Turn on the UUT

k) Validate the UUT completes the POSTs tests sequence and enters Main Screen PASS

l) Turn off the UUT

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.3 Visual & Display Indicators

8.3.1 Main Screen Display

a) Turn On the UUT and wait to enter Main Screen

b) Validate the General look of the Main Screen follows Figure 1 below PASS

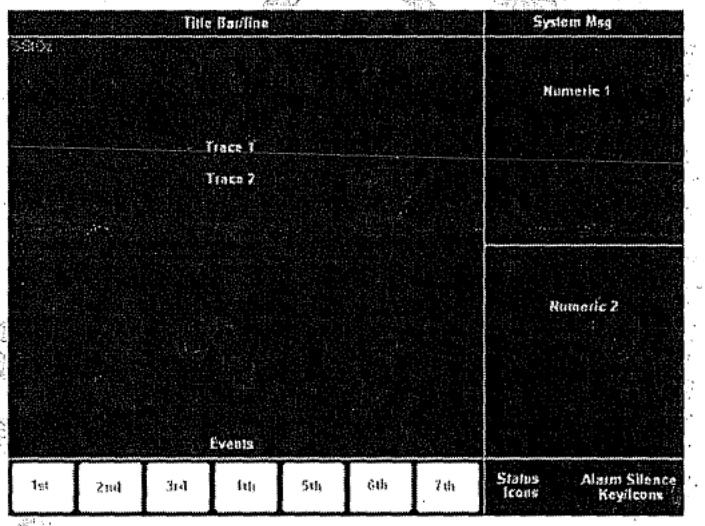

Figure 1 – Initial Power On Screen (e.g. 2 Channels Mode)

c) Validate the background color for normal operations is black PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

Test Performed By (signature): [signature] Date of Test: 12.12.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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8.3.1.1 Title Bar/Line Area

a) Validate the current date and time do appear at the right corner of the Title Bar/Line area PASS

b) Validate the time is displayed in 24-hour format: 2-digit hours and 2 digit minutes (e.g., 11:34, leading zeros) PASS

c) Validate the date is displayed as a 2-digit day, 3-letter abbreviated month and 2-digit year (e.g., 02-Jun-11, leading zeros) PASS

d) Click on the Time/Date area of the Title Bar to validate the Data & Time entry menu opens up and any changes made there are readily implemented. PASS

e) Validate the Patient ID do appear at the left corner of the Title Bar. PASS

f) Click on the Patient ID area to validate the Patient ID entry menu opens up and any changes made there are readily implemented PASS

g) Validate the current View do appear in the middle section of the Title Bar. PASS

h) Click on the View area to validate the View entry menu opens up and any changes made there are readily implemented. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.3.1.2 System Message Area

a) Validate all system messages appear in the System message area PASS

b) Validate all System Alarm message texts are able to fit in the System message area PASS

c) Validate all translated System Alarm messages are able to fit in the System Message area. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.3.1.3 Trace Area

a) Validate the trace area has a black background PASS

b) Validate there is a maximum of four distinct sub areas for the traces PASS

c) Access any of the sub menus by selecting one of the available 1st then 2nd Level touch buttons to validate the trace area is covered/ replaced by the new menu PASS

d) Validate all trace areas have the same vertical scale with reference marks/values along the left side PASS (0-100%)

e) Validate all trace areas have the same view scale with reference time values along the top side PASS

f) Validate all active Channels are each represented by a trace. PASS

g) Validate user has the possibility to select:

All channels in one single trace area PASS

Two channels in one trace area 1&2 or 3&4. PASS

Test Performed By (signature): [signature] Date of Test: 12.12.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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One channel per trace area. PASS

h) Validate traces have the same color as the matching Channel's Numeric PASS

i) Validate traces do not present any spike from bottom of graph to initial value. PASS

j) Cycle powers to the UUT to validate the traces are maintained across power cycles. PASS (If same patient and Off Time < 15 Minutes)

k) Connect Preamp and StO2 simulators to the UUT and wait for StO2 Numerics to be displayed

l) Enable the Ethernet connection and open a telnet session using the UUT's IP address.

m) Send the "Reset" command to the UUT at least 20 times to validate the UUT reset itself and return to the Main menu with all traces maintained PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.3.1.4 Numeric Field

a) Validate there are four numeric areas along the right side of the display (one for each channel: ①, ②, ③, ④) if the UUT is set for three to four valid Channels PASS

b) Validate there are only two numeric areas along the right side of the display (one for each channel: ①, ②, ③ or ④) if the UUT is set for one to two Channels (1&2, 1&3, 1&4, 2&3, 2&4 or 3&4) PASS

c) Open all menus and sub-menus from the selection below to validate the Numeric fields are always displayed:

- Patient/Case Selection P ☑ F ☐
- Patient Setup P ☑ F ☐
- Body Location Menu P ☑ F ☐
- High/Low Limits Menu P ☑ F ☐
- Setup Menu P ☑ F ☐
- Brightness Menu P ☑ F ☐
- Volume setting Menu P ☑ F ☐
- View Menu P ☑ F ☐
- Date & Time Menu P ☑ F ☐

d) Validate each of the following item below are represented in the numeric area at the indicated location per Figure 2 (If Channel active)

		4-Ch Mode	2-Ch Mode
• Channel ID	Area 1	P ☑ F ☐	P ☑ F ☐
• Numeric in associated color	Area 2	P ☑ F ☐	P ☑ F ☐
• Sensor location icons in associated color	Area 3	P ☑ F ☐	P ☑ F ☐
• Left/Right/Somatic indicator	Area 4	P ☑ F ☐	P ☑ F ☐
• TPI value Icon	Area 5	P ☑ F ☐	P ☑ F ☐
• Channel specific messages	Area 6	P ☑ F ☐	P ☑ F ☐

Test Performed By (signature): [signature] Date of Test: 12.19.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

• Reference saturation value	Area 7	P ☑ F ☐	P ☑ F ☐
• High and Low Alarm Limits	Area 8	P ☑ F ☐	P ☑ F ☐

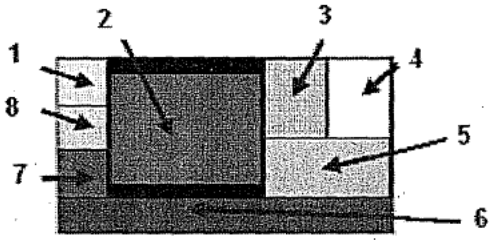

Figure 2 – Numeric Field Organization

e) Click in the area below to verify the Expected sub-menu appears as pop-up.

		4-Ch Mode	2-Ch Mode
• Sensor location icons	Patient Setup Menu	P ☑ F ☐	P ☑ F ☐
• Left/Right indicator	Patient Setup Menu	P ☑ F ☐	P ☑ F ☐
• High and Low Alarm Limits	Patient Setup Menu	P ☑ F ☐	P ☑ F ☐
• StO2 Numeric	Patient Setup Menu	P ☑ F ☐	P ☑ F ☐

a) Connect Preamp and StO2 simulators to the UUT and wait for StO2 Numerics to be displayed
b) Enable the Ethernet connection and open a telnet session using the UUT's IP address.
c) Send the "Reset" command to the UUT at least 20 times to validate the UUT reset itself and return to the Main menu with all traces maintained PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.3.1.5 1ST, 2nd Levels Touch button

a) Cycle power to the UUT.
b) Validate all 1st level touch button appear available PASS
c) Select any of the available touch button to validate they appear as touched PASS
d) Release the button to validate the intended action is performed PASS
e) Validate that only one button could be activated at the same time PASS
f) Validate that once any of the 1st level buttons is activated, the 1st Level buttons row is replaced by either a set of 2nd level buttons that is specific to the 1st Level button pressed or there will be a new menu, specific to the button pressed and rendering all other 1st level touch button unavailable until all secondary menus are exited PASS
g) Validate that once any of the 2nd level buttons is activated, there will be a new menu activated, specific to the button pressed and rendering all other 2nd level touch buttons unavailable until all menus are exited PASS

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h) Validate all 1st, 2nd or event 3rd level buttons are made out of both an Icon and a Text below the icon that properly match the function of the button. PASS

i) Validate there are no inactive buttons in any menu or submenu. PASS

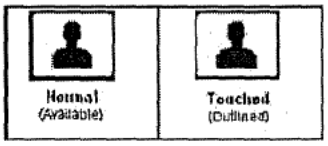

Figure 3 – Examples of button's Activation State

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.3.1.6 Alarm Silence button

a) Press on Alarm Silence button to disable Audio
b) Validate the disabled Audio remains on for 2 minutes PASS
c) The 2 Min-Audio Paused Icon & disabled Audio time is displayed PASS
d) Validate the 2 Min-Audio Paused Icon & disabled Audio time is removed after 2 minutes PASS
e) Press on Alarm Silence button to disable Audio
f) Turn the UUT off and back On
g) Validate the Alarm Silence defaults to off (Audio Enabled) after power on PASS
h) Enter the menu list in Table 1 below and validate the Alarm Silence button can always be pressed. (toggle from disabled to enabled for each menu)

Menu / Sub Menu	Validate
Patient	P ☑ F ☐
Patient Setup	P ☑ F ☐
Patient ID	P ☑ F ☐
High/Low Limits Menu	P ☑ F ☐
Events Menu	P ☑ F ☐
Data Menu	P ☑ F ☐
Files Menu	P ☑ F ☐
Files Manage Menu	P ☑ F ☐
Setup Menu	P ☑ F ☐
Brightness Menu	P ☑ F ☐
Language Menu	P ☑ F ☐
Volume setting Menu	P ☑ F ☐
View Menu	P ☑ F ☐
Date & Time Menu	P ☑ F ☐
Ports Menu	P ☑ F ☐

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Menu / Sub Menu	Validate
Alarm Delay Menu	P ☑ F ☐

Table 1 – Alarm Silence Activation Access availability

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4 User Controls

8.4.1 Patient Menu

8.4.1.1 Patient Menu Selections

a) Click on **Patient button** (1st level buttons row).

b) Validate the touch buttons **New Patient**, **Patient Setup**, and **Patient ID** buttons are all available PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.1.2 Body Location Settings

8.4.1.2.1 US Configuration

a) Turn On the UUT

b) Enter the Setup menu before entering the appropriated password for **Manufacturing.**

c) Make sure the current and **default** Monitor configuration is set to **US.** PASS

d) Cycle power to the UUT and proceed to the **Main** menu.

e) Select the Patient Menu from the 1st Level Target menu.

f) Click on the **Patient Setup** key to enter the Body Location and Alarm settings menu.

g) Validate the **Body Location** Menu is available once one of Ch1-Ch4 Body Location Icon within the **Patient Setup** Menu is selected PASS

h) Validate **only** the body Location **Left Brain**, **Right Brain** and **Unused** available and the Menu resembles **Figure 4** below. PASS

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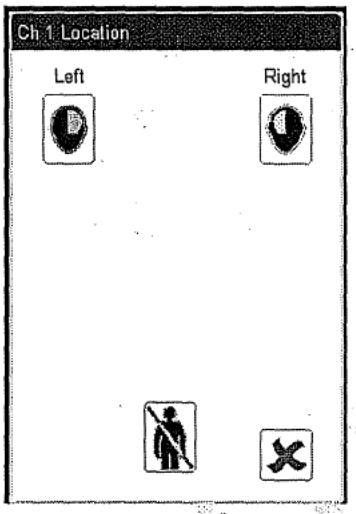

Figure 4 – Adult Cerebral (US) Body Location Menu

Select the "**Left Brain**" for the Ch1 area PASS

i) Validate "**Accept**" and "**Cancel**" buttons are available PASS

j) Validate the **Left Brain** Icon now appears in Ch1 area within the Patient Configuration Menu PASS

k) Select **Accept** from the **Patient Setup** Menu to validate the menu is closed

l) Validate there is a menu asking whether to start a new Patient. PASS

m) Select No to validate the change of Body Location is still performed. PASS

n) Validate the **Left Brain** Icon now appears in Ch1 area on the Right side of the Main menu area. PASS (Letter "**L**" next to Left Brain Icon)

o) Re-enter the Body location menu by pressing on the Body Location icon on Ch1 and set all body locations for CH2-CH4 to "**Unused**"

p) Validate it is not possible to set all Body Locations for CH1-CH4 to "**Unused**". PASS

q) Select **Accept** to validate channel CH2-CH4 body locations revert to **Unused** PASS

r) Return to Main menu to validate there are no Body Location Icons (Unused Icon) or any other Information in the Numeric area for CH3-CH4 PASS (See Figure 2)

s) Connect and disconnect Preamp and Sensor in Ch2 to Ch4 to validate there are no Preamp or Sensor disconnection Audio or Visual Alarms. PASS

t) Re-enter the **Patient** menu, make the entries for "**Right Brain**" for Ch3 before selecting **Accept** (Body Location Menu and new patient) to validate the User is redirected toward the Main Screen and the selected **Right Brain** Icon and letter "**R**" appear within the Numeric area for Ch3 PASS

u) Validate the UUT remains in a 2-Channels Mode with CH1 and CH3 activated while CH2 and CH4, set to Unused do not have any Numeric menu. PASS

v) Cycle power to the UUT and wait to enter the Main Screen. Accept to continue with the same patient.

w) Validate **Left Brain** Icon and letter "**L**" appear for CH1, **Right Brain** Icon and letter "**R**" appear for CH3 while Ch2 & Ch4 Numerics areas are not represented PASS

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PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.1.2.2 OUS Configuration

a) Turn On the UUT
b) Enter the **Setup** menu before entering the appropriated password for **Manufacturing.**
c) Make sure the current and **default** Monitor configuration is set to **OUS.** PASS
d) Exit the **Setup** menu and proceed to the **Main** menu.
e) Select the Patient Menu from the 1st Level Target menu.
f) Click on the **Patient Setup** key to enter the Body Location and Alarm settings menu.
g) Validate the **Body Location** Menu is available once one of Ch1-Ch4 Body Location Icon within the **Patient Setup** Menu is selected PASS
h) Validate the body Location **Left Brain**, **Left Arm**, **Left Flank**, **Left Leg**, **Right Brain**, **Right Arm**, **Right Flank**, **Right Leg** and **Unused** are available and the Menu resembles **Figure 5** below. PASS

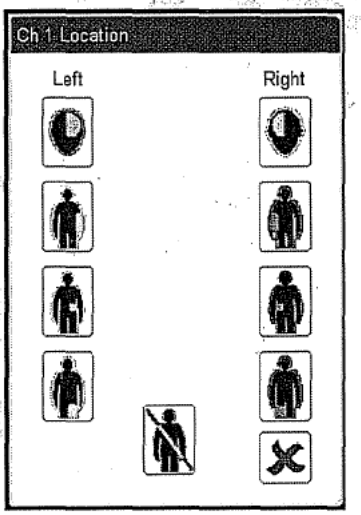

Figure 5 – Adult Tissue (OUS) Body Location Menu

i) Select the "**Left Flank**" for the Ch1 area PASS
j) Validate "**Accept**" and "**Cancel**" buttons are available PASS
k) Validate the **Left Flank** Icon now appears in Ch1 area within the Patient Configuration Menu PASS
l) Select **Accept** from the **Patient Setup** Menu to validate the menu is closed
m) Validate there is a menu asking whether to start a new Patient. PASS
n) Select **No** to validate the change of Body Location is still performed. PASS
o) Validate the **Left Flank** Icon now appears in Ch1 area on the Right side of the Main menu area. PASS (Letter "S" next to **Left Flank** Icon) L TT 12.13.13

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p) Re-enter the Body location menu by pressing on the Body Location icon on Ch1 and set all body locations for CH2-CH4 to "**Unused**"

q) Validate it is not possible to set all Body Locations for CH1-CH4 to "**Unused**". PASS

r) Select **Accept** to validate channel CH2-CH4 body locations revert to **Unused** PASS

s) Return to Main menu to validate there are no Body Location Icons (Unused Icon) or any other Information in the Numeric area for CH3-CH4 PASS (See Figure 2)

t) Connect and disconnect Preamp and Sensor in Ch2 to Ch4 to validate there are no Preamp or Sensor disconnection Audio or Visual Alarms. PASS

u) Re-enter the **Patient** menu, make the entries for "**Right Brain**" for Ch2, "**Right Leg**" for Ch3 and "**Left Arm**" for Ch4 before selecting **Accept** (Body Location Menu and new patient) to validate the User is redirected toward the Main Screen and the selected Icons and Letters do appear in the Numeric area

   i. **Left Flank** Icon and letter "**L**" for Ch1 PASS
   ii. **Right Brain** Icon and letter "**R**" for Ch2 PASS
   iii. **Right Leg** Icon and letter "**R**" for Ch3 PASS
   iv. **Left Arm** Icon and letter "**L**" for Ch4 PASS

v) Cycle power to the UUT and wait to enter the Main Screen. Accept to continue with the same patient.

w) Validate THE Numeric area configuration:

   i. **Left Flank** Icon and letter "**L**" for Ch1 PASS
   ii. **Right Brain** Icon and letter "**R**" for Ch2 PASS
   iii. **Right Leg** Icon and letter "**R**" for Ch3 PASS
   iv. **Left Arm** Icon and letter "**L**" for Ch4 PASS

x) Turn Off the UUT.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.1.3 Alarm Limits Settings

a) Turn On the UUT and wait to enter the Main menu.

b) Enter the **Patient Setup** Menu under Patient

c) Validate it is possible to set the alarm limits for each channel individually. PASS

d) Validate the current set of **High** and **Low** alarm limits are displayed in the numeric area on Main Menu as long as the channel is active. PASS

e) Reenter the Patient Configuration Menu then select to change the **High** or **Low** limits setting on any of the channels to validate the **Accept** key is only executed if a valid or no entry at all was made. PASS (Accept key within Numeric menu)

f) Make changes to the **High** and **Low** settings before hitting the **Accept** key within the **Numeric** entry menu.

g) Depress the **Cancel** key once in the **Patient Configuration** Menu to validate the changes made to the **High** and **Low** alarm limits were not implemented. PASS

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h) Make changes to the **High** and **Low** settings before hitting the **Accept** key within the **Numeric** entry menu.

i) Depress the **Accept** key once in the **Patient Configuration** Menu to validate the changes made to the **High** and **Low** alarm limits were implemented. PASS

j) Validate **High** & **Low** alarm limit setting changes made from the **Patient Setup, Limit's** value **or Body Location** Icon are all implemented. PASS

k) Validate all steps above are valid for **US** and **OUS** Monitor Configuration. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.1.4 Alarm Limit Range

a) Enter the **Patient Setup** Menu

b) Set the **Low** Limit to the value in **Table 2** below then attempt to enter the recommended **High** Limit values to validate the expected test outcome

c) Set the **High** Limit to the value in **Table 2** below then attempt to enter the recommended **Low** Limit values to validate the expected test outcome

d) Validate all steps above are valid for **US** and **OUS** Monitor Configuration. PASS

Limit Low	Attempt High	Expected Outcome	Validate
3	0 to 7	Invalid	P ☑ F ☐
3	8 to 98	Valid	P ☑ F ☐
3	99	Invalid	P ☑ F ☐
93	0 to 97	Invalid	P ☑ F ☐
93	98	Valid	P ☑ F ☐
93	99	Invalid	P ☑ F ☐
Limit High	**Attempt Low**	**Expected Outcome**	**Validate**
8	4 to 99	Invalid	P ☑ F ☐
8	3	Valid	P ☑ F ☐
8	0 to 2	Invalid	P ☑ F ☐
98	94 to 99	Invalid	P ☑ F ☐
98	3 to 93	Valid	P ☑ F ☐
98	0 to 2	Invalid	P ☑ F ☐

Table 2 – Alarm Limit Range

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

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8.4.1.5 Patient ID

a) Enter the **Patient ID** Menu

b) Validate up to 20 Alphanumeric Characters could be entered for the Patient ID PASS

c) Validate the entered Patient ID is displayed at the Upper Left corner of the Display in the title bar. PASS

d) Validate the Patient ID could be entered and altered any time during the same case. PASS

e) Validate it is the last entered ID that is displayed on Main menu and as Case ID under Files\Manage for the active case. PASS

f) Enter a new Patient ID but press the Cancel ✗ to validate the newly entered but not accepted ID is not displayed on title bar while the previous one is still on the title bar. PASS

g) Validate all steps above are valid for **US** and **OUS** Monitor Configuration. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.1.6 New Patient

a) Power on the UUT then start to monitor a patient

b) Enter a Patient ID, Event Marks to the case

c) Enter the **Patient** Menu then select New Patient to validate there is a menu requester user's confirmation. PASS

d) Select ✗ to validate the same case continues. PASS

e). Select ✓ to validate:

- Current trace is removed from the display P ☑ F ☐
- Patient ID blanked P ☑ F ☐
- Events removed P ☑ F ☐
- Ref value blanked out P ☑ F ☐
- All other settings (Alarm limits, Body Location, View, time) remain P ☑ F ☐

f) Validate all steps above are valid for **US** and **OUS** Monitor Configuration. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.2 Event Marks

8.4.2.1 Events Menu Selection

a) Click on the **Events** key (1st level buttons row).

b) Validate the buttons **Home**, **OR**, **ICU**, **Vascular** & **Undo** (in that order) are all available PASS

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c) Validate each Event dialog/listing has the Listing Name on the Menu Title PASS
d) Validated only one listing is available at the same time. PASS
e) Validate the **NICU** listing is not available. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.2.2 Events from List Addition

a) Power on the UUT and start a new case "**OR EVENTS**"
b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data.
c) Connect the UUT to an IBM PC then use the Ports menu to set either one of the Ports for Scientific data output.
d) Start the appropriate LabView program that could store and display the UUT's scientific output data.
e) Select the Events from the List in **Table 3** below then proceed to add each Event to the data set. (Separately Note time of addition).
f) Validate the Event menu is always closed promptly after the event has been selected allowing for a fast redraw of the Numeric field area PASS (the event menu is closed at once)
g) Validate for every added Event there is a new dot, color matched to the Event Category that is added to the bottom right corner of the display. PASS
h) Click on the new dot to validate the Event mark represented by the dot appears with date stamp right next to the dot with a color matched to the Event category. PASS
i) Validate only one event mark at a time is displayed by the UUT. PASS
j) Validate the displayed time matches the time above the Graph area. PASS
g) Review the scientific data set saved to validate in **Table 3** that all Events (with matching data code) were properly incorporated and saved within the scientific data output. PASS
h) Save the case into a USB from the Files\Manage menu and review the file to validate all added Event Marks have been saved with the appropriate time stamp. PASS
i) Start a new Case ""**ICU EVENTS**" and start a new LabView data collection session.
k) Validate in Table below all steps **e)** to **h)** continue to pass using **Table 4**. PASS
l) Start a new Case ""**Vascular EVENTS**" and start a new LabView data collection session.
m) Validate in Table below all steps **e)** to **h)** continue to pass using **Table 5**. PASS
j) Select the **Home** key to return to the Main Menu.
k) Start a new Patient called "Mixed Events" an attempt to enter many events coming from different Lists and validate it is possible to add Event Marks out of different lists in the same case. PASS
l) Validate it is not possible to change the position (Vertical & Horizontal) of the Event Mark. PASS
m) Save the case into a USB from the Files\Manage menu and review the file to validate all added Event Marks have been saved with the appropriate time stamp. PASS

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EVENT	Code	Validate	EVENT	Code	Validate
Miscellaneous ✓	900	P ☑ F☐	Antegrade SCP ON ✓	172	P ☑ F☐
Cannulation ✓	100	P ☑ F☐	Blood Transfusion ✓	64	P ☑ F☐
Cardioplegia ✓	101	P ☑ F☐	Defib/Cardioversion ✓	160	P ☑ F☐
Closing Sternum ✓	102	P ☑ F☐	ECLS On ✓	71	P ☑ F☐
Cooling ✓	103	P ☑ F☐	Fluid/Volume Expander ✓	162	P ☑ F☐
CPB On/Off ✓	109	P ☑ F☐	Hemoconcentrate/MUF ✓	163	P ☑ F☐
Cross Clamp Off ✓	105	P ☑ F☐	Increase Anesthetic ✓	164	P ☑ F☐
Cross Clamp On ✓	106	P ☑ F☐	Increase CO2 ✓	165	P ☑ F☐
Extubation ✓	2	P ☑ F☐	Increase FiO2 ✓	267	P ☑ F☐
Induction of Anesth ✓	111	P ☑ F☐	Increase Pressure ✓	173	P ☑ F☐
Intubation ✓	3	P ☑ F☐	Increase Pump Flow ✓	166	P ☑ F☐
Sternotomy ✓	110	P ☑ F☐	Inotrope ✓	75	P ☑ F☐
Warming ✓	104	P ☑ F☐	Pacing: Atrial ✓	174	P ☑ F☐
Arrhythmia ✓	31	P ☑ F☐	Pacing: A-V ✓	175	P ☑ F☐
Circulatory Arrest ✓	130	P ☑ F☐	Pacing: Ventricular ✓	176	P ☑ F☐
Hypocapnia ✓	131	P ☑ F☐	Reposition Cannula ✓	168	P ☑ F☐
Hypotension ✓	132	P ☑ F☐	Reposition Clamp ✓	169	P ☑ F☐
Low SpO2 ✓	133	P ☑ F☐	Reposition Head/Heart ✓	170	P ☑ F☐
Pump Flow Down ✓	134	P ☑ F☐	Retrograde SCP ON ✓	177	P ☑ F☐
Venous Return Down ✓	135	P ☑ F☐	Vasopressor ✓	81	P ☑ F☐
Afterload Reduction ✓	60	P ☑ F☐			

Table 3 – OR Event Marks List

EVENT	Code	Validate	EVENT	Code	Validate
Miscellaneous ✓	900	P ☑ F☐	Defib/Cardioversion ✓	85 ~~160~~	P ☑ F☐ PT 12.13.13
Enteral Feeding ✓	1	P ☑ F☐	Dialysis/CRRT ✓	84	P ☑ F☐
Extubation ✓	2	P ☑ F☐	Diuretic ✓	68	P ☑ F☐
Intubation ✓	3	P ☑ F☐	ECLS Off ✓	70	P ☑ F☐
Apnea ✓	30	P ☑ F☐	ECLS On ✓	71	P ☑ F☐
Arrhythmia ✓	31	P ☑ F☐	ET Tube Suctioned ✓	72	P ☑ F☐
Bradycardia ✓	32	P ☑ F☐	Fluid Bolus ✓	73	P ☑ F☐
ICP Changes ✓	34	P ☑ F☐	High Frequency Vent ✓	83	P ☑ F☐
LOC Changes ✓	35	P ☑ F☐	Hypothermia ✓	74	P ☑ F☐
Painful Procedure ✓	36	P ☑ F☐	Inotrope ✓	75	P ☑ F☐
Seizure Activity ✓	37	P ☑ F☐	Nitric Oxide ✓	76	P ☑ F☐
Tamponade ✓	38	P ☑ F☐	Paralytic ✓	77	P ☑ F☐
Afterload Reduction ✓	60	P ☑ F☐	PDA Ligated ✓	78	P ☑ F☐

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EVENT	Code	Validate	EVENT	Code	Validate
Anti-Arrhythmic ✓	61	P ☑ F☐	Prostaglandin ✓	79	P ☑ F☐
Anti-Epileptic ✓	62	P ☑ F☐	Reposition Patient ✓	4	P ☑ F☐
Blood Transfusion ✓	64	P ☑ F☐	Sedation ✓	80	P ☑ F☐
Chest Closed ✓	65	P ☑ F☐	Vasopressor ✓	81	P ☑ F☐
			Ventilator Change ✓	82	P ☑ F☐

Table 4 – ICU Event Marks List

EVENT	Code	Validate	EVENT	Code	Validate
Miscellaneous ✓	900	P ☑ F☐	BiVAD On/Off ✓	274	P ☑ F☐
Cannulation ✓	100	P ☑ F☐	Blood Transfusion ✓	64	P ☑ F☐
Clamp Off Vessel ✓	200	P ☑ F☐	EPD Deployed ✓	262	P ☑ F☐
Clamp On Vessel ✓	201	P ☑ F☐	Fogarty Catheter In ✓	263	P ☑ F☐
Decannulation ✓	202	P ☑ F☐	IAB Catheter Off ✓	264	P ☑ F☐
Extubation ✓	3	P ☑ F☐	IAB Catheter On ✓	265	P ☑ F☐
Heparin Given ✓	203	P ☑ F☐	IAB Pump Off ✓	275	P ☑ F☐
Incision ✓	204	P ☑ F☐	IAB Pump On ✓	276	P ☑ F☐
Intubation ✓	2	P ☑ F☐	Increase Anesthetic ✓	164	P ☑ F☐
Arrhythmia ✓	31	P ☑ F☐	Increase ETCO2 ✓	266	P ☑ F☐
Blood Loss ✓	230	P ☑ F☐	Increase FiO2 ✓	267	P ☑ F☐
Contrast Dye Injected ✓	231	P ☑ F☐	LVAD On/Off ✓	277	P ☑ F☐
Dissection ✓	232	P ☑ F☐	RVAD On/Off ✓	278	P ☑ F☐
EEG Change ✓	233	P ☑ F☐	Shunt Flushed ✓	268	P ☑ F☐
Hypocapnia ✓	131	P ☑ F☐	Shunt Open ✓	269	P ☑ F☐
Hypotension ✓	132	P ☑ F☐	Shunt Reposition ✓	270	P ☑ F☐
Shunt Clamped ✓	234	P ☑ F☐	Stent Deployed ✓	271	P ☑ F☐
Thrombus Suspected ✓	235	P ☑ F☐	Thrombus Removed ✓	272	P ☑ F☐
Balloon Deflated ✓	260	P ☑ F☐	Vasodilator ✓	273	P ☑ F☐
Balloon Inflated ✓	261	P ☑ F☐	Vasopressor ✓	81	P ☑ F☐

Table 5 – Vascular Event Marks List

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.2.3 Removing placed Events

a) Power on the UUT and start a new case "**Remove EVENTS**"

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b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data.

c) Connect the UUT to an IBM PC then use the Ports menu to set either one of the Ports for Scientific data output.

d) Place two events on trace and validate they both appear on the Graph. PASS

e) Press on "Undo" to validate the last placed event is removed. PASS

f) Press on "Undo' a second time to remove the first placed event and validate the event is not being removed. PASS (Only the last placed event could be removed)

g) Cycle power to the UUT to validate as the UUT is entering Main menu that the first placed event is still available on the trace. PASS

h) Press on "Undo" to validate the event is not removed. PASS

i) End the Case, save the file into a USB to validate only the first placed event is available on the data set. PASS

j) Validate the both placed events are available in the saved Scientific serial output. PASS

k) Select an event from the menu below then quickly remove it by pressing "Undo" to validate the event is removed. Repeat the quick series of adding/removing at least 10 times to validate no adverse reaction of the system is observed (make note of any occurrence)

   i. OR List PASS
   ii. ICU List PASS
   iii. Vascular List PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.2.4 Auto Events

a) Power on the UUT and start a new case "**AUTO EVENTS**"

b) Set one of the Ports "A" or "B" to the "Scientific" serial Output mode.

c) Connect appropriate Preamps and sensors to the monitor and wait for the UUT to start collecting data.

d) Start to create the individual Conditions in **Table 6** below and wait for the appropriate messages to be displayed on the UUT before initiating a new one.

e) Make note on as separate piece of paper about the time, type & Chanel ID for each specific auto event.

f) Validate there are no Event dots placed on the Display for the Auto Events. PASS

g) Enter some of the Events from the Events lists and make note of the time and name of the event entered. PASS

h) Create some High and Low StO2 conditions for some of the Channels and make note of the time and type of Limit violation.

i) Disconnect then reconnect the sensors and wait for StO2 data to be displayed.

j) Disconnect then reconnect the Preamps and wait for the StO2 data to be displayed.

k) Close the case once all conditions have been created and save the case into a USB.

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l) Connect the USB and use "Notepad" to review the case.

m) Validate the header format and content of the Patient file do match the format defined in 21-07-0342 and 21-07-0360 specifications. PASS

n) Using the FORE-SIGHT ELITE Graphing Tool, open the Patient file and proceed to compare the events reported to those recorded in the Scientific data output.

o) Validate in **Table 6** that the Auto Events do match the incidents reported in the Scientific data output and as noted.

p) Validate all Limit violation alarms were properly captured and reported. PASS

q) Validate none of the sensor or Preamp disconnect events were captured or represented otherwise as Auto Events. PASS

Condition	SCB Message	CH1	CH2	CH3	CH4	Validate
Brain Signal Low Brain Signal High	**Signal Out Of range**	X	-	-	-	P ☑ F☐
Scalp Signal Low Scalp Signal High	**Signal Out Of range**	X	X	-	-	P ☑ F☐
Monitor Signal Low Monitor Signal High	**Signal Out Of range**	-	-	-	X	P ☑ F☐
(b)(4) [redacted]					-	P ☑ F☐
(b)(4) [redacted]		X	-	X	-	P ☑ F☐
Excessive Ambient light	**High Ambient Light**	X	X	X	X	P ☑ F☐
High Ambient light	**Ambient Light**	-	-	X	-	P ☑ F☐
Signal Out of Range (AGC)	**Signal Out Of range**	-	-	-	X	P ☑ F☐
sensor not secured	**Check under sensor**	-	X	-	-	P ☑ F☐
Low Total Hb		X	-	-	-	P ☑ F☐
Unstable StO2 (Bovie)	**External Interference**	-	-	X	-	P ☑ F☐
Sensor Off StO2 not in range	**Sensor off**	X	-	-	-	P ☑ F☐

Table 6 – NSAM Conditions Auto Events

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.3 Data Menu

8.4.3.1 Data Menu Selection

a) Click on the **Data** key (1st level buttons row).

b) Validate the buttons **Home**, **STS Starts/Stops**, **REF Reference** and **STS View** are all available PASS

c) Validate the **STS Starts/Stops** Key is displayed as **STS Start** if the Data collection has not started. PASS

Test Performed By (signature): [signature] Date of Test: 12.13.13

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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d) Validate the **STS Starts/Stops** Key is displayed as **STS Stop** if the Data collection is ongoing. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.3.2 STS View Menu

a) Enter the STS View Menu to validate all elements contained within **Figure** 6 below are available (Arrangement and Look of Menu may differ) PASS

b) Validate fields are constantly being updated during ongoing data collection while the menu remain open. PASS

c) Validate the data under "Cumulative Saturation Below…" and "Regional Oxygen …" are represented with one decimal digit as long as space permit. PASS

d) Starts a new Patient/Case session while STS DATA collection is ongoing on the previous case to validate the previously collected data have been cleared from the STS View menu. PASS

e) Validate unused Channel do not have any field filled out in the STS View. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

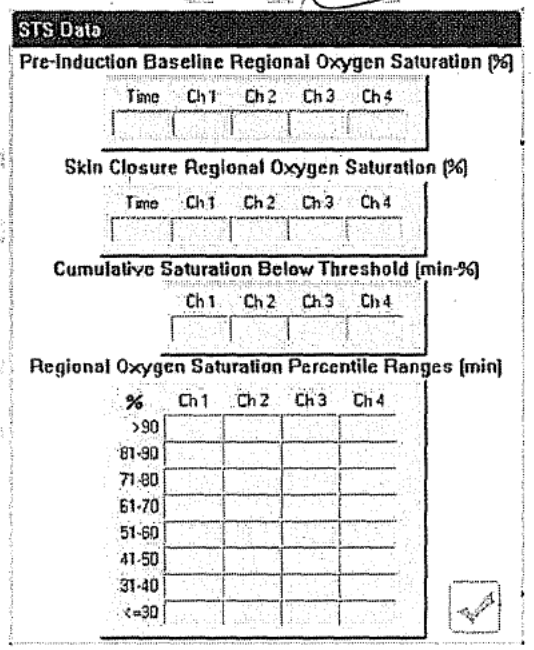

Figure 6 – STS View Menu content

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8.4.3.3 STS Data Collection and Verification

a) Connect appropriate Preamps and sensors to the monitor.

b) Attempts to start the Data Collection while there are no StO2 data on either one of the Channels to validate there is a Pop Up alerting the user the Data Collection could not start until there are valid StO2 values on at least one channel. PASS

c) Wait for the UUT to display valid StO2 data.

d) Enter the **Data** menu and press on Click on **STS Start** to start the Data collection and validate the **STS Start** switches to **STS Stop.** PASS

e) Validate the wording **STS DATA** appears on top of the Graph area as soon as the Data collection has started. PASS

f) Click on **STS Stop** to stop the Data collection and validate there is a popup "Do you really want to..." appearing on the display. PASS

g) Press on "NO" to validate the popup is removed and the data collection not stopped. PASS

h) Click on **STS Stop** to stop the Data collection and confirm once ask to validate the popup is removed and the data collection stopped. PASS

i) Validate the **STS Stop** switches to **STS Start.** PASS

j) Restart an STS Data Collection session and validate the Data Collection could be stopped at any time whether there are valid data on the display or not. PASS

k) Starts a new Case "**STS DATA Verification**"

l) Set the UUT to monitor the Left Brain on CH1 & CH3 while monitoring the Right Brain on CH2 and CH4.

m) Start the Data Collection and note the StO2 values on the display for each channel

	Main Display	STS View	Threshold (75%)
➢ CH1	61	61	46
➢ CH2	59	59	44
➢ CH3	83	83	62
➢ CH4	65	65	49

n) Enter the STS View menu to verify the Pre-Induction Baseline Regional Oxygen Saturation values reported to match those recorded in the step above. PASS

o) Verify the Time reported under Pre-Induction Baseline Regional Oxygen Saturation do match the Time reported in the step above. PASS

p) Calculate the **Threshold** that will be used for the **Cumulative Saturation below Threshold** as 75% of the **first valid** %StO2 value displayed and recorded in the **STS Review** Menu as **Pre-Induction Baseline Regional Oxygen Saturation**

q) Click on STS/FS Stop to stop the Data collection and note the Time (18:00) and StO2 values on the four channels (CH1 61, CH2 59, CH3 58, CH4 64)

r) Disconnect both preamps from the Monitor to stop the data collection without restarting a new Patient.

s) Enter the STS View Menu to validate the values recorded as **last valid** %StO2 values do match with the values recorded as **Skin Closure** for the respective channels. PASS

t) Using the Table Below, records all values from the **STS Review** Menu

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	CH1	CH2	Ch3	Ch4
Pre-Induction Baseline Regional Oxygen Saturation (%)				
TIME	**CH1**	**CH2**	**Ch3**	**Ch4**
14:25	61	59	83	65
Skin Closure Regional Oxygen Saturation (%)				
TIME	**CH1**	**CH2**	**Ch3**	**Ch4**
15:00	61	59	58	64
Cumulative Saturation below Threshold (min %)				
	CH1	**CH2**	**Ch3**	**Ch4**
	–	57.5	106.4	119.6
Regional Oxygen Saturation Percentile Ranges (min)				
	CH1	**CH2**	**Ch3**	**Ch4**
> 90 %	0.0	0.0	0.0	0.0
81 – 90 %	0.0	0.0	2.3	0.0
71 – 80 %	6.0	0.0	1.3	0.0
61 – 70 %	29.4	0.0	10.9	18.7
51 – 60 %	0.0	28.8	20.8	2.6
41 – 50 %	0.0	0.3	0.0	3.8
	CH1	**CH2**	**Ch3**	**Ch4**
31 – 40 %	0.0	4.9	0.0	1.7
≤30 %	0.0	0.9	0.0	3.5

Table 7 – STS View Data Record

u) Enter the Files\Manage menu to save the file "**STS DATA Verification**" into a connected USB.

v) Using Excel, open the saved Patient Data to verify the values reported in the **STS Data** portions do match with the values reported in **Table 7** above. PASS

w) Using Excel, proceed to calculate the **Cumulative Saturations** and all **Percentile Ranges** values for all channels.

x) Using the sample in **Table 8** & **Table 9** below, enter the proper formulas in the Cells to calculate the values.

- **Cumulative Saturation below STS DATA Threshold: (CSBT)**

  Calculation Formulas to be entered into the cells.

  Chx Cuml. Cells = (IF (**CHx** > 0, (IF ((**T_{CHx}** - **CHx**) > 0, (**T_{CHx}** - **CHx**) * 2, 0)), 0)) = **C_{CHxi}**

  SUM: CHx CSBT = (Σ C_{CHxi})/60 Minute-%

- **Regional Oxygen Saturation Percentile Ranges Calculation**
  - **Formula to be entered into the cells for ≤ 30%:**

    Chx Linear Cells =(IF(**CHx** > 0, (IF((31 - **CHx**) > 0, 2, 0)), 0)) = **C_{CHxi}**

  - **Formula to be entered into the cells for 31- 40 %**

    Chx Linear Cells =(IF(**CHx** > 30, (IF((41 - **CHx**) > 0, 2, 0)), 0)) = **C_{CHxi}**

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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- **Formula to be entered into the cells for 41-50%**

  Chx Linear Cells =(IF(**CHx** > 40, (IF((51 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for 51 - 60%**

  Chx Linear Cells =(IF(**CHx** > 50, (IF((61 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for 61 - 70%**

  Chx Linear Cells =(IF(**CHx** > 60, (IF((71 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for 71 - 80%**

  Chx Linear Cells =(IF(**CHx** > 70, (IF((81 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for 81 - 90%**

  Chx Linear Cells =(IF(**CHx** > 80, (IF((91 - **CHx**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

- **Formula to be entered into the cells for > 90%**

  Chx Linear Cells =(IF(**CHx** > 0, (IF((**CHx - 90**) > 0, 2, 0)), 0)) = $\mathbf{C_{CHxl}}$

SUM (for each Range): Ch1 Linear Percentile Range = (Σ C_{CHxl})/60 Minutes

y) Enter the calculated values into **Table 10** below. Print and attach a copy of the calculated data.
z) Validate all calculated data in **Table 10** do match within ± 1.0 unit to those reported by the UUT's Display and as recorded in **Table 7**. PASS
aa) Power Down the UUT

USB Values						Cumulative Saturations			
Date	Time	Ch1	Ch2	Ch3	Ch4	Ch1	Ch2	Ch3	Ch4
7/7/2013									
	10:54:11	90	68	90	68	0	0	0	0
	10:54:13	42	44	42	44	52	14	52	14
	10:54:15	59	68	59	68	18	0	18	0
	10:54:17	86	56	86	56	0	0	0	0
					SUM	**1.17**	**0.23**	**1.17**	**0.23**

Table 8 – STS DATA Calculation Data Sheet

Date	Time	CHx	≤ 30%	31 - 40 %	41 – 50 %	51 – 60 %	61 – 70 %	71 – 80 %	81 – 90 %	> 90 %
7/7/2013										

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Date	Time	CHx	≤ 30%	31- 40 %	41 – 50 %	51 – 60 %	61 – 70 %	71 – 80 %	81 – 90 %	> 90 %
	10:54:11	90	0	0	0	0	0	0	2	0
	10:54:13	42	0	0	2	0	0	0	0	0
	10:54:15	59	0	0	0	2	0	0	0	0
	10:54:17	86	0	0	0	0	0	0	2	0
		SUM	**0.0**	**0.0**	**0.03**	**0.03**	**0.0**	**0.0**	**0.07**	**0.0**

Table 9 – Regional Oxygen Saturation Percentile Ranges Calculation

Cumulative Saturation below Threshold (Min %)			
Channel 1	**Channel 2**	**Channel 3**	**Channel 2**
0.0	57.5	106.6	119.7

Ranges	Regional Oxygen Saturation Percentile Ranges (Min)			
	Channel 1	**Channel 2**	**Channel 3**	**Channel ~~2~~ 4**
> 90 %	0.0	0.0	0.0	0.0
81 – 90 %	0.0	0.0	2.4	0.0
71 – 80 %	6.0	0.0	1.4	0.0
61 – 70 %	29.4	0.0	10.9	18.8
51 – 60 %	0.0	28.8	20.9	2.6
Ranges	**Channel 1**	**Channel 2**	**Channel 3**	**Channel 2**
41 – 50 %	0.0	0.3	0.0	3.8
31 – 40 %	0.0	4.9	0.0	1.7
≤30 %	0.0	1.0	0.0	3.5

JT 12.14.13

Table 10 – Calculated STS Data

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.3.4 Reference Value REF

a) Power up the UUT
b) Start a new Case "REFERENCE REF"
c) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data.
d) Validate the space reserved for the REF value is blank at the beginning of any new case. PASS

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e) Cycle power to the UUT and keep the same patient to validate the REF space continue to be blank. PASS

f) Enter the DATA menu then click on the **Ref** key to validate the current StO2 values now appears above **Ref** in the appropriate position (see **Figure 2**). PASS

g) Validate there is a dotted line now appearing on the Graph matching the displayed Ref value for that specific channel and matching the Body Location color. PASS

h) Press on the **Ref** value within the Numeric field the dotted line is removed. PASS

i) Press again on the **Ref** value to validate the dotted line reappears on the Graph. PASS

j) Disconnect one of the Sensor from the Preamp then click again on the Ref Key to validate the all reference values are updated and the channel with disconnected sensor is now displaying a blank as Reference value. PASS

k) Reconnect the sensor to the Preamp and wait for the UUT to display valid StO2 values for that channel.

l) Click on Ref again and verify all channels are updated with the current StO2 values. PASS

m) Cycle power to the UUT and **keep the same patient** to verify the UUT returns with the pre-shut down Ref values and dotted lines. N/A

n) Wait for the UUT to start reporting StO2 values then click on the **Ref** key to validate all Ref values are updated for all channels. PASS

o) Start a new case to verify the last **Ref** value and dotted line are removed from the display as soon as a new case is started. PASS

p) Activate a new Reference value for all active channels and validate they all get an updated "Ref" value assigned. PASS

q) Deactivate one channel by assigning them "Unused" as Body Location to validate the Ref value remains set to blank event after repeated attempts to reset it on all channels. PASS

r) Reactivate the channel (L or R Brain Body Location) then wait for the channel to restart displaying valid StO2 Data and validate there are no Ref values displayed for that channel until after the "Ref" key has been pressed again. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.4.4 Patient Data Management

8.4.4.1 Multiple Patients Storage

a) Power up the UUT

b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data. (create at least three new patient cases)

c) Click on the **Files** key (1st level buttons row) then on **Manage** to enter the Patient Data Management menu.

d) Validate multiple Patient Files are stored. PASS

e) Validate each Patient file is represented by an individual Button on the menu. PASS

f) Validate the patient ID (if entered) is included in the Patient file name with the format **"yyyy-mm-dd-hhxxss-ID.csv"** PASS

Test Performed By (signature): [signature] Date of Test: 12-13-13
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g) Validate the current case is not available. PASS

h) Cycle power to the UUT and wait to enter the Files menu to validate the current case is still not being displayed. PASS

i) Click on any file to validate it now appears highlighted/outlined. PASS

j) Click on the file again to validate it now appears deselected. PASS

k) Validate the keys "**Save**" and "**Delete** only become available after a file has been selected. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.4.2 Saving Selected Files to the USB

a) Power up the UUT

b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data. (create at least three new patient cases)

c) Select a File then click on "**Save**" to validate there is a menu alerting the User a USB has to be connected before the file could be saved. PASS

d) Connected an appropriate USB to the UUT then attempt to save the file into the USB to validate the data transfer is effectively started. PASS

e) Validate there is a percentage File Progression update. PASS

f) Validate the word "**Done**" is displayed once the data saving is done. PASS

g) Validate saved files are still available in the menu once the file transfer done. PASS

h) Validate it is possible to stop the data saving at any time once started and the incomplete file is not available on the USB. PASS (Note any observed system crash, reset or frozen)

i) Validate a case cannot be saved while it is ongoing but only after it is closed. PASS

j) Validate it is not possible to select a second file for saving in the middle of an ongoing USB data saving. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.4.3 Reviewing Data Saved to the USB

a) Power up the UUT

b) Connect appropriate Preamps and sensors to monitor and wait for the UUT to start collecting data.

c) Create the four types of cases below

i. No STS Data Collection: Name "**Regular Test Case**" (No STS COLLECTION)

ii. STS Data Collection Done: Name "**STS Data Done**"

iii. Ongoing STS Data Collection: "**STS Data Ongoing**"

iv. Case without Name: " "

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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d) Add Event Marks, High and Low Parameter Alarms on all channels and note the time and duration of each event and alarms on a separate piece of paper.

e) Note for each case the High & Low Parameter Alarm and Body Locations on all channels for each case on a separate sheet of paper.

f) Save the cases into a USB

g) Connect the USB to a free USB slot on the PC.

h) Validate the saved files have the file name format "**yyyy-mm-dd-hhmmss-ID**[1] e.g. "**2013-05-09-152649.csv**". PASS, PASS, PASS, PASS

i) Validate there are no two files with the same file name. PASS

j) Double click on the FORE-SIGHT files in the USB stick to open it using **Notepad**.

k) Validate for the three cases the **File Header Information** has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

l) Validate the **Patient/Case Information** section has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

m) Validate the **Gemini Created STS Information** section has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

n) Validate the **Viewer Created STS Information** section has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

o) Validate the **Case Info** section has the Format defined in Doc 21-07-0342. PASS, PASS, PASS, PASS

p) Validate the case Info content does match the patient settings in the monitor at the end of the case for old cases or at the time of data saving for ongoing cases. PASS, PASS, PASS, PASS

q) Validate the **Patient Data Information** section has the Format defined in Doc 21-07-0360. PASS, PASS, PASS, PASS

r) Validate all events Marks entered in the cases are properly represented in the Patient Data Information section. PASS, PASS, PASS, PASS

s) Validate all Parameter Alarms enunciated during the cases are properly represented in the Patient Data Information section following the High/Low Alarm index in **Table 11** below: PASS, PASS, PASS, PASS

CH1 Low	CH1 High	CH2 Low	CH2 High	CH3 Low	CH3 High	CH4 Low	CH4 High	VALUE	CH1 Low	CH1 High	CH2 Low	CH2 High	CH3 Low	CH3 High	CH4 Low	CH4 High	VALUE
X		-	-	-	-	-	-	1	-	X	X	-	X	-	X	-	86
-	X	-	-	-	-	-	-	2	-	-	-	X	X	-	X	-	88
-	-	X	-	-	-	-	-	4	X	-	-	X	X	-	X	-	89
X	-	X	-	-	-	-	-	5	-	X	-	X	X	-	X	-	90
-	X	X	-	-	-	-	-	6	-	-	-	-	-	X	X	-	96
-	-	-	X	-	-	-	-	8	X	-	-	-	-	X	X	-	97
X	-	-	X	-	-	-	-	9	-	X	-	-	-	X	X	-	98
-	X	-	X	-	-	-	-	10	-	-	X	-	-	X	X	-	100
-	-	-	-	X	-	-	-	16	X	-	X	-	-	X	X	-	101
X	-	-	-	X	-	-	-	17	-	X	X	-	-	X	X	-	102

[1] **yyyy-mm-dd-hhmmss**: Date and Time of Case start; **ID**: Last Patient ID entered.

Test Performed By (signature): [signature] Date of Test: 12.13.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CH1 Low	CH1 High	CH2 Low	CH2 High	CH3 Low	CH3 High	CH4 Low	CH4 High	VALUE	CH1 Low	CH1 High	CH2 Low	CH2 High	CH3 Low	CH3 High	CH4 Low	CH4 High	VALUE
-	X	-	-	X	-	-	-	18	-	-	-	X	-	X	X	-	104
-	-	X	-	X	-	-	-	20	X	-	-	X	-	X	X	-	105
X	-	X	-	X	-	-	-	21	-	X	-	X	-	X	X	-	106
-	X	X	-	X	-	-	-	22	-	-	-	-	-	-	-	X	128
-	-	-	X	X	-	-	-	24	X	-	-	-	-	-	-	X	129
X	-	-	X	X	-	-	-	25	-	X		-	-	-	-	X	130
-	X	-	X	X	-	-	-	26	-		X	-	-	-	-	X	132
-	-	-	-	-	X	-	-	32	X		X	-	-	-	-	X	133
X	-	-	-	-	X	-	-	33	-	X	X	-	-	-	-	X	134
-	X	-	-	-	X	-	-	34	-	-	-	X	-	-	-	X	136
-	-	X	-	-	X	-	-	36	X	-	-	X	-	-	-	X	137
X	-	X	-	-	X	-	-	37	-	X	-	X	-	-	-	X	138
-	X	X	-	-	X	-	-	38	-	-	-	-	X	-	-	X	144
-	-	-	X	-	X	-	-	40	X	-	-	-	X	-	-	X	145
X	-	-	X	-	X	-	-	41	-	X	-	-	X	-	-	X	146
-	X	-	X	-	X	-	-	42	-	-	X	-	X	-	-	X	148
-	-	-	-	-	-	X	-	64	X	-	X	-	X	-	-	X	149
X	-	-	-	-	-	X	-	65	-	X	X	-	X	-	-	X	150
-	X	-	-	-	-	X	-	66	-	-	-	X	X	-	-	X	152
-	-	X	-	-	-	X	-	68	X	-	-	X	X	-	-	X	153
X	-	X	-	-	-	X	-	69	-	X	-	X	X	-	-	X	154
-	X	X	-	-	-	X	-	70	-	-	-	-	-	X	-	X	160
-	-	-	X	-	-	X	-	72	X	-	-	-	-	X	-	X	161
X	-	-	X	-	-	X	-	73	-	X	-	-	-	X	-	X	162
-	X	-	X	-	-	X	-	74	-	-	X	-	-	X	-	X	164
-	-	-	-	X	-	X	-	80	X	-	X	-	-	X	-	X	165
X	-	-	-	X	-	X	-	81	-	X	X	-	-	X	-	X	166
-	X	-	-	X	-	X	-	82	-	-	-	X	-	X	-	X	168
-	-	X	-	X	-	X	-	84	X	-	-	X	-	X	-	X	169
X	-	X	-	X	-	X	-	85	-	X	-	X	-	X	-	X	170

Table 11 – Alarm Index Table

Note: X = Alarm present, - = Alarm not present

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

Test Performed By (signature): _____ Date of Test: 12.13.13
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8.4.4.4 Deleting Selected Files

a) Select a File then click on "**Delete**" to validate there is a menu alerting the User and requiring a confirmation. PASS

b) Validate the Patient case is not removed if user decide not to delete. PASS

c) Validate the case is removed from the list if the user agrees to delete it. PASS

d) Validate only the selected case has been removed. PASS

e) Attempt to delete the current case to validate the current case could not be removed. PASS

f) Delete all cases from the UUT until there is just the current case left. Attempt to delete the last case to validate there is a warning that the current case could not be removed. PASS

g) Disconnect the Preamps from the Monitor to force a data collection stop without starting a new case.

h) Attempt to delete the last case to validate there is a warning that the current case could not be removed. PASS

i) Return to the Main menu and start a new Patient/Case.

j) Attempt to delete the previous case to validate the case could be removed. PASS

k) Attempt to delete the last case to validate there is a warning that the current case could not be removed. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5 Setup Menu

8.4.5.1 Setup Menu Selection

a) Click on the **Setup** key (1st level buttons row).

b) Validate the buttons **View, Brightness, Volume, Time/Date, Alarm Delay, Log** and **Home** buttons are all available PASS

c) Click on the **Log In** key to validate there is a Menu requiring the User to enter the appropriate Password PASS

d) Enter a wrong password to validate a Popup menu appears and alert about a wrong password being entered. PASS

e) Enter the appropriate Password to validate the selection in Table appears.

Selection / Password	Language	Ports	Defaults	Model Number	View FAT	TCP IP On	Core Dump	Eng Settings	Validate
BIOMED 2466	X	X	X	-	-	-	-	-	P ☑ F ☐
FSMANUF 3762	-	-	-	X	-	-	-	-	P ☑ F ☐
ACCESS1 2223771	-	-	-	-	X	X	X	X	P ☑ F ☐

Table 12 – Password Protected Menu Screen

Test Performed By (signature): Prof or Tda Date of Test: 12.13.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5.2 View Settings

a) Enter the **View** Menu from the **Setup** Menu selection.
b) Validate the current View setting is highlighted in the View menu PASS
c) Validate it is possible to select any of the other choices. PASS
d) Touch the **Cancel** button to validate the View menu is closed and the current selection maintained. PASS
e) Re-enter the View menu and select each of the settings per **Table 13**
f) Validate the time scale is adjusted to match the current view setting PASS
g) Cycle Power to the UUT to validate the view setting is maintained once back into Main menu.
h) Reenter the View menu to make rapid changes from one setting to the next to validate the system does not crash or otherwise becomes irresponsive and all new settings are executed accordingly. PASS

View	Validate	View	Validate
15 Min	P ☑ F ☐	4 Hr	P ☑ F ☐
30 Min	P ☑ F ☐	8 Hr	P ☑ F ☐
1 Hr	P ☑ F ☐	12 Hr	P ☑ F ☑
2 Hr	P ☑ F ☐	24 Hr	P ☑ F ☐

Table 13 – View Settings

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5.3 Volume Settings

a) Enter the **Volume** from the **Setup** Menu selection.
b) Validate the current **Volume** level is highlighted in the Volume menu PASS
c) Validate all allowed Volume level selections are available PASS (20%, 40%, 60%, 80% and 100%)
d) Press on **Cancel** button
e) Validate the **Volume** menu is exited and the UUT returned to the **Setup** menu. PASS
f) Re-enter the **Volume** menu to set the Volume to 100%..
g) Create a High Priority Alarm (e.g. High or Low Limit violation) to validate the Audio corresponds to the set Volume level PASS
h) Create a Medium Priority Alarm (e.g. Sensor or Cable disconnected) to validate the Audio corresponds to the 100% Volume level PASS

Test Performed By (signature): [signature] Date of Test: 12-14-13
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i) Create a Low Priority Alarm (e.g. External Interference) to validate the Audio Volume corresponds to the 100% Volume level PASS

j) Set the Volume to the 20%.

k) Validate at this Volume the Audio is still noticeable PASS (above system own operating noise)

l) Cycle power to UUT and validate the tone initiated during Initialization are at 20% PASS

m) Set the Volume to 100%

n) Cycle power to UUT and validate the tones initiated during Initialization are at 100% PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.5.4 Brightness Settings

a) Enter the **Brightness** Menu from the **Setup** Menu selection.

b) Validate the current Brightness level is highlighted in the Brightness menu PASS

c) Validate it is possible to select any of the other choices. PASS

d) Touch the **Cancel** button to validate the Brightness menu is closed and the current setting maintained. PASS

e) Re-enter the Brightness menu and select each of the settings per **Table 14**

f) Validate the Brightness level is adjusted to match the current setting PASS

g) Cycle Power to the UUT to validate the Brightness level is maintained.

Brightness	Validate	Brightness	Validate
20 %	P ☑ F ☐	80 %	P ☑ F ☐
40 %	P ☑ F ☐	100 %	P ☑ F ☐
60 %	P ☑ F ☐		

Table 14 – Brightness Settings

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.4.5.5 Ports Settings

a) Enter the **Ports** from the **Setup** Menu selection.

b) Validate the current **Ports setup** and **Baud Rate** are displayed PASS

c) Validate following Serial Output mode **IntelliBridge, VueLink, 2 Ch CAS, 4 Ch CAS, 2 Ch CSV, 4 Ch CSV, Scientific** and **None** are available. PASS

d) Validate the Baud Rates could be selected separately from the Serial Output selection per **Table 15** below PASS

e) Validate each of the two Serial Output **Port A** or **Port B** could be setup individually. PASS

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		Protocol						
		IntelliBridge	VueLink	2 Ch CAS	4 Ch CAS	2 Ch CSV	4 Ch CSV	Scientific
Baud	4800	-	X	X	X	X	X	-
	9600	X	X	X	X	X	X	-
	19200	X	X	X	X	X	X	-
	38400	-	-	X	X	X	X	-
	57600	-	-	X	X	X	X	X
	115200	-	-	X	X	X	X	X
	Validate	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐

Table 15 – Serial Protocols Baud Rates Selections

f) Set the UUT for simultaneous Serial Port Output per **Table 16** below to validate all ports are operating accordingly and all necessary data are serially and accurately outputted. PASS
g) Validate there is no need to restart the UUT following the Changes to the ports. PASS
h) Cycle power to the UUT to validate the Port configuration is kept. PASS
i) Validate the UUT could operate in each of the settings below without any system crash, reset or otherwise becoming unresponsive. PASS

Port A		Port B		Pass /Fail
Output	Baud Rate	Output	Baud Rate	
2 Ch CSV	4800	4 Ch CSV	115200	P ☑ F ☐
IntelliBridge	19200	2 Ch CAS	115200	P ☑ F ☐
IntelliBridge	19200	VueLink	4800	P ☑ F ☐
2 Ch CAS	115200	4 Ch CAS	19200	P ☑ F ☐
IntelliBridge	9600	CVS-2Ch	9600	P ☑ F ☐
2 Ch CAS	4800	4 Ch CSV	4800	P ☑ F ☐
Scientific	115200	VueLink	9600	P ☑ F ☐
Scientific	115200	Scientific	57200	P ☑ F ☐
Scientific	57200	4 Ch CAS	19200	P ☑ F ☐

Table 16 – Simultaneous Serial Output Table

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5.6 Time and Date Settings

a) Select the **Setup button.**
b) Validate the current Time and Date setting are individually displayed PASS
c) Validate there is a warning that the current case will be closed if the time is changed during a case. PASS **(Figure 7)**

Test Performed By (signature): [signature] Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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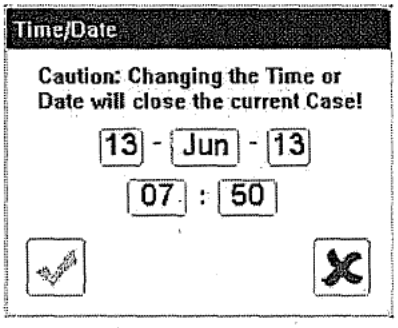

Figure 7 – Time & Date Menu

d) Touch the **Cancel** button to validate the menu is exited without any change to the time and the current case is not closed. PASS
e) Re-enter the **Time & Date** menu, make changes to the Time or Date
f) Touch the **Cancel** button to validate the menu is exited without any change to the time and the current case is not closed. PASS
g) Re-enter the **Time & Date** menu and make changes to the time and date per **Table 17** and validate only the indicated ranges are acceptable PASS
h) Validate the Leap and non-leap years exceptions are respected PASS
i) Click on the **Accept** button after entering the date and time
j) Validate the time and date on the Main Screen are updated accordingly and the current case is stopped while another case is restarted PASS
k) Turn off the UUT (Note Time & Date: PASS 12 Dec 13 15:50)
l) Disconnect the line cord and battery pack, wait 5 minute
m) Reconnect the battery pack to the UUT and power on the UUT
n) Validate appropriate date and time are displayed PASS (Note Time & Date: 12 Dec 13 15:57)

Setting	Range	Validate
Hour	0 to 23	P ☑ F ☐
Min	0 to 59	P ☑ F ☐
Day[2]	1 to 31	P ☑ F ☐
Month	Jan to Dec	P ☑ F ☐
Year	12 to 99	P ☑ F ☐

Table 17 – Time and Date setting

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

[2] Max Acceptable value for Days is 31, 30, 29 or 28 based on current Month whether Leap or Non-Leap Year

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8.4.5.7 Language Settings

a) Select the **Biomed** Menu then enter the **Language** menu.

b) Validate the following Languages are available:

English PASS **Spanish** PASS **French** PASS
Italian PASS **German** PASS **Dutch** PASS **Russian** PASS

c) Validate each Language appears in the native language translation. PASS

d) Validate any of the language could be selected. PASS

e) Validate the change is applied and the menu closed as soon as a selection is made. PASS

f) Validate the QWERTY keyboard type is used for all Languages except Russian. PASS

g) Validate the Cyrillic keyboard is used for the Russian language selection. (See **Figure 8** below) PASS

h) Enter each one of the menu & submenu to verify all strings fit in the respective fields.

ENGLISH	FRENCH	SPANISH	GERMAN	DUTCH	ITALIAN	RUSSIAN
MAIN	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
PATIENT	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
EVENT	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
DATA	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
FILES	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
SETUP	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
HELP	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐

i) Save a Patient File to the **USB** while each of the language below is selected and review the file to validate the header section is are translated according to the language selected and that events entered while in that language are also available in the event section as translated. PASS (Use as Patient ID the name of the Language being used)

English PASS **Spanish** PASS **French** PASS
Italian PASS **German** PASS **Dutch** PASS **Russian** PASS

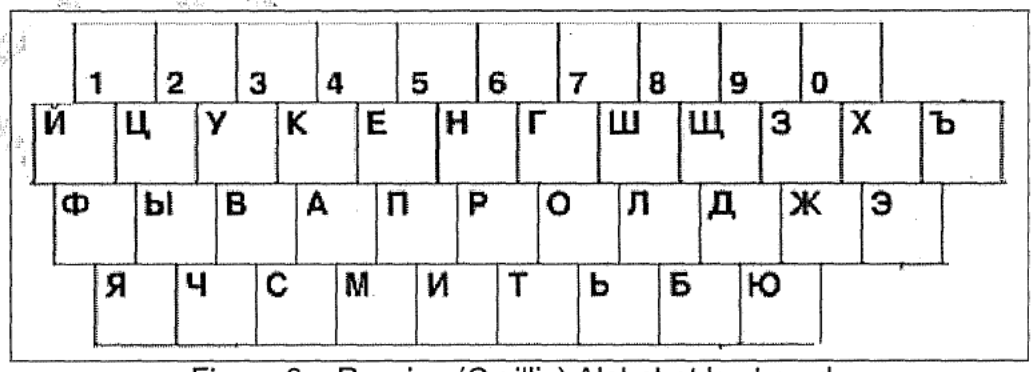

Figure 8 – Russian (Cyrillic) Alphabet keyboard

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.4.5.8 Alarm Delay

a) Select the **Setup button** then enter the **Alarm Delay** menu
b) Validate the selections **0**, **5**, **10** & **15** seconds are available PASS
c) Provoke a StO2 Limit violation Alarm. Validate the Parameter Alarms (High Priority Audio and Visuals) are initiated within the set delay PASS
d) While there is no Alarm present, click on the Audio Silence/Reset Key to activate the 2-Min Audio Disable.
e) Provoke a StO2 Limit violation Alarm. Validate the Parameter Alarms (Visuals) are initiated within the set delay PASS
f) Wait for the two minute Audio disable to be over and verify the High Priority Audio is started if the Parameter Alarm condition is still present. PASS

Alarm Delay	Audio Enabled	Audio Disabled
0 Sec	P☑ F☐	P☑ F☐
5 Sec	P☑ F☐	P☑ F☐
10 Sec	P☑ F☐	P☑ F☐
15 Sec	P☑ F☐	P☑ F☐

Table 18 – Alarm Delay

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.4.5.9 Factory Defaults Settings

a) Select the **Biomed** Menu then select the **Defaults** key.
b) Validate the user is warned "**This will cause all settings to change to Factory Defaults**" PASS
c) Select Cancel ✖ to validate the currents settings are kept. PASS
d) Set the UUT for the values in **Table 19** below under "**Settings**"
e) Cycle Powers to the UUT to validate upon returning to main menu all new settings are still available. PASS

Test Performed By (signature): [signature] Date of Test: 12-14-13
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f) Reenter the "**Factory Defaults**" menu to set all settings and validate all settings are effectively returned to the Defaults per **Table 19** below. PASS (Only the group "**Altered by pressing Restore Factory Defaults**")

g) Cycle Powers to the UUT to validate upon returning to main menu all Default settings are still available. PASS

h) Validate the entered settings under "**Should not be Altered by pressing Restore Factory Defaults**" have not been changed/affected by the factory defaults settings restoration and numerous system power cycles. PASS

FEATURE	SETTINGS	DEFAULT	Validate
Altered by pressing Restore Factory Defaults			
Ch 1 High	**75 %**	**90 %**	P☑ F☐
Ch 1 Low	**15 %**	**50 %**	P☑ F☐
Ch 2 High	**80 %**	**90 %**	P☑ F☐
Ch 2 Low	**20 %**	**50 %**	P☑ F☐
Ch 3 High	**85 %**	**90 %**	P☑ F☐
Ch 3 Low	**25 %**	**50 %**	P☑ F☐
Ch 4 High	**98 %**	**90 %**	P☑ F☐
Ch 4 Low	**3 %**	**50 %**	P☑ F☐
Trace View	**2 Hours**	**30 Min**	P☑ F☐
Volume	**20 %**	**100 %**	P☑ F☐
Brightness	**80 %**	**100 %**	P☑ F☐
Port A Protocol	**2 Ch CSV**	**None**	P☑ F☐
Port A Baud	**57600**	**115200**	P☑ F☐
Port B Protocol	**VueLink**	**None**	P☑ F☐
Port B Baud	**19600**	**115200**	P☑ F☐
Language	**French**	**English**	P☑ F☐
Alarm Limit Delay	**15 Sec**	**0 Sec**	P☑ F☐
Should not be Altered by pressing Restore Factory Defaults			
Ch 1 Body Location	R-Brain	L-Brain	P☑ F☐
Ch 2 Body Location	L-Arm	R-Brain	P☑ F☐
Ch 3 Body Location	L-Leg	Unused	P☑ F☐
Ch 4 Body Location	R-Flank	Unused	P☑ F☐
Patient ID	John Doe	Blank	P☑ F☐
References	X	Blank/Invalid	P☑ F☐
STS Data Collection	Ongoing	Disabled & Stopped	P☑ F☐
Eng. Audio Settings	Disabled	Enabled	P☑ F☐
Eng. LED Alarm	Disabled	Enabled	P☑ F☐
US/OUS	OUS	US	P☑ F☐

Test Performed By (signature): Jonathan Tolc Date of Test: 12.14.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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FEATURE	SETTINGS	DEFAULT	Validate
Serial Number	1234567	000000	P☑ F☐
Asset Number	101010	000000	P☑ F☐
Time/Date	Current	1 Jan 2013 / 00:00	P☑ F☐
Stored Patient Data	Data	No data	P☑ F☐
Ethernet IP Address	Current	192.168.10.90	P☑ F☐
TCP	Enabled	Disabled (each Power cycle)	P☑ F☐

Table 19 - Factory Default Settings

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.4.5.10 Help Menu

a) Select the **Setup button** then enter the **Help** menu. (US Monitors PT 12.14.13)

b) Validate following Help menu Selections are available
Sensor Selection PASS ; **Start Monitoring** PASS
Applying the Sensor PASS ; **Numeric Field** PASS ; **About** PASS

c) Select About to validate the menu reassembles **Figure 9** below. PASS

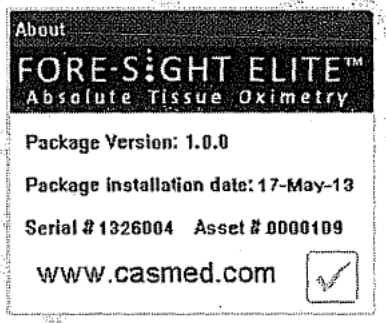

Figure 9 – About Help Menu

d) Validate the displayed **Package** version is the same under the **Bootloader\About** Menu PASS

e) Validate the displayed **Serial Number** and **Asset #** are the same under **Bootloader\About** Menu PASS

f) Validate the **Package Installation date** does match the last Package upgrade installation for that specific unit PASS

g) Validate the Outlook and content of the **Sensor Selection Help** menu resembles **Figure 10** below. PASS

h) Validate all sensor allowed on the System are represented. PASS

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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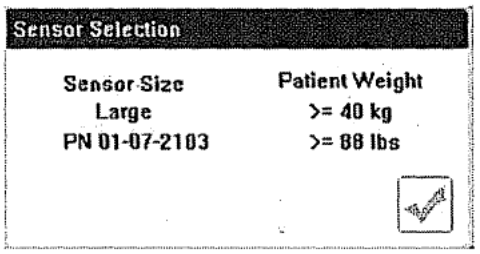

Figure 10 – Sensor Selection Help Screen

i) Validate the Outlook and content of the **Start Monitoring Help** menu resembles **Figure 11** below. _____

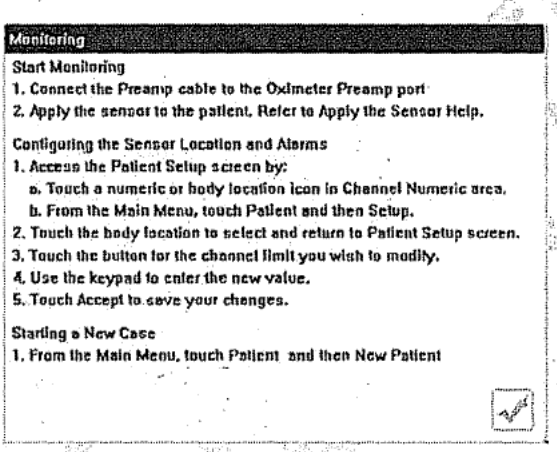

Figure 11 – Start Monitoring Help Screen

j) Validate the Outlook and content of the **Applying the Sensor Help** menu resembles **Figure 12** _____

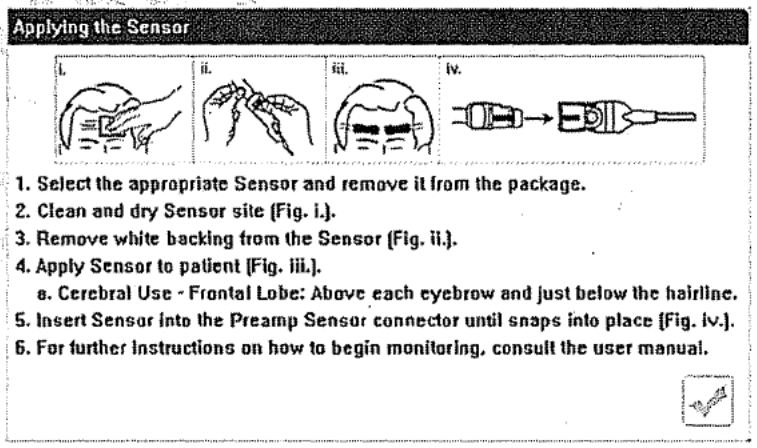

Figure 12 – Applying Sensors Help Screen

Test Performed By (signature): _____ Date of Test: 12.13.6

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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k) Validate the Outlook and content of the **Numeric Field Help** menu resembles **Figure 13.** PASS

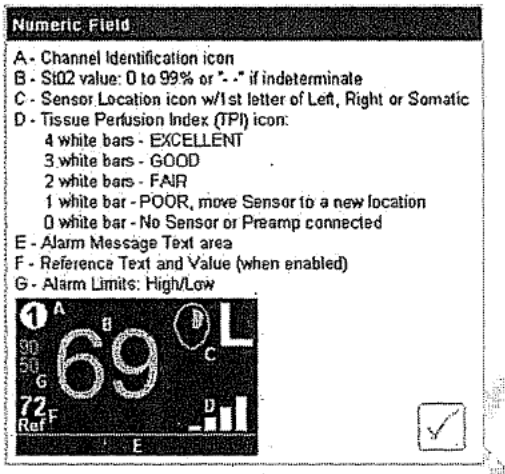

Figure 13 – Numeric Field Help Screen

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.5 Connection Status & StO2 Data Collection

8.5.1 Patient & Monitor Cable Status

8.5.1.1 Connection Status at Power on

a) Enter the **Patient Configuration** menu, select Left brain (Ch1 & Ch3) or Right (Ch2 & Ch4) brain

b) Power down the UUT

c) Connect Preamps and Sensor to the UUT following **Table 20** below

d) Power on the UUT

e) Validate the expected message per **Table 20** is displayed in the individual Numeric field and the appropriate Audio Alarm[3] is initiated. PASS

f) Performs the recommended action and validate the expected outcome (message, Alarm or Data) after a maximum of 30 seconds

g) Validate the Sensor connection Status LED on the preamp does match the Channel ID
- Ch1 or Ch3 on Preamp Left Side. PASS
- Ch2 or Ch4 on Preamp Right Side. PASS

h) Validate there was no occurrence of "Incorrect Sensor Size" errors after valid and calibrated sensors (Large & Medium) were connected to the Preamp. PASS

[3] See 21-07-0243 for accompanying Alarm Audio type (High, Medium, Low and No Audio)

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Initial State	Preamp LED Status	Message[4]	Action[5]	Preamp LED Status	New Message[6]	Validate
No Preamp	OFF	Connect Preamp	Nothing	OFF	Connect Preamp	P ☑ F☐
No Preamp	OFF	Connect Preamp	Connect Preamp	White	Connect Sensor	P ☑ F☐
Preamp, No Sensor	White	Connect Sensor	Nothing	White	Connect Sensor	P ☑ F☐
Preamp, No Sensor	White	Connect Sensor	Connect Sensor	Green	Acquiring Data	P ☑ F☐
Preamp & Sensor	Green	Acquiring Data	Nothing	Green	"No Message"	P ☑ F☐

Table 20 – Power On Connection Status

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.5.1.2 Disconnection Status after Power on

a) Connect Preamps and Sensors to the UUT.
b) Validate valid StO2 values are displayed in the Numeric area of each channel PASS
c) Disconnect Preamps and/or Sensor from the UUT following **Table 21** below.
d) Performs the recommended action to validate the expected outcome (message, Alarm or Data) after a maximum of 30 seconds

Action	Message[7]	Preamp LED Status	Validate
Disconnect Preamp	Preamp Disconnected	OFF	P ☑ F☐
Disconnect Sensor	Sensor Disconnected	White	P ☑ F☐

Table 21 – Connection Status during Monitoring.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.5.2 Sensor Connection and StO2 Data Acquisition

a) Connect Preamps on each channel on the UUT, no sensor attached
b) Enter the Patient Menu and select the appropriate Body Location or Unused per **Table 22**

[4] See 21-07-0243 for accompanying Alarm Audio type (High, Medium, Low and No Audio)
[5] Monitor will issue a special "Preamp connected" Audio once Preamp connected or a special "Sensor connected" Audio tone once a sensor is newly connected.
[6] UUT is displaying dashes "- -" as a numeric value for case without "Acquiring Data" status.
[7] UUT is displaying dashes "- -" as a numeric value for case without "Acquiring Data" status.

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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c) Connect the suggested sensor to validate the UUT does start acquiring data or the expected message is displayed

d) Validate the displayed trace is smoothed. PASS

e) Disconnect Preamp and Sensors before powering down the UUT.

Body Location	Suggested Sensor	Expected Outcome[8]	Validate
Left Brain	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Right Brain	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Left Arm	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Right Arm	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Left Flank	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Right Flank	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Left Leg	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Right Leg	Large	Acquiring Data	P ☑ F☐
	None	Connect Sensor	P ☑ F☐
Unused	Large	No Data, Messages or Audio Alarm	P ☑ F☐
	None	No Data, Messages or Audio Alarm	P ☑ F☐

Table 22 – Sensor Selection and StO2 Data Acquisition

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.5.3 New /Continue Patient Timer & Prompting

a) Power up the UUT and select to monitor the Left Brain on CH1 and the Right Brain on CH2.

b) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE 1**" and some Event Marks.

c) Validate the Event Marks and the Patient ID are properly reported on the display in the appropriate position. PASS

d) Let UUT undisturbed and collecting data for at least 40 minutes before powering down the Unit.

e) Wait for maximum 10 minutes before powering the UUT back on to validate there is menu asking the user whether or not to continue with the current case. PASS

f) Validate the previous case is continued (Patient ID, trace, Event Marks) if the User accept to continue the case PASS

[8] UUT is displaying dashes "- -" as a numeric value for case without "Acquiring Data" status. See 21-07-0243 for accompanying Alarm Audio type (High, Medium, Low and No Audio).

Test Performed By (signature): [signature] Date of Test: 12-14-13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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g) Let UUT undisturbed and collecting data for at least 40 minutes before powering down the Unit.

h) Wait for a minimum of 31 minutes before powering the UUT back on to validate the previous case is discontinued (previous Patient ID, trace, Event Marks removed) without any warning or menu PASS

i) Do enter the Patient ID "**CASE 2**" and some Event Marks. Let UUT undisturbed and collecting data for at least 40 minutes before powering down the Unit.

j) Disconnect the Sensor from the Preamp cables.

k) Wait for maximum 10 minutes before powering the UUT back on. Agree to keep the same case.

l) Validate the UUT is automatically switching to a new patient 30 minutes after power up. PASS

m) Enter the Patient ID "**CASE 3**" then wait 10 minutes before starting the data collection (connect the sensors/Phantom back to the Preamp). Let UUT undisturbed and collecting data for at least 40 minutes.

n) Disconnect the sensors from the Preamp and press the silence Key in order to dismiss the equipment alarm.

o) Validate after 30 minutes the case is closed and a new case is automatically started. PASS

p) Reconnect the sensors /Phantom to the Preamp then enter the Patient ID "**CASE 4**". Let UUT undisturbed and collecting data for at least 40 minutes.

q) Change the body location from Left to Right Brain for Channel 1 and from Right to Left Brain for Channel 2.

r) Validate that once exiting the Patient settings menu there is a menu asking whether the user will like to start a new case. PASS

s) Select **No** to validate the current case is continued. PASS

t) Let UUT undisturbed and collecting data for at least 5 minutes.

u) Change the body location from Left to Right Brain for Channel 2 and from Right to Left Brain for Channel 1.

v) Validate that once exiting the Patient settings menu there is a menu asking whether the user will like to start a new case. PASS

w) Select **Yes** to validate the current case is discontinued. PASS

x) Validate the Patient cases "**CASE 1**", "**CASE 2**", "**CASE 3**" & "**CASE 4**" were saved and are available under "Files\Manage" menu. PASS

y) Repeat above tests steps with **Left Arm** on **Ch3** and **Right Leg** on **Ch3** to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.5.4 TPI Status Indicator

a) Turn on the UUT.

b) Set the UUT to monitor the Left Brain on Ch1, Right Brain on Ch2, Left Brain on Ch3 and leaving Ch4 as unused channel.

c) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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d) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**Scientific**"

e) Start the appropriate LabView program that could store and display the UUT's scientific output data. (Using the **21-07-0345** Gemini Scientific Data Serial Output Protocol)

f) Record in **Table 23** & **Table 24** below the TotalHb values

g) Connect Preamps and sensor according to **Table 23** & **Table 24** below to validate the TPI value remains blank or is adjusted to the signal level.

Preamp & Sensor Status	TPI Status	TotalHb Range	Recorded TotalHb	TPI Symbol	Validate
Preamp & Sensor	TPI symbol adjusted to signal	> 50	63		P ☑ F☐
		42 to 49.99	43		P ☑ F☐
		35 to 41.99	40		P ☑ F☐
		< 35	29		P ☑ F☐
Preamp, No Sensor	TPI symbol set to "Blank"	0	—		P ☑ F☐
No Preamp	TPI symbol set to "Blank"	0	—		P ☑ F☐
Unused, Preamp & Sensor	No TPI symbol	--	--	--	P ☑ F☐

Table 23 – TPI Symbol Status – Cerebral Monitoring

Preamp & Sensor Status	TPI Status	TotalHb Range	Recorded TotalHb	TPI Symbol	Validate
Preamp & Sensor	TPI symbol adjusted to signal	> 30	30.6		P ☑ F☐
		20 to 29.99	25		P ☑ F☐
		10 to ~~11.99~~ 19.99 PT 12.14.13	11		P ☑ F☐

Test Performed By (signature): [signature] Date of Test: 12.14.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Preamp & Sensor Status	TPI Status	TotalHb Range	Recorded TotalHb	TPI Symbol	Validate
		< 10	9.9		P ☑ F ☐
Preamp, No Sensor	TPI symbol set to "Blank"	0	✓		P ☑ F ☐
No Preamp	TPI symbol set to "Blank"	0	✓		P ☑ F ☐
Unused, Preamp & Sensor	No TPI symbol	--	--	--	P ☑ F ☐

Table 24 – TPI Symbol Status – Somatic Tissues Monitoring

h) Allow the Sensor to be properly applied to optical simulator to validate the maximum TPI level is reached. PASS

i) Start to gradually lift off the cable end of the sensor from the simulator while avoiding any Ambient Light disturbance to validate the TPI level is reduced from 4 to 3, 3 to 2 or even to level 1. PASS

j) Validate the displayed TPI matches the TotalHb value. PASS

k) Validate the UUT is reporting a **"Check under Sensor"** Alarm as soon as the TPI level reaches **"level 1"** as an indication of a poorly perfused area. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.5.5 Adult TOP Calibration Rule

a) Power up the UUT.

b) Set the UUT to monitor the Left Brain on Ch1, Right Brain on Ch2, Left Brain on Ch3 and leaving Ch3 as unused channel.

c) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.

d) Enter the **"Ports"** Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as **"Scientific"**

e) Start the appropriate LabView program that could store and display the UUT's scientific output data. (Using the **21-07-0345** Gemini Scientific Data Serial Output Protocol)

f) Verify following steps to calculate a new TOP value: PASS

   i) Sensor is connected to Preamp
   ii) Monitor is displaying "**Acquiring Data**" during the Top calculation
   iii) Monitor is displaying an StO2 value ca 20 seconds after start of "**Acquiring data**" status
   iv) Top value on the LabView Application is fluctuating and is updated during the calculation period.

Test Performed By (signature): [signature] Date of Test: 12-14-13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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v) Once Top is calculate, the message "**Acquiring Data**" is no longer displayed on the UUT and the Top value is locked

g) Let the lasers turned on for the indicated time in **Table 25**

h) Perform the recommended actions and validate the outcome. PASS

i) Repeat above tests steps with **Left Arm** on **Ch3** and **Right Leg** on **Ch3** to validate all tests continue to pass. PASS

j) Power down the UUT.

Sensor Connection	Event	Action		Expected Outcome	Validate Cerebral	Validate Somatic
T > 15 Minutes	Disconnect Sensor	Reconnect < 3 Min		Same TOP	P ☑ F ☐	P ☑ F ☐
		Reconnect > 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		Reconnect New Sensor < 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		New Body Location	Reconnect same sensor < 3 Min	New TOP	P ☑ F ☐	P ☑ F ☐
		New Patient	Reconnect same sensor <3 Min	Same TOP	P ☑ F ☐	P ☑ F ☐
		New Patient	Reconnect Diff sensor <3 Min	New TOP	P ☑ F ☐	P ☑ F ☐
	Excessive Ambient Light	T > 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		T < 3 Min		Same TOP	P ☑ F ☐	P ☑ F ☐
T < 15 Minutes	Disconnect Sensor	Reconnect < 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		Reconnect > 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		Reconnect New Sensor < 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐
		New Body Location	Reconnect same sensor < 3 Min	New TOP	P ☑ F ☐	P ☑ F ☐
		New Patient	Reconnect same sensor <3 Min	New TOP	P ☑ F ☐	P ☑ F ☐
	Excessive Ambient Light	T < 3 Min		New TOP	P ☑ F ☐	P ☑ F ☐

Table 25 – NSAM TOP Calculation Rule

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.5.6 NSAM Application Adult Cerebral Algorithm Verification

a) Validate a verification plan for the implementation of the Adult Cerebral Algorithm into The NSAM Application Software has been drafted and executed. PASS (Record Doc # VeIN-App-001)

b) Validate all tests passed. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

Test Performed By (signature): [signature] Date of Test: 12-14-13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.5.7 NSAM Application Adult Somatic Tissues Algorithm Verification

a) Validate a verification Plan for the implementation of the Adult Somatic Tissues Algorithm into The NSAM Application Software has been drafted and executed. PASS (Record Doc # VaPN-App-000 V2.10

b) Validate all tests passed. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.6 Data Communication

8.6.1 2-CH Comma Separated Value (CSV)

a) Power the Oximeter with full monitor/patient cables connected.
b) Select to monitor the Left Brain on CH1 and the Right Brain on CH2. (2 Channels only)
c) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.
d) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**2-CH CSV**"
e) Click on the "**Setup**" Box right next to the Port and set the Baud.
f) Verify the port settings now appears next to the Port in the form e.g. "**57600**" PASS
g) Set the Baud rate in HyperTerminal to the one currently being displayed on the port being tested, set the Data Bits to "**8**", Parity to "**None**", Stop Bits to "**1**" and the Flow Control to "**None**"
h) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE CSV1**" and some Event Marks
i) Verify the matching StO2 values are continuously displayed and updated on Hyper Terminal PASS
j) Verify the output format of the SCT do match with the description in document **21-07-0202** "**FORE-SIGHT Simple Comma Text Serial Output Format**" for two Channels PASS
k) Validate the Alarm Index values follows **Table 11** and are updated with a maximum 2 seconds delay. PASS
l) Validate entered events are not represented on the serial stream. PASS
m) Validate NSAM Auto Events are not represented on the serial stream. PASS
n) Cycle power to the UUT to validate the **2-CH CSV** data output is restarted as soon as the UUT is back in Main Menu. PASS
o) Pull the SRS232 cable to validate the UUT continue to run without any issues or Alarms. PASS
p) Repeat all Test steps above this time with Left Brain on Ch1, Right Brain on CH2, Left Flank on Ch3 and Right Arm on Ch4. (4 Channels only) to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.6.2 4-CH Comma Separated Value (CSV)

a) Select to monitor the Left Brain on CH1 and the Right Brain on CH2. (2 Channels only)
b) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.

Test Performed By (signature): [signature] Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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c) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**4-CH CSV**"
d) Click on the "**Setup**" Box right next to the Port and set the Baud.
e) Verify the port settings now appears next to the Port in the form e.g. "**57600**" PASS
f) Set the Baud rate in HyperTerminal to the one currently being displayed on the port being tested, set the Data Bits to "**8**", Parity to "**None**", Stop Bits to "**1**" and the Flow Control to "**None**"
g) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE CSV2**" and some Event Marks
h) Verify the matching StO2 values are continuously displayed and updated on Hyper Terminal PASS
i) Verify the output format of the SCT do match with the description in document **21-07-0346** "**Gemini 4-Ch Comma Separated Value Serial Output Format**" for two Channels PASS
j) Validate the Alarm Index values follows **Table 11** and are updated with a maximum 2 seconds delay. PASS
k) Validate entered events are not represented on the serial stream. PASS
l) Validate NSAM Auto Events are not represented on the serial stream. PASS
m) Cycle power to the UUT to validate the **4-CH CSV** data output is restarted as soon as the UUT is back in Main Menu. PASS
n) Pull the SRS232 cable to validate the UUT continue to run without any issues or Alarms. PASS
o) Repeat all Test steps above this time with Left Brain on Ch1, Right Brain on CH2, Left Flank on Ch3 and Right Arm on Ch4. (4 Channels only) to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.6.3 2-CH CAS Protocol (ATE)

a) Select to monitor the Left Brain on CH1 and the Right Brain on CH2. (2 Channels only)
b) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.
c) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**2- CH CAS**"
d) Click on the "**Setup**" Box right next to the Port and set the Baud.
e) Verify the port settings now appears next to the Port in the form e.g. "**57600**" PASS
f) Set the Baud rate in HyperTerminal to the one currently being displayed on the port being tested, set the Data Bits to "**8**", Parity to "**None**", Stop Bits to "**1**" and the Flow Control to "**None**"
g) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE CAS ATE 1**" and some Event Marks
h) Attempts to send the following command in **Table 26** per **FORE-SIGHT ATE Serial Protocol** to verify all commands are being executed accordingly.
i) Set the UUT for ATE Streaming Measurement Values output. (Command "72")
j) Verify the output format of the UUT do match the description in document "**FORE-SIGHT ATE Serial Protocol**" for **CH1** & **CH2** PASS
k) Validate the Alarm Index values follows **Table 11** for the **CH1** & **CH2.** PASS
l) Validate entered events are not represented on the serial stream. PASS
m) Validate NSAM Auto Events are not represented on the serial stream. PASS
n) Pull the SRS232 cable to validate the UUT continue to run without any issues or Alarms. PASS
o) Let the UUT in Streaming data output mode for at least 12 Hours (Overnight) nonstop to verify the UUT is still outputting the required set of data and is still operating without interruption. PASS

Test Performed By (signature): [signature] Date of Test: 12.13.12
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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p) Repeat all Test steps above this time with Left Brain on Ch1, Right Brain on CH2, Left Flank on Ch3 and Right Arm on Ch4. (4 Channels only) to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.6.4 4-CH CAS Protocol (ATE)

a) Select to monitor the Left Brain on CH1 and the Right Brain on CH2. (2 Channels only)
b) Connect one end of the appropriate RS232 DB9 cable to any of **Port A** or **Port B** while the other end connect into a free Port of an IBM PC.
c) Enter the "**Ports**" Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**4- CH CAS**"
d) Click on the "**Setup**" Box right next to the Port and set the Baud.
e) Verify the port settings now appears next to the Port in the form e.g. "**57600**" PASS
f) Set the Baud rate in HyperTerminal to the one currently being displayed on the port being tested, set the Data Bits to "**8**", Parity to "**None**", Stop Bits to "**1**" and the Flow Control to "**None**"
g) Connect valid Preamps and Optical StO2 Simulator then wait for the UUT to start collecting data. Do enter the Patient ID "**CASE CAS ATE 2**" and some Event Marks
h) Attempts to send the following commands in **Table 26** per **FORE-SIGHT ATE Serial Protocol** to verify all commands are being executed accordingly.
i) Verify the output format of the serial output from the UUT do match the description in document **21-07-0204** "**FORE-SIGHT CAS Serial Command Protocol Specifications**" PASS
j) Set the UUT for ATE Streaming Measurement Values output. (Command "72")
k) Validate the Alarm Index values follows **Table 11.** PASS
l) Validate entered events are not represented on the serial stream. PASS
m) Validate NSAM Auto Events are not represented on the serial stream. PASS
n) Pull the RS232 cable to validate the UUT continue to run without any issues or Alarms. PASS
o) Reconnect the RS232 cable to validate the streaming data output is restarted immediately. PASS
p) Let the UUT in Streaming data output mode for at least 12 Hours (Overnight) nonstop to verify the UUT is still outputting the required set of data and is still operating without interruption. PASS
q) Repeat all Test steps above this time with Left Brain on Ch1, Right Brain on CH2, Left Flank on Ch3 and Right Arm on Ch4. (4 Channels only) to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

Command	Validate 2-CH CAS	Validate 4-CH CAS
'50' Model Number	P ☑ F ☐	P ☑ F ☐
'51' Device Serial Number		P ☑ F ☐
'52' Software Versions		P ☑ F ☐
'53' Communication Version	P ☑ F ☐	P ☑ F ☐
'54' Channel Capacity of Device	P ☑ F ☐	P ☑ F ☐
'55' Time/Date		P ☑ F ☐

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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Command		Validate 2-CH CAS	Validate 4-CH CAS
'56' Patient ID			P ☑ F ☐
'57' Patient Age Range			~~P ☐ F ☐~~ N/A
'59' Channel Numeric/Trace values		P ☑ F ☐	P ☑ F ☐
'60' Channel Low Alarm Limit values			P ☑ F ☐
'61' Channel High Alarm Limit values			P ☑ F ☐
'63' Channel Body Location values			P ☑ F ☐
'64' Channel Sensor Sizes			P ☑ F ☐
'65' Channel TPI Calculations			P ☑ F ☐
'66' Patient Alarms	No Alarm	P ☑ F ☐	P ☑ F ☐
	Low StO_2	P ☑ F ☐	P ☑ F ☐
	High StO_2	P ☑ F ☐	P ☑ F ☐
	Ambient Light	P ☑ F ☐	P ☑ F ☐
	Check under Sensor	P ☑ F ☐	P ☑ F ☐
	High Ambient Light	P ☑ F ☐	P ☑ F ☐
	No Signal/ Sensor Off	P ☑ F ☐	P ☑ F ☐
	Signal out of Range	P ☑ F ☐	P ☑ F ☐
	Preamp Disconnected	P ☑ F ☐	P ☑ F ☐
	Sensor Disconnected	P ☑ F ☐	P ☑ F ☐
	Faulty Sensor/Faulty Preamp N/A	~~P ☐ F ☐~~	~~P ☐ F ☐~~
	Unstable Signal repeat K	P ☑ F ☐	P ☑ F ☐
'68' Equipment Alarms	No error	P ☑ F ☐	P ☑ F ☐
	(b)(4) [redacted]	P ☑ F ☐	P ☑ F ☐
		P ☑ F ☐	P ☑ F ☐
	Dead Battery/ Depleted Battery	P ☑ F ☐	P ☑ F ☐
	Low Battery	P ☑ F ☐	P ☑ F ☐
	Connect to AC	P ☑ F ☐	P ☑ F ☐
	Set Clock/ Set Time/Date	P ☑ F ☐	P ☑ F ☐
	Faulty Clock Battery	P ☑ F ☐	P ☑ F ☐
	2-Min Audio Disable is Off – Audio is Enabled	P ☑ F ☐	P ☑ F ☐
	2-Min Audio Disable is On – Audio is Disabled	P ☑ F ☐	P ☑ F ☐
'69' Specific Channel FORE-SIGHT (FS) Data Values N/A			~~P ☐ F ☐~~
'70' Specific Channel Time Under Threshold (TUT) Values N/A			~~P ☐ F ☐~~
'71' Specific Channel STS Data Calculations Values			P ☑ F ☐
'72' Request Enable/Disable Streaming Measurement Values Output	'80' Without Checksum	P ☑ F ☐	P ☑ F ☐
	'80' With Checksum	P ☑ F ☐	P ☑ F ☐

Table 26 - ATE Serial Output Commands

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

Test Performed By (signature): Smita Tale Date of Test: 12.12.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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8.6.5 Philips VueLink and IntelliBridge Communication

a) Review the **VaP/VR120010** to validate all tests were executed. PASS
b) Validate all tests passed. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.6.6 Scientific Communication

a) Review the **VeP/VeR130033** to validate all tests were executed. PASS
b) Validate all tests for the Scientific Serial output passed. PASS

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7 Alarms Handling & Management

8.7.1 System LEDs

a) Connect Preamps and Sensors to the UUT.
b) Validate the UUT starts to display valid StO_2 values in the Numeric Area
c) Create a **High** priority Alarm while there is no other ongoing Alarm and validate the **Red** Alarm LEDs are **flashing** PASS
d) Remove the High limit condition and validate all LEDs are now off PASS
e) Create a **Medium** priority Alarm while there is no other ongoing Alarm and validate the **Yellow** Alarm LEDs are **flashing** PASS
f) Reconnect the Preamp and validate all LEDs are now off PASS
g) Create a **Low** priority Alarm (e.g. External Interference) while there is no other ongoing Alarm and validate the **Yellow** Alarm LEDs are **on** but **not flashing** PASS
h) Clear the Low Priority Alarm to validate all LEDs are now off PASS
i) Create an **Information signal** (AC disconnected) while there is no other ongoing Alarm and validate the **All** LEDs are **off** PASS
j) Reconnect the AC and validate all LEDs remain off PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.2 Parameter Alarms

8.7.2.1 2-Min Audio Disable Inactive

a) Create the High or Low Parameter Alarm as indicated in **Table 27**
b) Press the **Silence button** to validate the Audio is muted for 2 minutes PASS
c) Validate visual Alarms continue (red flashing LEDs & message) PASS

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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d) Validate the Audio is restarted at the end of the 2 minutes PASS

e) Clear the parameter alarm

Alarm	Message[9]	LED	Audio[10]	Silence button Pressed	Validate
Low %StO_2		Red Flashing	YES	Audio silenced, Visual remains	P ☑ F☐
High %StO_2					P ☑ F☐

Table 27 – Parameter Alarms Control (2-Min Audio Disable inactive)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.2.2 2-Min Audio Disable Active

a) Press the Alarm Silence button while there are no other Alarms present

b) Validate the Audio disabled Icon is displayed and the Audio disable timer is running PASS

c) Create the High or Low Parameter Alarm as indicated in **Table 28** below

d) Validate there is no Alarm Audio initiated while Audio disable icon is displayed PASS

e) Remove the limits violation

f) Validate the Alarms are removed.

Alarm	Message[11]	LED	Audio	CH1
Low %StO_2		Red Flashing	No	P ☑ F☐
High %StO_2				P ☑ F☐

Table 28 – Parameter Alarms Control (2-Min Audio Disable active)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.3 Equipment Alarm

Whenever possible, many subsections could be run in parallel

8.7.3.1 Ambient Light Condition

a) Enter the **"Ports"** Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as **"Scientific"**

b) Start the appropriate LabView program that could store and display the UUT's scientific output data. (Using the **21-07-0345** Gemini Scientific Data Serial Output Protocol)

c) Connect Preamps and Sensors to the UUT.

d) Place the sensor on the tester forehead

[9] Message color is white over Red Background
[10] The audio associated with these alarms are always High priority.
[11] Message color is white over Red Background

Test Performed By (signature): _____ Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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e) Enter the Patient Configuration menu to enter a Cerebral Body location e.g. Left Brain.

f) Covers the sensors in such a ways that they will be protected from any Ambient light disturbances

g) Validate the UUT start to report valid StO2 values PASS

h) Validate the Ambient Light levels are displayed for each Channel on the LabView application. PASS

i) Gradually lift off the sensor from the subject skin to Create a minor Ambient Light disturbance

j) Validate the UUT displays "**Ambient Light**" message and an Informational Alarm is generated in the numeric area for that channel as soon as the Ambient Light is above **4.5V** PASS

k) Validate the StO2 values continue to be displayed PASS

l) Continue to lift off the sensor so they are more exposed to ambient light.

m) Validate the "**High Ambient Light"** Medium Priority Alarm is generated in the numeric area for that channel as soon as the Ambient Light for that Threshold is above **6.5V**. PASS

n) Validate StO2 are no longer reported by that channel (- -) PASS

o) Continue to lift off the sensor until they are completely exposed to ambient light to validate the alarm is not removed, the ambient light level continue to increase (until max value of **10V**) and the StO2 value remain dashed. PASS

p) Gradually and slowly start to lower/replace the sensor to reduce the ambient light level and validate the UUT restart to display valid StO2 data as soon as the Ambient Light level drops below **6.5V**. PASS

q) Validate the alarm switches from Medium back to informational Priority and the message display switches from **High Ambient Light** to **Ambient Light** while the level is between **6.5** and **4.5V**. PASS

r) Validate the UUT restarts to display valid StO2 values for that channel PASS

s) Continue to reduce the Ambient light exposure until the level is below **4.5V**. PASS

t) Validate all Alarms are removed PASS

u) Validate the UUT continues to display valid StO2 values for that channel PASS

v) Set the UUT to monitor a Non-Cerebral Body Location e.g. Right Arm.

w) Repeat above tests steps to validate all tests continue to pass. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.7.3.2 Sensor Temperature Monitoring

a) Enter the "**Ports"** Menu on the FORE-SIGHT Oximeter to set the Proper Port connected as "**Scientific**"

b) Start the appropriate LabView program that could store and display the UUT's scientific output data. (Using the **21-07-0345** Gemini Scientific Data Serial Output Protocol)

c) Connect Preamps and Sensors to the UUT.

d) Place the sensor on an optical simulator.

e) Enter the Patient Configuration menu to enter a Cerebral (e.g. Left Brain) Body location

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Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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f) Covers the sensors in such a ways that they will be protected from any Ambient light disturbances

g) Validate the Sensor Temperature levels are displayed for each Channel on the LabView application. PASS (as soon as UUT is reporting "**Acquiring Data**")

h) Validate the UUT is displaying a **Sensor Off** message and is not reporting any StO2 value if after 10 Minutes the Temperature reported by the sensor is still below 28.2ºC. PASS

i) Validate the UUT start to acquire and report valid StO2 values once the Temperature is higher than 28.2ºC. PASS (with sensor placed on Forehead)

j) Place the Sensor on optical simulator once UUT has been reporting valid StO2 for at least 10 minutes.

k) Place a warm fluid or medium on top of the sensor and validate there is a gradual (no sudden jump) increase of Temperature on that specific channel. PASS

l) Validate the UUT is reporting a Medium Priority alarm with the message "**Sensor Over Temp**" as soon as the Temperature reported by the sensor for that channel is above **43.0ºC.** PASS

m) Validate the UUT is no longer reporting StO2 data for that channel until the Temperature drops below **41.0ºC.** PASS (Remove fluid or medium)

n) Place a cold fluid or medium on top of the sensor and validate there is a gradual (no sudden jump) decrease of Temperature on that specific channel. PASS

o) Validate the UUT continues to report valid StO2 data while the Temperature is gradually decreasing. PASS

p) Validate the UUT is reporting an Informational Priority alarm with the message "**Sensor Under Temp**" as soon as the Temperature reported by the sensor for that channel is below **8.0ºC.** PASS

q) Validate the UUT continues to report StO2 data. PASS

r) Disconnect the sensor then reconnect a different one.

s) Set the UUT to monitor a Non-Cerebral Body Location e.g. Right Arm.

t) Covers the sensors in such a ways that they will be protected from any Ambient light disturbances

u) Validate the Sensor Temperature levels are displayed for each Channel on the LabView application. PASS (as soon as UUT is reporting "**Acquiring Data**")

v) Validate the UUT is displaying a **Sensor Off** message and is not reporting any StO2 value if after 10 Minute the Temperature reported by the sensor is still below 27.0ºC. PASS

w) Validate the UUT start to acquire and report valid StO2 values once the Temperature is higher than 27.0ºC. PASS (Sensor placed on Arm)

x) Place the Sensor on optical simulator once UUT has been reporting valid StO2 for at least 10 minutes.

y) Place a warm fluid or medium on top of the sensor and validate there is a gradual (no sudden jump) increase of Temperature on that specific channel. PASS

z) Validate the UUT is reporting a Medium Priority alarm with the message "**Sensor Over Temp**" as soon as the Temperature reported by the sensor for that channel is above **43.0ºC.** PASS

aa) Validate the UUT is no longer reporting StO2 data for that channel until the Temperature drops below **41.0ºC.** PASS (Remove fluid or medium)

bb) Place a cold fluid or medium on top of the sensor and validate there is a gradual (no sudden jump) decrease of Temperature on that specific channel. PASS

Test Performed By (signature): [signature] Date of Test: 12.14.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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cc) Validate the UUT continues to report valid StO2 data while the Temperature is gradually decreasing. PASS

dd) Validate the UUT is reporting an Informational Priority alarm with the message "**Sensor Under Temp**" as soon as the Temperature reported by the sensor for that channel is below **8.0°C**. PASS

ee) Validate the UUT continues to report StO2 data. PASS

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.3.3 ESU Disturbance Condition

a) Properly attach a sensor to an Optical Simulator

b) Connect the ESU Test fixture to the UUT and connect it to a power source without turning it on.

c) Wait at least 60 seconds for the UUT to display valid StO2 values (StO2 = 62)

d) Turn On the ESU test Fixture in order to induce the ESU disturbance

e) Validate the StO2 value is dashed "- -" with possible showing of "**Unstable Signal**" or "**Signal out of Range**" messages and appropriate Low or Medium Priority Alarm Audio and LEDs activation PASS

f) Maintain the ESU fixture in a cycle of maximum 10 seconds On, Maximum 5 seconds Off before turning back On for another 10 seconds.

g) Validate the StO2 values remain dashed as long as the ESU interference is present PASS (Stop the interference after a minimum of 60 seconds)

h) Validate the StO2 values are displayed again after a maximum of 20 seconds once the interferences are no longer generated PASS

i) Validate the values displayed are within the simulator tolerances as recorded before the noise injection PASS **c)** above (Records StO2 = 63)

j) Let the UUT continue to run for at least 3 minutes to validate the displayed StO2 values continue to be within the Simulator's tolerances PASS

k) Cycle power to the UUT.

l) Restart the interference injection before any StO2 values are displayed.

m) Validate the StO2 value are dashed with possible showing of "**Unstable Signal**" or "**Signal out of Range**" messages and appropriate Low or Medium Alarm Audio and LEDs activation PASS

n) Validate the StO2 values are displayed after a maximum of 30 seconds once the interferences are no longer generated PASS

PASS/FAIL CRITERIA:
PASS: All validate statements are filled with Pass.
FAIL: Any of the validate statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.3.4 2-Min Audio Disable Inactive

Test Performed By (signature): [signature] Date of Test: 12/14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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a) Simulate the conditions in **Table 29** below.
b) Validate in **Table 29** the appropriate High, Medium, Low or Informational Alarm Priority (LEDs and Audio) are initiated by the UUT.
c) Press the **Silence button** for each condition
d) Validate the Audio is disabled
e) Re-enable the Audio after generating each alarm

Error/Condition	Message	Numeric	Priority	Silence Pressed	Validate	
Faulty Preamp connected	Faulty Preamp	Blank	Medium	Audio & Visual Removed[12]	~~P ☐ F ☐~~	N/A
Preamp unplugged after monitoring started	Preamp Disconnected				P ☑ F ☐	
Sensor faulty	Faulty Sensor	Dashed			~~P ☐ F ☐~~	N/A
Sensor unplugged after monitoring started	Sensor Disconnected	Blank			P ☑ F ☐	
Computed StO_2 not in valid range Hb value < 0 & HbO_2 value < 0 Low input Brain Signal **or** Wavelength ratios out of Spec	Sensor Off	Dashed			P ☑ F ☐	
(b)(4) [redacted]				Audio removed, Visual remains	P ☑ F ☐	
Sensor on inappropriate object, or data not consistent with tissue measurements	Signal out of Range				P ☑ F ☐	
Tissue under Sensor is too little perfused. May have fluid accumulation/edema	Check under Sensor				P ☑ F ☐	
Sensor is not in correct contact with patient or excessive light interference	High Ambient Light				P ☑ F ☐	
Wrong size Sensor connected	Incorrect Sensor Size	Dashed	Low		P ☑ F ☐	
Expired Sensor connected	Sensor Use Ended				~~P ☐ F ☐~~	N/A
StO2 Values cannot be computed	Unstable Signal				P ☑ F ☐	
Sensor is not in contact with patient or excessive light interference	Ambient Light	Valid	Info	Visual remains, 2-min Silence start	P ☑ F ☐	
(b)(4) [redacted]					PASS	
Sensor connected; Body Location set to Unused	Set Body Location	Blank			~~P ☐ F ☐~~	N/A
No Preamp connected	Connect Preamp				P ☑ F ☐	
No Sensor connected; Valid Body Location	Connect Sensor				P ☑ F ☑	
Initial StO2 values being computed	Acquiring Data	Dashed			P ☑ F ☐	

Table 29 – Equipment Alarms Control (2-Min Audio Disable inactive)

PASS/FAIL CRITERIA:

[12] After pressing on the Silence key the message is switched from "**Preamp Disconnected**" to "**Connect Preamp**" and from "**Sensor Disconnected**" to "**Connect Sensor**"

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PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.7.3.5 2-Min Audio Disable Active

a) Press on the Silence button to disable Audio
b) Create the Alarm as indicated in **Table 30** below
c) Validate the appropriate Priority Alarm is initiated (LED status and message)
d) Validate there is no Alarm Audio initiated
e) Clear the alarm condition
f) Validate the Alarm indicators are removed

Error/Condition	Message	Numeric	LEDs	Validate
Faulty Preamp connected	Faulty Preamp	Blank	Yellow & Flashing	P ☐ F ☐
Preamp unplugged after monitoring started	Preamp Disconnected[13]			P ☑ F ☐
Sensor faulty	Faulty Sensor	Dashed		P ☐ F ☐
Sensor unplugged after monitoring started	Sensor Disconnected[14]	Blank		P ☑ F ☐
Computed StO_2 not in valid range Hb value < 0 & HbO_2 value < 0 Low input Brain Signal **or** Wavelength ratios out of Spec	Sensor Off	Dashed		P ☑ F ☐
(b)(4) [redacted]				P ☑ F ☐
Sensor on inappropriate object, or data not consistent with tissue measurements	Signal out of Range			P ☑ F ☐
Tissue under Sensor is too little perfused. May have fluid accumulation/edema	Check under Sensor			P ☑ F ☐
Sensor is not in correct contact with patient or excessive light interference	High Ambient Light			P ☑ F ☐
Wrong size Sensor connected	Incorrect Sensor Size	Dashed	Yellow	P ☑ F ☐
Expired Sensor connected	Sensor Use Ended			P ☐ F ☐
StO2 Values cannot be computed	Unstable Signal			P ☑ F ☐
Sensor is not in contact with patient or excessive light interference	Ambient Light	Valid	Off	P ☑ F ☐
(b)(4) [redacted]		Valid		PASS
Sensor connected; Body Location set to Unused	Set Body Location	Blank		P ☐ F ☐
No Preamp connected	Connect Preamp			P ☑ F ☐
No Sensor connected; Valid Body Location	Connect Sensor			P ☑ F ☐
Initial StO2 values being computed	Acquiring Data	Dashed		P ☑ F ☐

Table 30 – Equipment Alarms Control (2-Min Audio Disable active)

[13] Press on the Silence key to validate all visual alarms are removed and the message is switched from "**Preamp Disconnected**" to "**Connect Preamp**"
[14] Press on the Silence key to validate all visual alarms are removed and the message is switched from "**Sensor Disconnected**" to "**Connect Sensor**"

Test Performed By (signature): _____ Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.7.4 System Alarms

8.7.4.1 Battery Status

a) Make sure UUT has power cord connected to an AC outlet and a battery pack is installed
b) Turn on the UUT and wait for the Unit to enter Main menu.
c) Validate the Battery status resembles while the UUT is on AC. PASS
d) Connect Preamps and Sensors to the Unit then place the Sensor on an optical Simulator.
e) Validate the UUT starts to acquire and display valid StO2 data. PASS
f) Wait for the Battery to be sufficiently charged before disconnecting the AC.
g) Validate the Battery status icon resembles . PASS
h) Validate the UUT does not shut down and continue to acquire and display valid StO2 data PASS
a) Validate the UUT is displaying the message "**Connect to AC**", there are no Audio Alarm and the Alarm LEDs are off PASS
i) Cycle power to the UUT
j) Validate the UUT continues to display the message "**Connect to AC**", no Audio and the Alarm LEDs are off PASS
k) Validate the Battery status icon resembles . PASS
l) Allow the UUT to run undisturbed until occurrence of a low Battery condition occurs to validate the UUT is reporting a **Low** Priority "**Low Battery**" condition PASS (ca 1 Hour)
m) Validate the Battery status icon resembles . PASS
n) Allow the UUT to continue to run on Battery while acquiring and displaying StO2 data. PASS
o) Validate the UUT will report a "**Depleted Battery**" alarm condition and a **Medium** priority Alarm is generated PASS
p) Validate the Battery status icon resembles . PASS
q) Validate the UUT will shut down after 2 minutes PASS
r) Connect the UUT to AC and allow the battery pack to be fully recharged (ca 4 Hours)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.7.4.2 System Fan Status

b) Connect the UUT to the AC power cord and make sure the internal battery is securely mounted.

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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c) Validate the Green LED in front of the UUT is lit up (green) PASS
d) Validate the System Fan is not running PASS
e) Power up the UUT
f) Validate the System Fan is operating PASS
g) Connect the proper set of Preamps and sensor to start the monitoring of the Left or Right brain on all Channels PASS
h) Validate all channels soon start to report valid StO2 values. PASS
i) Carefully jam the System Fan to validate the UUT continue to run PASS
j) Validate the UUT is displaying the message "**Faulty System Fan**", there are no Audio Alarm and the LEDs are all off PASS
k) Let the UUT undisturbed for another 30 minutes to validate the displayed StO2 values are still within tolerances PASS
l) Remove the Jam to validate the message is no longer displayed and the UUT continue to run PASS
m) Power down the UUT.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.7.4.3 System Temperature

a) Power off the UUT
b) Disconnect the Fan Connector from the SCB and install a "Fan-Installed" jumper in its place
c) Power on the UUT and connect appropriate Sensors and optical simulators to monitor either a Cerebral or Non-Cerebral Body Location.
d) Validate the System is not reporting a Fan error and the UUT is reporting valid StO2 data PASS
e) Place the UUT in an elevated Temperature environment (starting at 38 ºC); A Lamp with high heat radiation could also be placed in a way that it is radiating into the UUT. (**UUT should never be left alone during the test**)
f) The UUT should be connected to the TELNET program running on a PC in order to monitor the internal Temperature sensors.
g) Validate the Telnet application reports temperatures measurement values from all internal sensors PASS (Temperature and Fan speed using Telnet's "**systemtemperatures**" command)
h) Validate the Fan speed is gradually adjusted to match the internal temperatures reported. PASS
i) Validate the UUT starts to report an internal temperature error "**High Internal Temp**" as soon as any of the reported Temperature rises above the **Warning threshold** set for the specific internal sensor PASS (see attached **FSE Thermal Thresholds Rev01** document)
j) Validate the appropriate **Low Priority** Alarm Audio and LEDs are initiated. PASS
k) Continue to watch the system as the temperature continue to rise to validate the Fan speed is adjusted accordingly. PASS
l) Validate the reported StO2 values are still within the simulator tolerances if displayed or dashed PASS

Test Performed By (signature): [signature] Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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m) Validate the UUT starts to report an internal temperature error **"Max Internal Temp"** as soon as any of the reported Temperature rises above the **Maximum threshold** set for the specific internal sensor PASS (see attached **FSE Thermal Thresholds Rev01** document)

n) Validate the appropriate **Medium Priority** Alarm Audio and LEDs are initiated. PASS

o) Validate the UUT shuts off **2 minutes** after the internal Temperature error condition PASS

p) Remove "Fan-Installed" jumper and reconnecting the Fan Connector to the SCB

q) Power On the UUT and allow UUT to cool down.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or-FAIL

8.7.4.4 2-Min Audio Disable Inactive

a) Power On the UUT.

b) Enter the New Patient menu and enter the Proper Age/Weight and Body location in order to use the connected Sensors.

c) Properly attach the sensors to the Optical Simulators.

d) Make sure the Audio is in the enabled state. PASS

e) Simulate following System Error conditions in **Table 31** below

f) Press the **Silence Key** and validate the appropriate Audio and/or Visual are removed as expected.

g) Continue with the same case and sensors into the next section.

h) Press on the On /Standby key to power On the UUT.

i) Continue with the same case and sensor into the next section.

Error/Condition	Message	Numeric	Priority	Silence Key Pressed	Validate	
System Error	System Error Exx	Dashed	Medium	Audio removed, Visual remains	~~P ☐ F ☐~~	
Depleted Battery	Depleted Battery	Blank			P ☑ F ☐	
Internal Temp > Max	Max Internal Temp				P ☑ F ☐	
Low Battery	Low Battery	Valid or Dashed	Low	Audio removed, Visual remains	P ☑ F ☐	
Monitor Internal Temp > normal limit	High Internal Temp				P ☑ F ☐	
No AC, Unit operating on Battery	Connect to AC	Valid or Dashed	Informal	Visual remains, 2-min Silence start	P ☑ F ☐	
Communications with external Wired device problem	Port X Comm Lost				P ☑ F ☐	
Faulty/Inoperative Fan	Faulty System Fan				P ☑ F ☐	
Battery problem	Faulty Battery				N/A	
Battery 1-wire Memory or Temp device problem	Unknown Battery				~~P ☐ F ☐~~	N/A
RTC Time/Date not set	Set Time/Date				~~P ☐ F ☐~~	N/A
USB & VGA power problem	Faulty USB/VGA				N/A	
Serial port problem	Faulty Serial Port				~~P ☐ F ☐~~	N/A
Front USB Power Problem	Faulty Front USB				~~P ☐ F ☐~~	N/A
Rear USB Power Problem	Faulty Rear USB				~~P ☐ F ☐~~	N/A
RTC Battery low or not present	Faulty Clock Battery				P ☑ F ☐	

Test Performed By (signature): [signature] Date of Test: 12-14-13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

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Table 31 – System Alarms Control (2-Min Audio Disable inactive)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.4.5 2-Min Audio Disable Active

a) Continuing with the previous case
b) Press on the Silence Key.
c) Validate the Audio disabled Icon is displayed. PASS
d) Provoke the System Alarms as indicated in **Table 32** below to validate the appropriate Priority Alarm is initiated (LED status and message). PASS
e) Validate there is no Alarm Audio initiated. PASS
f) Clear the equipment alarm condition and validate the **Alarm visual indicators** are removed (messages) or turned off (LEDs) while the Audio is still turned off. PASS
g) Power down the UUT.

Error/Condition	Message	Numeric	LEDs	Validate	
System Error	System Error Exx	**Dashed**	**Yellow & Flashing**	P ☐ F ☐	N/A
Depleted Battery	Depleted Battery	**Blank**		P ☑ F ☐	
Internal Temp > Max	Max Internal Temp			P ☑ F ☐	
Low Battery	Low Battery	**Valid or Dashed**	**Yellow**	P ☑ F ☐	
Monitor Internal Temp > normal limit	High Internal Temp			P ☑ F ☐	
No AC, Unit operating on Battery	Connect to AC	**Valid or Dashed**	**Off**	P ☑ F ☐	
Communications with external Wired device problem	Port X Comm Lost			P ☑ F ☐	
Faulty/Inoperative Fan	Faulty System Fan			P ☑ F ☐	
Battery problem	Faulty Battery			N/A	
Battery 1-wire Memory or Temp device problem	Unknown Battery			P ☐ F ☐	N/A
RTC Time/Date not set	Set Time/Date			P ☐ F ☐	N/A
USB & VGA power problem	Faulty USB/VGA			N/A	
Serial port problem	Faulty Serial Port			P ☐ F ☐	N/A
Front USB Power Problem	Faulty Front USB			P ☐ F ☐	N/A
Rear USB Power Problem	Faulty Rear USB			P ☐ F ☐	N/A
RTC Battery low or not present	Faulty Clock Battery			P ☑ F ☐	

Table 32 – System Alarms Control (2-Min Audio Disable active)

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

Test Performed By (signature): [signature] Date of Test: 12-14-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.7.5 Alarm Interference & Priority

8.7.5.1 Parameter and Equipment Alarms

a) Power On the UUT.
b) Enter the New Patient menu and enter the Proper Body location in order to use the connected Sensors.
c) Properly attach the sensors to the Optical Simulators.
d) Make sure the Audio is in the enabled state. PASS
e) Simulate following Error conditions in **Table 33** below
f) Validate the expected messages; Audio Alarm level and LEDs status are initiated by the UUT PASS
a) Press the **Silence Key** and validate the Audio is silenced but the Visuals remain PASS
b) Power down the UUT.

CASES	Error/Condition	Channel Message (s)	LED	Audio	Validate
1	Ch1 StO2 Low Ch1 Ambient Light	Ch1 Low StO2 & Ch1 Ambient Light	Red & Flashing	High Priority	P ☑ F☐
2	Ch1 StO2 High Ch2 Ambient Light Ch3 StO2 High	Ch1 High StO2 Ch2 Ambient Light Ch3 High StO2			P ☑ F☐
3	Ch1 Sensor Disconnected Ch2 StO2 High Ch2 Sensor Under Temp Ch3 Sensor Disconnected Ch4 Incorrect Sensor size	Ch1 Sensor Disconnected Ch2 High StO2 & Ch2 Sensor Under Temp Ch3 Sensor Disconnected Ch3 Incorrect Sensor size			P ☑ F☐

Table 33 – Parameter and Equipment Alarm condition Interference.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

8.7.5.2 Parameter and System Alarms

a) Power On the UUT.
b) Enter the New Patient menu and enter the Proper Body location in order to use the connected Sensors.
c) Properly attach the sensors to the Optical Simulators.
d) Make sure the Audio is in the enabled state. PASS
e) Simulate following Error conditions in **Table 34** below
f) Validate the expected messages; Audio Alarm level and LEDs status are initiated by the UUT PASS
g) Press the **Silence Key** and validate the Audio is silenced but the Visuals remain PASS
h) Power down the UUT.

Test Performed By (signature): [signature] Date of Test: 12.14.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CASES	Error/Condition	System Message	Channel Message	LED	Audio	Validate
1	Ch1 StO2 Low Battery Depleted	Battery Depleted	Ch1 Low StO2	Red & Flashing	High Priority	P ☑ F ☐
2	Ch2 StO2 High Connect to AC	Connect to AC	Ch2 High StO2			P ☑ F ☐
3	Ch3 StO2 High High Internal Temp Connect to AC	High Internal Temp	Ch3 High StO2			P ☑ F ☐

Table 34 – Parameter and System Alarm condition Interference.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.5.3 Equipment and System Alarms

a) Power On the UUT.
b) Enter the New Patient menu and enter the Proper Age/Weight and Body location in order to use the connected Sensors.
c) Properly attach the sensors to the Optical Simulators.
d) Make sure the Audio is in the enabled state. PASS
e) Simulate following Error conditions in **Table 35** below
f) Validate the expected messages; Audio Alarm and LEDs status are initiated by the UUT PASS
c) Press the **Silence Key** and validate the Audio is silenced but the Visuals remain PASS
d) Power down the UUT.

CASES	Error/Condition	System Messages	Channel Message	LED	Audio	Validate
1	Depleted Battery Ambient Light	Depleted Battery	Ambient Light	Yellow Flashing	Medium Priority	P ☑ F ☐
2	High Internal Temp Ch1 High Ambient Light Faulty System Fan Ch4 Sensor Disconnected	High Internal Temp	Ch1 High Ambient Light Ch4 Sensor Disconnected			P ☑ F ☐
3	Ch1 Ambient Light Connect to AC Ch2 Connect Sensor Ch3 Incorrect Sensor Size	Connect to AC	Ch1 Ambient Light Ch2 Connect Sensor Ch3 Incorrect Sensor Size	Yellow	OFF	P ☑ F ☐
4	Ch1 Ambient Light Connect to AC Ch2 Connect Sensor	Connect to AC	Ch1 Ambient Light Ch2 Connect Sensor	OFF	OFF	P ☑ F ☐

Table 35 – Equipment and System Alarm condition Interference.

PASS/FAIL CRITERIA:

Test Performed By (signature): [signature] Date of Test: 12.16.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

8.7.5.4 Parameter, Equipment and System Alarms

a) Power On the UUT.
b) Enter the New Patient menu and enter the Proper Age/Weight and Body location in order to use the connected Sensors.
c) Properly attach the sensors to the Optical Simulators.
d) Make sure the Audio is in the enabled state. PASS
e) Simulate following Error conditions in **Table 36** below
f) Validate the expected messages; Audio Alarm level and LEDs status are initiated by the UUT PASS
e) Press the **Silence Key** and validate the Audio is silenced but the Visuals remain PASS
f) Power down the UUT.

CASES	Error/Condition	System Messages	Channel Message	LED	Audio	Validate
1	Depleted Battery Ch1 Ambient Light Ch1 High StO2	Depleted Battery	Ch1 High StO2	Red Flashing	High Priority	P ☑ F☐
2	Ch3 Low StO2 High Internal Temp Ch4 High Ambient Light Faulty System Fan	High Internal Temp	Ch3 Low StO2 Ch4 High Ambient Light			P ☑ F☐
3	Ch1 High Ambient Light Connect to AC Ch4 Sensor Disconnected Ch 3 Low StO2	Connect to AC	Ch1 High Ambient Light Ch4 Sensor Disconnected Ch3 Low StO2			P ☑ F☐

Table 36 – Parameter, Equipment and System Alarm condition Interference.

PASS/FAIL CRITERIA:
PASS: All validation statements are filled with Pass.
FAIL: Any of the validation statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

Test Performed By (signature): [signature] Date of Test: 12.16.13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications? _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9 Summary

All Applicable Tests were performed
All performed Tests passed

Performed by: [illegible] Date: 12-16-13

Attachments:

21-07-0204
21-07-0343
21-07-0346
FS-ATE Serial Protocol
STS Verification
6x USB Header (Translation)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CASMED®	Document Number VaR 120019	Rev 9.0
TITLE: Gemini / FORE-SIGHT ELITE Software PEMS Validation Report		

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals:

Validation Engineer	P. Tala	12-16-13 Date
Project Engineer	R. Bystrianyk	12-16-13 Date
Eng Project Leader	H. Triebel	12/16/13 Date
VP R & D	J. Gamelin	12/16/2013 Date
Mktg Product Manager	M. Aceves	12/17/2013 Date
Quality Assurance Regulatory Affairs	R. Jeffrey	12/17/13 Date

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Rev	Author(s)	Description
1.0	P. Tala	Initial release, FORE-SIGHT ELITE Software Rev 0.2.0 Test Report
2.0	P. Tala	Update Test Report for Software Rev 0.3.3 build Package
3.0	P. Tala	Update Test Report for Software Rev 0.3.5 build Package
4.0	P. Tala	Update Test Report for Software Rev 0.3.6 build Package
5.0	P. Tala	Update Test Report for Software Rev 1.0.0 build Package
6.0	P. Tala	Update Test Report for Software Rev 1.0.1 build Package
7.0	P. Tala	Update Test Report for Software Rev 1.0.2 build Package
8.0	P. Tala	Update Test Report for Software Rev 1.1.0C build Package
9.0	P. Tala	Update Test Report for Software Rev 1.1.1A build Package

Table of Contents

1. INTRODUCTION 3
1.1 PURPOSE 3
1.2 SCOPE 3
1.3 REFERENCE DOCUMENTS 3
1.4 ACRONYMS 3
2. SUMMARY OF TESTING PERFORMED 3
3. DEFECTS, VARIANCES AND INCIDENTS 5
4. COMPREHENSIVE ASSESSMENT 5
5. EVALUATION 5

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1. INTRODUCTION

1.1 PURPOSE

This Validation Report summarizes the testing performed on the Gemini / FORE-SIGHT ELITE Software PEMS per VaP 120019 Rev9_0. For information on VaP 120019 Rev9_0 refers to the attached Validation plan (**Appendix A).**

1.2 SCOPE

Refer to VaP 120019 Rev9_0 for details on the scope of this testing.

Sample Size Rationale – 2 Fore-Sight Monitors were used as Unit Under Test (UUT) to execute VaP 120019 Rev9_0. 2 UUTs demonstrates sufficient consistency of performance in the Validation of the software features.

1.3 REFERENCE DOCUMENTS

- VaP 120019 Rev9_0 – Gemini / FORE-SIGHT ELITE Software PEMS Validation Plan

1.4 ACRONYMS

- VaP Validation Plan
- VaR Validation Report

2. SUMMARY OF TESTING PERFORMED

The following tests were conducted per VaP 120019 Rev9_0:

Section #	Test Description	Comments	Results
8.1	SCB & NSAM Software Code Upload & System Configuration		
8.1.1	***SCB & NSAM Package and Software Upload***		**PASS**
8.1.2	System Configuration		**PASS**
8.1.3	Touch Screen Calibration		**PASS**
8.2	Oximeter Start Up		
8.2.1	Standard Start Up		**PASS**
8.2.2	Start Up With Failed Power-On Self-Test		**PASS**
8.3	Visual & Display Indicators		
8.3.1	Main Screen Display		**PASS**
8.3.1.1	Title Bar/Line Area		**PASS**
8.3.1.2	System Message Area		**PASS**
8.3.1.3	Trace Area		**PASS**
8.3.1.4	Numeric Field		**PASS**
8.3.1.5	1st, 2nd Levels Touch button		**PASS**
8.3.1.6	Alarm Silence button		**PASS**
8.4	User Controls		
8.4.1	Patient Menu		**PASS**
8.4.1.1	Patient Menu Selections		**PASS**
8.4.1.2	Body Location Settings		**PASS**
8.4.1.2.1	US Configuration		**PASS**
8.4.1.2.2	OUS Configuration		**PASS**
8.4.1.3	Alarm Limits Settings		**PASS**
8.4.1.4	Alarm Limit Range		**PASS**

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Section #	Test Description	Comments	Results
8.4.1.5	Patient ID		PASS
8.4.1.6	New Patient		PASS
8.4.2	Event Marks		PASS
8.4.2.1	Events Menu Selection		PASS
8.4.2.2	Events from List Addition		PASS
8.4.2.3	Removing placed Events		PASS
8.4.2.4	Auto Events		PASS
8.4.3	Data Menu		PASS
8.4.3.1	Data Menu Selection		PASS
8.4.3.2	STS View Menu		PASS
8.4.3.3	STS Data Collection and Verification		PASS
8.4.3.4	Reference Value REF		PASS
8.4.4	Patient Data Management		
8.4.4.1	Multiple Patients Storage		PASS
8.4.4.2	Saving Selected Files to the USB		PASS
8.4.4.3	Reviewing Data Saved to the USB		PASS
8.4.4.4	Deleting Selected Files to the USB		PASS
8.4.5	Setup Menu		PASS
8.4.5.1	Setup Menu Selection		PASS
8.4.5.2	View Settings		PASS
8.4.5.3	Volume Settings		PASS
8.4.5.4	Brightness Settings		PASS
8.4.5.5	Ports Settings		PASS
8.4.5.6	Time and Date Settings		PASS
8.4.5.7	Language Settings		PASS
8.4.5.8	Alarm Delay		PASS
8.4.5.9	Factory Defaults Settings		PASS
8.4.5.10	Help Menu		PASS
8.5	Connection Status & StO2 Data Collection		
8.5.1	Patient & Monitor Cable Status		PASS
8.5.1.1	Connection Status at Power on		PASS
8.5.1.2	Disconnection Status after Power on		PASS
8.5.2	Sensor Connection and StO2 Data Acquisition		PASS
8.5.3	New /Continue Patient Timer & Prompting		PASS
8.5.4	TPI Status Indicator		PASS
8.5.5	Adult TOP Calibration Rule		PASS
8.5.6	NSAM Application Adult Cerebral Algorithm Verification		PASS
8.5.7	NSAM Application Adult Somatic Tissues Algorithm Verification		PASS
8.6	Data Communication		
8.6.1	2-CH Comma Separated Value (CSV)		PASS
8.6.2	4-CH Comma Separated Value (CSV)		PASS
8.6.3	2-CH CAS Protocol (ATE)		PASS
8.6.4	4-CH CAS Protocol (ATE)		PASS
8.6.5	Philips VueLink and IntelliBridge Communication		PASS
8.6.6	Scientific Communication		PASS
8.7	Alarms Handling & Management		
8.7.1	System LEDs		PASS
8.7.2	Parameter Alarms		PASS

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Section #	Test Description	Comments	Results
8.7.2.1	2-Min Audio Disable Inactive		PASS
8.7.2.2	2-Min Audio Disable Active		PASS
8.7.3	Equipment Alarm		PASS
8.7.3.1	Ambient Light Condition		PASS
8.7.3.2	(b)(4) [redacted]		PASS
8.7.3.3	ESU Disturbance Condition		PASS
8.7.3.4	2-Min Audio Disable Inactive		PASS
8.7.3.5	2-Min Audio Disable Active		PASS
8.7.4	System Alarms		PASS
8.7.4.1	Battery Status		PASS
8.7.4.2	System Fan Status		PASS
8.7.4.3	System Temperature		PASS
8.7.4.4	2-Min Audio Disable Inactive		PASS
8.7.4.5	2-Min Audio Disable Active		PASS
8.7.5	Alarm Interference & Priority		PASS
8.7.5.1	Parameter and Equipment Alarms		PASS
8.7.5.2	Parameter and System Alarms		PASS
8.7.5.3	Equipment and System Alarms		PASS
8.7.5.4	Parameter, Equipment and System Alarms		PASS

All data sheets (Printout) corresponding to each test have been completed and are included in **Appendix A** of this report.

3. DEFECTS, VARIANCES AND INCIDENTS

No defects, variances or incidents were noted in any of tests.

4. COMPREHENSIVE ASSESSMENT

The testing performed fully exercised the Operational Capabilities of the Gemini / FORE-SIGHT ELITE Software PEMS Rev 1.1.1 software Package.
No additional hazards or concerns were identified in the testing.

5. EVALUATION

All applicable Tests were executed.

All performed tests passed

The following SPRs were verified as resolved:

New Features, Improvements and Fixes
SPR # 741 - Possibility to delete more than the last Event entered (CR 1000)
SPR # 747 - System Reset after Factory Defaults activation (CR 1003)
SPR # 754 - Event Mark vertical dotted line (CR 1153)
SPR # 755 - NSAM Auto Event Mark on USB (CR 1150 & 1154)
SPR # 756 - STS Data Calculation (SPR 1149 & 1155)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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New Features, Improvements and Fixes
SPR # 757 - Reference Value: Horizontal dotted line not toggling (CR 1151 & 1156)
SPR # 758 - Active case total duration time. (CR 1148)
SPR # 760 - Active cases saved to the USB (CR 1148)
SPR # 762 - Dutch & Italian Strings under STS & View Menus (CR 1136 & 1158)
SPR # 763 - GUI Strings Translation (CR 1158 & 1159)
SPR # 764 - System Reset & StO2 Numerics on Display (CR 1147)
SPR # 765 - OUS Configuration & Body Location (CR 1129 & 1160)

The FS-ELITE US/OUS Software Update Package V1.1.1, consisting of the following SW parts, has not been determined to be safe and available for release:

- 15-06-0282 Rev1.0.0 FS-ELITE NSAM Bootloader Software
- 15-06-0283 Rev2.0.0g FS-ELITE NSAM Application Software
- 15-06-0284 Rev1.1.0A FS-ELITE MAIN Bootloader Software
- 15-06-0285 Rev1.1.1A FS-ELITE MAIN Application Software, US

APPENDIX A

VaP 120019 Rev9_0 (attached)

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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18. Electromagnetic Compatibility and Electrical Safety

PERFORMANCE COMPLIANCE INFORMATION

Standard, Guidance, Validation, or Requirement	Document Title or Test Requirement	Report / Results NOTE – A listing here indicates full testing and compliance with the standard
AAMI ES60601-1: 2005	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance	100742469BOX Complies with the requirements of the standards. Pass
CSA C22.2 No. 60601-1:2008	Ed: 3.0 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance	100742469BOX Complies with the requirements of the standards. Pass
IEC60601-1:2005	ED 3.0 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance.	100742469BOX Complies with the requirements of the standards. Pass
IEC60601-1-2:2007	Ed 3.0 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Electromagnetic Compatibility	100742469BOX-008 Complies with the requirements of the standards. Pass
IEC60601-1-6: 2010	Ed 3 Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard : Usability	100742469BOX Complies with the requirements of the standards. Pass
IEC 62366: 2007	Medical devices – application of Usability Engineering to Medical Devices	100742469BOX Complies with the requirements of the standards. Pass
IEC60601-1-8: 2006	Ed 2.0 Part 1-8: General Requirements for Basic Safety and Essential Performance – General Requirements, Test and Guidance for Alarm Systems in Medical Electrical Equipment and Systems.	100742469BOX Complies with the requirements of the standards. Pass

See Attachment F for Safety and EMC reports.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EMC TEST REPORT

Report Number: 100742469BOX-008a
Project Number: G100742469

Report Issue Date: 11/13/2013

Product Designation: FORE-SIGHT Elite Absolute Tissue Oximeter Part # 01-06-3000

Standards: IEC 60601-1-2 ed3.0 (2007-03)

Tested by:
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, MA 01719 USA

Client:
CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405 USA

Report prepared by

Rick Duval / Associate Engineer

Report reviewed by

Kouma Sinn / Senior Project Engineer

This report is for the exclusive use of Intertek's Client and is provided pursuant to the agreement between Intertek and its Client. Intertek's responsibility and liability are limited to the terms and conditions of the agreement. Intertek assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this report. Only the Client is authorized to permit copying or distribution of this report and then only in its entirety. Any use of the Intertek name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by Intertek. The observations and test results in this report are relevant only to the sample tested. This report by itself does not imply that the material, product, or service is or has ever been under an Intertek certification program.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 Introduction and Conclusion

The tests indicated in section 2.0 were performed on the product constructed as described in section 4.0. The remaining test sections are the verbatim text from the actual data sheets used during the investigation. These test sections include the test name, the specified test Method, a list of the actual Test Equipment Used, documentation Photos, Results and raw Data. No additions, deviations, or exclusions have been made from the standard(s) unless specifically noted.

Based on the results of our investigation, we have concluded the product tested **complies** with the requirements of the standard(s) indicated. The results obtained in this test report pertain only to the item(s) tested.

2 Test Summary

Section	Test full name	Result
3	Client Information	--
4	Description of Equipment Under Test	--
5	System Setup and Method	--
6	Radiated Emissions CISPR11 ed5.0 (with A1:2010)	Pass
7	AC Mains Conducted Emissions CISPR11 ed5.0 (with A1:2010)	Pass
8	Harmonics IEC 61000-3-2 ed3.0 (with A1:2008+A2:2009)	Pass
9	Flicker IEC 61000-3-3 ed2.0 (2008-06)	Pass
10	Electro-Static Discharge Immunity Test IEC 61000-4-2 ed2.0 (2008-12)	Pass
11	Radiated, Radio-Frequency, Electromagnetic Immunity IEC 61000-4-3 ed3.0 (with A1:2007+A2:2010)	Pass
12	Electrical Fast Transient/Burst Immunity Test IEC 61000-4-4 ed3.0 (2012-04)	Pass
13	Immunity to Surges IEC 61000-4-5 ed2.0 (2005-11)	Pass
14	Conducted, Radio-Frequency, Electromagnetic Immunity Test IEC 61000-4-6 ed2.0 (with A1:2004+A2:2006)	Pass
15	Power Frequency Magnetic Field Immunity Test IEC 61000-4-8 ed2.0 (2009-09)	Pass
16	Voltage Dips/Interruptions Immunity Test IEC 61000-4-11 ed2.0 (2004-03)	Pass
17	Section 5 User Information and Guidance Tables	--
18	Revision History	--

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 Client Information

This EUT was tested at the request of:

Company: CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405 USA
Contact: Mr. Ron Jeffrey
Telephone: (203) 488-6056
Fax: (203) 315-6344
Email: rjeffrey@casmed.com

4 Description of Equipment Under Test

Equipment Under Test			
Description	Manufacturer	Model Number	Serial Number
Absolute Tissue Oximetry	CAS Medical	FORE-SIGHT Elite Absolute Tissue Oximeter Part # 01-06-3000	ENG-15
*Absolute Tissue Oximetry	CAS Medical	FORE-SIGHT Elite Absolute Tissue Oximeter Part # 01-06-3000	1345005

Receive Date:	08/01/2012 & 11/11/2013
Received Condition:	Good
Type:	Production

Description of Equipment Under Test (provided by client)
Absolute Tissue Oximetry to measure oxygen saturation levels.

Equipment Under Test Power Configuration			
Rated Voltage	Rated Current	Rated Frequency	Number of Phases
100-240 VAC	1.5 A	50/60 Hz	1

Operating modes of the EUT:

No.	Descriptions of EUT Exercising
1	Measuring a signal through a medium simulating human tissue.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 System Setup and Method

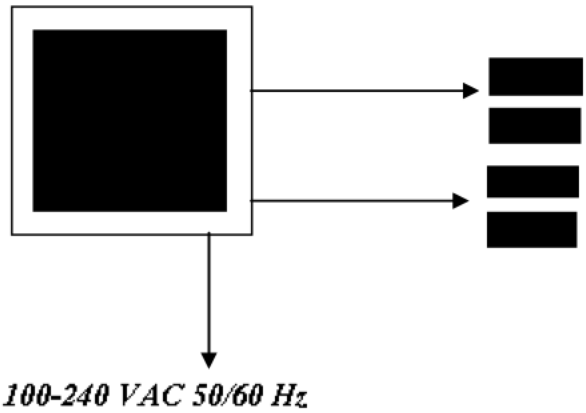
Cables					
ID	Description	Length (m)	Shielding	Ferrites	Termination
1	AC Cable	3.0	None	Yes	AC
2	Patient Leads	2.9	Yes	No	Simulator

Support Equipment			
Description	Manufacturer	Model Number	Serial Number
None			

5.1 Method:

Configuration as required by IEC 60601-1-2.

5.2 EUT Block Diagram:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.3 EUT Performance Criteria and Monitoring:

Performance as required by IEC 60601-1-2. Basic Safety and Essential Performance must be maintained throughout testing.

Product Essential Functions:

No.	Description
1	Absolute Tissue Oximetry to measure oxygen saturation levels of tissue.

Product Specific Performance:

No.	Description
1	Continuous operation with +/- 15% deviation during all testing.
2	Under the test conditions specified in 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide the BASIC SAFETY and ESSENTIAL PERFORMANCE. The following DEGRADATIONS, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, shall not be allowed: – component failures; – changes in programmable parameters; – reset to factory defaults (MANUFACTURER'S presets); – change of operating mode; – false alarms; – cessation or interruption of any intended operation, even if accompanied by an alarm; – initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm; – error of a displayed numerical value sufficiently large to affect diagnosis or treatment; – noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring; – artifact or distortion in an image in which the artifact would interfere with diagnosis, treatment or monitoring; – failure of automatic diagnosis or treatment ME EQUIPMENT and ME SYSTEMS to diagnose or treat, even if accompanied by an alarm. For ME EQUIPMENT and ME SYSTEMS with multiple FUNCTIONS, the criteria apply to each FUNCTION, parameter and channel. The ME EQUIPMENT or ME SYSTEM may exhibit DEGRADATION of performance (e.g. deviation from MANUFACTURER'S specifications) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE

Description of how performance was observed during testing:

No.	Description
1	The EUT was monitored ensuring the following artifact readings did not deviate by greater that 15%: The 4 readings monitored were 66, 65, 67, and 67
2	The EUT was monitored ensuring no alarm was present

General notes: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

6 Radiated Emissions

6.1 Method

Tests are performed in accordance with CISPR 11.

TEST SITE: 10m ALSE

The 10m ALSE is 13m (Length) x 21m (Depth) x 10m (Height) with the effective size in terms of space from the tips of the absorber is 12m (Length) x 20m (Depth) x 8.5m (Height). This chamber achieves broadband performance using a unique arrangement of hybrid and ferrite tile absorber. This chamber has a built in 3m diameter turntable (Embedded type). The metal structure of the table makes electrical connection around the entire circumference of the turntable to the ground plane with a metal brush type connection. The turntable is located on one end of the chamber and the antennas are mounted 3 and 10 meters away at the other end of the chamber on the adjustable an Antenna Mast. The antenna mast is a non-conductive bore sighted type with remote control of antenna height and polarization. The Antenna Mast and the turntable can be remotely controlled through the controller located in the adjacent Control room. A wooden table 80 cm high is used for table-top equipment.

Measurement Uncertainty

For radiated emissions, U_{lab} (3.5 dB at 3m and 3.5 dB at 10m below 1 GHz, and 4.2 dB at 3m above 1 GHz) < U_{CISPR} (5.2 dB), which is the reference value in CISPR 16-4-2 Table 1, hence the compliance of the product is only based on the measured value, and no measurement uncertainty correction is required, based on CISPR 22 and CISPR 11 (for 2006 and later revisions) Clause 11.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sample Calculation

The field strength is calculated by adding the Antenna Factor and Cable Factor, and subtracting the Amplifier Gain (if any) from the measured reading. The basic equation with a sample calculation is as follows:

FS = RA + AF + CF - AG

Where FS = Field Strength in dBμV/m
RA = Receiver Amplitude (including preamplifier) in dBμV
CF = Cable Attenuation Factor in dB
AF = Antenna Factor in dB
AG = Amplifier Gain in dB

In the following table(s), the reading shown on the data table reflects the preamplifier gain. An example for the calculations in the following table is as follows.

Assume a receiver reading of 52.0 dBμV is obtained. The antenna factor of 7.4 dB and cable factor of 1.6 dB is added. The amplifier gain of 29 dB is subtracted, giving a field strength of 32 dBμV/m. This value in dBμV/m was converted to its corresponding level in μV/m.

RA = 52.0 dBμV
AF = 7.4 dB/m
CF = 1.6 dB
AG = 29.0 dB
FS = 32 dBμV/m

To convert from dBμV to μV or mV the following was used:

$UF = 10^{(NF / 20)}$ where UF = Net Reading in μV
NF = Net Reading in dBμV

Example:

FS = RA + AF + CF – AG = 52.0 + 7.4 + 1.6 – 29.0 = 32.0
$UF = 10^{(32\ dB\mu V / 20)}$ = 39.8 μV/m

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
145 106	Bilog Antenna (30MHz - 5GHz)	Sunol Sciences	JB5	A111003	08/15/2011	08/15/2012
145 003	Preamplifier (150 KHz to 1 3 GHz)	Hewlett Packard	8447D	2443A04077	10/04/2011	10/04/2012
145 128	EMI Receiver 40 GHz (20 Hz - 40 Ghz)	Rohde & Schwarz	ESI	8392831001	08/23/2011	08/23/2012
145 410	Cables 145-400 145-403 145-405 145-406 145-407	Huber + Suhner	10m Track A Cables	multiple	09/04/2011	09/04/2012
Dav 001	Weather Station	Davis Instruments	7400	PE80519A61	08/17/2011	08/17/2012

Test equipment used on 11/13/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
145-410'	Cables 145-400 145-403 145-405 145-406 145-407	Huber + Suhner	10m Track A Cables	multiple	10/04/2013	10/04/2014
145003'	Preamplifier (150 KHz to 1.3 GHz)	Hewlett Packard	8447D	2443A04077	10/07/2013	10/07/2014
145128'	EMI Receiver 40 GHz (20 Hz - 40 Ghz)	Rohde & Schwarz	ESI	8392831001	10/01/2013	10/01/2014
Ant2a'	BROADBAND ANTENNA	Compliance Design	B100	1852	03/26/2013	03/26/2014
Ant2b'	BROADBAND ANTENNA	Compliance Design	B200	1850	03/26/2013	03/26/2014
Ant2c'	BROADBAND ANTENNA	Compliance Design	B300	00674	03/26/2013	03/26/2014
Dav004'	Weather Station	Davis Instruments	7400	PE80529A61A	09/25/2012	09/25/2014

Software Utilized:

Name	Manufacturer	Version
C5	Teseq	5.26.46.46

6.3 Results:

The sample tested was found to Comply.

Note: On 11/13/2013 testing, the unit was scanned at 100VAC 50 and 60Hz and was determined that 60Hz was the worst case. The final testing was performed at 100V/60Hz.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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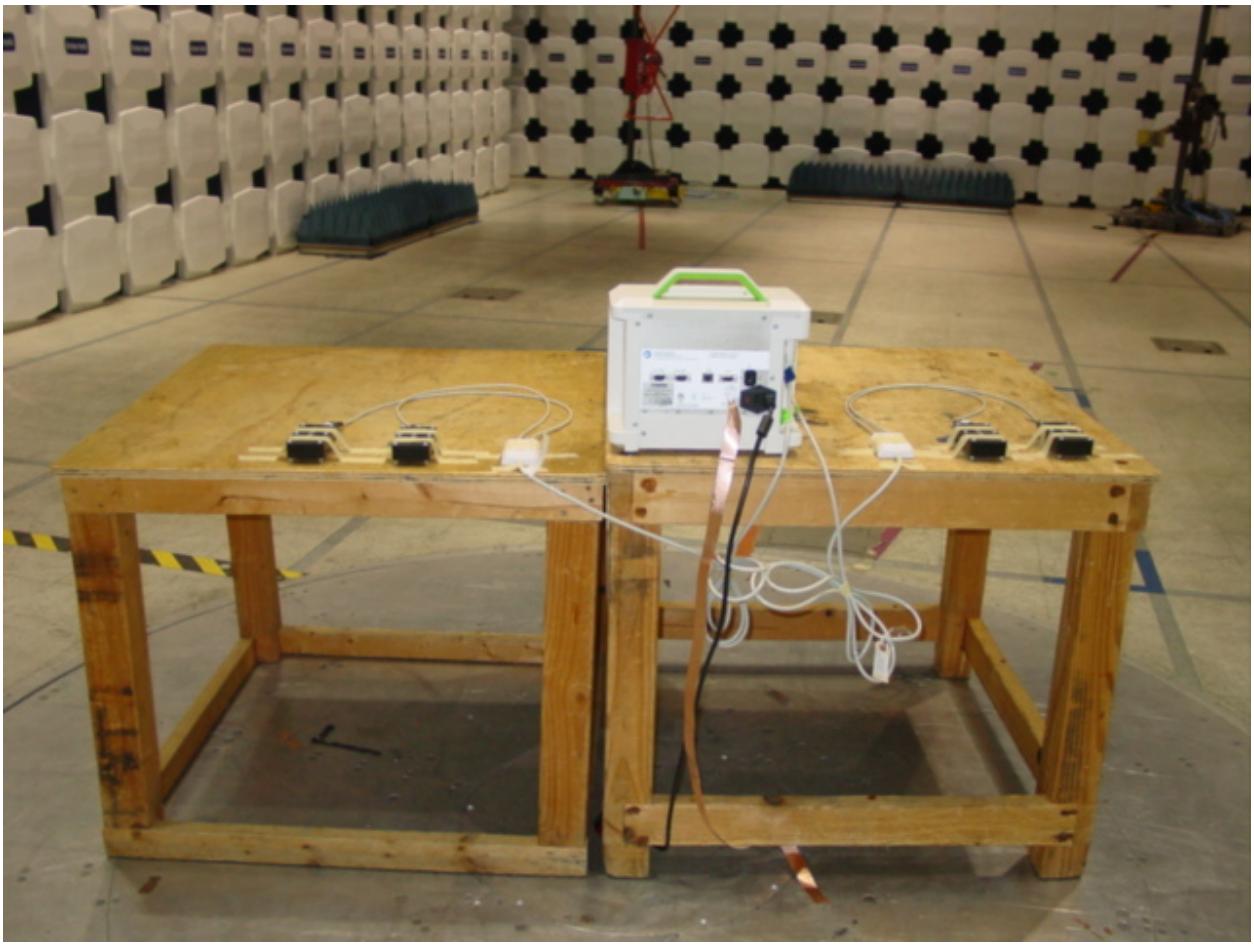
6.4 Setup Photographs:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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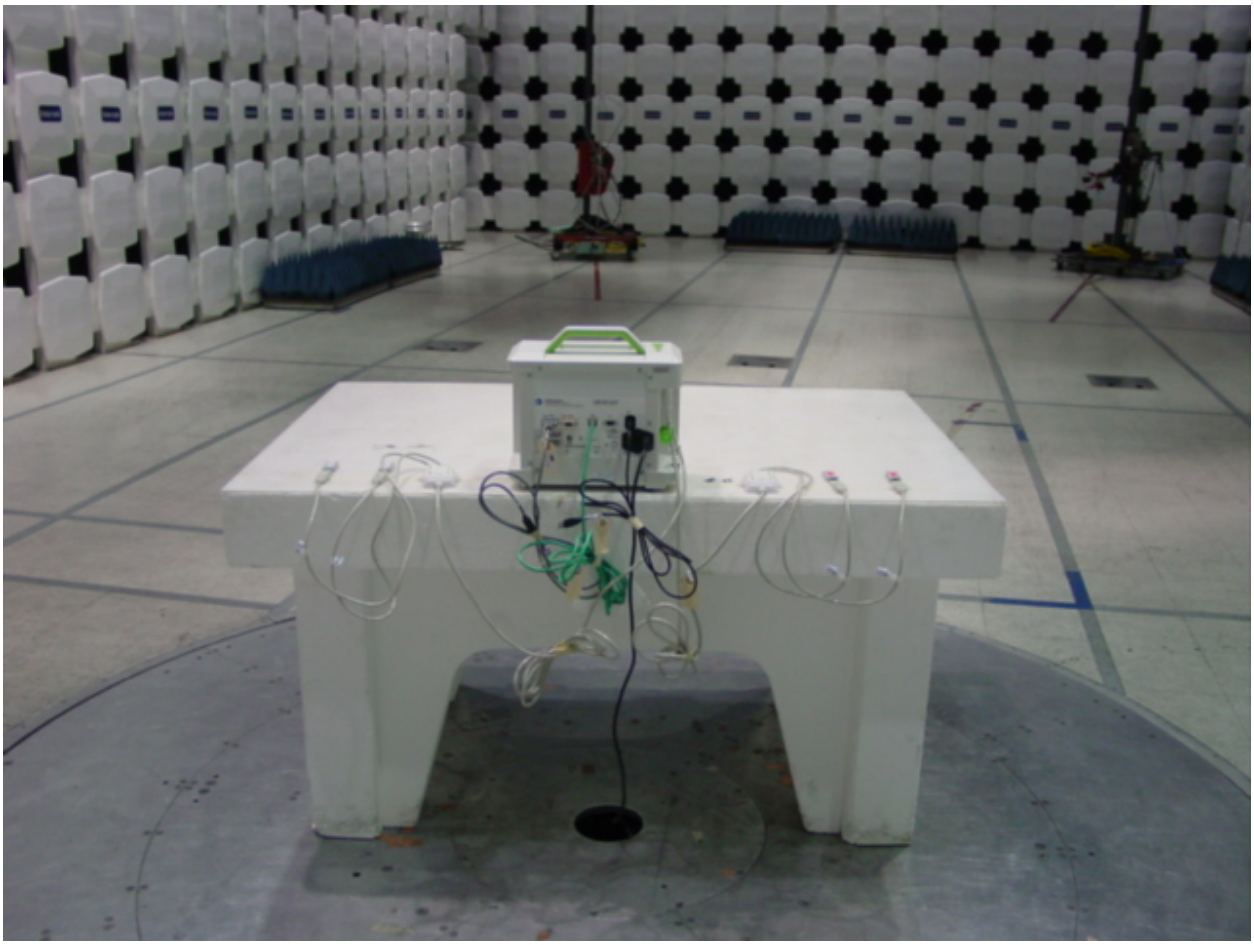
11-13-2013 100V 60Hz



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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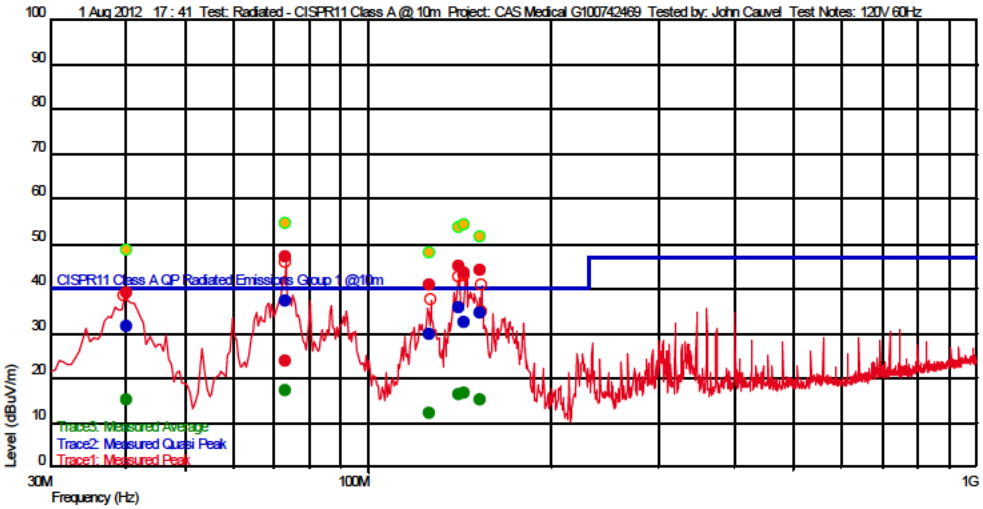
6.5 Plots/Data:

120V 60Hz

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	120V 60Hz	
Tested by:	John Cauvel	
Test Started:	1 Aug 2012 17 : 41	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

__ Swept Peak Data
__ Swept Quasi Peak Data
__ Swept Average Data

Emissions Test Data
Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	Hor (–), Ver (|)	Azimuth (deg)(Deg)	Mast Height(m)	RBW(Hz)
126.495 M	29.68	14.000	-25.014	40.000	-10.32	|	272	1.78	120 k
40 081 M	31.60	14.135	-26.078	40.000	-8.40	|	253	1.04	120 k
143.936 M	32.48	13.200	-24.792	40.000	-7.52	|	342	1.35	120 k
153.255 M	34.34	12.500	-24.689	40.000	-5.66	|	261	1.15	120 k
141.239 M	35.64	13.300	-24.826	40.000	-4.36	|	280	1.46	120 k
73.199 M	37.13	8.100	-25.765	40.000	-2.87	|	0	1.55	120 k

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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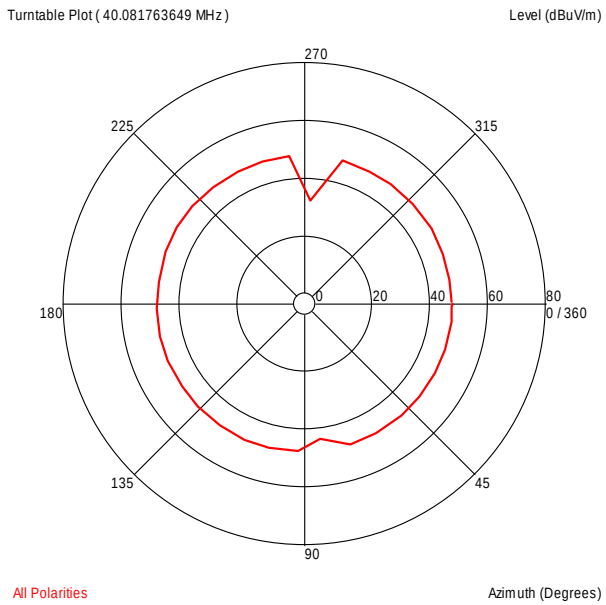
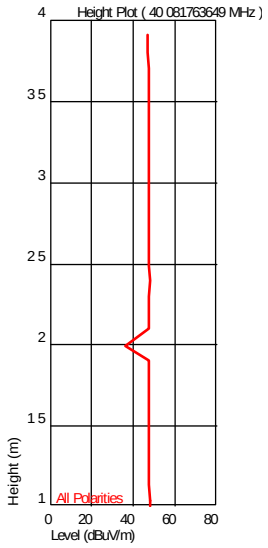
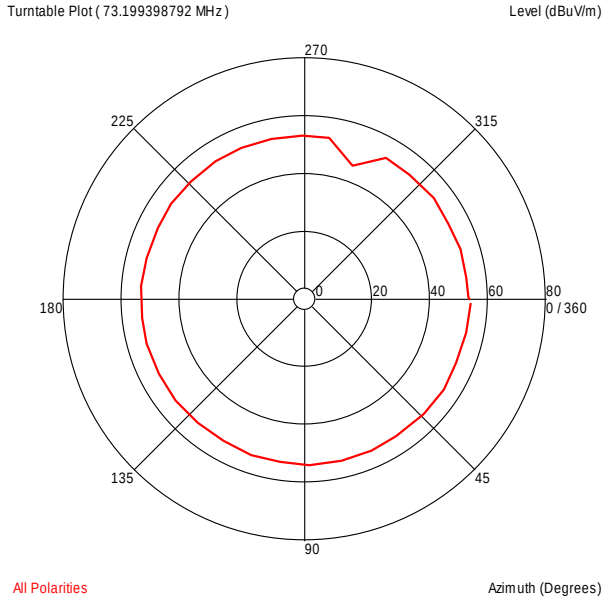
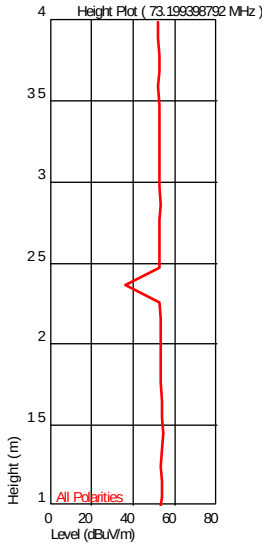
Azimuth Plots



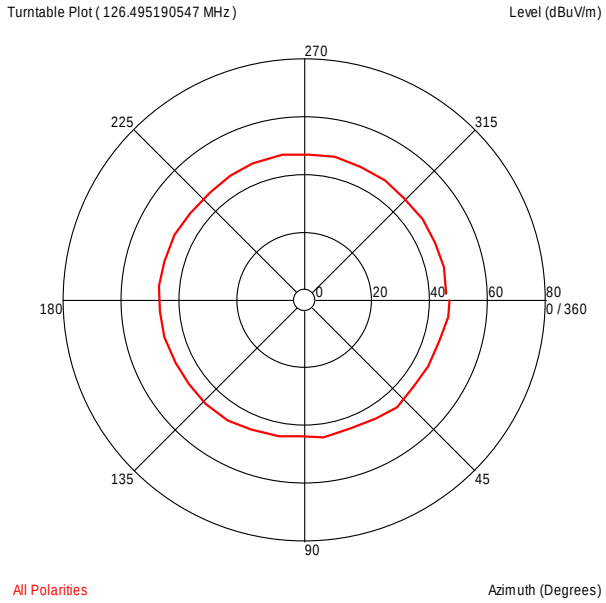
Turntable Plots

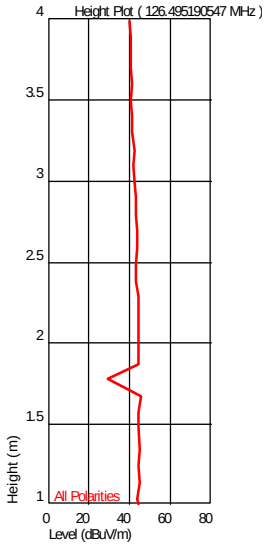


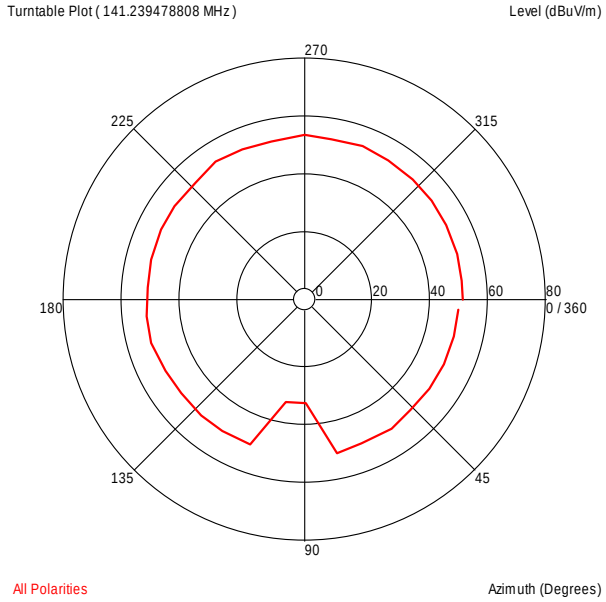


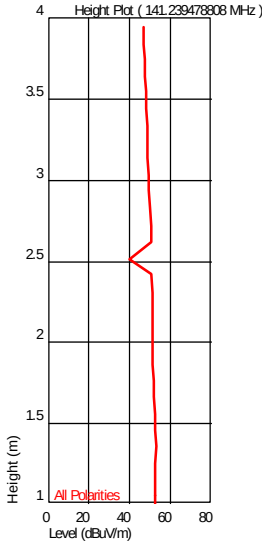


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

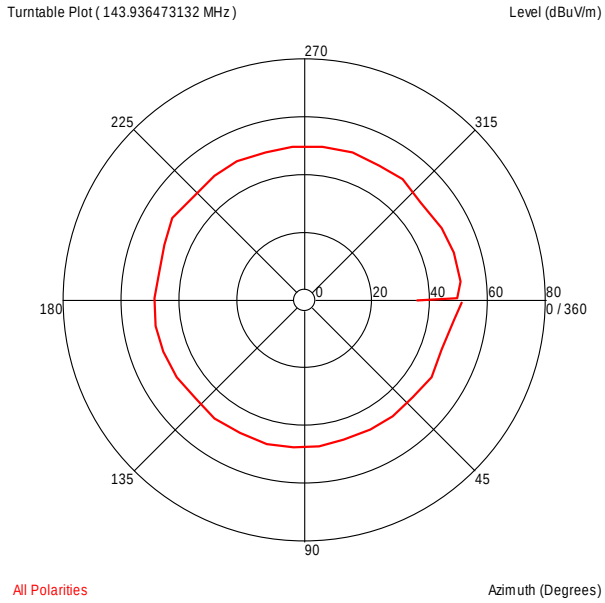


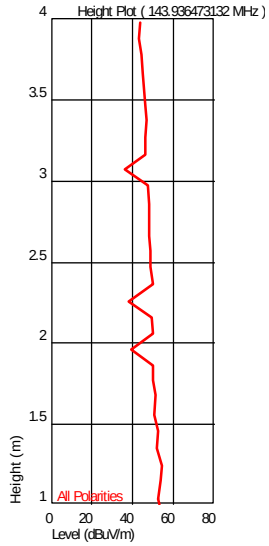


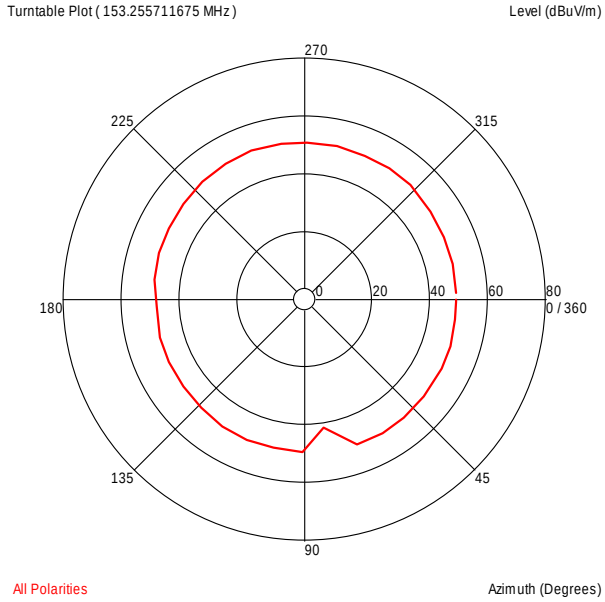


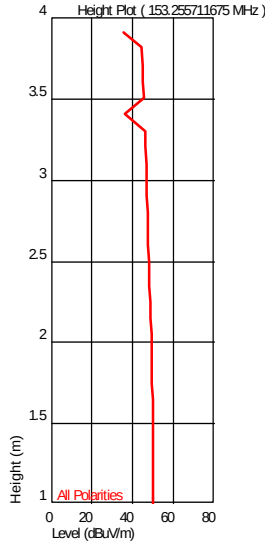


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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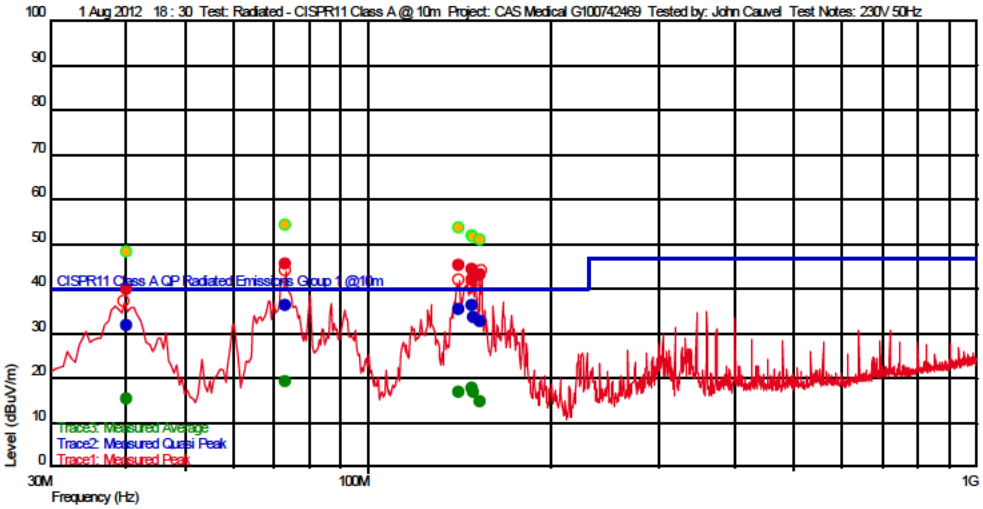
230V 50Hz

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	230V 50Hz	
Tested by:	John Cauvel	
Test Started:	1 Aug 2012 18 : 30	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

__ Swept Peak Data
__ Swept Quasi Peak Data
__ Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

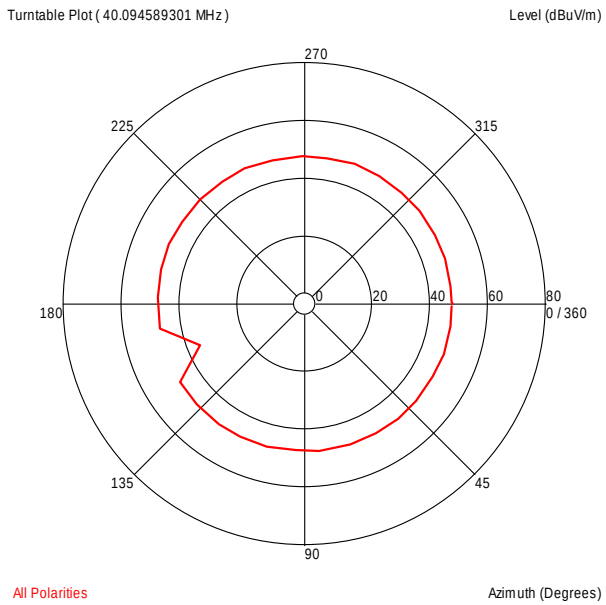
Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	Hor (–), Ver (|)	Azimuth (deg)(Deg)	Mast Height(m)	RBW(Hz)
40 094 M	31.90	14.124	-26.078	40.000	-8.10	|	279	2.56	120 k
153.407 M	32.76	12.500	-24.688	40.000	-7.24	|	258	1.45	120 k
149.544 M	33.44	12.746	-24.721	40.000	-6.56	|	226	1.34	120 k
141.192 M	35.29	13.300	-24.827	40.000	-4.71	|	240	1.45	120 k
73 365 M	36.24	8.100	-25.763	40.000	-3.76	|	28	1.55	120 k
148.303 M	36.40	12.870	-24.737	40.000	-3.60	|	300	1.25	120 k

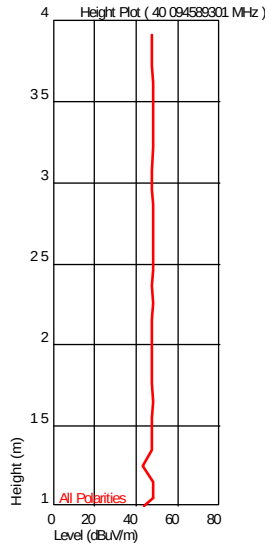
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

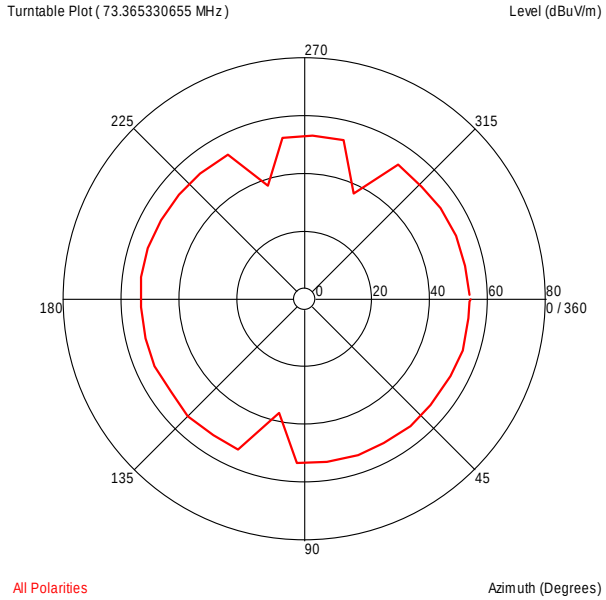
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

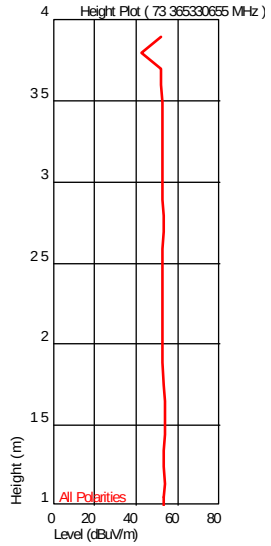
Azimuth Plots

Turntable Plots





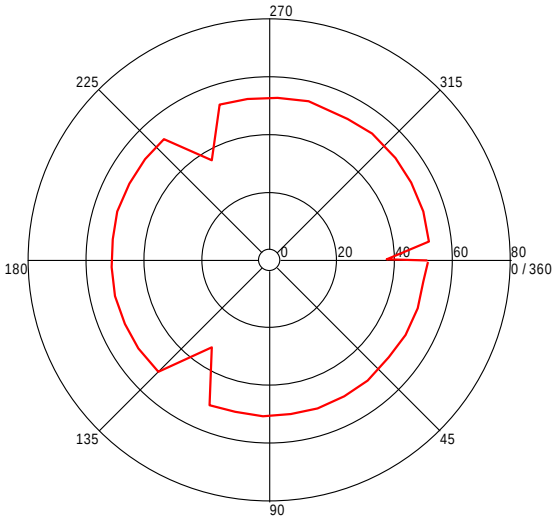




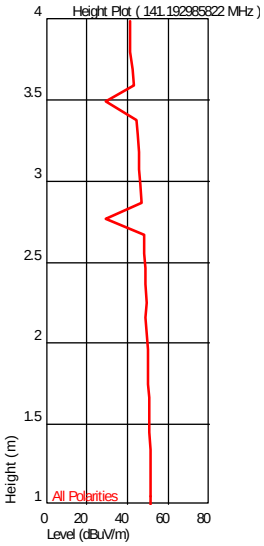
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

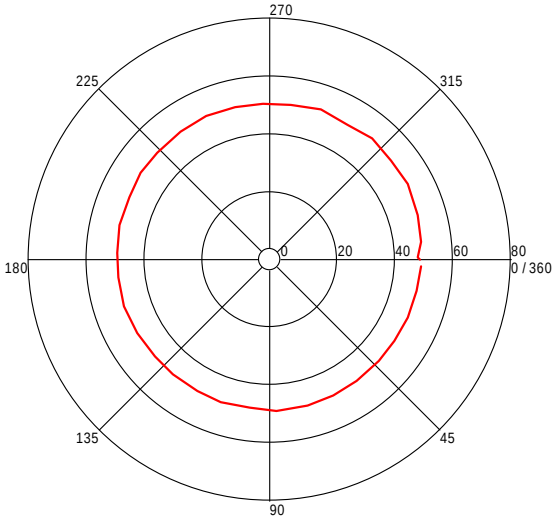
Turntable Plot (141.192985822 MHz) Level (dBuV/m)



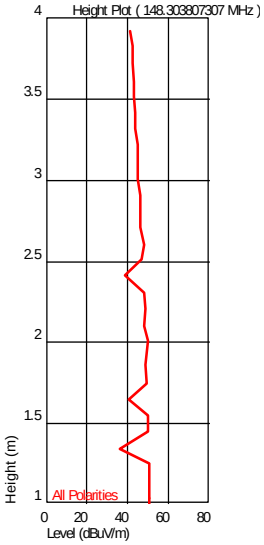
All Polarities Azimuth (Degrees)



Turntable Plot (148.303807307 MHz) Level (dBuV/m)



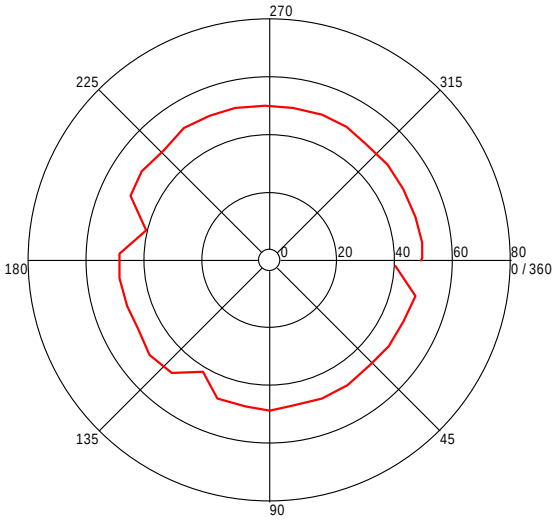
All Polarities Azimuth (Degrees)



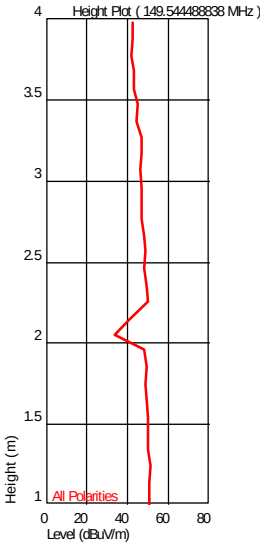
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

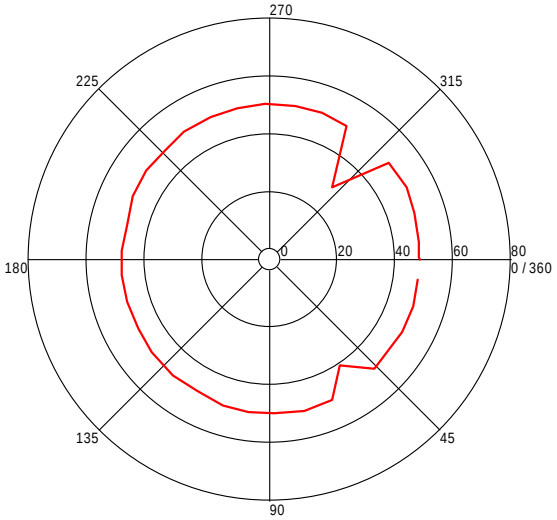
Turntable Plot (149.544488838 MHz) Level (dBuV/m)



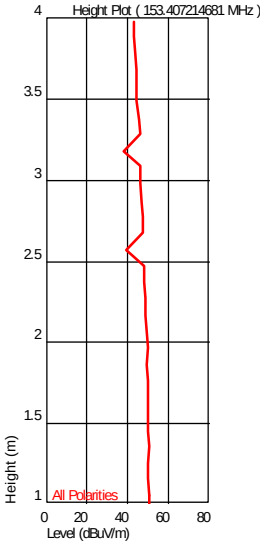
All Polarities Azimuth (Degrees)



Turntable Plot (153.407214681 MHz) Level (dBuV/m)



All Polarities Azimuth (Degrees)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

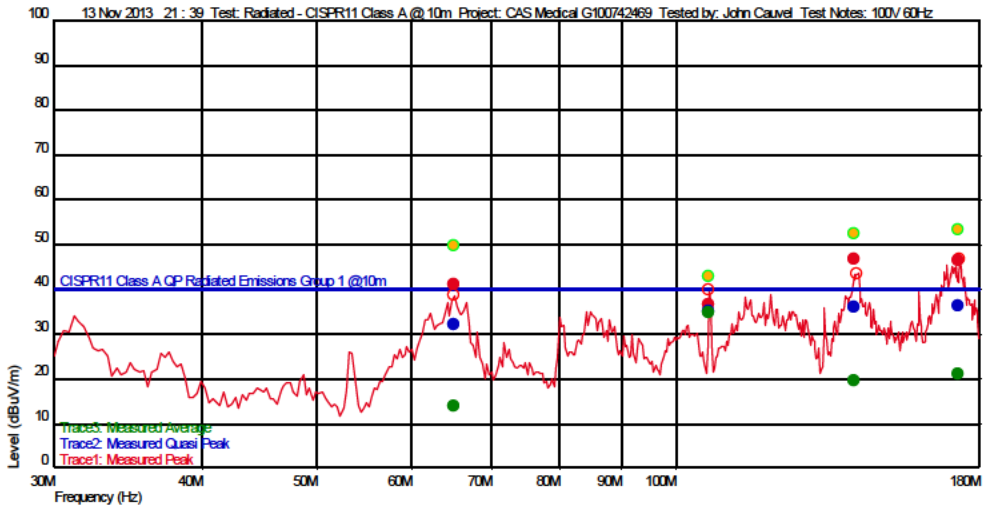
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz (30-180 MHz)

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	100V 60Hz	
Tested by:	John Cauvel	
Test Started:	13 Nov 2013 21 : 39	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

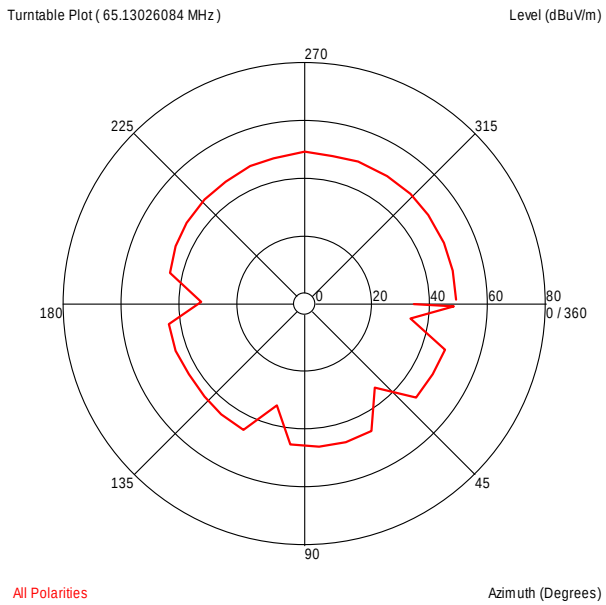
Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dB)	Hor (–), Ver (|)	Azimuth (Deg)	Mast Height(m)	RBW(Hz)
65.130 M	32 06	7.974	-25 959	40 000	-7.94	|	324	1.74	120 k
106.674 M	35 09	11.867	-25.449	40 000	-4.91	|	29	3.70	120 k
141.450 M	35 93	11.145	-25.289	40 000	-4.07	|	242	1.25	120 k
172.976 M	36 35	16.398	-24.625	40 000	-3.65	|	38	1.54	120 k

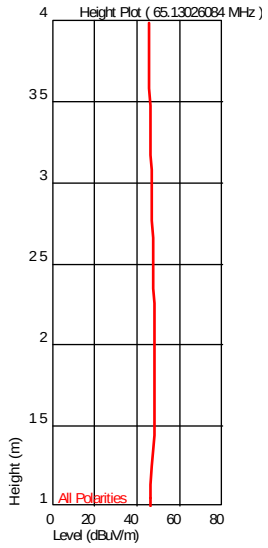
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

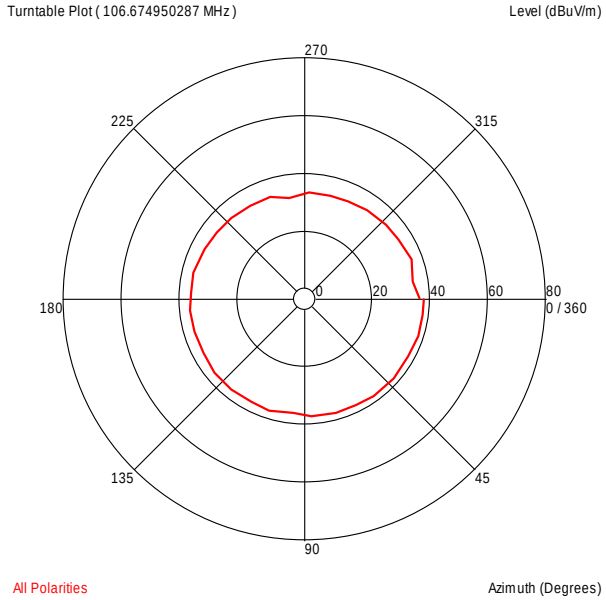
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

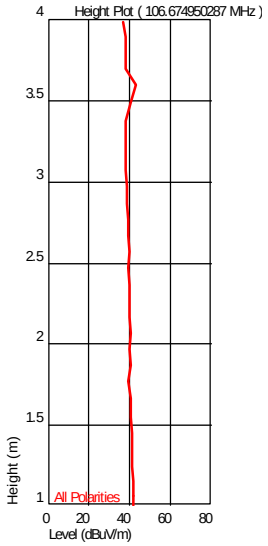
Azimuth Plots

Turntable Plots





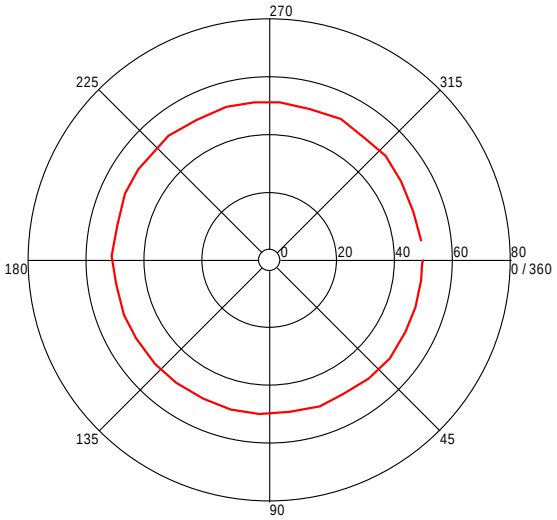




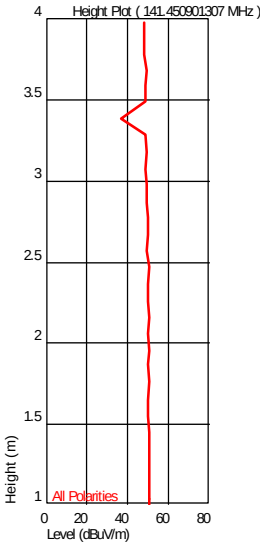
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

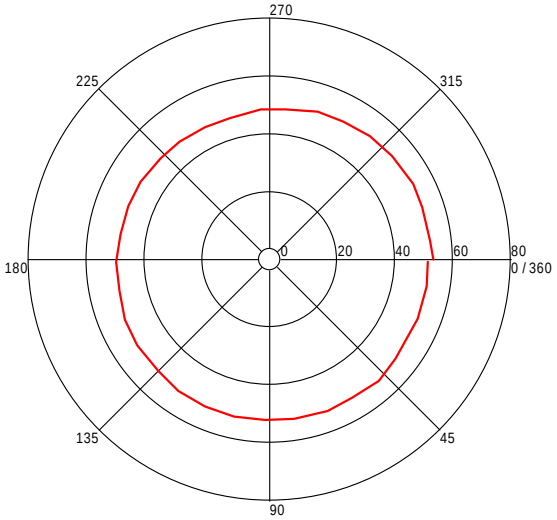
Turntable Plot (141.450901307 MHz) Level (dBuV/m)



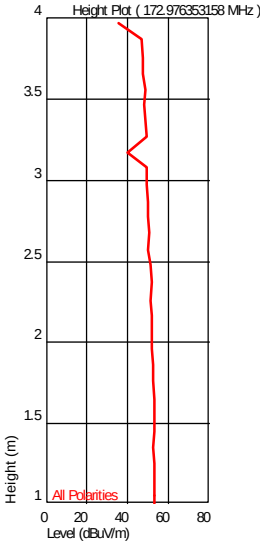
All Polarities Azimuth (Degrees)



Turntable Plot (172.976353158 MHz) Level (dBuV/m)



All Polarities Azimuth (Degrees)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

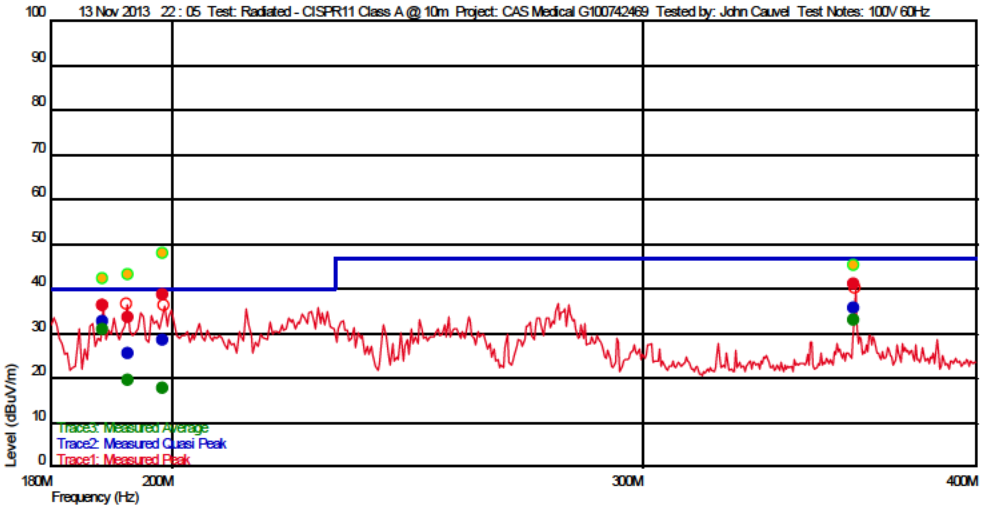
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz (180-400 MHz)

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	100V 60Hz	
Tested by:	John Cauvel	
Test Started:	13 Nov 2013 22 : 05	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

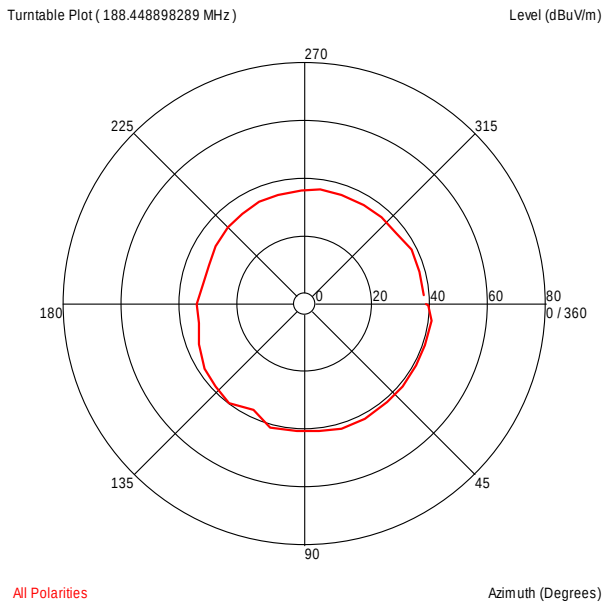
Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dB)	Hor (–), Ver (|)	Azimuth (Deg)	Mast Height(m)	RBW(Hz)
192.602 M	25.48	15.200	-24.091	40 000	-14 52	|	96	1.34	120 k
198.349 M	28.38	15.334	-23.935	40 000	-11 62	|	299	1.04	120 k
360.119 M	35.66	22.090	-23.292	47 000	-11 34	|	1	1.16	120 k
188.448 M	32.66	15.138	-24.204	40 000	-7.34	|	73	1.05	120 k

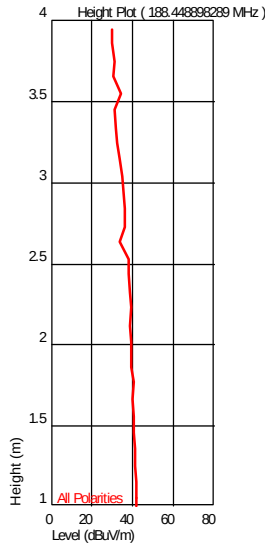
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

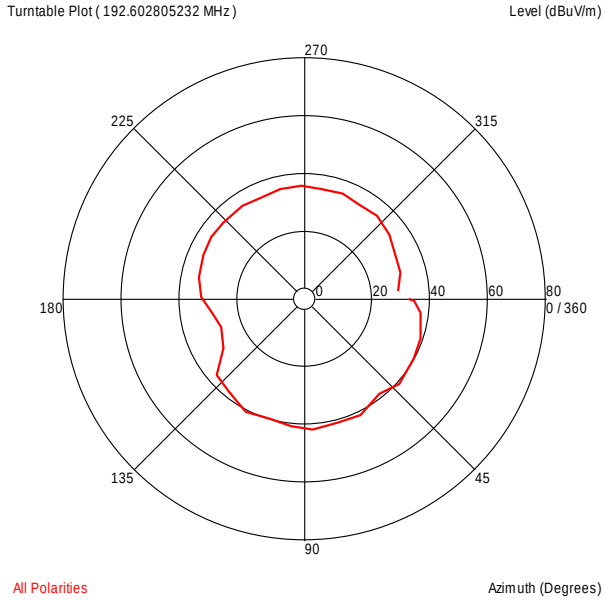
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

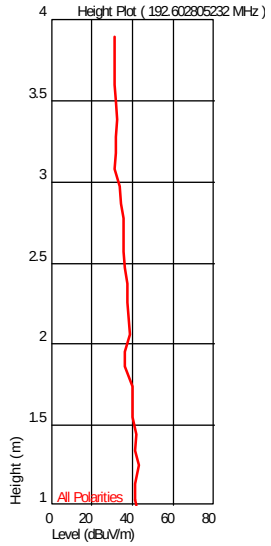
Azimuth Plots

Turntable Plots

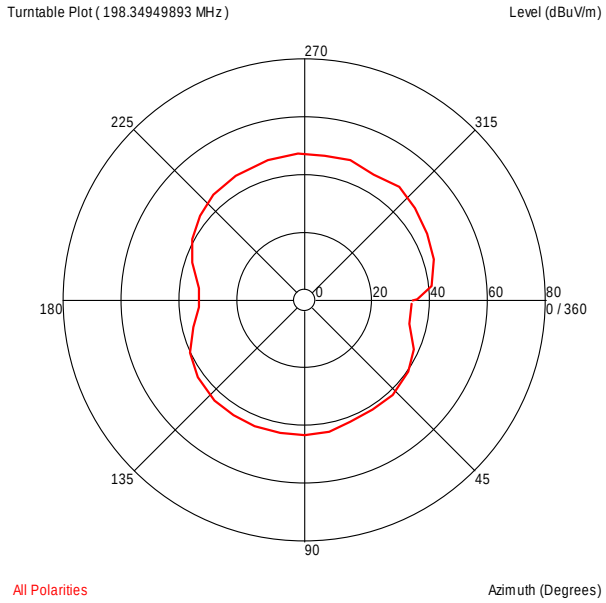


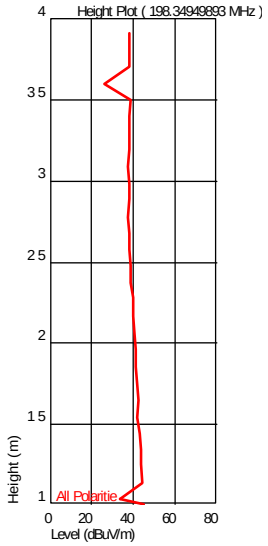


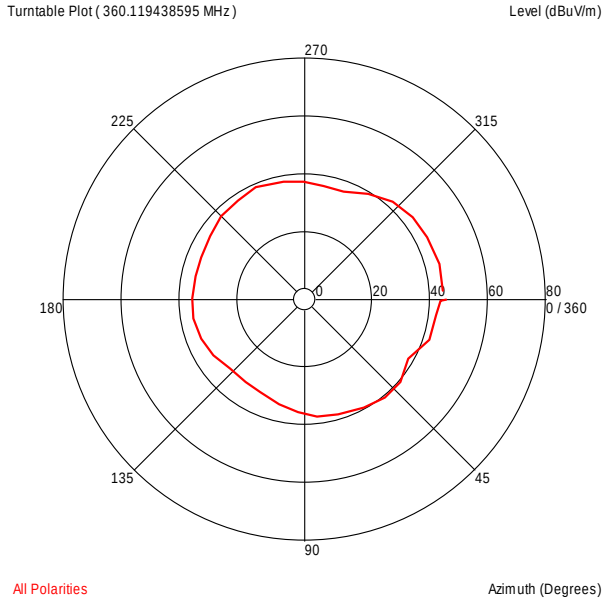


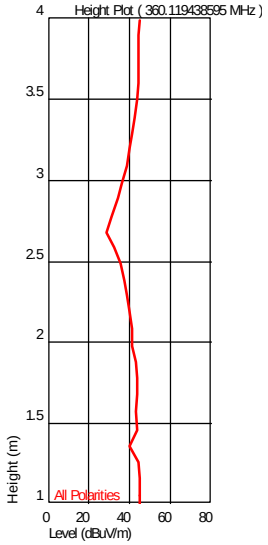


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

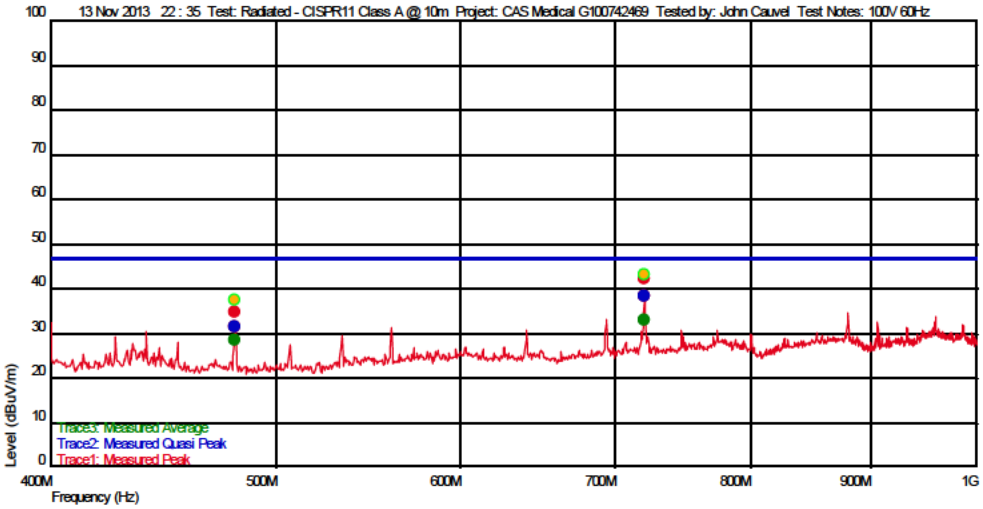
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz (400-1000 MHz)

Test Information

Test Details	User Entry	Additional Information
Test:	Radiated - CISPR11 Class A @ 10m	
Project:	CAS Medical G100742469	
Test Notes:	100V 60Hz	
Tested by:	John Cauvel	
Test Started:	13 Nov 2013 22 : 35	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

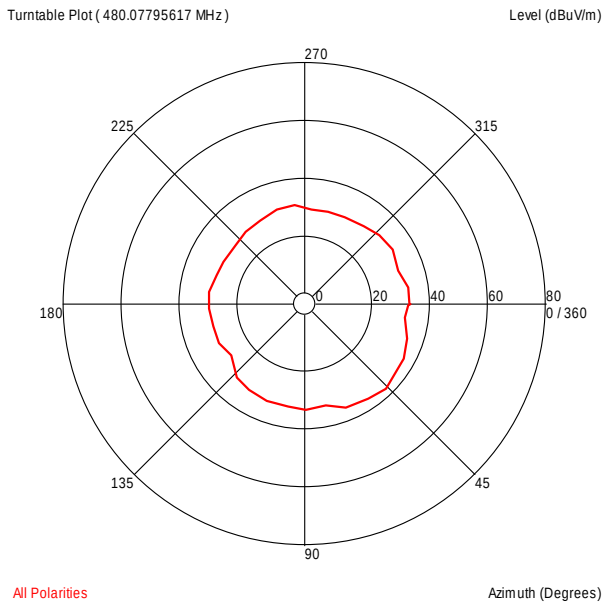
Trace2: Measured Quasi Peak

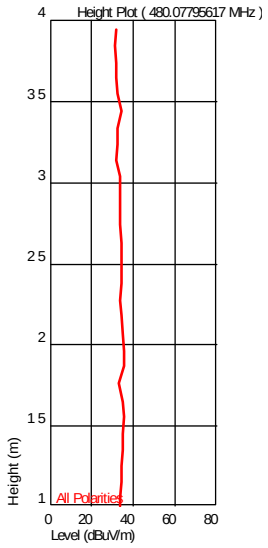
Frequency(Hz)	Level(dBuV/m)	AF	PA+CL	Limit(dBuV/m)	Margin(dB)	Hor (–), Ver (|)	Azimuth (Deg)	Mast Height(m)	RBW(Hz)
480.077 M	31 50	22.497	-24 561	47 000	-15 50	–	56	2.07	120 k
720.136 M	38.42	25.600	-23 611	47 000	-8.58	–	210	1.05	120 k

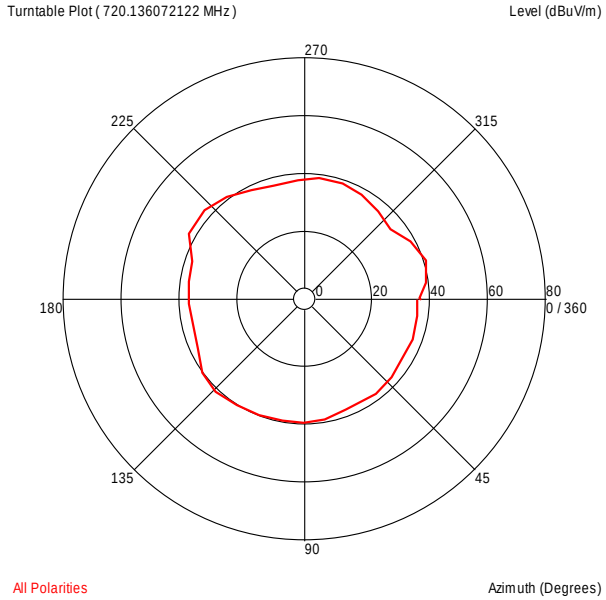
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

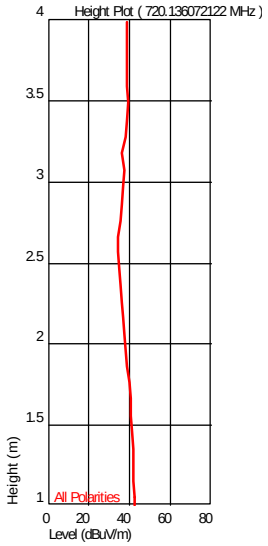
Azimuth Plots

Turntable Plots









Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Personnel:	John R. Cauvel J.R.C	Test Date:	8/1/2012
	John R. Cauvel J.R.C		11-13-2013
Supervising/Reviewing Engineer: (Where Applicable)	Vathana Ven VJV		
Product Standard:	IEC 60601-1-2	Test Levels:	CISPR 11 Group 1 Class A
Input Voltage:	120V/60Hz, 230V/50Hz, 100V/60Hz (Worst Case)		
Pretest Verification w/ Ambient Signals or BB Source:	Yes, Ambient Signals	Ambient Temperature:	21,20 ºC
		Relative Humidity:	64,17 %
		Atmospheric Pressure:	1000,1012 mbars

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

7 AC Mains Conducted Emissions

7.1 Method

Tests are performed in accordance with CISPR 11.

TEST SITE: BUMP OUT (AMAP) and EMC Lab

The AMAP Building and Lab includes general lab space that can be used for testing where a shielded/enclosed environment is not required.

Measurement Uncertainty

For conducted emissions, U_{lab} (3.2 dB in worst case) < U_{CISPR} (3.6 dB), which is the reference value in CISPR 16-4-2 Table 1, hence the compliance of the product is only based on the measured value, and no measurement uncertainty correction is required, based on CISPR 22 and CISPR 11 (for 2006 and later revisions) Clause 11.

Sample Calculations

The following is how net line-conducted readings were determined:

NF = RF + LF + CF + AF
Where NF = Net Reading in dBμV
RF = Reading from receiver in dBμV
LF = LISN Correction Factor in dB
CF = Cable Correction Factor in dB
AF = Attenuator Loss Factor in dB

To convert from dBμV to μV or mV the following was used:

$UF = 10^{(NF / 20)}$ where UF = Net Reading in μV
NF = Net Reading in dBμV

Example:

NF = RF + LF + CF + AF = 28.5 + 0.2 + 0.4 + 20.0 = 49.1 dBμV
$UF = 10^{(49.1\ dB\mu V / 20)}$ = 285.1 μV/m

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

7.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Ros 002	9kHz to 3GHz EMI Test Receiver	Rohde & Schwartz	ESCI 1166.5950K03	100067	06/13/2012	06/13/2013
Cblbnc 51'	50 ohm Coaxial Cable	Pomona	RG58C/U	CBLBNC51	09/08/2011	09/08/2012
Ds 26a	Attenuator, 20dB	Mini Circuits	20dB, 50 ohm	DS26A	10/04/2011	10/04/2012
145 015	LISN: 50 Ohm/50 microHenry	Solar Electronics	9252-50-R-24-BNC	971617	02/06/2012	02/06/2013
Dav 001	Weather Station	Davis Instruments	7400	PE80519A61	08/17/2011	08/17/2012

Test equipment used on 11/13/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 001	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
ROS 002	9kHz to 3GHz EMI Test Receiver	Rohde & Schwartz	ESCI 1166.5950K03	100067	06/18/2013	06/18/2014
CBLBNC 2012-7	50 Ohm Coaxial Cable	Pomona	RG58C/U	CBLBNC2012-7	11/13/2012	11/13/2013
DS 26A	Attenuator, 20dB	Mini Circuits	20dB, 50 ohm	DS26A	10/04/2013	10/04/2014
145 015	LISN: 50 Ohm/50 microHenry	Solar Electronics	9252-50-R-24-BNC	971617	03/07/2013	03/07/2014

Software Utilized:

Name	Manufacturer	Version
C5	Teseq	5.26.46.46

7.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

7.4 Setup Photographs:

120V 50 & 60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

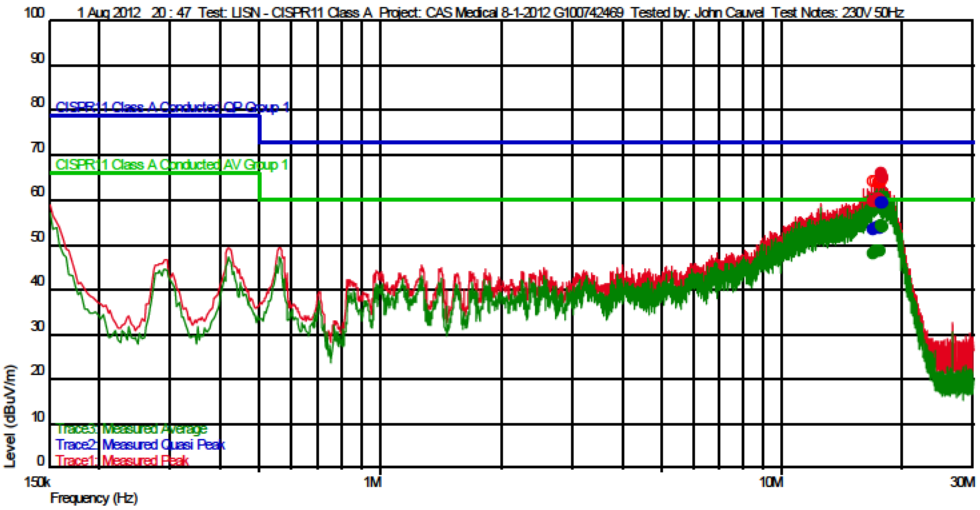
7.5 Plots/Data:

230V 50Hz

Test Information

Test Details	User Entry	Additional Information
Test:	LISN - CISPR11 Class A	
Project:	CAS Medical 8-1-2012 G100742469	
Test Notes:	230V 50Hz	
Tested by:	John Cauvel	
Test Started:	1 Aug 2012 20 : 47	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV/m)	TF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	RBW(Hz)	Comment	LINE
16 944 M	53.18	0.475	21.029	73 000	-19.82	9 k		L1
17.196 M	53.58	0.485	21.032	73 000	-19.42	9 k		L1
17 643 M	53.60	0.503	21.036	73 000	-19.40	9 k		L1
17.466 M	53.81	0.496	21.035	73 000	-19.19	9 k		L1
17 97 M	59 25	0.517	21.040	73 000	-13.75	9 k		N
17 823 M	59 37	0.511	21.038	73 000	-13.63	9 k		N

Trace3: Measured Average

Frequency(Hz)	Level(dBuV/m)	TF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	RBW(Hz)	Comment	LINE
16 944 M	48.03	0.475	21.029	60 000	-11.97	9 k		L1
17 643 M	48.37	0.503	21.036	60 000	-11.63	9 k		L1
17.196 M	48.48	0.485	21.032	60 000	-11.52	9 k		L1
17.466 M	48.63	0.496	21.035	60 000	-11.37	9 k		L1
17 97 M	54 02	0.517	21.040	60 000	-5 98	9 k		N
17 823 M	54.11	0.511	21.038	60 000	-5 89	9 k		N

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

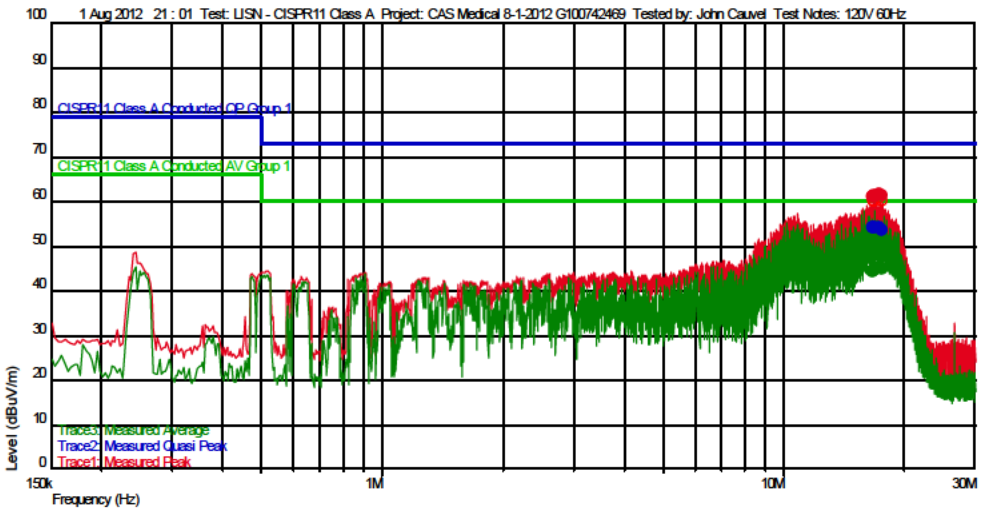
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

120V 60Hz

Test Information

Test Details	User Entry	Additional Information
Test:	LISN - CISPR11 Class A	
Project:	CAS Medical 8-1-2012 G100742469	
Test Notes:	120V 60Hz	
Tested by:	John Cauvel	
Test Started:	1 Aug 2012 21 : 01	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV/m)	TF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	RBW(Hz)	L NE
17 61 M	53.49	0.502	21.036	73 000	-19.51	9 k	L1
16.758 M	54.05	0.467	21.028	73 000	-18.95	9 k	L1
16 899 M	54.10	0.473	21.029	73 000	-18.90	9 k	L1
17.445 M	54.11	0.495	21.034	73 000	-18.89	9 k	L1
16 854 M	54.12	0.471	21.029	73 000	-18.88	9 k	L1
16 914 M	54.16	0.473	21.029	73 000	-18.84	9 k	L1

Trace3: Measured Average

Frequency(Hz)	Level(dBuV/m)	TF	PA+CL	Limit(dBuV/m)	Margin(dBuV/m)	RBW(Hz)	L NE
16.758 M	44.47	0.467	21.028	60 000	-15.53	9 k	L1
16 854 M	44.60	0.471	21.029	60 000	-15.40	9 k	L1
16 899 M	44.68	0.473	21.029	60 000	-15.32	9 k	L1
16 914 M	44.77	0.473	21.029	60 000	-15.23	9 k	L1
17 61 M	44.92	0.502	21.036	60 000	-15.08	9 k	L1
17.445 M	45.16	0.495	21.034	60 000	-14.84	9 k	L1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

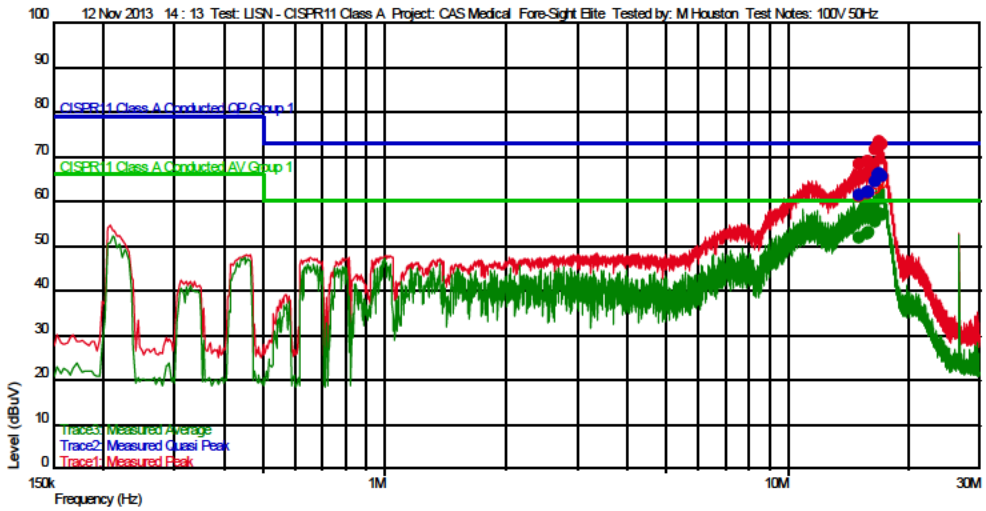
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 50Hz

Test Information

Test Details	User Entry	Additional Information
Test:	LISN - CISPR11 Class A	
Project:	CAS Medical Fore-Sight Elite	
Test Notes:	100V 50Hz	
Tested by:	M.Houston	
Test Started:	12 Nov 2013 14 : 13	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV)	TF	Losses	Gains	Limit(dBuV)	Margin(dBuV)	L NE
15.159 M	61.30	0.460	0.000	0 000	73.000	-11.70	L1
15 912 M	62.02	0.488	0.000	0 000	73.000	-10 98	L1
15 969 M	62.02	0.490	0.000	0 000	73.000	-10 98	L1
16 647 M	64.31	0.514	0.000	0 000	73.000	-8.69	N
17 229 M	65.65	0.534	0.000	0 000	73.000	-7.35	N
16 857 M	65.81	0.521	0.000	0 000	73.000	-7.19	L1
16 926 M	65.90	0.524	0.000	0 000	73.000	-7.10	L1
16 962 M	66.15	0.525	0.000	0 000	73.000	-6.85	L1

Trace3: Measured Average

Frequency(Hz)	Level(dBuV)	TF	Losses	Gains	Limit(dBuV)	Margin(dBuV)	L NE
15.159 M	51.82	0.460	0.000	0 000	60.000	-8.18	L1
15 912 M	52.79	0.488	0.000	0 000	60.000	-7.21	L1
15 969 M	52.85	0.490	0.000	0 000	60.000	-7.15	L1
16 647 M	55.26	0.514	0.000	0 000	60.000	-4.74	N
17 229 M	56.75	0.534	0.000	0 000	60.000	-3.25	N
16 857 M	56.77	0.521	0.000	0 000	60.000	-3.23	L1
16 926 M	57.06	0.524	0.000	0 000	60.000	-2.94	L1
16 962 M	57.20	0.525	0.000	0 000	60.000	-2.80	L1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

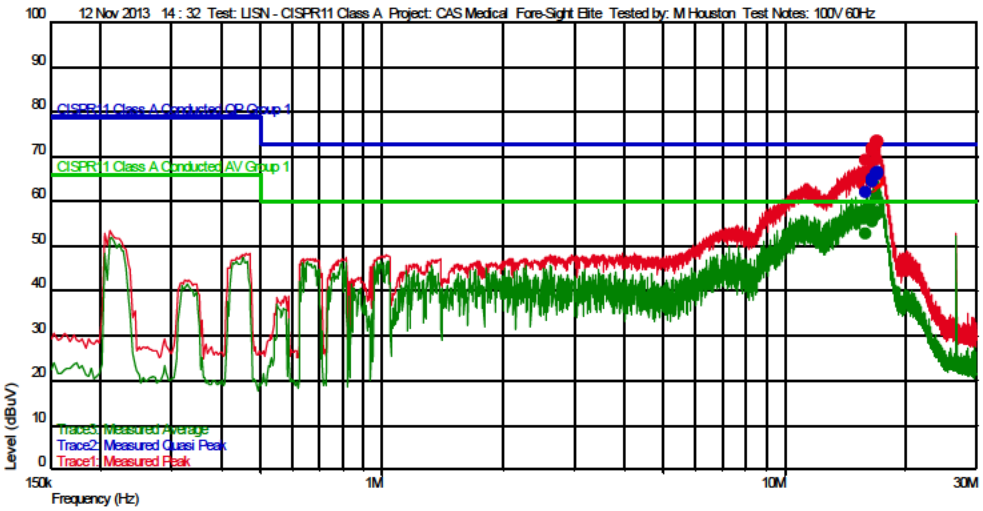
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz

Test Information

Test Details	User Entry	Additional Information
Test:	LISN - CISPR11 Class A	
Project:	CAS Medical Fore-Sight Elite	
Test Notes:	100V 60Hz	
Tested by:	M.Houston	
Test Started:	12 Nov 2013 14 : 32	

Prescan Emission Graph



- Measured Peak Value
- Measured Quasi Peak Value
- Measured Average Value
- Maximum Value of Mast and Turntable

- Swept Peak Data
- Swept Quasi Peak Data
- Swept Average Data

Emissions Test Data

Trace2: Measured Quasi Peak

Frequency(Hz)	Level(dBuV)	TF	Losses	Gains	Limit(dBuV)	Margin(dBuV)	L NE
15 972 M	62.06	0.490	0.000	0 000	73.000	-10 94	L1
16 59 M	64.45	0.512	0.000	0 000	73.000	-8.55	L1
16 632 M	64.81	0.514	0.000	0 000	73.000	-8.19	L1
16 971 M	65.81	0.525	0.000	0 000	73.000	-7.19	N
17 04 M	66.07	0.528	0.000	0 000	73.000	-6.93	N
17 031 M	66.16	0.527	0.000	0 000	73.000	-6.84	L1
17.136 M	66.26	0.531	0.000	0 000	73.000	-6.74	L1
17 058 M	66.48	0.528	0.000	0 000	73.000	-6.52	L1

Trace3: Measured Average

Frequency(Hz)	Level(dBuV)	TF	Losses	Gains	Limit(dBuV)	Margin(dBuV)	L NE
15 972 M	52.79	0.490	0.000	0 000	60.000	-7.21	L1
16 59 M	55.37	0.512	0.000	0 000	60.000	-4.63	L1
16 632 M	55.64	0.514	0.000	0 000	60.000	-4.36	L1
16 971 M	56.79	0.525	0.000	0 000	60.000	-3.21	N
17 04 M	56.99	0.528	0.000	0 000	60.000	-3.01	N
17 031 M	57.30	0.527	0.000	0 000	60.000	-2.70	L1
17 058 M	57.31	0.528	0.000	0 000	60.000	-2.69	L1
17.136 M	57.35	0.531	0.000	0 000	60.000	-2.65	L1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Personnel:	John R. Cauvel J.R.C	Test Date:	8-1-2012
	Michael Houston MH		11/12/2013
Supervising/Reviewing Engineer: (Where Applicable)	Vathana Ven VJV		
Product Standard:	IEC 60601-1-2	Test Levels:	CISPR 11 Group 1 Class A
Input Voltage:	120V 60Hz, 230V 50Hz 100V 50 & 60Hz	Ambient Temperature:	21, 23 ºC
Pretest Verification w/ Ambient Signals or BB Source:	Yes, Ambient Signals	Relative Humidity:	64, 40 %
		Atmospheric Pressure:	1000, 1008 mbars

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8 Harmonics

8.1 Method

Tests are performed in accordance with IEC 61000-3-2.

TEST SITE: EMC

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

The AMAP Building and Lab includes general lab space that can be used for testing where a shielded/enclosed environment is not required.

8.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
SCH 8	EMC Test System consisting of: NSG-1007-45 (SN 55512), CCN 1000-3 (SN 72203), INA 2197 (SN 72200), INA 2196 (SN 72198), INA 2145 (SN 72199), INA 2171 (SN 8006), NA 2141 (SN 6012)	Schaffner	MX45-3PI-CTSHL-SCH	43964	03/21/2012	03/21/2014

Test equipment used on 11/12/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV001'	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
145-141A'	Power Supply NSG 1007-5-208	California Instr. Co	5kVa	56119	03/22/2012	03/22/2014
145-141B'	Power Supply NSG 1007-5-208	California Instr. Co	5kVa	56120	03/22/2012	03/22/2014
145-141C'	Power Supply NSG 1007-5-208	California Instr. Co	5kVa	56121	03/22/2012	03/22/2014
145-141D'	3 Phase Profline AC Switching Unit	Schaffner	NSG 2200-3	200239-003EK	03/13/2010	Verified
145-141E'	Signal Conditioning Unit	Schaffner	CCN1000-3	72319	03/22/2012	03/22/2014
145-141F'	3 Phase Impedance Network	Schaffner	INA 2154	72320	03/22/2012	03/22/2014

Software Utilized:

Name	Manufacturer	Version
Win2100V3	California Instruments Corp.	3.2.0.28

8.3 Results:

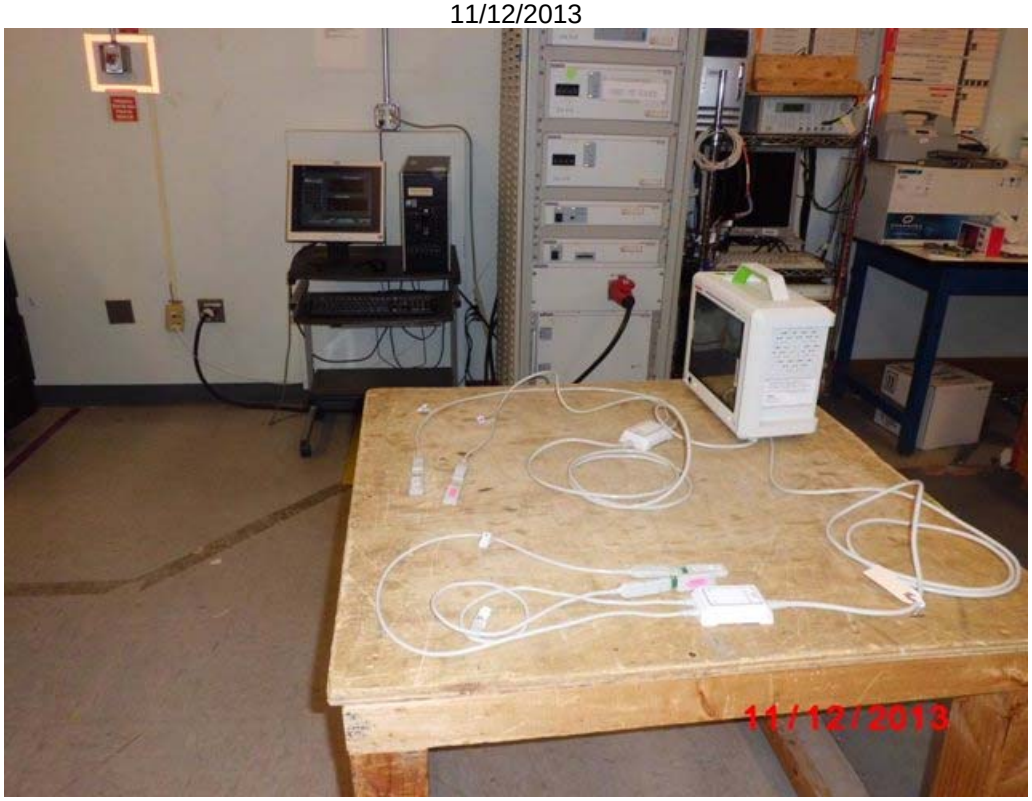
The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.4 Setup Photographs:

11/12/2013



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.5 Plots/Data:

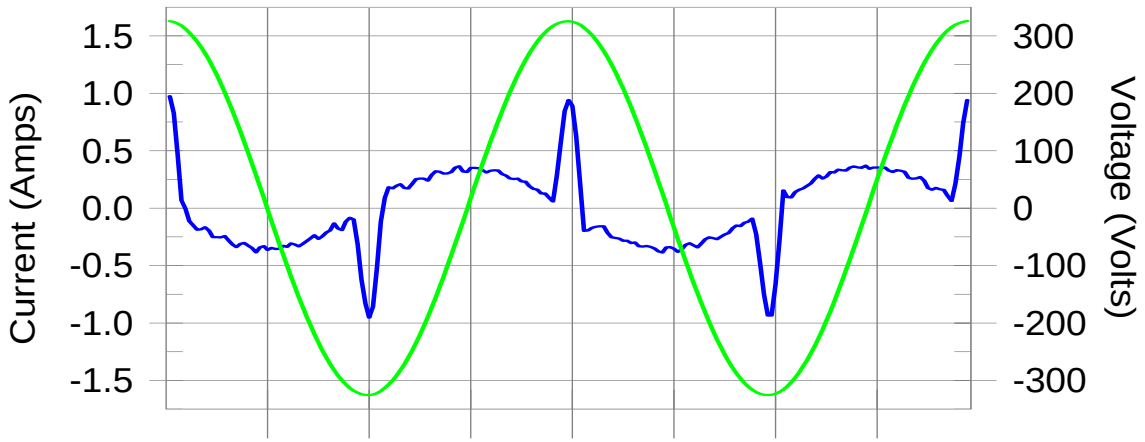
230V 50Hz

Harmonics – Class-A per Ed. 3.0 (2006) (Run time)

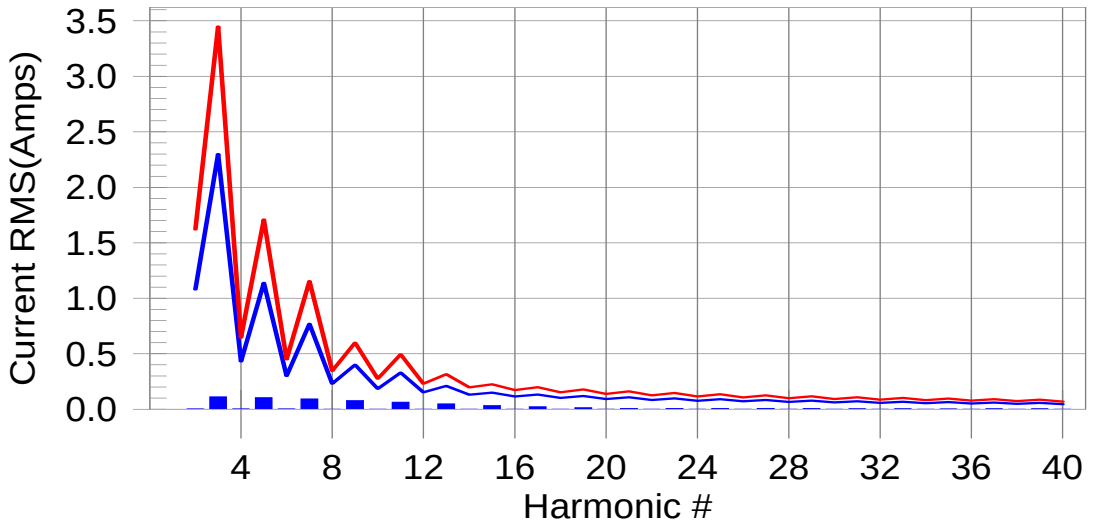
EUT: Model 3000 Oximetry **Tested by: Gary Ball**
Test category: Class-A per Ed. 3.0 (2006) (European limits) **Test Margin: 100**
Test date: 8/1/2012 **Start time: 9:32:36 AM** **End time: 9:42:57 AM**
Test duration (min): 10 **Data file name: H-000644.cts_data**
Comment: Comment
Customer: CAS Medical

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **European Limits**



<u>Test result: Pass Worst harmonic was #15 with 23.12% of the limit.</u>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Current Test Result Summary (Run time)

EUT: Model 3000 Oximetry **Tested by: Gary Ball**
Test category: Class-A per Ed. 3.0 (2006) (European limits) **Test Margin: 100**
Test date: 8/1/2012 **Start time: 9:32:36 AM** **End time: 9:42:57 AM**
Test duration (min): 10 **Data file name: H-000644.cts_data**
Comment: Comment
Customer: CAS Medical

Test Result: Pass **Source qualification: Normal**
THC(A): 0.21 **I-THD(%): 77.28** **POHC(A): 0.015** **POHC Limit(A): 0.277**
Highest parameter values during test:

V_RMS (Volts):	230.26	Frequency(Hz):	50.00
I_Peak (Amps):	1.038	I_RMS (Amps):	0.355
I_Fund (Amps):	0.274	Crest Factor:	2.949
Power (Watts):	27.2	Power Factor:	0.341

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.002	1.080	0.0	0.003	1.620	0.16	Pass
3	0.109	2.300	4.7	0.113	3.450	3.27	Pass
4	0.002	0.430	0.0	0.002	0.645	0.38	Pass
5	0.101	1.140	8.8	0.104	1.710	6.10	Pass
6	0.002	0.300	0.0	0.002	0.450	0.52	Pass
7	0.090	0.770	11.7	0.093	1.155	8.07	Pass
8	0.002	0.230	0.0	0.002	0.345	0.49	Pass
9	0.077	0.400	19.3	0.080	0.600	13.25	Pass
10	0.001	0.184	0.0	0.001	0.276	0.48	Pass
11	0.063	0.330	19.0	0.064	0.495	13.01	Pass
12	0.001	0.153	0.0	0.001	0.230	0.49	Pass
13	0.049	0.210	23.1	0.050	0.315	15.76	Pass
14	0.000	0.131	0.0	0.001	0.197	0.32	Pass
15	0.035	0.150	23.1	0.035	0.225	15.67	Pass
16	0.000	0.115	0.0	0.001	0.173	0.32	Pass
17	0.023	0.132	17.4	0.023	0.199	11.72	Pass
18	0.001	0.102	0.0	0.001	0.153	0.67	Pass
19	0.013	0.118	11.4	0.014	0.178	7.81	Pass
20	0.001	0.092	0.0	0.001	0.138	0.68	Pass
21	0.008	0.107	7.1	0.008	0.161	4.85	Pass
22	0.000	0.084	0.0	0.001	0.125	0.47	Pass
23	0.007	0.098	6.9	0.007	0.147	4.82	Pass
24	0.000	0.077	0.0	0.001	0.115	0.54	Pass
25	0.007	0.090	7.6	0.007	0.135	5.36	Pass
26	0.000	0.071	0.0	0.000	0.106	0.44	Pass
27	0.007	0.083	8.6	0.007	0.125	5.84	Pass
28	0.000	0.066	0.0	0.000	0.099	0.23	Pass
29	0.006	0.078	7.6	0.006	0.116	5.16	Pass
30	0.000	0.061	0.0	0.000	0.092	0.30	Pass
31	0.004	0.073	0.0	0.004	0.109	3.89	Pass
32	0.000	0.058	0.0	0.000	0.086	0.37	Pass
33	0.003	0.068	0.0	0.003	0.102	3.17	Pass
34	0.000	0.054	0.0	0.000	0.081	0.45	Pass
35	0.002	0.064	0.0	0.003	0.096	2.69	Pass
36	0.000	0.051	0.0	0.000	0.077	0.65	Pass
37	0.003	0.061	0.0	0.003	0.091	3.70	Pass
38	0.000	0.048	0.0	0.000	0.073	0.67	Pass
39	0.004	0.058	0.0	0.004	0.087	4.52	Pass
40	0.000	0.046	0.0	0.000	0.069	0.65	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Voltage Source Verification Data (Run time)

EUT: Model 3000 Oximetry **Tested by: Gary Ball**
Test category: Class-A per Ed. 3.0 (2006) (European limits) **Test Margin: 100**
Test date: 8/1/2012 **Start time: 9:32:36 AM** **End time: 9:42:57 AM**
Test duration (min): 10 **Data file name: H-000644.cts_data**
Comment: Comment
Customer: CAS Medical

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	230.26	Frequency(Hz):	50.00
I_Peak (Amps):	1.038	I_RMS (Amps):	0.355
I_Fund (Amps):	0.274	Crest Factor:	2.949
Power (Watts):	27.2	Power Factor:	0.341

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.046	0.460	9.94	OK
3	0.043	2.072	2.08	OK
4	0.012	0.460	2.53	OK
5	0.023	0.921	2.47	OK
6	0.016	0.460	3.49	OK
7	0.056	0.691	8.09	OK
8	0.006	0.460	1.27	OK
9	0.059	0.460	12.77	OK
10	0.006	0.460	1.35	OK
11	0.045	0.230	19.39	OK
12	0.012	0.230	5.02	OK
13	0.053	0.230	23.04	OK
14	0.005	0.230	2.08	OK
15	0.044	0.230	19.18	OK
16	0.003	0.230	1.24	OK
17	0.032	0.230	13.87	OK
18	0.008	0.230	3.63	OK
19	0.027	0.230	11.82	OK
20	0.010	0.230	4.15	OK
21	0.015	0.230	6.55	OK
22	0.003	0.230	1.28	OK
23	0.020	0.230	8.89	OK
24	0.005	0.230	2.01	OK
25	0.011	0.230	4.73	OK
26	0.004	0.230	1.80	OK
27	0.017	0.230	7.47	OK
28	0.003	0.230	1.38	OK
29	0.015	0.230	6.66	OK
30	0.005	0.230	2.19	OK
31	0.003	0.230	1.16	OK
32	0.003	0.230	1.21	OK
33	0.014	0.230	6.25	OK
34	0.004	0.230	1.80	OK
35	0.007	0.230	2.98	OK
36	0.005	0.230	2.09	OK
37	0.008	0.230	3.66	OK
38	0.004	0.230	1.67	OK
39	0.012	0.230	5.08	OK
40	0.008	0.230	3.39	OK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

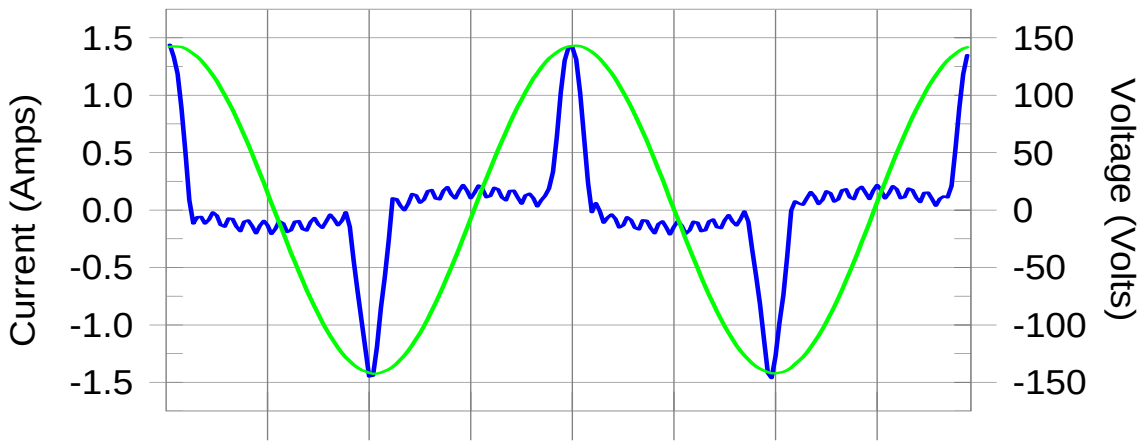
100V 50Hz

Harmonics – Class-A per Ed. 3.2 (2009) (Run time)

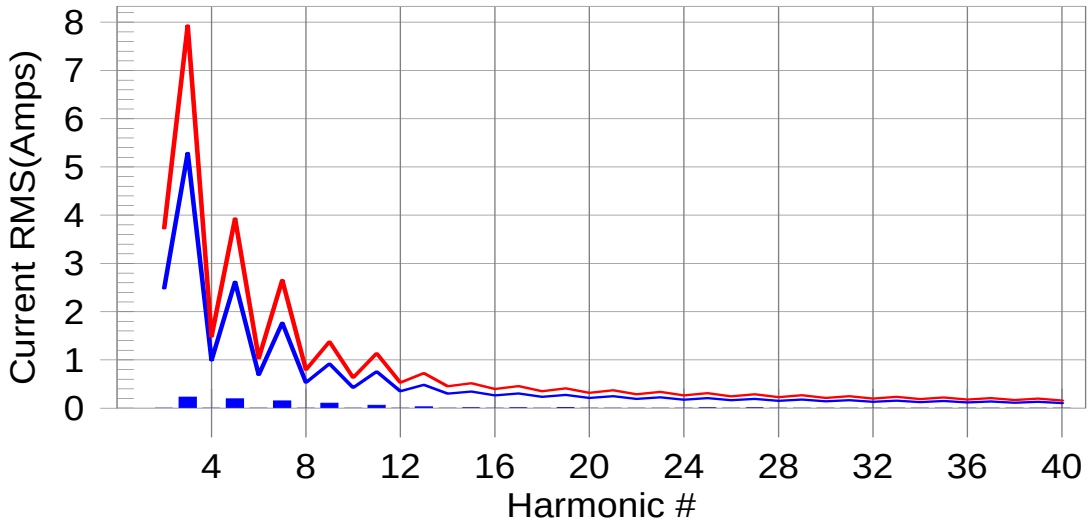
EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:39:40 AM** **End time: 11:50:02 AM**
Test duration (min): 10 **Data file name: H-000300.cts_data**
Comment: G100742469 PCOR 500488596 - 100V 50Hz
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **Japanese Limits**



Test result: Pass **Worst harmonic was #9 with 11.21% of the limit.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Current Test Result Summary (Run time)

EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:39:40 AM** **End time: 11:50:02 AM**
Test duration (min): 10 **Data file name: H-000300.cts_data**
Comment: G100742469 PCOR 500488596 - 100V 50Hz
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**
THC(A): 0.36 **I-THD(%): 129.00** **POHC(A): 0.006** **POHC Limit(A): 0.578**
Highest parameter values during test:

V_RMS (Volts):	100.81	Frequency(Hz):	50.00
I_Peak (Amps):	1.527	I_RMS (Amps):	0.459
I_Fund (Amps):	0.280	Crest Factor:	3.335
Power (Watts):	25.3	Power Factor:	0.548

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.000	2.484	0.0	0.001	3.726	0.01	Pass
3	0.231	5.290	4.4	0.231	7.935	2.91	Pass
4	0.001	0.989	0.1	0.001	1.484	0.05	Pass
5	0.196	2.622	7.5	0.196	3.933	4.98	Pass
6	0.001	0.690	0.1	0.001	1.035	0.13	Pass
7	0.151	1.771	8.5	0.151	2.657	5.67	Pass
8	0.001	0.529	0.1	0.001	0.794	0.11	Pass
9	0.103	0.920	11.2	0.103	1.380	7.48	Pass
10	0.001	0.423	0.2	0.001	0.635	0.13	Pass
11	0.060	0.759	7.9	0.060	1.139	5.31	Pass
12	0.001	0.352	0.2	0.001	0.529	0.17	Pass
13	0.027	0.483	5.6	0.027	0.725	3.75	Pass
14	0.000	0.301	0.1	0.000	0.453	0.09	Pass
15	0.006	0.345	1.9	0.007	0.518	1.26	Pass
16	0.000	0.265	0.1	0.000	0.398	0.07	Pass
17	0.006	0.304	2.0	0.006	0.458	1.36	Pass
18	0.000	0.235	0.1	0.000	0.352	0.08	Pass
19	0.007	0.272	2.7	0.007	0.409	1.81	Pass
20	0.000	0.212	0.0	0.000	0.317	0.04	Pass
21	0.005	0.246	1.9	0.005	0.370	1.25	Pass
22	0.000	0.192	0.1	0.000	0.288	0.06	Pass
23	0.003	0.225	1.3	0.003	0.338	0.90	Pass
24	0.000	0.176	0.1	0.000	0.265	0.07	Pass
25	0.005	0.207	2.4	0.005	0.311	1.58	Pass
26	0.000	0.163	0.1	0.000	0.244	0.10	Pass
27	0.006	0.192	2.9	0.006	0.288	1.95	Pass
28	0.000	0.152	0.1	0.000	0.228	0.05	Pass
29	0.004	0.178	2.3	0.004	0.267	1.57	Pass
30	0.000	0.141	0.1	0.000	0.212	0.13	Pass
31	0.003	0.167	1.5	0.003	0.251	1.04	Pass
32	0.000	0.132	0.1	0.000	0.198	0.07	Pass
33	0.003	0.157	1.7	0.003	0.235	1.15	Pass
34	0.000	0.124	0.1	0.000	0.186	0.08	Pass
35	0.003	0.148	2.2	0.003	0.221	1.46	Pass
36	0.000	0.118	0.1	0.000	0.177	0.09	Pass
37	0.003	0.140	2.0	0.003	0.209	1.35	Pass
38	0.000	0.111	0.1	0.000	0.168	0.07	Pass
39	0.002	0.133	1.3	0.002	0.200	0.88	Pass
40	0.000	0.106	0.1	0.000	0.159	0.13	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Voltage Source Verification Data (Run time)

EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:39:40 AM** **End time: 11:50:02 AM**
Test duration (min): 10 **Data file name: H-000300.cts_data**
Comment: G100742469 PCOR 500488596 - 100V 50Hz
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	100.81	Frequency(Hz):	50.00
I_Peak (Amps):	1.527	I_RMS (Amps):	0.459
I_Fund (Amps):	0.280	Crest Factor:	3.335
Power (Watts):	25.3	Power Factor:	0.548

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.017	0.202	8.64	OK
3	0.063	0.907	6.99	OK
4	0.009	0.202	4.26	OK
5	0.047	0.403	11.78	OK
6	0.044	0.202	22.02	OK
7	0.040	0.302	13.25	OK
8	0.020	0.202	9.71	OK
9	0.034	0.202	16.94	OK
10	0.009	0.202	4.60	OK
11	0.025	0.101	25.20	OK
12	0.019	0.101	18.84	OK
13	0.013	0.101	12.48	OK
14	0.004	0.101	4.04	OK
15	0.004	0.101	4.37	OK
16	0.005	0.101	4.60	OK
17	0.007	0.101	7.07	OK
18	0.010	0.101	10.22	OK
19	0.006	0.101	5.56	OK
20	0.005	0.101	4.92	OK
21	0.006	0.101	5.70	OK
22	0.004	0.101	3.74	OK
23	0.004	0.101	3.64	OK
24	0.006	0.101	6.15	OK
25	0.003	0.101	2.65	OK
26	0.004	0.101	4.28	OK
27	0.008	0.101	7.67	OK
28	0.003	0.101	3.32	OK
29	0.003	0.101	3.43	OK
30	0.007	0.101	6.94	OK
31	0.004	0.101	4.09	OK
32	0.003	0.101	3.22	OK
33	0.006	0.101	6.05	OK
34	0.002	0.101	1.73	OK
35	0.005	0.101	5.14	OK
36	0.004	0.101	4.08	OK
37	0.005	0.101	4.64	OK
38	0.002	0.101	1.52	OK
39	0.002	0.101	2.29	OK
40	0.005	0.101	4.50	OK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

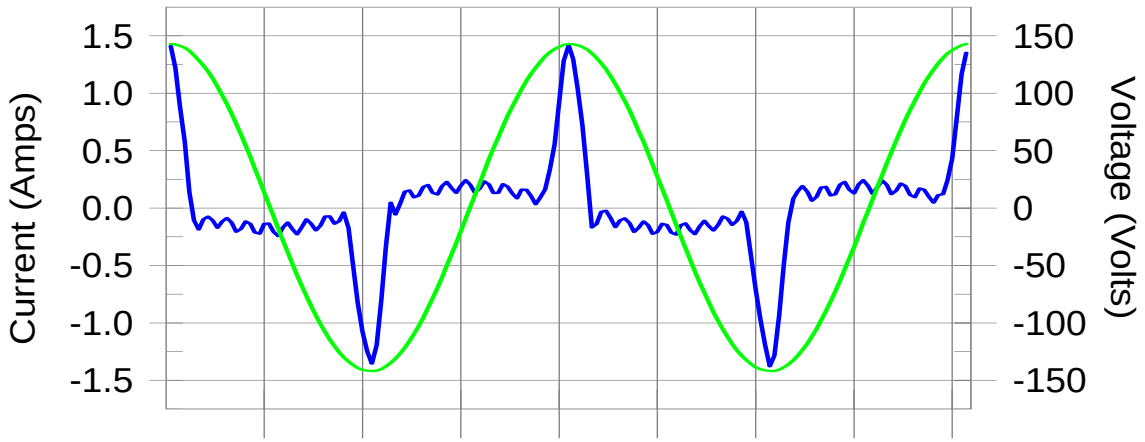
100V 60Hz

Harmonics – Class-A per Ed. 3.2 (2009)(Run time)

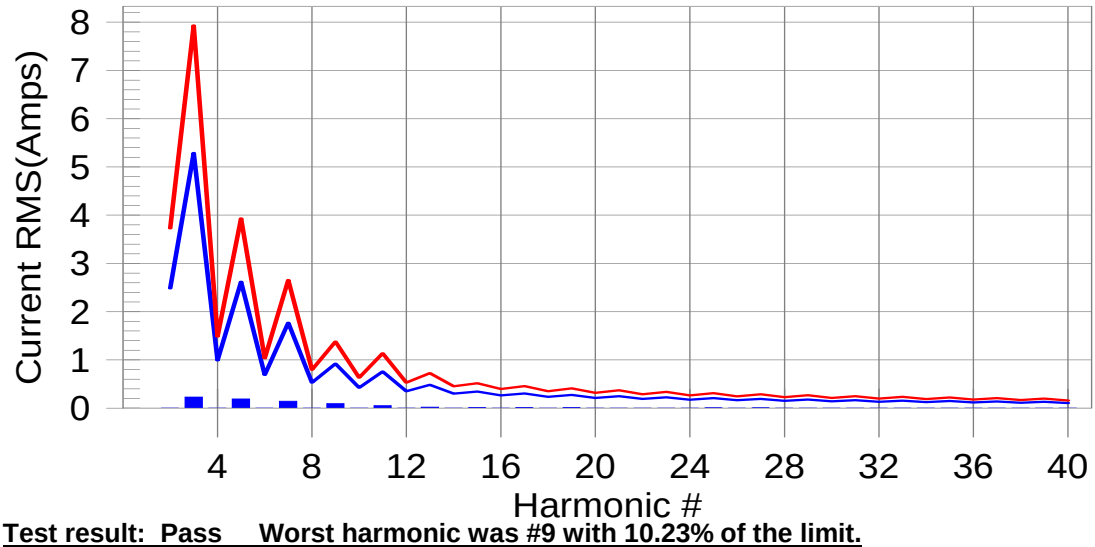
EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:27:12 AM** **End time: 11:37:34 AM**
Test duration (min): 10 **Data file name: H-000298.cts_data**
Comment: G100742469 PCOR 500488596 – 100V 60Hz
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **Japanese Limits**



Test result: Pass **Worst harmonic was #9 with 10.23% of the limit.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Current Test Result Summary (Run time)

EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:27:12 AM** **End time: 11:37:34 AM**
Test duration (min): 10 **Data file name: H-000298.cts_data**
Comment: G100742469 PCOR 500488596
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**
THC(A): 0.35 **I-THD(%): 123.03** **POHC(A): 0.008** **POHC Limit(A): 0.578**
Highest parameter values during test:

V_RMS (Volts):	100.82	Frequency(Hz):	60.00
I_Peak (Amps):	1.451	I_RMS (Amps):	0.454
I_Fund (Amps):	0.285	Crest Factor:	3.219
Power (Watts):	25.3	Power Factor:	0.555

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.002	2.484	0.1	0.003	3.726	0.07	Pass
3	0.229	5.290	4.3	0.230	7.935	2.90	Pass
4	0.001	0.989	0.1	0.002	1.484	0.13	Pass
5	0.191	2.622	7.3	0.191	3.933	4.87	Pass
6	0.001	0.690	0.1	0.001	1.035	0.09	Pass
7	0.143	1.771	8.1	0.144	2.657	5.41	Pass
8	0.001	0.529	0.2	0.001	0.794	0.17	Pass
9	0.094	0.920	10.2	0.094	1.380	6.84	Pass
10	0.001	0.423	0.2	0.001	0.635	0.18	Pass
11	0.052	0.759	6.8	0.052	1.139	4.55	Pass
12	0.001	0.352	0.2	0.001	0.529	0.15	Pass
13	0.021	0.483	4.4	0.022	0.725	2.98	Pass
14	0.000	0.301	0.1	0.000	0.453	0.11	Pass
15	0.009	0.345	2.6	0.009	0.518	1.80	Pass
16	0.000	0.265	0.1	0.000	0.398	0.11	Pass
17	0.010	0.304	3.4	0.011	0.458	2.31	Pass
18	0.000	0.235	0.1	0.000	0.352	0.06	Pass
19	0.008	0.272	3.0	0.008	0.409	2.05	Pass
20	0.000	0.212	0.1	0.000	0.317	0.08	Pass
21	0.004	0.246	1.7	0.004	0.370	1.16	Pass
22	0.000	0.192	0.1	0.000	0.288	0.08	Pass
23	0.004	0.225	2.0	0.005	0.338	1.34	Pass
24	0.000	0.176	0.1	0.000	0.265	0.08	Pass
25	0.006	0.207	2.9	0.006	0.311	1.97	Pass
26	0.000	0.163	0.1	0.000	0.244	0.13	Pass
27	0.005	0.192	2.9	0.006	0.288	1.94	Pass
28	0.000	0.152	0.1	0.000	0.228	0.10	Pass
29	0.004	0.178	2.0	0.004	0.267	1.37	Pass
30	0.000	0.141	0.1	0.000	0.212	0.08	Pass
31	0.003	0.167	1.9	0.003	0.251	1.29	Pass
32	0.000	0.132	0.1	0.000	0.198	0.13	Pass
33	0.004	0.157	2.6	0.004	0.235	1.76	Pass
34	0.000	0.124	0.1	0.000	0.186	0.08	Pass
35	0.004	0.148	2.6	0.004	0.221	1.75	Pass
36	0.000	0.118	0.1	0.000	0.177	0.16	Pass
37	0.003	0.140	2.1	0.003	0.209	1.41	Pass
38	0.000	0.111	0.1	0.000	0.168	0.12	Pass
39	0.002	0.133	1.7	0.002	0.200	1.16	Pass
40	0.000	0.106	0.2	0.000	0.159	0.19	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Voltage Source Verification Data (Run time)

EUT: Fore-Sight Elite **Tested by: Michael Houston**
Test category: Class-A per Ed. 3.2 (2009) (Japanese limits) **Test Margin: 100**
Test date: 11/12/2013 **Start time: 11:27:12 AM** **End time: 11:37:34 AM**
Test duration (min): 10 **Data file name: H-000298.cts_data**
Comment: G100742469 PCOR 500488596
Customer: CAS Medical Systems

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	100.82	Frequency(Hz):	60.00
I_Peak (Amps):	1.451	I_RMS (Amps):	0.454
I_Fund (Amps):	0.285	Crest Factor:	3.219
Power (Watts):	25.3	Power Factor:	0.555

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.119	0.202	58.97	OK
3	0.146	0.907	16.15	OK
4	0.064	0.202	31.93	OK
5	0.082	0.403	20.37	OK
6	0.036	0.202	17.94	OK
7	0.066	0.302	21.94	OK
8	0.040	0.202	19.85	OK
9	0.047	0.202	23.46	OK
10	0.024	0.202	12.07	OK
11	0.035	0.101	34.87	OK
12	0.008	0.101	8.25	OK
13	0.025	0.101	25.11	OK
14	0.013	0.101	12.95	OK
15	0.013	0.101	13.11	OK
16	0.009	0.101	9.01	OK
17	0.016	0.101	16.30	OK
18	0.006	0.101	6.23	OK
19	0.013	0.101	12.77	OK
20	0.007	0.101	7.10	OK
21	0.008	0.101	8.28	OK
22	0.005	0.101	5.37	OK
23	0.010	0.101	10.02	OK
24	0.004	0.101	4.10	OK
25	0.012	0.101	11.41	OK
26	0.006	0.101	5.76	OK
27	0.010	0.101	9.77	OK
28	0.004	0.101	3.95	OK
29	0.006	0.101	6.39	OK
30	0.004	0.101	3.92	OK
31	0.006	0.101	6.40	OK
32	0.004	0.101	3.69	OK
33	0.010	0.101	9.84	OK
34	0.003	0.101	2.49	OK
35	0.007	0.101	7.36	OK
36	0.004	0.101	3.77	OK
37	0.009	0.101	8.82	OK
38	0.002	0.101	2.17	OK
39	0.007	0.101	7.31	OK
40	0.003	0.101	2.75	OK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Personnel:	Gary Ball GB	Test Date:	08/01/2012
	Michael Houston MH		11/12/2013
Supervising/Reviewing Engineer: (Where Applicable)	N/A		
Product Standard:	IEC 60601-1-2	Test Levels:	See Data
Input Voltage:	230VAC/50 Hz, 100VAC/60 Hz	Ambient Temperature:	22, 23 ºC
Pretest Verification w/ Artifact:	Yes	Relative Humidity:	59, 40 %
		Atmospheric Pressure:	1001,1008 mbars

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

9 Flicker

9.1 Method

Tests are performed in accordance with IEC 61000-3-3.

TEST SITE: EMC

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

The AMAP Building and Lab includes general lab space that can be used for testing where a shielded/enclosed environment is not required.

9.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
SCH 8	EMC Test	Schaffner	MX45-3PI-CTSHL-SCH	43964	03/21/2012	03/21/2014

Software Utilized:

Name	Manufacturer	Version
Win2100V3	California Instruments Corp.	3.2.0.28

9.3 Results:

The sample tested was found to Comply.

9.4 Setup Photograph:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

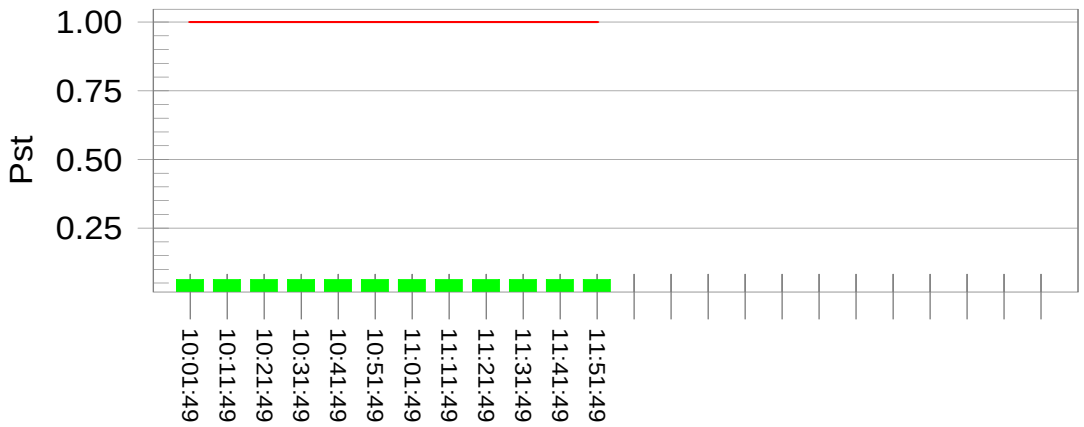
9.5 Plots/Data:

Flicker Test Summary per EN/IEC61000-3-3 (Run time)

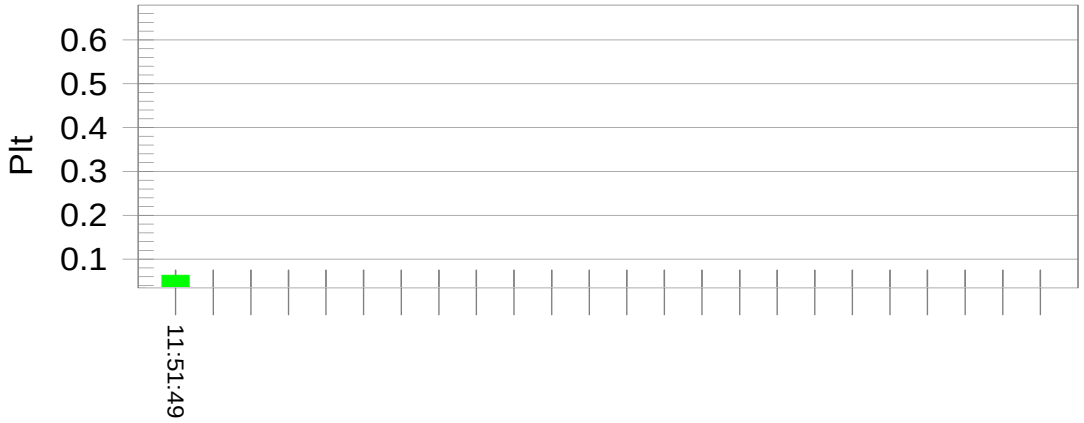
EUT: Model 3000 Oximetry **Tested by: Gary Ball**
Test category: All parameters (European limits) **Test Margin: 100**
Test date: 8/1/2012 **Start time: 9:51:29 AM** **End time: 11:51:50 AM**
Test duration (min): 120 **Data file name: F-000645.cts_data**
Comment: 230VAC 50Hz
Customer: CAS Medical

Test Result: Pass **Status: Test Completed**

Pst_i and limit line **European Limits**



Plt and limit line



Parameter values recorded during the test:

Vrms at the end of test (Volt):	**230.25**			
Highest dt (%):	**0.00**	**Test limit (%):**	**3.30**	**Pass**
Time(mS) > dt:	**0.0**	**Test limit (mS):**	**500.0**	**Pass**
Highest dc (%):	**0.00**	**Test limit (%):**	**3.30**	**Pass**
Highest dmax (%):	**0.00**	**Test limit (%):**	**4.00**	**Pass**
Highest Pst (10 min. period):	**0.064**	**Test limit:**	**1.000**	**Pass**
Highest Plt (2 hr. period):	**0.064**	**Test limit:**	**0.650**	**Pass**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Personnel:	Gary Ball GB	Test Date:	08/01/2012
Supervising/Reviewing Engineer: (Where Applicable)	N/A		
Product Standard:	IEC 60601-1-2	Test Levels:	See Data
Input Voltage:	230 VAC/50 Hz	Ambient Temperature:	22 ºC
Pretest Verification w/ Artifact:	Yes	Relative Humidity:	59 %
		Atmospheric Pressure:	1001 mbars

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

10 Electrostatic Discharge Immunity Test

10.1 Method

Tests are performed in accordance with IEC 61000-4-2.

TEST SITE: EMC LAB

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

The AMAP Building and Lab includes general lab space that can be used for testing where a shielded/enclosed environment is not required.

10.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Sch 12	ESD Test Set	Schaffner	NSG 438	588	02/20/2012	02/20/2013
Sen 01	Electrostatic Voltmeter	Sensitive Research	ESH	U24187	03/07/2011	03/07/2013
Dav 001	Weather Station	Davis Instruments	7400	PE80519A61	08/17/2011	08/17/2012

Testing performed on 11/13/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV001	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
147273	ESD Simulator	NoiseKen	ESS-2000	ESS0382050	10/15/2013	10/15/2014
Emc 82	1000X High Voltage Probe	Tektronix	P6015A	B055113	03/13/2013	03/13/2014
Agl002	1GHz 4CH O'Scope	Agilent Technologies	DSO6104A	MY44008115	08/02/2013	08/02/2014

Software Utilized:

Name	Manufacturer	Version
None		

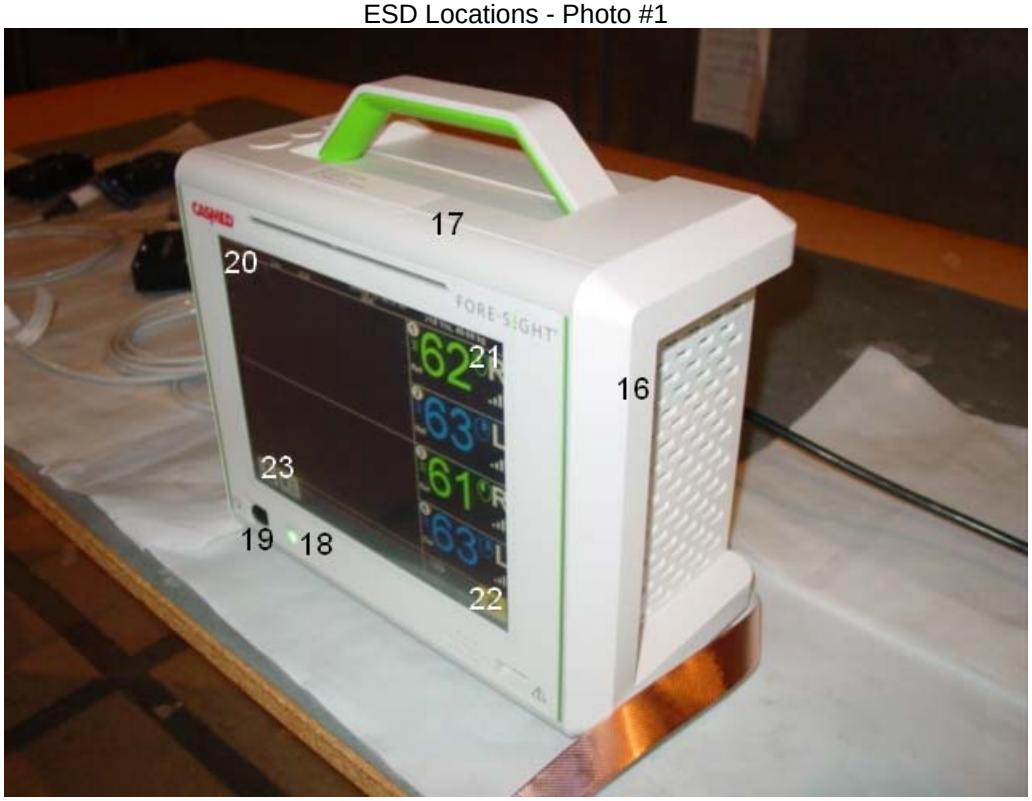
10.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

ESD Locations - Photo #1

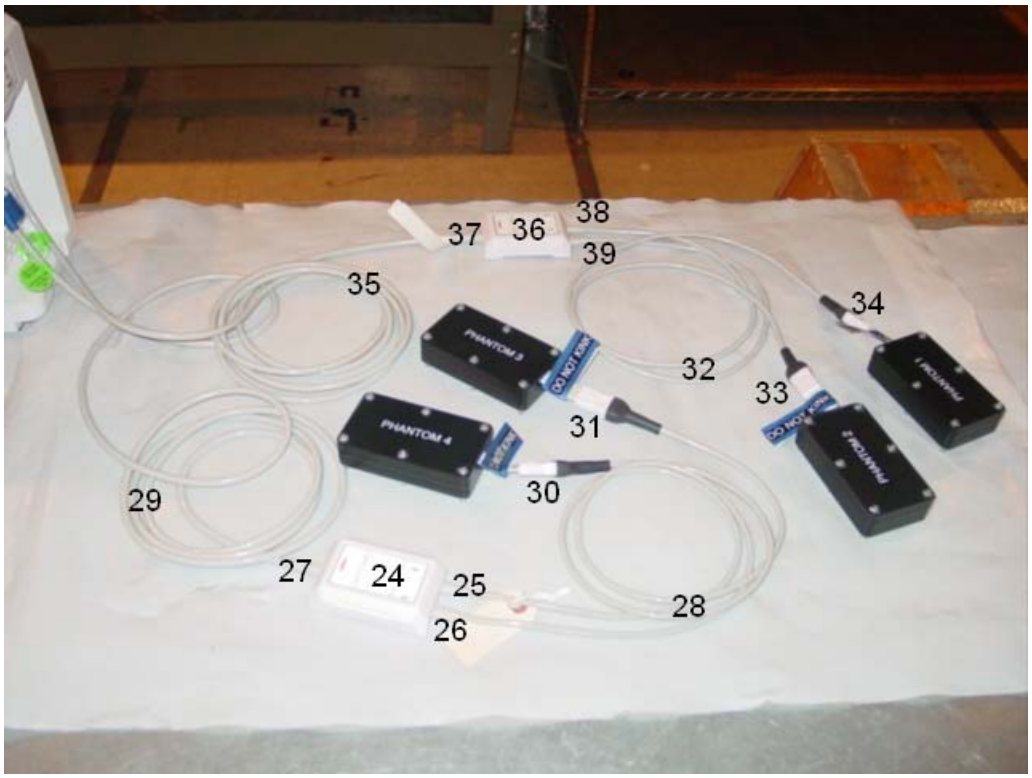


ESD Locations - Photo #2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

ESD Locations - Photo #3



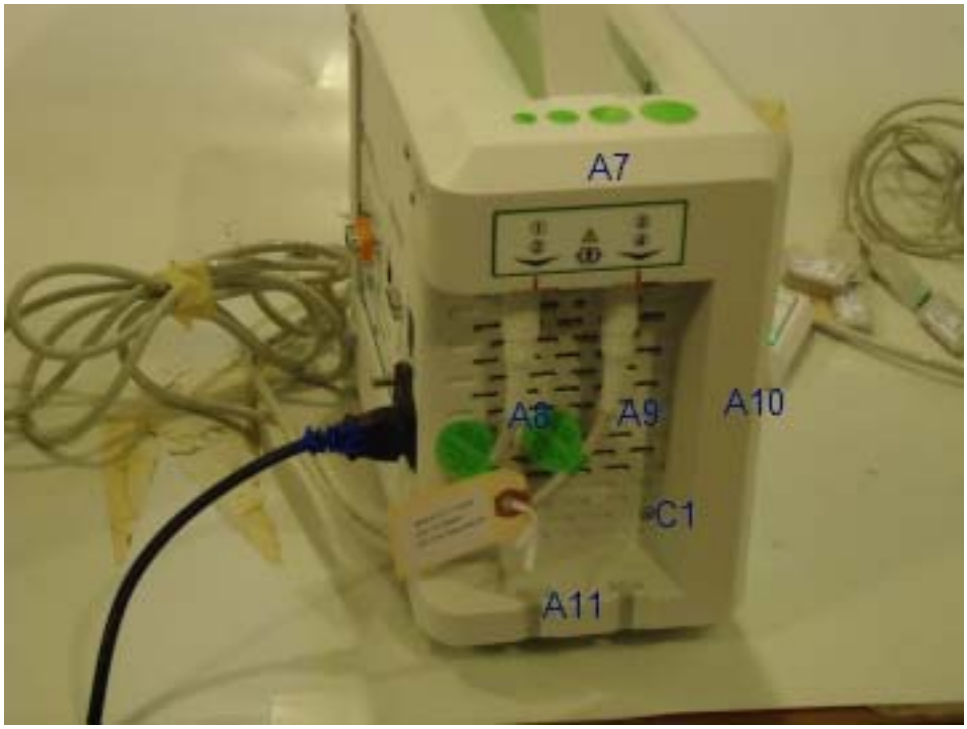
ESD Locations - Photo #4 100VAC 60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

ESD Locations - Photo #5 100VAC 60Hz

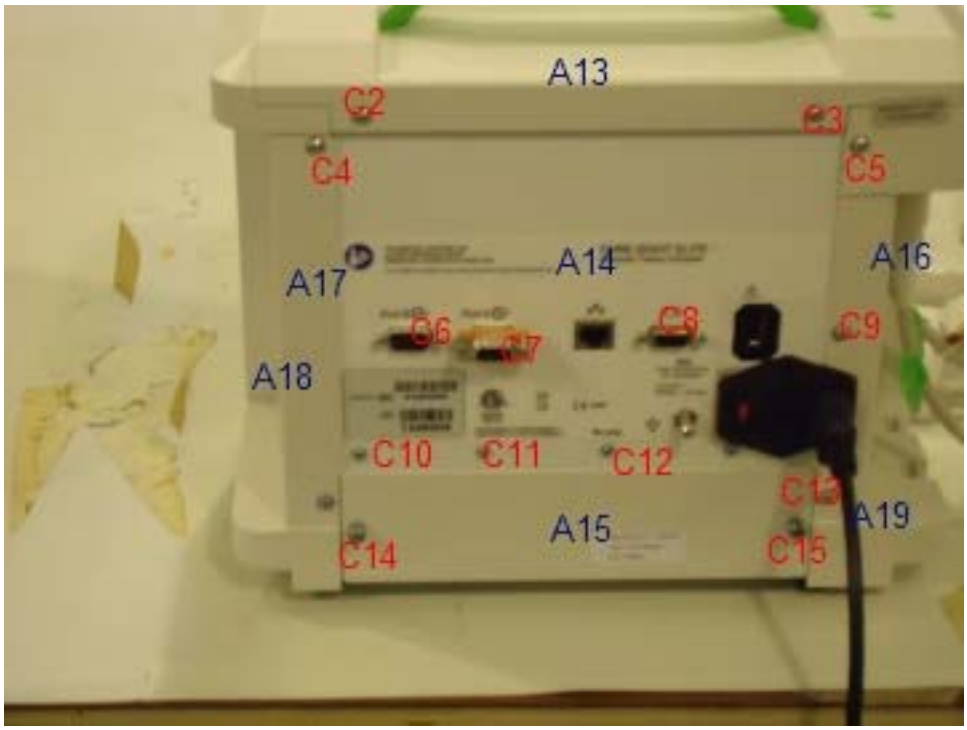
ESD Locations - Photo #6 100VAC 60Hz



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

ESD Locations - Photo #7 100VAC 60Hz



ESD Locations - Photo #8 100VAC 60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

10.4 Test Data:

230V 50Hz

Test Point	Discharge Voltage Type	Test Voltages, Polarities and Result Classification													
		2 kV		4 kV		6 kV		8 kV			15 kV		__ kV	
		Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg		Pos	Neg	Pos	Neg
HCP	Contact	(1)	(1)	(1)	(1)	(1)	(1)			Air Discharges only above 8 kV				
Edge	Contact	(2)	(2)	(2)	(2)	(2)	(2)							
VCP	Contact	(3)	(3)	(3)	(3)	(3)	(3)							
1	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
2	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
3	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
4	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
5	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
6	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
7	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
8	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
9	Contact	(4)	(4)	(4)	(4)	(4)	(4)							
10	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
11	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
12	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
13	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
14	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
15	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
16	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
17	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
18	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
19	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
20	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
21	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
22	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
23	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
24	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
25	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
26	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
27	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
28	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
29	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
30	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
31	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
32	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
33	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
34	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
35	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
36	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
37	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
38	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					
39	AIR	(5)	(5)	(5)	(5)	(5)	(5)	(5)	(5)					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz

Test Point	Discharge Voltage Type	Test Voltages, Polarities and Result Classification											
		2 kV		4 kV		6 kV		8 kV		15 kV		kV	
		Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
HCP	Contact	(6)	(6)	(6)	(6)	(6)	(6)						
VCP	Contact	(6)	(6)	(6)	(6)	(6)	(6)						
C1-C15	Contact	(6)	(6)	(6)	(6)	(6)	(6)						
A1-A28	Air	(6)	(6)	(6)	(6)	(6)	(6)	(6)	(6)				

Air Discharges only above 8 kV

Test Personnel: John R. Cauvel J.R.C

Rick Duval RD

Supervising/Reviewing Engineer: (Where Applicable) Tony L. TL

Product Standard: IEC 60601-1-2

Input Voltage: 230V 50Hz & 100V 60Hz

Verified on ESD Voltmeter: YES

470k x 2 Strap(s) Verified: YES

Test Date: 8-3-2012

11/13/2013

Test Levels: ±2kV, ±4kV, ±6kV, Contact
±2kV, ±4kV, ±8kV, Air

Performance Criteria: See Report Section 5.3

Ambient Temperature: 24, 23 ºC

Relative Humidity: 49, 40 %

Atmospheric Pressure: 1003, 1008 mbars

Notes:
(1) Discharged to Horizontal Coupling Plane, 4 locations.
(2) Discharged to front edge of Horizontal Coupling Plane
(3) Discharged to Vertical Coupling Plane, 4 locations
(4) No degradation of performance observed.
(5) Entire surface swept, No discharges observed, no change in operation.
(6) The EUT met the requirements without any degradation of performance.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

11 Radiated, radio-frequency, electromagnetic field immunity test

11.1 Method

Tests are performed in accordance with IEC 61000-4-3.

TEST SITE: Large Enclosure EMC

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

11.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
AMP 32	Antenna, Log Periodic, 80 - 1000MHz	Amplifier Research	AT1080	19465	VBU	Verified
EMC 03	ANTENNA, RIDGED GUIDE, 1-18 GHZ	EMCO	3115	2878	VBU	Verified
KAL 02	AMPLIF ER; 1kW; 10kHz-200MHz	Kalmus	137C/1-60-105-002	8044-1	VBU	Verified
OPH 001	RF Amplifier	Ophir RF	5227FE	1001	VBU	Verified
HEW 46	METER, POWER	Hewlett Packard	436A/022	2604A23768	04/05/2012	04/05/2013
HEW 63	Generator, Signal	Hewlett Packard	8648C	3847A05291	01/23/2012	01/23/2013
AMP 12	Isotropic Field Monitor	Amplifier Research	FM2000	14937	VBU	Verified
AMP 37	AMPLIF ER 50W .8 - 4.2GHz	Amplifier Research	50S1G4A	29183	11/2/2000	Verified
WER 3	COUPLER, BI-DIRECTIONAL	Werlatone inc.	C3910	5283	01/29/2012	01/29/2013
AMP 36	Dual Directional Coupler	Amplifier Research	DC7144, .8 - 4 2GHz	28765	01/24/2012	01/24/2013
AMP 12	Isotropic Field Monitor	Amplifier Research	FM2000	14937	VBU	Verified

Test equipment used on 11/14/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Dav001'	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
Oph001'	RF Amplifier	Ophir RF	5227FE	1001	VBU	Verified
Hew46'	METER, POWER	Hewlett Packard	436A/022	2604A23768	04/11/2013	04/11/2014
Hew63'	Generator, Signal	Hewlett Packard	8648C	3847A05291	01/25/2013	01/25/2014
Amp37"	AMPLIF ER, 50W, .8 - 4.2GHz	Amplifier Research	50S1G4A	29183	11/2/2000	Verified
Amp9'	Isotropic Field Monitor	Amplifier Research	FM2000	16839	VBU	Verified
Wer4'	COUPLER, BI-DIRECTIONAL	Werlatone inc.	C3910	5284	04/27/2013	04/27/2014
Amp36'	Dual Directional Coupler	Amplifier Research	DC7144, .8 - 4 2GHz	28765	01/28/2013	01/28/2014
Hew48'	SENSOR, POWER	Hewlett Packard	8481A	1928A17048	04/11/2013	04/11/2014
147085'	Antenna , BiLog	Schaffner	CBL 6140A	1201	11/18/2003	Verified
Emc03'	ANTENNA, RIDGED GUIDE, 1-18 GHZ	EMCO	3115	2878	VBU	Verified
TEL154'	Function Generator, .002 Hz to 2 MHz	Leader Electronics C	LFG-1300S	1040413	04/12/2013	04/12/2014

Software Utilized:

Name	Manufacturer	Version
TILE	Quantum Change	3.4.J.2

11.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

11.4 Setup Photographs:

100V 60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.5 Test Data:

230V 50Hz

Field Level (V/m)	Frequency Range MHz	Antenna Polarity, Azimuths and Result Classification							
		Vertical				Horizontal			
		0	90	180	270	0	90	180	270
3	80-2500	A(1)	A(1)	A(1)	A(1)	A(1)	A(1)	A(1)	A(1)

100V 50Hz

Field Level (V/m)	Frequency Range MHz	Antenna Polarity, Azimuths and Result Classification							
		Vertical				Horizontal			
		0	90	180	270	0	90	180	270
3	80-2500	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)

Test Personnel:	Gary Ball GB	Test Date:	08/03/2012
	Rick Duval RD		11/14/2013
Supervising/Reviewing Engineer: (Where Applicable)	N/A		
Product Standard:	IEC 60601-1-2	Test Levels:	3 V/m, 80% AM @ 1 kHz
Input Voltage:	230 V/50 Hz, 100 V/60 Hz	Performance Criteria:	See Report Section 5.3
		Ambient Temperature:	21,20 ºC
Field Level Monitored:	Yes	Relative Humidity:	62,12 %
		Atmospheric Pressure:	1004,1009 mbars

Notes:

(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

12 Electrical Fast Transient/Burst Immunity Test

12.1 Method

Tests are performed in accordance with IEC 61000-4-4.

TEST SITE: EMC Lab

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

12.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
SAF 774	Digital Storage Oscilloscope	Agilent	DSO6104A	MY50340108	01/11/2012	01/11/2013
Emc 82	1000X High Voltage Probe	Tektronix	P6015A	B055113	03/09/2012	03/09/2013
The 001	EMC Immunity Test System	Thermo Fisher	EMCPro Plus	0809207	02/10/2012	02/10/2013
Dav 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012

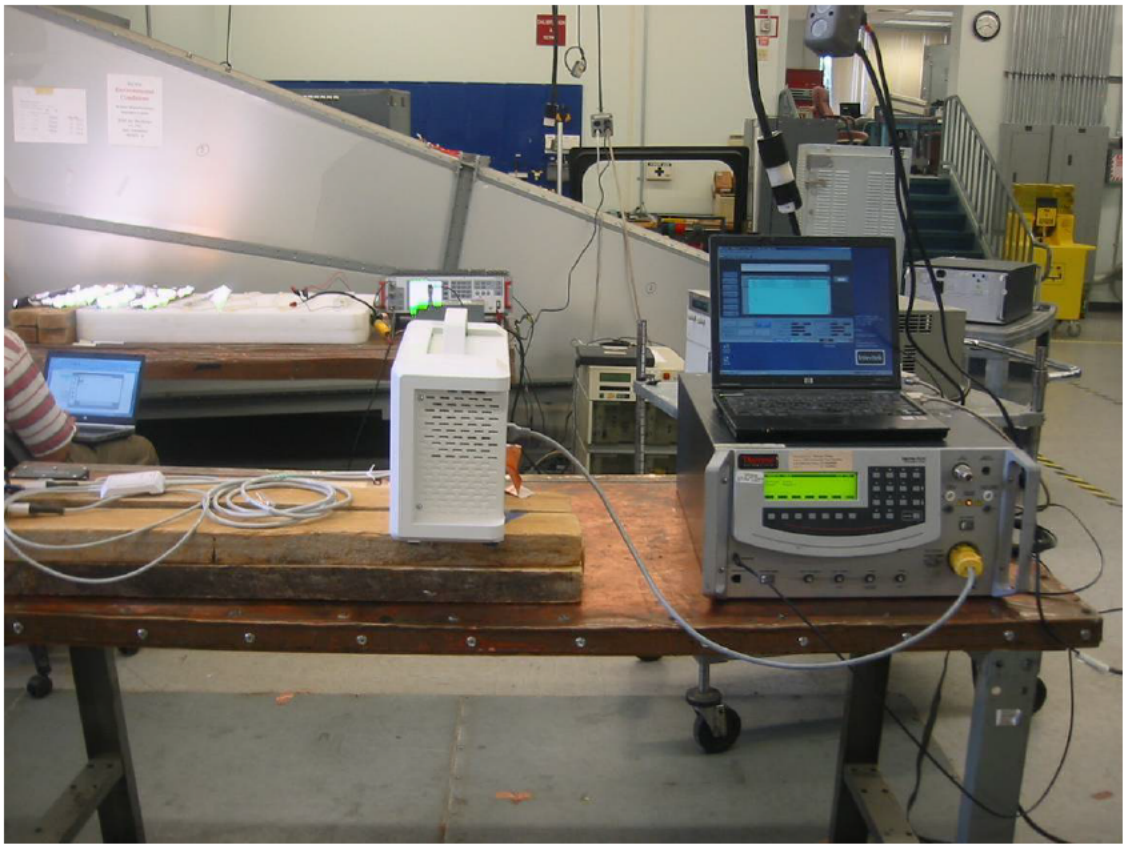
Software Utilized:

Name	Manufacturer	Version
CEWare32	Thermo Electron Corporation	4.00

12.3 Results:

The sample tested was found to Comply.

12.4 Setup Photographs:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

12.5 Test Data:

Test Point	Coupling Method	Test Voltages, Polarities, and Result Classification									
		0.25kV		0.5kV		1 kV		2 kV		4 kV	
		pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
Power L1	Direct			(1)	(1)	(1)	(1)	(1)	(1)		
Power L2	Direct			(1)	(1)	(1)	(1)	(1)	(1)		
Power PE	Direct			(1)	(1)	(1)	(1)	(1)	(1)		

Test Personnel: Gary Ball GB
Supervising/Reviewing Engineer: (Where Applicable) N/A
Product Standard: IEC 60601-1-2
Input Voltage: 100 VAC/60 Hz, 240 VAC/50 Hz
Waveform verified on Oscilloscope: Yes

Test Date: 08/01-02/2012
Test Levels: 500V 1 & 2kV
Performance Criteria: See Report Section 5.3
Ambient Temperature: 22, 21 ºC
Relative Humidity: 50, 64 %
Atmospheric Pressure: 1001, 1000 mbars

Notes:
(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

13 Immunity to Surge

13.1 Method

Tests are performed in accordance with IEC 61000-4-5.

TEST SITE: EMC Lab

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

13.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
SAF 774	Digital Storage Oscilloscope	Agilent	DSO6104A	MY50340108	01/11/2012	01/11/2013
Emc 82	1000X High Voltage Probe	Tektronix	P6015A	B055113	03/09/2012	03/09/2013
The 001	EMC Immunity Test System	Thermo Fisher	EMCPro Plus	0809207	02/10/2012	02/10/2013
Dav 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012

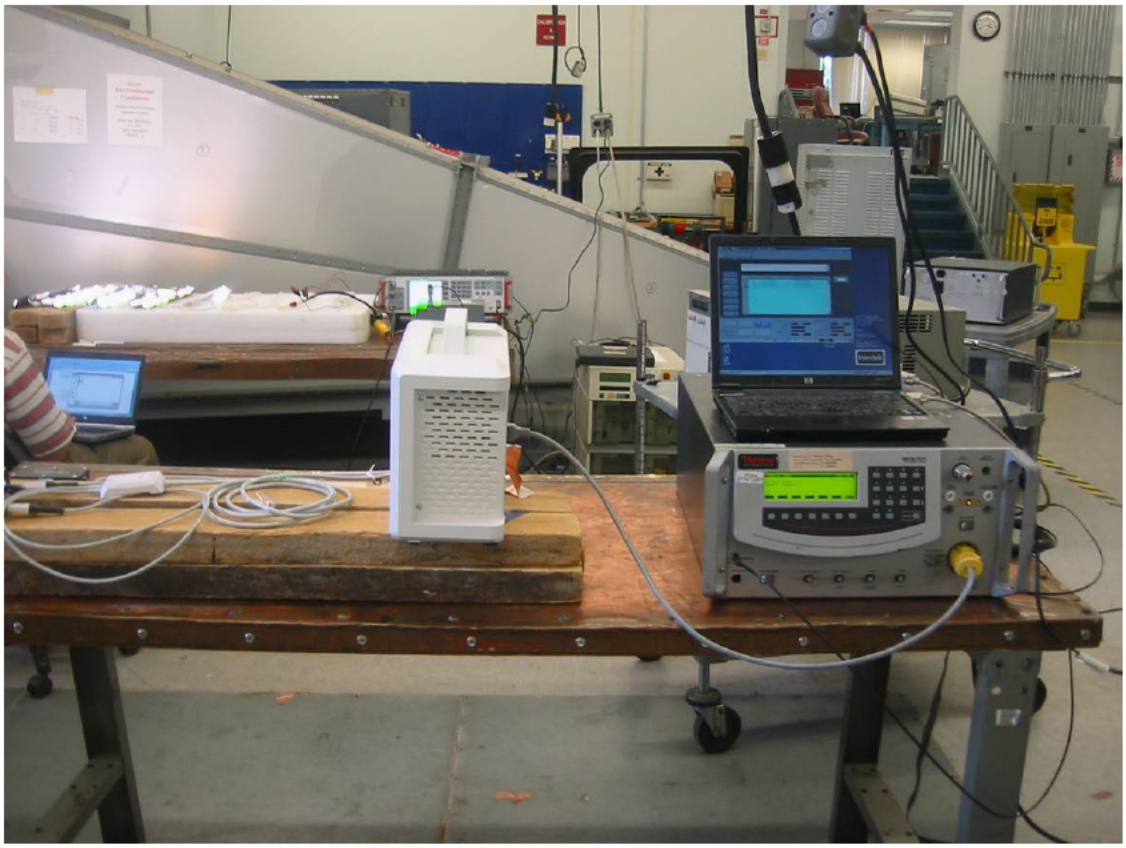
Software Utilized:

Name	Manufacturer	Version
CEWare32	Thermo Electron Corporation	4.00

13.3 Results:

The sample tested was found to Comply.

13.4 Setup Photograph:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

13.5 Test Data:

Test	Test Voltages, Polarities, and Result Classification							
	0.5kV		1kV		2kV		4kV	
	pos	neg	pos	neg	pos	neg	pos	neg
L1-PE, at 0 deg	(1)	(1)	(1)	(1)	(1)	(1)		
L1-PE, at 90 deg	(1)	(1)	(1)	(1)	(1)	(1)		
L1-PE, at 180 deg	(1)	(1)	(1)	(1)	(1)	(1)		
L1-PE, at 270 deg	(1)	(1)	(1)	(1)	(1)	(1)		
N-PE, at 0 deg	(1)	(1)	(1)	(1)	(1)	(1)		
N-PE, at 90 deg	(1)	(1)	(1)	(1)	(1)	(1)		
N-PE, at 180 deg	(1)	(1)	(1)	(1)	(1)	(1)		
N-PE, at 270 deg	(1)	(1)	(1)	(1)	(1)	(1)		
L1-N, at 0 deg	(1)	(1)	(1)	(1)				
L1-N, at 90 deg	(1)	(1)	(1)	(1)				
L1-N, at 180 deg	(1)	(1)	(1)	(1)				
L1-N, at 270 deg	(1)	(1)	(1)	(1)				

Gary Ball GB

Test Personnel: John R. Cauvel J.R.C

Supervising/Reviewing Engineer: (Where Applicable) Gary Ball GB

Product Standard: IEC 60601-1-2

Input Voltage: 100 VAC/60 240 VAC/50

Waveform verified on Oscilloscope: Yes

Test Date: 08/02/2012

Test Levels: 500V 1 & 2kV

Performance Criteria: See Report Section 5.3

Ambient Temperature: 21 ºC

Relative Humidity: 64 %

Atmospheric Pressure: 1000 mbars

Test Matrix	Line to Physical Earth (ground)	Line to Line (or Neutral)
AC:	2kV	500V & 1kV
DC:	N/A	N/A
Indoor Signal:	N/A	N/A
Outdoor Signal:	N/A	N/A

Notes:
(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

14 Conducted, radio-frequency, electromagnetic field immunity test

14.1 Method

Tests are performed in accordance with IEC 61000-4-6.

TEST SITE: EMC

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

14.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
FCC 16	Coupling, Decoupling Network	Fischer Custom Commu	FCC-801-M3-25	157	02/15/2011	02/15/2013
FCC 15	Kit, Calibration	Fischer Custom Commu	FCC-801-150-50-CDN	744 & 745	03/05/2012	03/05/2013
TES 002	Conducted RF Immunity Test Set	Teseq Ltd	NSG 4070	25826	04/23/2012	04/23/2013

Test equipment used on 13/11/2013

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV001'	Weather Station	Davis Instruments	7400	PE80519A61	08/28/2012	08/28/2014
EMC 63'	50-150 Ohm Adapter Set	Fischer Custom Comm.	FCC-150-50	310 and 311	09/02/2012	09/02/2013
TES002'	Conducted RF Immunity Test Set	Teseq Ltd	NSG 4070	25826	10/02/2013	10/02/2014
TEG8'	CAL BRATION JIG	Tegam	95241-1	12542	VBU	Verified
TEG10'	PROBE, CURRENT INJECTION	Tegam	95236-1	12499	VBU	Verified

Software Utilized:

Name	Manufacturer	Version
None		

14.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

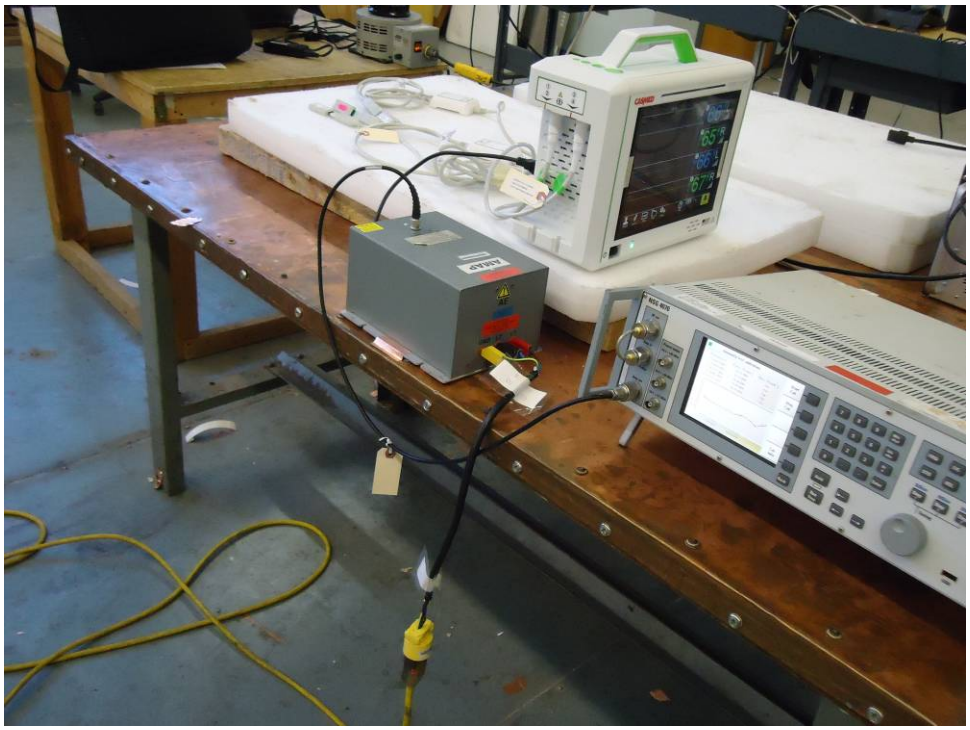
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

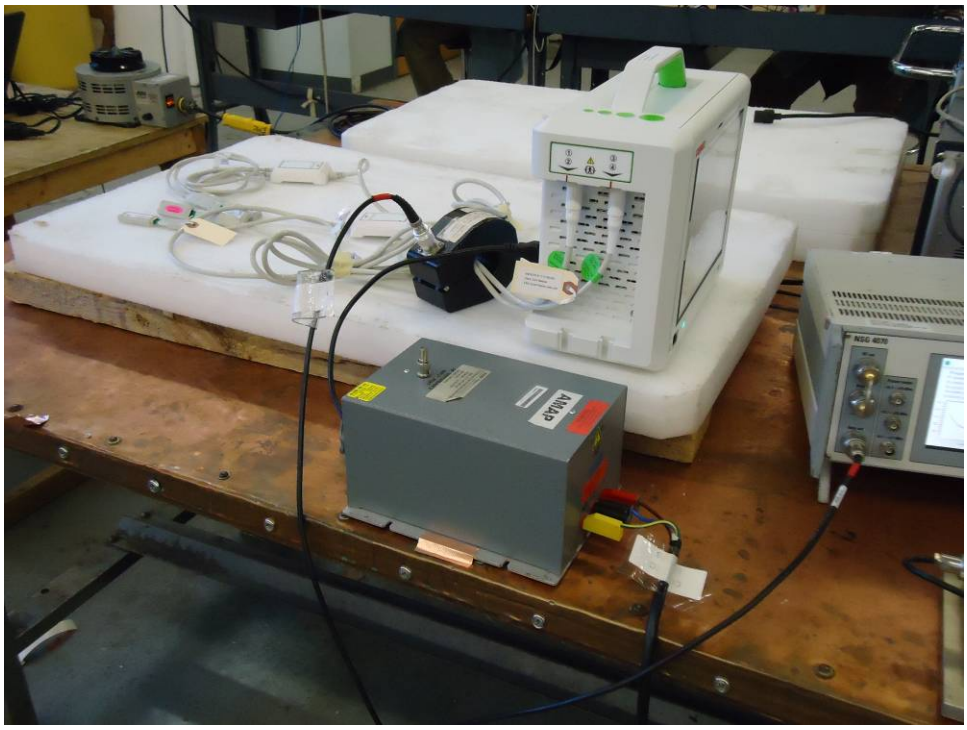
14.4 Setup Photographs:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

100V 60Hz





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

14.5 Test Data:

Injection Device Type	Port Description	Test Level (Vrms)	Result Classification
CDN	AC	3	(1)
Clamp	I/O Patient Leads	3	(1)

Testing Conducted on 11/13/2013

Injection Device Type	Port Description	Test Level (Vrms)	Result Classification
CDN	AC	3	(1)
Clamp	I/O Patient Leads	3	(1)

Test Personnel: Gary Ball GB
Rick Duval RD
Supervising/Reviewing Engineer: (Where Applicable) N/A
Product Standard: IEC 60601-1-2
Input Voltage: 230VAC/50Hz,100VAC/60Hz
Test Level Verification Performed: Yes

Test Date: 08/01/2012
11/13/2013
Test Levels: 3Vrms, 80% AM @ 1 kHz
Performance Criteria: See Report Section 5.3
Ambient Temperature: 22, 23 ºC
Relative Humidity: 59, 40 %
Atmospheric Pressure: 1001,1008 mbars

Notes:
(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

15 Power Frequency Magnetic Field Immunity Test

15.1 Method

Tests are performed in accordance with IEC 61000-4-8.

TEST SITE: EMC LAB

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

15.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Nar 011	Exposure Level Tester ELT-400	NARDA	2304/04	N-0024	11/21/2011	11/21/2012
Nar 012	B-Field Probe 100 cm2	NARDA	2300/90.10	M-0466	11/21/2011	11/21/2012
Dav 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012
Emc 34	Magnetic Field Test Generator	Fischer Custom Commu	F-1000-4-8-G	28	VBU	Verified
Hew 42	HARMONIC/FLICKER TEST SYSTEM	Hewlett Packard	6843A	3531A00114	05/02/2012	05/02/2014

Software Utilized:

Name	Manufacturer	Version
None		

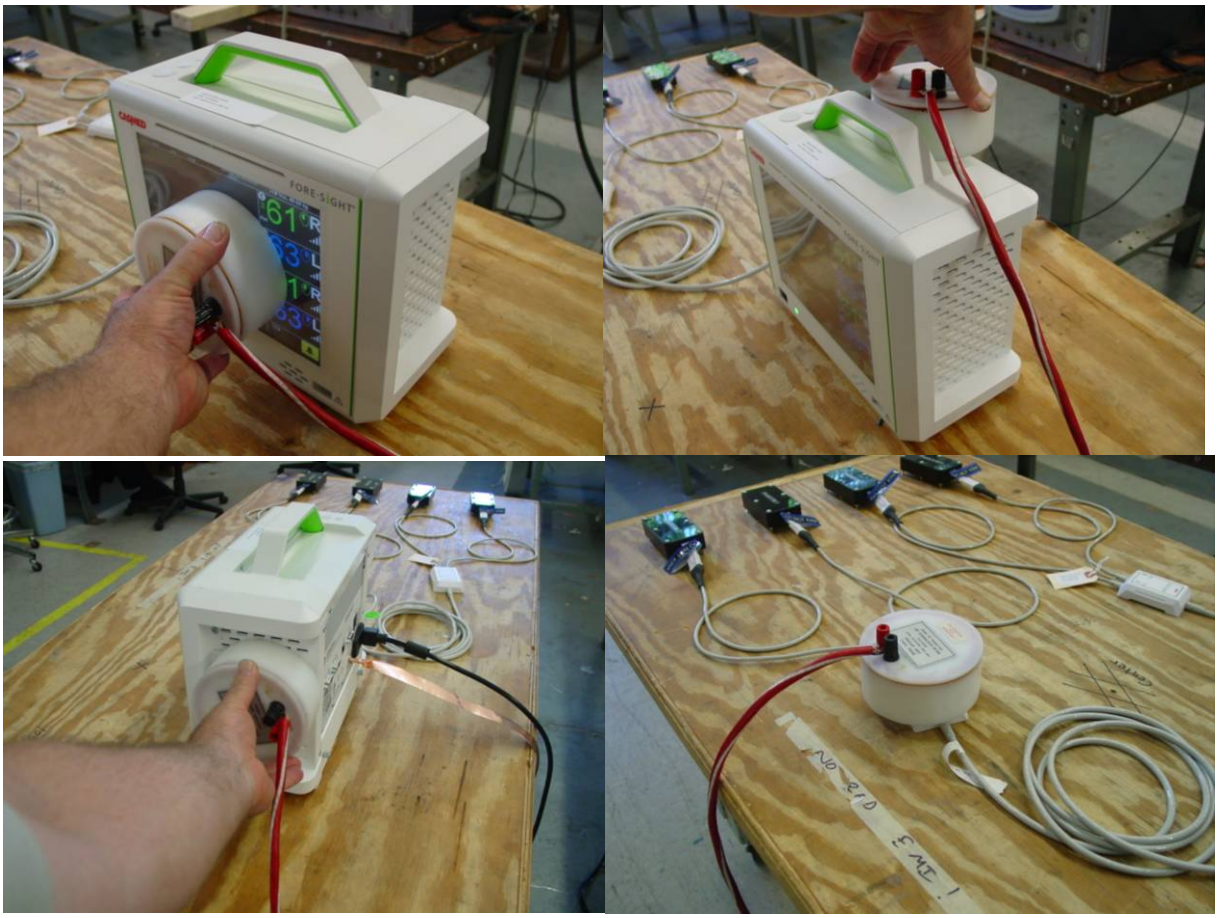
15.3 Results:

The sample tested was found to Comply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

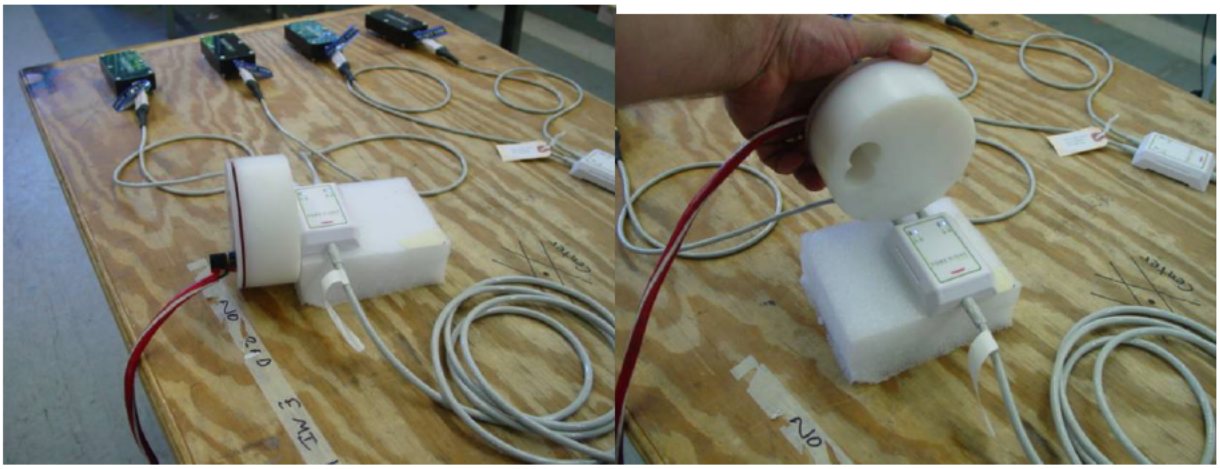
Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

15.4 Setup Photographs:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015



15.5 Test Data:

Test Location/ Mode/ EUT AC Input	Test Level (A/m)	Frequency (Hz)	Result Classification		
			X – Axis	Y – Axis	Z – Axis
Enclosure/ Operating/ 100V 50 Hz	3	50	(1)	(1)	(1)
Enclosure/ Operating/ 100V 60 Hz	3	60	(1)	(1)	(1)

Test Personnel: Gary Ball GB
Supervising/Reviewing Engineer: (Where Applicable) N/A
Product Standard: IEC 60601-1-2
Input Voltage: 100V 50/60Hz
Ambient Field Level: 0.048 microTesla
Test Field Level Verified: YES

Test Date: 8-3-2012
Test Levels: 3A/m
Performance Criteria: See Report Section 5.3
Ambient Temperature: 21 ºC
Relative Humidity: 60 %
Atmospheric Pressure: 1007 mbars

Notes:
(1) No degradation of performance was observed.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

16 Voltage Dips / Interruptions Immunity Tests

16.1 Method

Tests are performed in accordance with IEC 61000-4-11.

TEST SITE: EMC Lab

The EMC Lab has two Semi-anechoic Chambers and one Shielded Chamber. AC Mains Power is available at 120, 230, and 277 Single Phase; 208, 400, and 480 3-Phase. Large reference ground-planes are installed in the general lab area to facilitate EMC work not requiring a shielded environment.

16.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
The 002	EMC Immunity Test System	Thermo Fisher	EMCPro Plus	0809208	01/10/2012	01/10/2013
Tek 3	OSCILLOSCOPE	Tektronix	2440	B010178	08/24/2011	08/24/2012
Emc 82	1000X High Voltage Probe	Tektronix	P6015A	B055113	03/09/2012	03/09/2013
Dav 004	Weather Station	Davis Instruments	7400	PE80529A61A	08/17/2011	08/17/2012

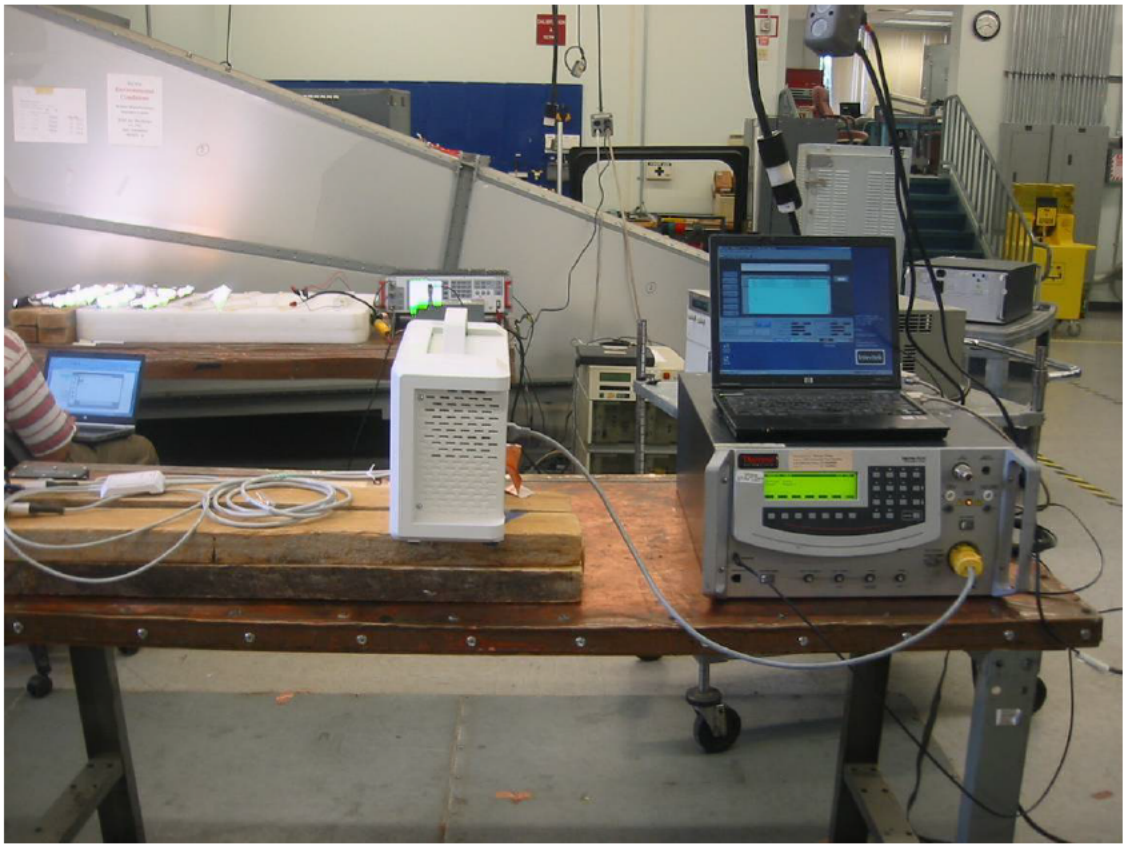
Software Utilized:

Name	Manufacturer	Version
CEWare32	Thermo Electron Corporation	4.00

16.3 Results:

The sample tested was found to Comply.

16.4 Setup Photograph:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

16.5 Test Data:

Specification	Rated Voltage (Vac)	Frequency (Hz)	Voltage Test Level (%)	Voltage Dip (%)	Test Voltage (Vac)	Duration (Periods)	Result Classification	
							0 deg	180 deg
Test Specification #1	100	50	0	100	0	.5	1	1
Test Specification #2	100	50	40	60	40	5	1	N/A
Test Specification #3	100	50	70	30	70	25	1	N/A
Test Specification #4	100	50	0	100	0	250	2	N/A
Test Specification #1	240	50	0	100	0	.5	1	1
Test Specification #2	240	50	40	60	96	5	1	N/A
Test Specification #3	240	50	70	30	168	25	1	N/A
Test Specification #4	240	50	0	100	0	250	2	N/A

Test Personnel: John R. Cauvel J.R.C
Supervising/Reviewing Engineer: (Where Applicable) Vathana Ven VJV
Product Standard: IEC 60601-1-2
Input Voltage: 100V/50Hz, 240V/50Hz
Waveform Verified on Oscilloscope: YES

Test Date: 8-2-2012
Test Levels: See Data Table
Performance Criteria: See Report Section 5.3
Ambient Temperature: 21 ºC
Relative Humidity: 60 %
Atmospheric Pressure: 1002 mbars

Notes:
(1) No degradation of performance was observed.
(2) AC Indicator light extinguished for the 5 second dropout, then lit when power was restored, no alarm was triggered, no change in operation.

Deviations, Additions, or Exclusions: None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

17 Section 5 User Information and Guidance Tables

5.2.1 Instructions for Use

The following statements need to be included in the user's manual for all equipment and systems:

1) "Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents."
2) "Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment."

5.2.2.1 Technical Description

The following information must be included in the Accompanying Documents provided to the end user for all equipment and systems:

a) A list of all cables and maximum lengths of cables (if applicable), transducers and other accessories with which the manufacturer claims compliance with the requirements of IEC60601-1-2 ed3.0 (2007-03) Sections 6.1 and 6.2.
b) A warning: "The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system."
c) Guidance Table 1 must be provided to the end user.
d) A warning: "The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used."
e) A justification must be provided for each reduced compliance level that is lower than the published levels for immunity tests in IEC 60601. The justifications must be based on physical, technological or physiological limitations that prevent compliance with the published test levels.
f) Guidance Table 2 must be provided to the end user.

5.2.2.2 Technical Description

The following information must be included in the Accompanying Documents provided to the end user for all equipment and systems:

Guidance Tables 4 and 6 must be provided to the end user for equipment and systems that are not Life-Supporting.

5.2.2.4 Guidelines to Include

For Equipment and Systems that intentionally apply RF energy for diagnosis or treatment, the accompanying documents shall include guidelines for avoiding or identifying and resolving adverse electromagnetic effects on other equipment that may result from operation of the Equipment or System.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

5.2.2.5 Accompanying Documents to Include

For Equipment that intentionally receive RF electromagnetic energy for the purpose of their operation, the accompanying documents shall include each frequency or frequency band of reception; the preferred frequency or frequency band, if applicable, and the bandwidth of the receiving section in those bands. A warning that ME Equipment/Systems may be interfered with by other equipment, even if that other equipment complies with CISPR Emissions requirements, must also be included.

5.2.2.6 Accompanying Documents to Include

For Equipment that include RF Transmitters, the accompanying documents shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the Effective Radiated Power (ERP).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Table 1 – Guidance and Manufacturer's Declaration – Emissions
All ME Equipment and ME Systems

Guidance and Manufacturer's Declaration - Emissions
The is intended for use in the electromagnetic environment specified below. The customer or user of the FORE-SIGHT Elite Absolute Tissue Oximeter should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The FORE-SIGHT Elite Absolute Tissue Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The FORE-SIGHT Elite Absolute Tissue Oximeter is suitable for use in all establishments, **other than** domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Table 2 – Guidance and Manufacturer's Declaration – Immunity
All ME Equipment and ME Systems

Guidance and Manufacturer's Declaration – Immunity
The FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use in the electromagnetic environment specified below. The customer or user of the FORE-SIGHT Elite Absolute Tissue Oximeter should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	Level 3 +/-6kV Contact +/- 8kV Air	Level 3 +/-6kV Contact +/- 8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FORE-SIGHT Elite Absolute Tissue Oximeter requires continued operation during power mains interruptions, it is recommended that the FORE-SIGHT Elite Absolute Tissue Oximeter be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Table 4 – Guidance and Manufacturer's Declaration – Immunity
ME Equipment and ME Systems that are NOT Life-supporting

Guidance and Manufacturer's Declaration – Immunity
The FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use in the electromagnetic environment specified below. The customer or user of the FORE-SIGHT Elite Absolute Tissue Oximeter should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	(V1)=3Vrms (E1)=3V/m	Portable and mobile communications equipment should be separated from the FORE-SIGHT Elite Absolute Tissue Oximeter by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150kHz to 80MHz D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Table 6 – Recommended Separation Distances between portable and mobile RF Communications equipment and the FORE-SIGHT Elite Absolute Tissue Oximeter
ME Equipment and ME Systems that are NOT Life-supporting

Recommended Separations Distances for the FORE-SIGHT Elite Absolute Tissue Oximeter
The FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the FORE-SIGHT Elite Absolute Tissue Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the FORE-SIGHT Elite Absolute Tissue Oximeter as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800MHz to 2.5GHz D=(7/E1)(Sqrt P)
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

18 Revision History

Revision Level	Date	Report Number	Prepared By	Reviewed By	Notes
0	11/13/2013	10742469BOX-008a	rd RD	KPS KPS	Original Issue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Report issued under the responsibility of:

Intertek

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	100742469BOX-001
Date of issue.....:	2012, November 15, M2: 2013-11-05
Total number of pages.....:	22 .....
CB Testing Laboratory.....:	Intertek Testing Services NA Inc.
Address.....:	70 Codman Hill Road Boxborough, MA 01719 USA
Applicant's name .....:	CAS Medical Systems Inc.
Address.....:	44 East Industrial Road Branford, CT 06405, USA
Test specification:	
Standard .....:	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
Test procedure.....:	CB Scheme
Non-standard test method……..:	
Test Report Form No.....:	IEC60601_1G
Test Report Form Originator.....:	Underwriters Laboratories Inc.
Master TRF.....:	Dated 2010-11

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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo shall be removed

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description.....:	Absolute Tissue Oximeter
Trade Mark .....:	CASMED®
Manufacturer.....:	Same as Applicant
Model/Type reference.....:	FORE-SIGHT Elite 01-06-3000 (US) and 01-06-3005 (OUS)
Ratings.....:	100-240 V~, 50/60 Hz, 1.5 A Max

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Testing procedure and testing location:	
☒ CB Testing Laboratory:	Intertek Testing Services NA Inc.
Testing location/ address ..... :	70 Codman Hill Road Boxborough, MA 01719 USA
☐ Associated CB Test Laboratory:	
Testing location/ address ..... :	
Tested by (name + signature)..... :	Brett Gagnon
Approved by (+ signature) ..... :	Tell Bailey
☐ Testing procedure: TMP	
Tested by (name + signature)..... :	
Approved by (+ signature) ..... :	
Testing location/ address ..... :	
☐ Testing procedure: WMT	
Tested by (name + signature)..... :	
Witnessed by (+ signature) ..... :	
Approved by (+ signature) ..... :	
Testing location/ address ..... :	
☐ Testing procedure: SMT	
Tested by (name + signature)..... :	
Approved by (+ signature) ..... :	
Supervised by (+ signature)..... :	
Testing location/ address ..... :	
☐ Testing procedure: RMT	
Tested by (name + signature)..... :	
Approved by (+ signature) ..... :	
Supervised by (+ signature)..... :	
Testing location/ address ..... :	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

List of Attachments (including a total number of pages in each attachment):

N/A		

Summary of testing:

Tests performed (name of test and test clause):

Clause	Test
8.7.4.5	Earth Leakage Current
8.7.4.6	Touch Leakage Current
8.7.4.7a	Patient Leakage Current
8.7.4.7b	Patient Leakage Current
8.7.4.7h	Total Patient Leakage
8.7.4.8	Patient Auxiliary Current
8.8.3	Dielectric Strength
11.1	Temperatures

Testing location:

Intertek Testing Services NA Inc.

70 Codman Hill Road

Boxborough, MA 01719 USA

Summary of compliance with National Differences

List of countries addressed: US, CA, CH, EN, JP

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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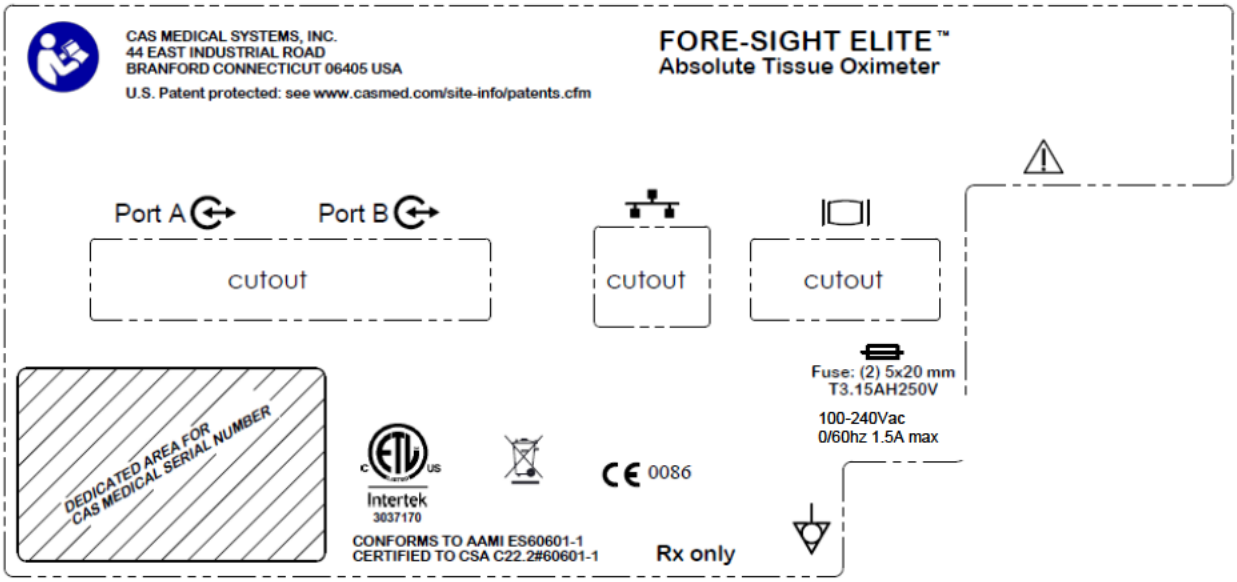
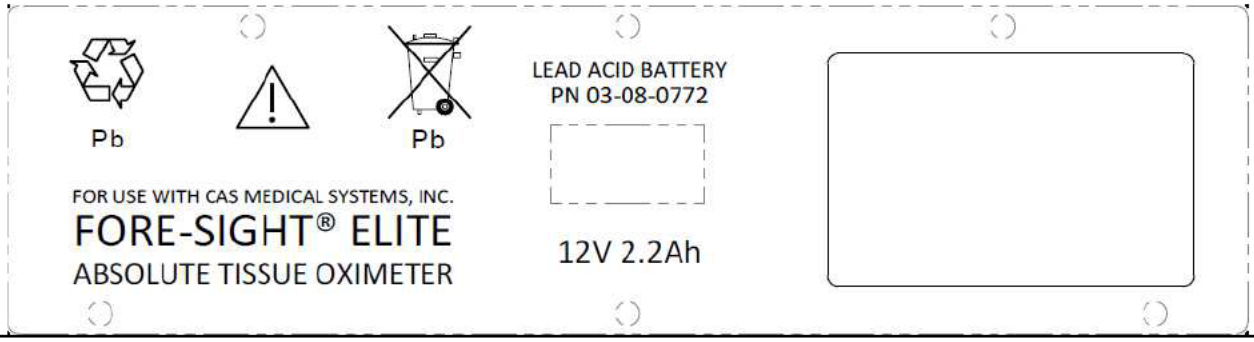
Copy of marking plate





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

FORE-SIGHT
Absolute Tissue Oximetry ELITE™

x20

LARGE SENSORS
(includes alcohol prep pad)
REF 01-07-2103

SP: Sensor Grande **IT:** Sensore Grande **RU:** Большой Сенсор **FI:** Suuri Anturi
FR: Capteur Grand **NL:** Grote Sensor **DA:** Stor Sensor **NO:** Stor Sensor
PT: Sensor Grande **DE:** Großer Sensor **PL:** Duży Czujnik **CS:** Velký snímač

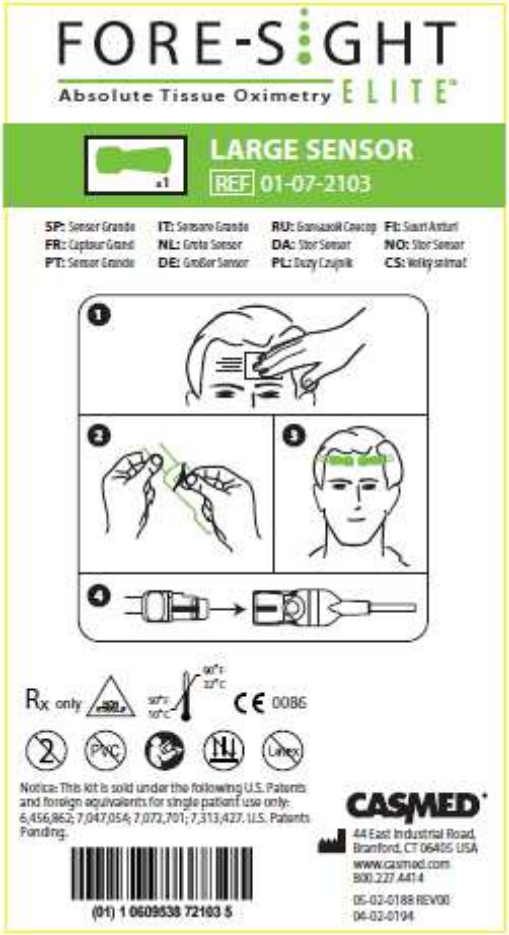
90°F 32°C
50°F 10°C
Rx only
CE 0086

05-02-0188 REV00
04-02-0194

CASMED®
44 East Industrial Road,
Branford, CT 06405 USA
www.casmed.com
800.227.4414

EC REP
MediMark® Europe.
11 rue E. Zola 38100
Grenoble. France

(01) 1 0609538 72103 5



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	portable
Device type (component/sub-assembly/ equipment/ system). :	Equipment
Intended use (Including type of patient, application location) . :	continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle
Mode of operation ..... :	Continuous
Supply connection ..... :	internally powered / appliance coupler
Accessories and detachable parts included ..... :	Preamp cables, Sensors
Other options include..... :	N/A
Testing	
Date of receipt of test item(s) ..... :	2013/10/31
Dates tests performed ..... :	2013/11/1 – 2013/11/05
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement.....:	N/E
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition .....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection .....: MOPP

General remarks:
"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Manufacturer's Declaration per sub-clause 6.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ Yes ☒ Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) ..... :	CAS Medical Systems 44 East Industrial Road Branford, CT 06405
General product information: The product covered in this report is a 110-240 VAC, Single Phase, ABSOLUTE TISSUE OXIMETER, intended to be installed indoors The Model FORE-SIGHT ELITE™ 01-06-3000 Series Monitor is a pre-configured monitor that can include the following measurement functions • Absolute tissue oxygen saturation (StO2) The FORE-SIGHT ELITE Oximeter is indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

M2: G100742469 2013-11-05

Modification 2 was created to add Japanese deviations along with the additional tests results for 10% above the nominal 100Vac at both 50Hz and 60Hz

Note: 110Vac inputs were not needed due to the fact that they were completed in the original evaluation

- New leakages added (before and after humidity)
- New dielectrics added (before and after humidity)
- New temps added
- Japanese country deviations added
- Ratings changed from 110Vac to 100Vac (label updated to match)

M1: G100742469 2013-10-28

03-05-0511 03+ Oximeter sensor construction had following changes

- Use alternate 5 mil (0.127 mm) thick FEP film into sensor bottom foam laminate construction for insulation;
- flexible circuit assembly increased sealed edge perimeter to 1 mm and insulating cover lay thickness to 25 µm; also the stiffener behind the photodiodes on flexible circuit changed to non-conductive FR4

Also the report updates are listed in the following pages

- Added test list on page 3
- Added M1 information in product general information on page 7
- Added alternate Teflon FEP in critical component list on page 9
- Added oximeter sensor in critical components list on page 10
- Add test data due to the modification on page 10 to 14
- Pictures for modified new Oximeter sensor on page 15
- Added test equipment list page 16

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TEST EQUIPMENT LIST					
Item	**Equipment Type**	**Make**	**Model No.**	**Serial No.**	**Next Cal. Due**
1	Weather condition Station*	Davis Instruments	Vue / 6351	G120802D005	01/29/2014
2	A/C Power Source	Chroma	6415	641500000506	09/23/2014
3	Medical/ITS/Industrial switch and leakage box	Intertek	JP2	SAF771	01/07/2014
4	Hipot Tester	QuadTech	Sentry Plus	S00300001097	10/04/2014
5	Data Acquisition Switch Unit	Agilent Technolgies	34907A	MY44071449	09/23/2014
6	20 Channel Armature Multiplexer	Agilent Technolgies	34901A	MY41156028	09/24/2014
7	Large Temperature/Humidity Chamber (Walk In)	Bryant Manufacturing	WR-197	2177	02/19/2014
8	Chart Recorder (Walk-in)	Honeywell	DR45AT	0028Y0471539000	02/19/2014
9	True RMS Multimeter	Fluke	87 V	19020110	05/02/2014

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8.7	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks	
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
B, NC, S5-1,S12-1	110	60	125		
B, NC, S5-1, S12-0	110	60	126		
B, NC, S5-0, S12-1	110	60	125		
B, NC, S5-0, S12-0	110	60	125		
A, NC, S5-1,S12-1	110	60	93.7		
A, NC, S5-1, S12-0	110	60	94.2		
A, NC, S5-0, S12-1	110	60	92.3		
A, NC, S5-0, S12-0	110	60	92.8		
B, SFC, S5-1,S12-1	110	60	234		
B, SFC, S5-1, S12-0	110	60	230		
B, SFC, S5-0, S12-1	110	60	231		
B, SFC, S5-0, S12-0	110	60	230		
A, SFC, S5-1,S12-1	110	60	174.2		
A, SFC, S5-1, S12-0	110	60	175.0		
A, SFC, S5-0, S12-1	110	60	174		
A, SFC, S5-0, S12-0	110	60	175		
B, NC, S5-1,S12-1	110	50	124		
B, NC, S5-1, S12-0	110	50	124		
B, NC, S5-0, S12-1	110	50	124		
B, NC, S5-0, S12-0	110	50	124		
A, NC, S5-1,S12-1	110	50	90.1		
A, NC, S5-1, S12-0	110	50	96.7		
A, NC, S5-0, S12-1	110	50	94.8		
A, NC, S5-0, S12-0	110	50	91.9		
B, SFC, S5-1,S12-1	110	50	235		
B, SFC, S5-1, S12-0	110	50	231		
B, SFC, S5-0, S12-1	110	50	232		
B, SFC, S5-0, S12-0	110	50	231		
A, SFC, S5-1,S12-1	110	50	170		
A, SFC, S5-1, S12-0	110	50	171		
A, SFC, S5-0, S12-1	110	50	172		
A, SFC, S5-0, S12-0	110	50	173		

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
B, S1-1, S5-1, S7-1, S12-1	110	60	4.1	
B, S1-1, S5-1, S7-1, S12-0	110	60	3.6	
B, S1-1, S5-1, S7-0, S12-1	110	60	9.5	
B, S1-1, S5-1, S7-0, S12-0	110	60	9.6	
B, S1-1, S5-0, S7-1, S12-1	110	60	3.9	
B, S1-1, S5-0, S7-1, S12-0	110	60	3.6	
B, S1-1, S5-0, S7-0, S12-1	110	60	9.6	
B, S1-1, S5-0, S7-0, S12-0	110	60	9.0	
B, S1-0, S5-1, S7-1, S12-1	110	60	6.1	
B, S1-0, S5-1, S7-1, S12-0	110	60	4.9	
B, S1-0, S5-0, S7-1, S12-1	110	60	6.1	
B, S1-0, S5-0, S7-1, S12-0	110	60	6.0	
A, S1-1, S5-1, S7-1, S12-1	110	60	1.4	
A, S1-1, S5-1, S7-1, S12-0	110	60	1.0	
A, S1-1, S5-1, S7-0, S12-1	110	60	2.1	
A, S1-1, S5-1, S7-0, S12-0	110	60	3.0	
A, S1-1, S5-0, S7-1, S12-1	110	60	2.1	
A, S1-1, S5-0, S7-1, S12-0	110	60	1.0	
A, S1-1, S5-0, S7-0, S12-1	110	60	1.6	
A, S1-1, S5-0, S7-0, S12-0	110	60	2.9	
A, S1-0, S5-1, S7-1, S12-1	110	60	1.8	
A, S1-0, S5-1, S7-1, S12-0	110	60	1.1	
A, S1-0, S5-0, S7-1, S12-1	110	60	1.5	
A, S1-0, S5-0, S7-1, S12-0	110	60	0.9	
B, S1-1, S5-1, S7-1, S12-1	110	50	4.0	
B, S1-1, S5-1, S7-1, S12-0	110	50	3.6	
B, S1-1, S5-1, S7-0, S12-1	110	50	9.4	
B, S1-1, S5-1, S7-0, S12-0	110	50	9.5	
B, S1-1, S5-0, S7-1, S12-1	110	50	3.8	
B, S1-1, S5-0, S7-1, S12-0	110	50	3.5	
B, S1-1, S5-0, S7-0, S12-1	110	50	9.5	
B, S1-1, S5-0, S7-0, S12-0	110	50	9.0	
B, S1-0, S5-1, S7-1, S12-1	110	50	6.0	
B, S1-0, S5-1, S7-1, S12-0	110	50	4.8	
B, S1-0, S5-0, S7-1, S12-1	110	50	6.0	

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B, S1-0, S5-0, S7-1, S12-0	110	50	6.0	
A, S1-1, S5-1, S7-1, S12-1	110	50	1.3	
A, S1-1, S5-1, S7-1, S12-0	110	50	1.1	
A, S1-1, S5-1, S7-0, S12-1	110	50	2.1	
A, S1-1, S5-1, S7-0, S12-0	110	50	3.1	
A, S1-1, S5-0, S7-1, S12-1	110	50	2.4	
A, S1-1, S5-0, S7-1, S12-0	110	50	1.5	
A, S1-1, S5-0, S7-0, S12-1	110	50	1.3	
A, S1-1, S5-0, S7-0, S12-0	110	50	2.5	
A, S1-0, S5-1, S7-1, S12-1	110	50	1.2	
A, S1-0, S5-1, S7-1, S12-0	110	50	1.2	
A, S1-0, S5-0, S7-1, S12-1	110	50	1.5	
A, S1-0, S5-0, S7-1, S12-0	110	50	1.0	
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)
Sensor one				
B, S1-1, S5-1, S7-1, S13-1	110	60	0.9	
B, S1-1, S5-1, S7-1, S13-0	110	60	0.8	
B, S1-1, S5-1, S7-0, S13-1	110	60	1.1	
B, S1-1, S5-1, S7-0, S13-0	110	60	1.3	
B, S1-1, S5-0, S7-1, S13-1	110	60	0.9	
B, S1-1, S5-0, S7-1, S13-0	110	60	0.6	
B, S1-1, S5-0, S7-0, S13-1	110	60	1.3	
B, S1-1, S5-0, S7-0, S13-0	110	60	1.2	
B, S1-0, S5-1, S7-1, S13-1	110	60	1.0	
B, S1-0, S5-1, S7-1, S13-0	110	60	1.1	
B, S1-0, S5-0, S7-1, S13-1	110	60	1.1	
B, S1-0, S5-0, S7-1, S13-0	110	60	1.0	
A, S1-1, S5-1, S7-1, S13-1	110	60	0.5	
A, S1-1, S5-1, S7-1, S13-0	110	60	0.5	
A, S1-1, S5-1, S7-0, S13-1	110	60	0.6	
A, S1-1, S5-1, S7-0, S13-0	110	60	0.7	
A, S1-1, S5-0, S7-1, S13-1	110	60	0.6	
A, S1-1, S5-0, S7-1, S13-0	110	60	0.5	
A, S1-1, S5-0, S7-0, S13-1	110	60	0.5	

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

A, S1-1, S5-0, S7-0, S13-0	110	60	0.8	
A, S1-0, S5-1, S7-1, S13-1	110	60	0.8	
A, S1-0, S5-1, S7-1, S13-0	110	60	0.7	
A, S1-0, S5-0, S7-1, S13-1	110	60	0.6	
A, S1-0, S5-0, S7-1, S13-0	110	60	0.6	
B, S1-1, S5-1, S7-1, S13-1	110	50	0.8	
B, S1-1, S5-1, S7-1, S13-0	110	50	0.7	
B, S1-1, S5-1, S7-0, S13-1	110	50	1.0	
B, S1-1, S5-1, S7-0, S13-0	110	50	1.3	
B, S1-1, S5-0, S7-1, S13-1	110	50	0.8	
B, S1-1, S5-0, S7-1, S13-0	110	50	0.7	
B, S1-1, S5-0, S7-0, S13-1	110	50	1.2	
B, S1-1, S5-0, S7-0, S13-0	110	50	1.1	
B, S1-0, S5-1, S7-1, S13-1	110	50	1.0	
B, S1-0, S5-1, S7-1, S13-0	110	50	1.0	
B, S1-0, S5-0, S7-1, S13-1	110	50	1.0	
B, S1-0, S5-0, S7-1, S13-0	110	50	0.7	
A, S1-1, S5-1, S7-1, S13-1	110	50	0.8	
A, S1-1, S5-1, S7-1, S13-0	110	50	0.6	
A, S1-1, S5-1, S7-0, S13-1	110	50	0.6	
A, S1-1, S5-1, S7-0, S13-0	110	50	0.7	
A, S1-1, S5-0, S7-1, S13-1	110	50	0.8	
A, S1-1, S5-0, S7-1, S13-0	110	50	0.8	
A, S1-1, S5-0, S7-0, S13-1	110	50	0.7	
A, S1-1, S5-0, S7-0, S13-0	110	50	0.7	
A, S1-0, S5-1, S7-1, S13-1	110	50	0.6	
A, S1-0, S5-1, S7-1, S13-0	110	50	0.6	
A, S1-0, S5-0, S7-1, S13-1	110	50	0.7	
A, S1-0, S5-0, S7-1, S13-0	110	50	0.6	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 uA Type CF AP: 50 uA
Sensor one				
B, S5-1, S9-1, S13-1	110	60	30.1	
B, S5-1, S9-1, S13-0	110	60	32.3	
B, S5-1, S9-0, S13-1	110	60	34.1	
B, S5-1, S9-0, S13-0	110	60	32.2	

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

B, S5-0, S9-1, S13-1	110	60	31.1	
B, S5-0, S9-1, S13-0	110	60	31.1	
B, S5-0, S9-0, S13-1	110	60	30.2	
B, S5-0, S9-0, S13-0	110	60	32.2	
A, S5-1, S9-1, S13-1	110	60	34.5	
A, S5-1, S9-1, S13-0	110	60	34.8	
A, S5-1, S9-0, S13-1	110	60	36.4	
A, S5-1, S9-0, S13-0	110	60	35.2	
A, S5-0, S9-1, S13-1	110	60	34.6	
A, S5-0, S9-1, S13-0	110	60	36.4	
A, S5-0, S9-0, S13-1	110	60	36.2	
A, S5-0, S9-0, S13-0	110	60	34.5	-
B, S5-1, S9-1, S13-1	110	50	30.1	
B, S5-1, S9-1, S13-0	110	50	32.3	
B, S5-1, S9-0, S13-1	110	50	34.1	
B, S5-1, S9-0, S13-0	110	50	32.2	
B, S5-0, S9-1, S13-1	110	50	31.1	
B, S5-0, S9-1, S13-0	110	50	31.1	
B, S5-0, S9-0, S13-1	110	50	30.2	
B, S5-0, S9-0, S13-0	110	50	32.2	
A, S5-1, S9-1, S13-1	110	50	38.2	
A, S5-1, S9-1, S13-0	110	50	36.8	
A, S5-1, S9-0, S13-1	110	50	35.4	
A, S5-1, S9-0, S13-0	110	50	36.6	
A, S5-0, S9-1, S13-1	110	50	38.2	
A, S5-0, S9-1, S13-0	110	50	34.7	
A, S5-0, S9-0, S13-1	110	50	36.2	
A, S5-0, S9-0, S13-0	110	50	37.5	
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC(d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)
N/A	-	-	-	-
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 uA Type CF: N/A
N/A	-	-	-	-
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values:

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

				Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC;50 uA SFC (d.c. or a.c. current)
Sensor one				
B, S7-1, S1-1, S5-1	110	60	0.9	
B, S7-1, S1-1, S5-0	110	60	0.8	
B, S7-1, S1-0, S5-1	110	60	1.1	
B, S7-1, S1-0, S5-0	110	60	1.0	
B, S7-0, S1-1, S5-1	110	60	1.9	
B, S7-0, S1-1, S5-0	110	60	1.9	
A, S7-1, S1-1, S5-1	110	60	1.2	
A, S7-1, S1-1, S5-0	110	60	1.3	
A, S7-1, S1-0, S5-1	110	60	2.0	
A, S7-1, S1-0, S5-0	110	60	2.1	
A, S7-0, S1-1, S5-1	110	60	3.1	
A, S7-0, S1-1, S5-0	110	60	2.9	
B, S7-1, S1-1, S5-1	110	50	0.9	
B, S7-1, S1-1, S5-0	110	50	0.8	
B, S7-1, S1-0, S5-1	110	50	1.1	
B, S7-1, S1-0, S5-0	110	50	1.0	
B, S7-0, S1-1, S5-1	110	50	0.3	
B, S7-0, S1-1, S5-0	110	50	0.3	
A, S7-1, S1-1, S5-1	110	50	1.1	
A, S7-1, S1-1, S5-0	110	50	1.3	
A, S7-1, S1-0, S5-1	110	50	1.9	
A, S7-1, S1-0, S5-0	110	50	1.8	
A, S7-0, S1-1, S5-1	110	50	2.0	
A, S7-0, S1-1, S5-0	110	50	3.1	
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
B, S1-1, S5-1, S7-1, S12-1	110	60	0.1	
B, S1-1, S5-1, S7-1, S12-0	110	60	0.1	
B, S1-1, S5-1, S7-0, S12-1	110	60	0.1	
B, S1-1, S5-1, S7-0, S12-0	110	60	0.1	

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

B, S1-1, S5-0, S7-1, S12-1	110	60	0.1	
B, S1-1, S5-0, S7-1, S12-0	110	60	0.1	
B, S1-1, S5-0, S7-0, S12-1	110	60	0.1	
B, S1-1, S5-0, S7-0, S12-0	110	60	0.1	
B, S1-0, S5-1, S7-1, S12-1	110	60	0.1	
B, S1-0, S5-1, S7-1, S12-0	110	60	0.1	
B, S1-0, S5-0, S7-1, S12-1	110	60	0.1	
B, S1-0, S5-0, S7-1, S12-0	110	60	0.1	
A, S1-1, S5-1, S7-1, S12-1	110	60	0.9	
A, S1-1, S5-1, S7-1, S12-0	110	60	0.5	
A, S1-1, S5-1, S7-0, S12-1	110	60	0.4	
A, S1-1, S5-1, S7-0, S12-0	110	60	1.0	
A, S1-1, S5-0, S7-1, S12-1	110	60	0.8	
A, S1-1, S5-0, S7-1, S12-0	110	60	0.4	
A, S1-1, S5-0, S7-0, S12-1	110	60	0.3	
A, S1-1, S5-0, S7-0, S12-0	110	60	0.2	
A, S1-0, S5-1, S7-1, S12-1	110	60	0.2	
A, S1-0, S5-1, S7-1, S12-0	110	60	0.2	
A, S1-0, S5-0, S7-1, S12-1	110	60	0.2	
A, S1-0, S5-0, S7-1, S12-0	110	60	0.2	
B, S1-1, S5-1, S7-1, S12-1	110	50	0.1	
B, S1-1, S5-1, S7-1, S12-0	110	50	0.1	
B, S1-1, S5-1, S7-0, S12-1	110	50	0.1	
B, S1-1, S5-1, S7-0, S12-0	110	50	0.1	
B, S1-1, S5-0, S7-1, S12-1	110	50	0.1	
B, S1-1, S5-0, S7-1, S12-0	110	50	0.1	
B, S1-1, S5-0, S7-0, S12-1	110	50	0.1	
B, S1-1, S5-0, S7-0, S12-0	110	50	0.1	
B, S1-0, S5-1, S7-1, S12-1	110	50	0.1	
B, S1-0, S5-1, S7-1, S12-0	110	50	0.1	
B, S1-0, S5-0, S7-1, S12-1	110	50	0.1	
B, S1-0, S5-0, S7-1, S12-0	110	50	0.1	
A, S1-1, S5-1, S7-1, S12-1	110	50	0.7	
A, S1-1, S5-1, S7-1, S12-0	110	50	0.6	
A, S1-1, S5-1, S7-0, S12-1	110	50	0.7	
A, S1-1, S5-1, S7-0, S12-0	110	50	0.7	

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A, S1-1, S5-0, S7-1, S12-1	110	50	0.5	
A, S1-1, S5-0, S7-1, S12-0	110	50	0.8	
A, S1-1, S5-0, S7-0, S12-1	110	50	0.4	
A, S1-1, S5-0, S7-0, S12-0	110	50	0.5	
A, S1-0, S5-1, S7-1, S12-1	110	5	0.5	
A, S1-0, S5-1, S7-1, S12-0	110	50	0.6	
A, S1-0, S5-0, S7-1, S12-1	110	50	0.4	
A, S1-0, S5-0, S7-1, S12-0	110	50	0.7	
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC;1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
N/A	-	-	-	-
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000uA Type CF: 100 uA
N/A	-	-	-	-
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 uA Type CF: N/A
N/A	-	-	-	-

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PAT ENT LEAKAGE CURRENT values are only relative to equipment with multiple APPL ED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PAT ENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQU PMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER - Earth leakage current
TC – Touch current
P - Patient leakage current
PA – Patient auxiliary current
TP – Total Patient current
PM - Patient leakage current with mains on the applied parts
MD - Measuring device

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				Pass
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
Primary to Metal Enclosure	BI	110	-	1500	No
Secondary to Metal Enclosure	BI	110	-	1500	No
Preamp connector to preamp enclosure	BI	110	-	1500	No
Sensor connection to Preamp enclosure	BI	110	-	1500	No
Sensor to Sensor connector	BI	110	-	1500	No
Sensor connection to Metal Enclosure	BI	110	-	1500	No
Primary to Plastic Enclosure	RI	110	-	4000	No
Sensor Connection to Primary	BI	110	-	1500	No

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.
[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

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11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No. .....:		FORE-SIGHT Elite			
Test ambient (°C) .....:		23.8			
Test supply voltage/frequency (V/Hz)[4] .....:		110VAC/60HZ			
Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
	1	Ambient	-	23.8	
	2	Power Supply Board	105	47.2	
	3	PE Cable	105	24.7	
	4	Internal cables	105	26.5	
	5	PCB	105	28.8	
	6	Screen	70	25.5	
Model No. .....:			FORE-SIGHT Elite		
Test ambient (°C) .....:			23.8		
Test supply voltage/frequency (V/Hz)[4] .....:			110VAC/50HZ		
	1	Ambient	-	22.6	
	2	Power Supply Board	105	48.1	
	3	PE Cable	105	24.9	
	4	Internal cables	105	26.8	
	5	PCB	105	29.0	
	6	Screen	70	25.9	

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT TO TEST REPORT IEC 60601-1 JP- JAPAN NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Differences according to ..... :	National standard JIS T0601-1:2012		
Attachment Form No. ..... :	JP_ND_IEC60601_1A		
Attachment Originator..... :	TÜV Rheinland Japan Ltd.		
Master Attachment..... :	2009-08		
Copyright © 2009 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.			
—	Throughout the report, HAZARD shall be referred to as HAZARDOUS SITUATION	Informative	P
7	ME Equipment Identification, Marking, and Documents		—
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to JIS Z8202 (ISO 31 (IDT)) except the base quantities listed in Table 1 expressed in the indicated units		P
7.7.4	Addition: If polyvinyl chloride (JIS C3306) or rubber (JIS C3301) insulated flexible cord is used, the conductor may be colored “white”	Informative	P
7.7.5	Addition: If polyvinyl chloride (JIS C3306) or rubber (JIS C3301) insulated flexible cord is used, conductors may be the color specified in cited standards	Informative	P
8	Protection Against Electrical Hazards from ME Equipment		—
8.4.2	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V or more (VA or J) ..... :		P
8.8.2	For a), add the following NOTE: NOTE – Generally, “distance through insulation” means the thickness of insulation. However, for example, if a transformer installed into a metal case is insulated by filler, the thickness is always not uniformly. Therefore, such expression was used.	Note added	P
8.8.3	During the test of this clause, the state of the power switch shall be kept with closed circuit		P
8.9	Creepage Distances and Air Clearances		P
8.9.1.2	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.3	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.4	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.5	Creepage distances and air clearances of this clause shall be applied to MOOP and MOPP		P
8.9.1.6	Creepage distances and air clearances of this clause shall be applied to MOOP and MOPP		P
8.9.1.7	Creepage distances and air clearances of this		P

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	clause shall be applied to MOOP		
8.9.1.8	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.9	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.10	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.11	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.12	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.13	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.9.1.14	Creepage distances and air clearances of this clause shall be applied to MOOP		P
8.11.3.2	POWER SUPPLY CORDS are no less robust than rubber (JIS C3301), polyvinyl chloride (JIS C3306), or cords of which the robustness is equal to or more than those are usable.	Supply cords to be provided by end user	N/A
	Cords of JIS C 3306 shall not use:		N/A
	- for polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 60 °C		N/A
	- for grade heat-resistant polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 75 °C		N/A
9.2.2.2	In the bottom column of Table 20, replace the existing text with the following: [a] The values in this table are taken from JIS B9711 (ISO 13854 (IDT)).	Replaced	P
9.7.5	In the last paragraph, delete “unmarked”.	Deleted	P
9.8.4.1	Replace the existing NOTE with the following: NOTE The upper carriage of the human body test mass apparatus is formed of wood or a similar material. The bottom portion is foam. The resiliency or spring factor of the foam (ILD or IFD ratings) has not been specified. The foam is cylindrical, rather than spherical.	Replaced	P
10	Protection Against Unwanted and Excessive Radiation Hazards		—
10.1.1	X-radiation dose-rate was ≤ 36 pA/kg (5 μSv/h) (0.5 mR/h ≈ 5 μGy/h) 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation :	No radiation hazards	N/A
11.1.1	To the existing text of a in the Table 22, add the following: (For example, the maximum temperature limit of a transformer with three insulating materials of Class A, Class B and Class E shall be 105 °C of Class A		N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	of the lowest limit.)		
13.2.10	In Table 26, replace the existing NOTE with the following: NOTE The temperature limits in this table were derived from Table B.1 of IEC 60950-1:2001 (in the corresponding international standard, IEC 61010-1:2001 [22]).	Replaced	P
16	ME Systems		—
16.1	Non-ME equipment used in the ME system shall be in compliance with applicable JIS standards or Technical Requirements of the Electrical Appliance and Material Safety Act	Not an ME system	N/A
	Equipment relying only on basic insulation for protection against electric shock not used in ME system.		N/A
	For measures for ensuring safety, e.g. the case combined with a separating transformer with double insulation or reinforced insulation, equipment only with basic insulation may be used		N/A
16.9.2.1	c) Multiple socket-outlet complied with IEC 60884-1 or JIS C82821		N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Report issued under the responsibility of:

Intertek

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	100742469BOX-001
Date of issue.....:	2012, November 15, M1: 2013-10-28
Total number of pages.....:	16 .....
CB Testing Laboratory.....:	Intertek Testing Services NA Inc.
Address.....:	70 Codman Hill Road Boxborough, MA 01719 USA
Applicant's name .....:	CAS Medical Systems Inc.
Address.....:	44 East Industrial Road Branford, CT 06405, USA
Test specification:	
Standard .....:	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
Test procedure.....:	CB Scheme
Non-standard test method……..:	
Test Report Form No.....:	IEC60601_1G
Test Report Form Originator.....:	Underwriters Laboratories Inc.
Master TRF.....:	Dated 2010-11

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This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description.....:	Absolute Tissue Oximeter
Trade Mark .....:	CASMED®
Manufacturer.....:	Same as Applicant
Model/Type reference.....:	FORE-SIGHT Elite 01-06-3000 (US) and 01-06-3005 (OUS)
Ratings.....:	110-240 V~, 50/60 Hz, 1.5 A Max

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Testing procedure and testing location:		
☒ CB Testing Laboratory:	Intertek Testing Services NA Inc.	
Testing location/ address ..... :	70 Codman Hill Road Boxborough, MA 01719 USA	
☐ Associated CB Test Laboratory:		
Testing location/ address ..... :		
Tested by (name + signature)..... :	Yaqing Liu	*Signature on file*
Approved by (+ signature) ..... :	Tell Bailey	*Signature on file*
☐ Testing procedure: TMP		
Tested by (name + signature)..... :		
Approved by (+ signature) ..... :		
Testing location/ address ..... :		
☐ Testing procedure: WMT		
Tested by (name + signature)..... :		
Witnessed by (+ signature) ..... :		
Approved by (+ signature) ..... :		
Testing location/ address ..... :		
☐ Testing procedure: SMT		
Tested by (name + signature)..... :		
Approved by (+ signature) ..... :		
Supervised by (+ signature)..... :		
Testing location/ address ..... :		
☐ Testing procedure: RMT		
Tested by (name + signature)..... :		
Approved by (+ signature) ..... :		
Supervised by (+ signature)..... :		
Testing location/ address ..... :		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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List of Attachments (including a total number of pages in each attachment):

N/A		

Summary of testing:

Tests performed (name of test and test clause):

Clause	Test
8.5.5.1a	Defibrillation-Proof Applied Parts
8.5.5.1b	Defibrillation-Proof Recovery Time
8.5.5.2	Energy Reduction
8.7	Leakage Current
8.8.3	Dielectric Strength

Testing location:

Intertek Testing Services NA Inc.

70 Codman Hill Road

Boxborough, MA 01719 USA

Summary of compliance with National Differences

List of countries addressed: US, CA, CH, EN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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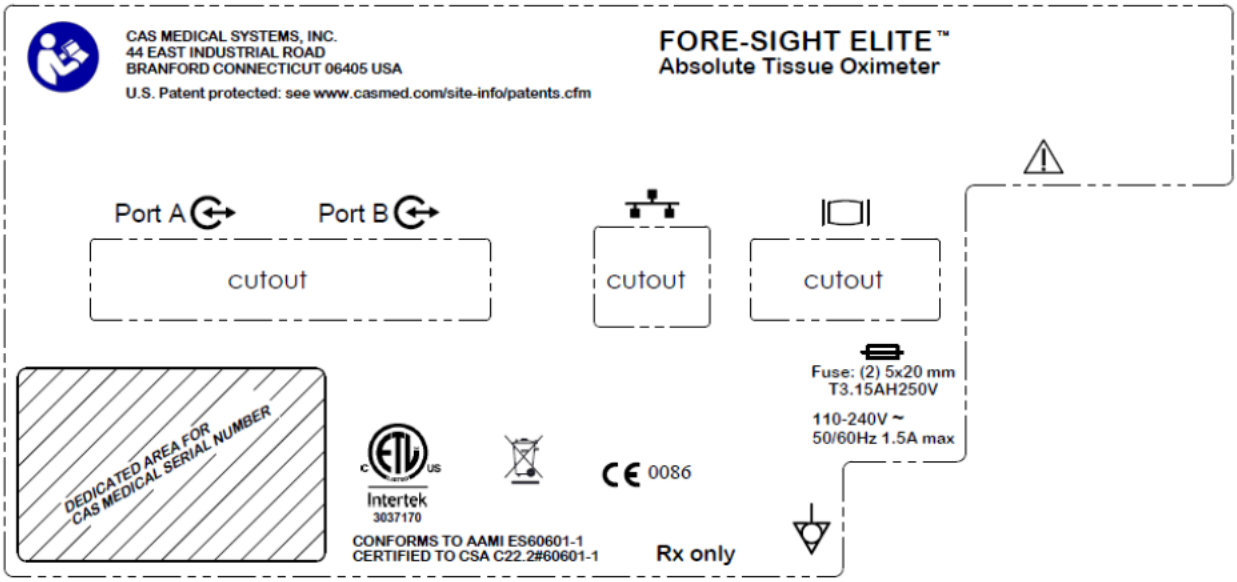
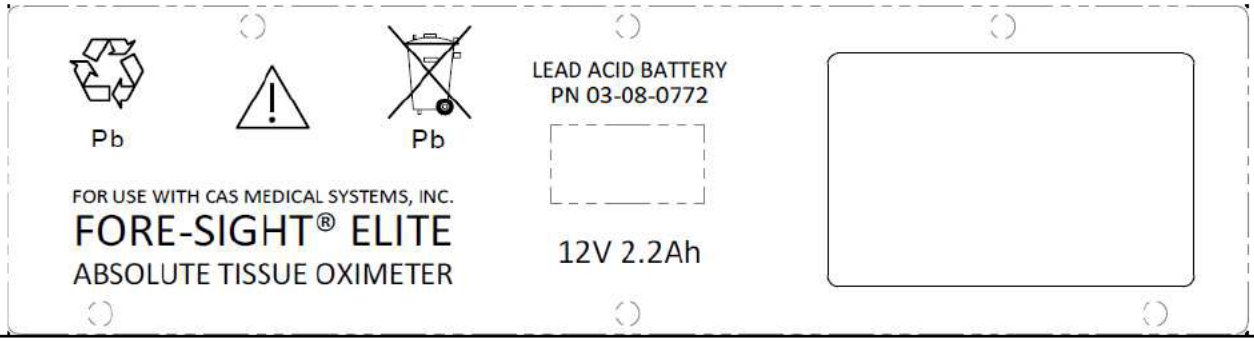
Copy of marking plate





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FORE-SIGHT
Absolute Tissue Oximetry ELITE™

x20

LARGE SENSORS
(includes alcohol prep pad)
REF 01-07-2103

SP: Sensor Grande **IT:** Sensore Grande **RU:** Большой Сенсор **FI:** Suuri Anturi
FR: Capteur Grand **NL:** Grote Sensor **DA:** Stor Sensor **NO:** Stor Sensor
PT: Sensor Grande **DE:** Großer Sensor **PL:** Duży Czujnik **CS:** Velký snímač

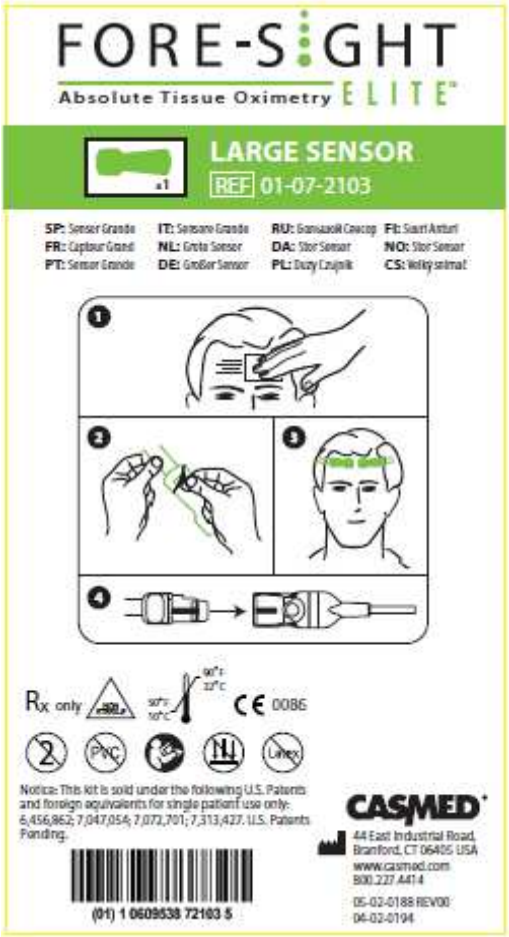
90°F 32°C
50°F 10°C
Rx only
CE 0086

05-02-0188 REV00
04-02-0194

CASMED®
44 East Industrial Road,
Branford, CT 06405 USA
www.casmed.com
800.227.4414

EC REP
MediMark® Europe.
11 rue E. Zola 38100
Grenoble. France

(01) 1 0609538 72103 5



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GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	portable
Device type (component/sub-assembly/ equipment/ system). :	Equipment
Intended use (Including type of patient, application location) . :	continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle
Mode of operation ..... :	Continuous
Supply connection ..... :	internally powered / appliance coupler
Accessories and detachable parts included ..... :	Preamp cables, Sensors
Other options include..... :	N/A
Testing	
Date of receipt of test item(s) ..... :	2013/09/16
Dates tests performed ..... :	2013/09/09/ – 2013/09/20
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement.....:	N/E
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition .....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection .....: MOPP

General remarks:
"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Manufacturer's Declaration per sub-clause 6.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :

☐ Yes
☒ Not applicable

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) ..... : CAS Medical Systems
44 East Industrial Road
Branford, CT 06405

General product information:

The product covered in this report is a 110-240 VAC, Single Phase, ABSOLUTE TISSUE OXIMETER, intended to be installed indoors

The Model FORE-SIGHT ELITE™ 01-06-3000 Series Monitor is a pre-configured monitor that can include the following measurement functions

- Absolute tissue oxygen saturation (StO2)

The FORE-SIGHT ELITE Oximeter is indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states.

M1: G100742469 2013-10-28

03-05-0511 03+ Oximeter sensor construction had following changes

- Use alternate 5 mil (0.127 mm) thick (b)(4) into sensor bottom foam laminate construction for insulation;
- flexible circuit assembly increased sealed edge perimeter to 1 mm and insulating cover lay thickness to 25 µm; also the stiffener behind the photodiodes on flexible circuit changed to non-conductive (b)

Also the report updates are listed in the following pages

- Added test list on page 3
- Added M1 information in product general information on page 7
- Added alternate (b)(4) in critical component list on page 9
- Added oximeter sensor in critical components list on page 10
- Add test data due to the modification on page 10 to 14
- Pictures for modified new Oximeter sensor on page 15
- Added test equipment list page 16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.10	TABLE: List of critical components				Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity [1]
CAS Medical Hospital Grade Power Cord with Ferrite Bead	Feller Power Cords CCA-WESCO	Part No. 6922 CBL-PWR-SP30-FB-UK	SJT 3x 18AWG, rated 125VAC, 10A H05VV-F 32/0.2 BAx3C 250Vac,13A	UL62	UL, CSA VDE
AC Power Entry Module, Filtered	Tyco / Corcom	PE000DL6C	250VAC, 6A	UL 544, IEC 60601-1	UL, CSA, TUV
Primary Fuses (2 Provided)	Littelfuse	02153.15P	5x20mm type, T3.15AH250V, rated 250V, 3.15A slow-blow	IEC 60127	UL, CSA, TUV
Power Supply	Emerson / Astec	NPS-44M	100/250 VAC, 50/60Hz 2.5A	UL 60601-1/A2:1995	UL, CSA, TUV
Battery	Panasonic	LC-R122R2P	12V, 2.2aH, 0.33A Trickle Charge Current	UL 1989	UL
92x22mm Tube Axial Cooling Fan	NIDEC	U92T12MUA7-58 T92T12MUA7-58	12VDC, 0.25A, 3.0W, 3100RPM, 52CFM	UL 507	UL, CSA, TUV
Power Line Filter	Tyco / Corcom	3EHQ3	250VAC, 3A Medical Grade	UL60601-1	UL, CSA, TUV
F1	Littlefuse	0154002.DR	FUSEBLOCK W/2.0A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
F2,F4	Littlefuse	154.250DR	FUSEBLOCK W/.250A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
F3,F5	Littlefuse	154.125DR	FUSEBLOCK W/.125A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
T1	HALO	TGS110-S055NCRL	ETHERNET ISOLATION TRANSFORMER, UL, 1500V, 4MM CREEPAGE	UL 60601-1/A2:1995	UL
U44,U46	Linear Technology	LTM2882CY-3#PBF	IC, Transceiver, RS232, Isolated Isolated 2500 VRMS	UL 60950,RoHS	UR
U63	RECOM	RSO-1205S/H3 RS-1205S/H3	DC-DC Converter, 9-18V in, 5V out, Isolated 3kV	Tested in end system	-

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

C280 on PCB Assy # 03-59-0402	TDK	CD85-E2GA102MYNS	Cap, Cer, 1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	IEC/EN 60384-14 IEC/EN 60065 UL 1414 CSA C22.2 No.0 & No.1	UL, VDE, CSA, BSI, SEMKO, SEV, FIMKO, DEMKO, NEMKO, IMQ
C1 on PCB assy # 03-59-0403	TDK	CD85-E2GA102MYNS	Cap, Cer, 1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	IEC/EN 60384-14 IEC/EN 60065 UL 1414 CSA C22.2 No.0 & No.1	UL, VDE, CSA, BSI, SEMKO, SEV, FIMKO, DEMKO, NEMKO, IMQ
Coin cell battery on PCB assy 03-59-0402	Panasonic	BR1225	Battery, Coin Cell, Lithium, 48 mAh, 12.5 mm	UL 1642	UL
U64,U65,U66, U67	Silicon Laboratories	Si8640ED-B-IS Si8640BD-B-IS	IC, Digital Isolator, Quad channel, Wide Body SOIC-16, RoHS	IEC 60950-1, 61010-1, 60601-1 (reinforced insulation)	UL, CSA, VDE
(b)(4) [redacted] Fluorocarbon Film Tape	(b)(4) [redacted] (b)(4) [redacted] Performance Films	(b)(4) [redacted]	(b)(4) [redacted] film w/ Silicone Adhesive, 0.0035" Thick	Tested by Intertek met 5000VAC dielectric withstand	-
Alternate (b)(4) [redacted] (b)(4) [redacted] Film Tape	(b)(4) [redacted] Performance Films	(b) [redacted]	(b)(4) [redacted]) film w/ Silicone Adhesive, 0.005" Thick, 6500 V/mil	Tested by Intertek met 5000VAC dielectric withstand	-
(b)(4) [redacted]	(b)(4) [redacted]	4701-30-25035-34	(b)(4) [redacted] 0.0035" thick	Tested by Intertek met 2500VAC dielectric withstand	-
Plastic enclosure	Plastic Design International	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene	UL 94	UR
Metal enclosure	Metalmen	Aluminum 5052-H32	Aluminum 5052-H32	Tested in end system	-
Sensors	CASMEDICAL	03-05-0511 03+	Disposable oximeter sensor	Tested in end system	-
Mylar Tape	3M™	(b)(4) [redacted] m (b)(4) [redacted]	(b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] Dielectric Strength: 7000 volts	UL 94 Tested by Intertek met 4000 VAC dielectric withstand	UL
Supplementary information: 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies				Pass
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
9	Foil underneath equipment	All 03-05-0511 03+ sensors tied together	+	490 mV	Pass
9	Foil underneath equipment		-	400 mV	Pass
9	Foil on enclosure		+	490 mV	Pass
9	Foil on enclosure		-	400 mV	Pass
9	Monitor SIP SOP		+	450 mV	Pass
9	Monitor SIP SOP		-	470 mV	Pass
9	Ethernet		+	450 mV	Pass
9	Ethernet		-	470 mV	Pass
9	Port A		+	840 mV	Pass
9	Port A		-	580 mV	Pass
9	Port B		+	450 mV	Pass
9	Port B		-	470 mV	Pass
9	USB		+	450 mV	Pass
9	USB		-	470 mV	Pass
9	USB front		+	840 mV	Pass
9	USB front		-	580 mV	Pass
10	Foil underneath equipment	One 03-05-0511 03+ sensor, rest tied to ground	+	760 mV	Pass
10	Foil underneath equipment		-	580 mV	Pass
10	Foil on enclosure		+	0.0 mV	Pass
10	Foil on enclosure		-	0.0 mV	Pass
10	Monitor SIP SOP		+	820 mV	Pass
10	Monitor SIP SOP		-	760 mV	Pass
10	Ethernet		+	820 mV	Pass
10	Ethernet		-	760 mV	Pass
10	Port A		+	0.0 mV	Pass
10	Port A		-	600 mV	Pass
10	Port B		+	820 mV	Pass
10	Port B		-	760 mV	Pass
10	USB		+	820 mV	Pass
10	USB		-	760 mV	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

10	USB front	+	0.0 mV	Pass
10	USB front	-	600 mV	Pass
Supplementary information:				

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time			Pass
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
All 03-05-0511 03+ sensor tied together	+/-	20	0.0	Remained 0 at all measurements made above
Supplementary information:				

8.5.5.2	TABLE: defibrillation-proof applied parts or patient connections of defibrillation-proof applied parts - Energy reduction test –measurement of Energy delivered to a 100 Ω load		Pass
Test Voltage applied to	Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy E1 as % of E2 (%)
one 03-05-0511 03+ sensor with the rest of 3 same type sensors connected to earth	375.7	375.4	100%
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 Ω with ME Equipment connected; E2= Measured energy delivered to 100 Ω without ME equipment connected.			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

8.7	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks	
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
Only Oximeter sensor structure changed. No earth leakage re-test required					
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC	
Only Oximeter sensor structure changed. No touch current re-test required					
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)	
B, NC (S1=0, S5=1, S7=1, S13=1)	264	60	0.8	03-05-0511 03+	
B, SFC (S1=0, S5=0, S7=0, S13=0)	264	60	2.1	03-05-0511 03+	
A, NC (S1=0, S5=1, S7=1, S13=1)	264	60	1.5	03-05-0511 03+	
A, SFC (S1=0, S5=0, S7=0, S13=0)	264	60	4.0	03-05-0511 03+	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 uA Type CF AP: 50 uA	
B, SFC (S5=1, S9=0, S13=1)	264	60	11.0	03-05-0511 03+	
A, SFC (S5=0, S9=1, S13=1)	264	60	31.0	03-05-0511 03+	
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC(d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)	
N/A	-	-	-	-	
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 uA Type CF: N/A	
N/A	-	-	-	No unearthed metal accessible part	
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC;50 uA SFC (d.c. or a.c. current)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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B, NC (S1=0, S5=0, S7=1)	264	60	0.7	03-05-0511 03+ One sensor tested at a time with all others tied together
B, SFC (S1=0, S5=0, S7=0)	264	60	3.5	
A, NC (S1=0, S5=0, S7=1)	264	60	2.8	
A, SFC (S1=1, S5=0, S7=0)	264	60	8.5	
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
B, NC (S1=0, S5=1, S7=1)	264	60	2.2	03-05-0511 03+ All sensors tied together
B, SFC (S1=0, S5=0, S7=0)	264	60	9.3	
A, NC (S1=1, S5=0, S7=1)	264	60	15.9	
A, SFC (S1=0, S5=0, S7=0)	264	60	33.8	
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC;1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
N/A	-	-	-	-
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000uA Type CF: 100 uA
N/A	-	-	-	-
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 uA Type CF: N/A
N/A	-	-	-	NO unearthed accessible metal part

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device	A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				Pass
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
Sensor to Sensor connector (B-d)	BI	240	-	1500	No
Sensor to plastic enclosure (B-d)	BI	240	-	1500	No
Sensor to Primary(B-a)	BI	240	-	4000	No

Supplementary information: 03-05-0511 03+ before and after humidity condition

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Oximeter sensor 03-05-0511 03+

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

TEST EQUIPMENT LIST (Tested 2013/09/09/ – 2013/09/20)					
Item	**Equipment Type**	**Make**	**Model No.**	**Serial No.**	**Next Cal. Due**
1	Weather condition station	Davis Instruments	Vue / 6351	G120425D113	01/29/2014
2	A/C Power Source	Chroma	6415	641500000517	12/20/2013
3	Medical/ITS/Industrial switch and leakage test box	ITS	JP2	SAF507	12/27/2013
4	True RMS Multimeter	Fluke	87 V	14840227	02/27/2014
5	Impulse Tester	Compliance West	MegaPulse Defib-5P	431777	Verified
6	High Voltage Probe	Tektronix	P6015A	B041429	03/11/2014
7	Electrical safety Compliance Analyzer	Associated Research	8006	9340041	01/30/2014
8	Digital Oscilloscope	Rigol Technologies	DS6104	DS6125200116	12/04/2013
9	Temp/Humidity Chamber	Envirotronics	SH27C	08015563S11263	10/18/2013
10	Temp/Humidity Chamber	Envirotronics	SH27C	08015563S11264	10/18/2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Test Report issued under the responsibility of:

Intertek

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No. ..... :	100742469BOX-001
Date of issue ..... :	2012, November 15 .....
Total number of pages ..... :	200 .....
CB Testing Laboratory ..... :	Intertek Testing Services NA Inc.
Address ..... :	70 Codman Hill Road Boxborough, MA 01719 USA
Applicant's name ..... :	CAS Medical Systems Inc.
Address ..... :	44 East Industrial Road Branford, CT 06405
Test specification:	
Standard ..... :	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
Test procedure ..... :	CB Scheme
Non-standard test method……..:	
Test Report Form No. ..... :	IEC60601_1G
Test Report Form Originator ..... :	Underwriters Laboratories Inc.
Master TRF ..... :	Dated 2010-11

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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo shall be removed

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description ..... :	Absolute Tissue Oximeter
Trade Mark ..... :	CASMED®
Manufacturer ..... :	CAS Medical Systems
Model/Type reference ..... :	FORE-SIGHT Elite 01-06-3000 (US) and 01-06-3005 (OUS)
Ratings ..... :	110-240 V~, 50/60 Hz, 1.5 A Max

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Testing procedure and testing location:		
☒ CB Testing Laboratory:	Intertek Testing Services NA Inc.	
Testing location/ address ..... :	70 Codman Hill Road Boxborough, MA 01719 USA	
☐ Associated CB Test Laboratory:		
Testing location/ address ..... :		
Tested by (name + signature) ..... :	Tell Bailey	*Signature on file*
Approved by (+ signature)..... :	Greg Wheeler	*Signature on file*
☐ Testing procedure: TMP		
Tested by (name + signature) ..... :		
Approved by (+ signature)..... :		
Testing location/ address ..... :		
☐ Testing procedure: WMT		
Tested by (name + signature) ..... :		
Witnessed by (+ signature) ..... :		
Approved by (+ signature)..... :		
Testing location/ address ..... :		
☐ Testing procedure: SMT		
Tested by (name + signature) ..... :		
Approved by (+ signature)..... :		
Supervised by (+ signature) ..... :		
Testing location/ address ..... :		
☐ Testing procedure: RMT		
Tested by (name + signature) ..... :		
Approved by (+ signature)..... :		
Supervised by (+ signature) ..... :		
Testing location/ address ..... :		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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List of Attachments (including a total number of pages in each attachment):

Attachment #	Description	Pages
1	Photographs of System	181-184
2	Country Deviations	185-196
3	Test Equipment List	195-198
4	CB certificate for power supply	199-200
100742469BOX-005A	IEC 60601-1-6	9
100742469BOX-005B	IEC 62366	13
100742469BOX-006	IEC 60601-1-8	18

Summary of testing:

Tests performed (name of test and test clause):

4.11	Power Input	8.11.3.6	Cord Guard Flexing (Cord Bending)
5.7	Humidity Preconditioning	9.3	Surfaces, Corners and Edges
5.9, 8.3	Determination of Applied Parts and Access ble Parts	9.4.2.1	Instability in Transport Position
7.1.2	Leg bility of Markings	9.4.2.2	Instability Excluding Transport
7.1.3	Durability of Markings	9.6.2.1	Sound Pressure Level Measurement
8.4.3	Residual Voltage in Attachment Plug	11.1	Temperatures
8.5.5.1a	Def brillation-Proof Applied Parts	11.6.3	Spillage
8.5.5.1b	Def brillation-Proof Recovery Time	11.6.6 11.6.7	Cleaning of ME equipment
8.5.5.2	Energy Reduction	11.8	Interruption of power supply
8.6.4	Earthing	13.2.7	Impairment of cooling
8.7	Leakage Current	15.3.2	Push Test (30mm dia plane)
8.8.3	Dielectric Strength	15.3.3	Impact Test (300 g steel ball)
8.8.4.1	Ball Pressure	15.3.4.1	Drop test hand-held ME equipment (drop test)
8.9.4	Creepage Distances and Air Clearance	15.3.4.2	Drop test portable ME equipment (rough handling)
8.11.3.5	Strain Relief (Cord Anchorage)	15.3.6	Mold Stress relief

Testing location:

Intertek Testing Services NA Inc.

70 Codman Hill Road

Boxborough, MA 01719 USA

Summary of compliance with National Differences

List of countries addressed: US, CA, CH, EN

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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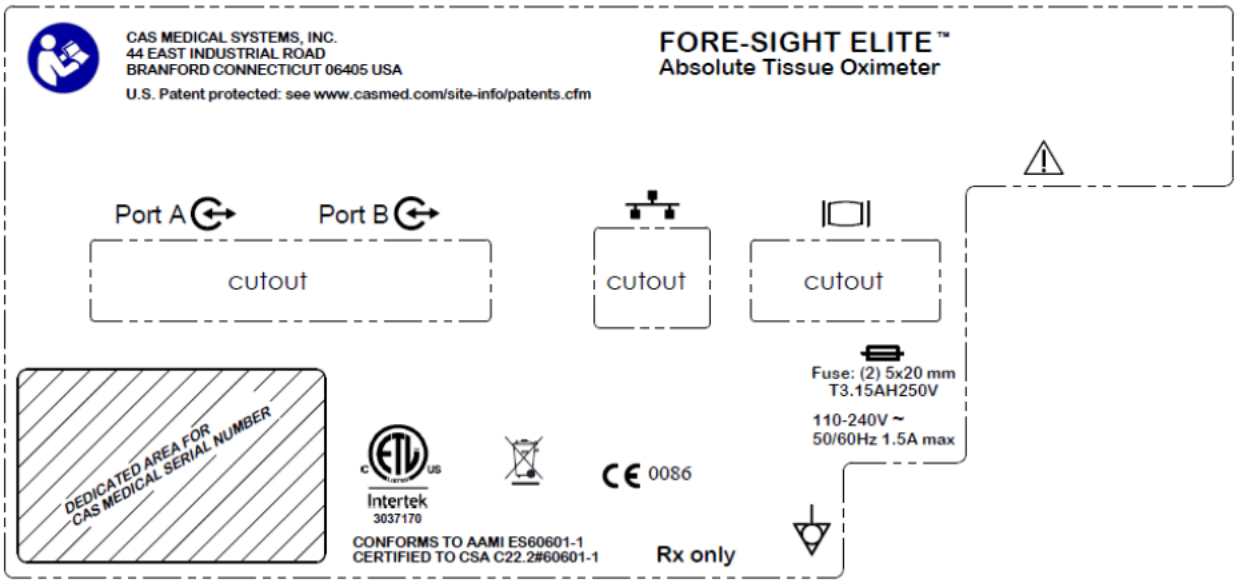
Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FORE-SIGHT
Absolute Tissue Oximetry ELITE™

x20

LARGE SENSORS
(includes alcohol prep pad)
REF 01-07-2103

SP: Sensor Grande **IT:** Sensore Grande **RU:** Большой Сенсор **FI:** Suuri Anturi
FR: Capteur Grand **NL:** Grote Sensor **DA:** Stor Sensor **NO:** Stor Sensor
PT: Sensor Grande **DE:** Großer Sensor **PL:** Duży Czujnik **CS:** Velký snímač

50°F 10°C / 90°F 32°C
Rx only
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04-02-0194

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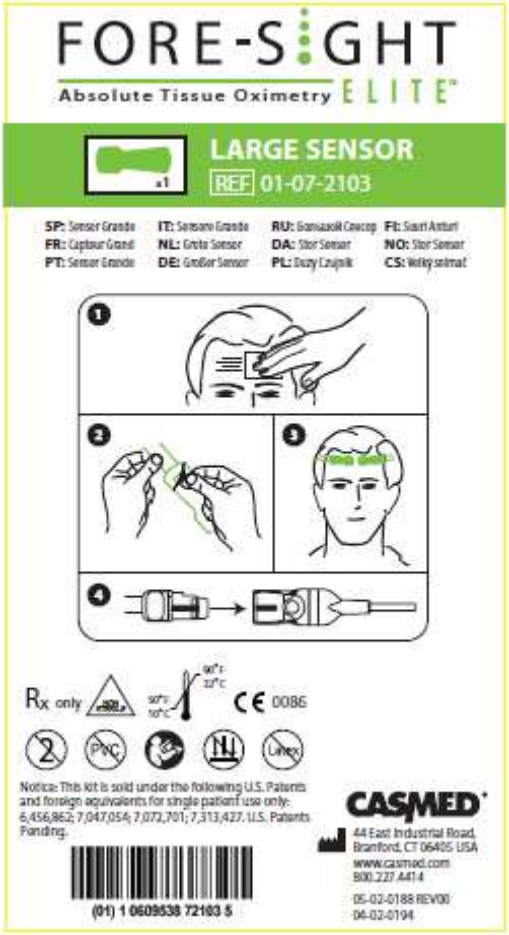

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GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	portable
Device type (component/sub-assembly/ equipment/ system). :	Equipment
Intended use (Including type of patient, application location) . :	continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle
Mode of operation ..... :	Continuous
Supply connection ..... :	internally powered / appliance coupler
Accessories and detachable parts included ..... :	Preamp cables, Sensors
Other options include..... :	N/A
Testing	
Date of receipt of test item(s) ..... :	2012/08/07
Dates tests performed ..... :	2012/08/07/2012 – 2012/11/15
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement.....:	N/E
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition .....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection .....: MOPP

General remarks:
"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Manufacturer's Declaration per sub-clause 6.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ Yes ☒ Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) ..... :	CAS Medical Systems 44 East Industrial Road Branford, CT 06405
General product information: The product covered in this report is a 110-240 VAC, Single Phase, ABSOLUTE TISSUE OXIMETER, intended to be installed indoors The Model FORE-SIGHT ELITE™ 01-06-3000 Series Monitor is a pre-configured monitor that can include the following measurement functions • Absolute tissue oxygen saturation (StO2) The FORE-SIGHT ELITE Oximeter is indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

(b)(4)

[redacted]

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: To insulation diagram		Pass
Pollution degree .....:	II	—
Overvoltage category.....:	II	—
Altitude.....:	132.6 meters above sea level	—
Additional details on parts considered as applied parts.....:	☐ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage Vrms	Working voltage Vpk	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	Basic OP	IIIb	250	354	3	1.6	7.5	7.5	Between L and N Worst case is the appliance inlet also has a certified power supply
B	1 MOPP	IIIb	250	354	4	2.5	4.3	4.3	Primary trace near F2/C1 to PE
C	2 MOPP	IIIb	250	354	8	5	Certified power supply		Primary to secondary
D	1 MOPP	IIIb	250	354	4	2.5	4.3	4.3	From 15 VDC to the enclosure
F	1 MOPP	IIIb	250	354	4	2.5	4	4	Ethernet
G	1 MOPP	IIIb	250	354	4	2.5	4	4	SIPSOP
H	1 MOPP	IIIb	250	354	4	2.5	4	4	SIPSOP
L	1 MOPP	IIIb	250	354	4	2.5	11.3	11.3	Power switch
M	1 MOPP	IIIb	250	354	4	2.5	36	36	Screen
N	1 MOPP	IIIb	250	354	4	2.5	36	36	LEDs
R	1 MOPP 2 MOPP	IIIb	250 -	354 15	4 4	2.5 2.0	Met by solid insulation		Preamp enclosure to preamp connection
S	1 MOPP 2 MOPP	IIIb	250 -	354 15	4 4	2.5 2.0	Met by solid insulation		Sensor voltage to preamp enclosure
T	1 MOPP 2 MOPP	IIIb	250 -	354 15	4 4	2.5 2.0	4	4	Applied part to live parts

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

U	1 MOPP	IIIb	250	354	4	2.5	4	4	Sensor voltage to the enclosure

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4	GENERAL REQUIREMENTS		—
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		Pass
4.2	A RISK MANAGEMENT PROCESS complying with ISO 14971 was performed ..... :	Compliance with ISO 14971, as required by subclause 4.2, has been established by performing an inspection (desk-top audit) of the Risk Management File. See Appended RM Results Table 4.2	Pass
4.3	ESSENTIAL PERFORMANCE functions identified according to MANUFACTURER'S policy for RISK acceptability in RISK MANAGEMENT FILE ..... :	See Appended Table 4.3 and RM Results Table 4.3	Pass
	ESSENTIAL PERFORMANCE functions maintained following particular tests as applicable		Pass
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE..... :	21-07-0304 Section 3.2 Expected Service Life 11 yrs	Pass
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means equal to or less than RESIDUAL RISKS resulting from requirements of this standard ..... :	See Appended RM Results Table 4.5	N/A
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10 ..... :	See Appended Insulation Diagram Table and RM Results Table 4.6	Pass
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2..... :	See Appended RM Results Table 4.7	Pass
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically ..... :	See Appended Table 13.2 for simulated physical test,	Pass
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation		Pass
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, except as specified, or by RISK MANAGEMENT PROCESS ..... :	See Appended RM Results Table 4.8	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following:		N/A
	a) Applicable safety requirements of a relevant IEC or ISO standard		N/A
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		N/A
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK ..... :	See appended Table 8.10 & RM Results Table 4.9	N/A
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 4.9	N/A
4.10	Power supply		Pass
4.10.1	ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three ..... :	Supply mains or internally powered	Pass
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS is 250 V for HAND-HELD ME EQUIPMENT (V) ..... :	Not hand-held	N/A
	– 250 V d.c. or single-phase a.c., or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V) ..... :	110-240 VAC	Pass
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
4.11	Power input		Pass
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use did not exceed marked rating by more than 10%..... :	See appended Table 4.11	Pass
	– Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range :	See appended Table 4.11	Pass
	Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage ..... :	See appended Table 4.11	Pass
5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		—
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2		Pass
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods..... :	See Appended RM Results Table 5.1	N/A
	Results of RISK ANALYSIS used to determine combination(s) of simultaneous faults to be tested		Pass
5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected ..... :		Pass
5.3	a) Tests conducted within the environmental conditions specified in technical description		Pass
	Temperature (ºC), Relative Humidity (%) ..... :	10 °C to 40 °C, 30 to 75% RH, non-condensing	Pass
	Atmospheric Pressure (kPa) ..... :	680 hPa to 1060 hPa	Pass
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests		Pass
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained ..... :		N/A
5.4	a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use and identified during RISK ANALYSIS, except as noted ..... :	See Appended RM Results Table 5.4a	Pass
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favourable for the relevant test per instructions for use		Pass
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits in technical description..... :		N/A
	d) Potable water used for cooling		N/A
5.5	Supply voltage during tests was the least favorable of the voltages specified in 4.10 or voltages marked on ME EQUIPMENT (V) ..... :	110-240 V~	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz) .....:	50/60 Hz	Pass
	ME EQUIPMENT with more than one RATED voltage, or both a.c./ d.c. tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current.....:	110-240 V~	Pass
	ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions.....:	Accessories found in the IFU	Pass
	ME EQUIPMENT connected to a separate power supply as specified in instructions for use		Pass
5.6	When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample		Pass
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted		N/A
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3 .....:	No covers	N/A
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached	No such parts	N/A
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93 % ± 3 % and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h		Pass
	When RISK MANAGEMENT PROCESS indicated ME EQUIPMENT can be exposed to high humidity for extended periods (i.e., out-door use), test time extended proportionally (h) .....:	See Appended RM Results Table 5.7	N/A
5.8	Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent results of one test on a subsequent test		Pass
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		Pass
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS .....:	See clause 4.6 Remark	Pass
5.9.2	ACCESSIBLE PARTS		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.9.2.1	Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position	See Appended Table 5.9.2	Pass
	Openings preventing entry of test finger of Fig. 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N		Pass
	When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening		N/A
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		Pass
	All additional parts that became accessible checked using standard test finger and by inspection		N/A
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS .....:		N/A
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL, and inspection of RISK MANAGEMENT FILE indicated the relevant part is unlikely to detach unintentionally during EXPECTED SERVICE LIFE of ME EQUIPMENT.:	See Appended RM Results Table 5.9.2.3	N/A
6	CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS		—
6.2	CLASS I ME EQUIPMENT, externally powered		Pass
	CLASS II ME EQUIPMENT, externally powered		N/A
	INTERNALLY POWERED ME EQUIPMENT		Pass
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		Pass
	TYPE B APPLIED PART		N/A
	TYPE BF APPLIED PART		Pass
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		Pass
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN_1N_2) as per IEC 60529.....:	IPX0 See RM Results Table 11.6.5.	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use .....:	No parts intended to be sterilized	N/A
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2		N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION .....:	Continuous	Pass
7	ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS		—
7.1.1	RISK of poor USABILITY associated with the design of ME EQUIPMENT'S identification and marking addressed in a USABILITY ENGINEERING PROCESS ... :		Pass
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6 .....:	See Appended Table 7.1.2	Pass
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE		Pass
	a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with requirements in Clause 7.1.2..... :	See appended Tables 7.1.3 and 8.10	Pass
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test..... :	See appended Tables 7.1.3 and 8.10	Pass
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		Pass
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ..... :	See attached copy of Marking Plate	Pass
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS..... :		Pass
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		Pass
	A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01)..... :		Pass
7.2.2	MANUFACTURER's name or trademark marked on ME EQUIPMENT and detachable components ..... :	Components inspected: entire unit	Pass
	Misidentification does not present an unacceptable risk	See Appended RM Results Table 7.2.2	N/A
	MODEL OR TYPE REFERENCE also marked, except when misidentification would not present an unacceptable RISK..... :	See attached copy of Marking Plate	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons..... :	Software version displayed on startup	Pass
7.2.3	Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		N/A
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		Pass
7.2.4	ACCESSORIES marked with name or trademark of MANUFACTURER or supplier, and with a MODEL or TYPE REFERENCE..... :	Accessories inspected: preamps	Pass
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		Pass
7.2.5	MODEL or TYPE REFERENCE of equipment to be connected to ME EQUIPMENT to provide power, is marked adjacent to the relevant connection point when this connection could result in an unacceptable RISK ..... :	See Appended RM Results Table 7.2.5	N/A
7.2.6	Connection to the Supply Mains		Pass
	Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point		Pass
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to supply connection terminals	Not permanently installed	N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V) ..... :	110-240	Pass
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..... :		N/A
	– Nature of supply (e.g., No. of phases, except single-phase) and type of current ..... :	Symbol 1 used	Pass
	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all DB: 2002-10) used, optionally, for same parameters ... :		Pass
	– RATED supply frequency or RATED frequency range in hertz ..... :	50/60 Hz	Pass
	– Symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02) used for CLASS II ME EQUIPMENT..... :	Class I	N/A
7.2.7	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)..... :	1.5 A	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W) :		N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)..... :		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)..... :		N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W) ..... :		N/A
7.2.8	Output connectors		N/A
7.2.8.1	See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT		N/A
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment		N/A
	Rated Voltage (V), Rated Current (A)..... :		N/A
	Rated Power (W), Output Frequency (Hz) ..... :		N/A
7.2.9	ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2)..... :	IPX0	N/A
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6):		Pass
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, DB: 2002-10), not applied in such a way as to give the impression of being inscribed within a square in order to distinguish it from symbol IEC 60417-5333 ..... :		N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, DB: 2002-10)..... :		Pass
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, DB: 2002-10)..... :		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 (IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336, all DB: 2002-10) :		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Proper symbol marked adjacent to or on connector for APPLIED PART, except marked on APPLIED PART when there is no connector, or connector used for more than one APPLIED PART and different APPLIED PARTS with different classifications ..... :		Pass
	Safety sign 2 of Table D.2 (ISO 7010-W001) placed near relevant outlet when protection against effect of discharge of a cardiac defibrillator is partly in the PATIENT cable ..... :		Pass
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use..... :	IFU: 21-22-3000 Rev 00Xe.pdf Pg 13	Pass
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION		Pass
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time..... :	No duty cycle	N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	Verified on equipment	Pass
	Fuse type ..... :	T3.15AH250V	Pass
	Voltage (V) and Current (A) rating ..... :	250V 3.15A	Pass
	Operating speed (s) and Breaking capacity ..... :	T, H	Pass
7.2.13	A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR..... :		N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use ..... :	See Appended RM Results Table 7.2.13	N/A
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10)		N/A
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air)..... :		N/A
7.2.16	ME EQUIPMENT with limited mechanical stability		N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage..... :	No special handling	N/A
	Permissible environmental conditions for transport and storage marked on outside of packaging .....:		Pass
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK ..... :	See Appended RM Results Table 7.2.17	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile	No sterile equipment or accessories	N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector .....:		N/A
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, DB:2002-10) marked on FUNCTIONAL EARTH TERMINAL..... :	no functional earth	N/A
7.2.20	Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed:		N/A
	No marking applied when an interlock provided		N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)..... :	No heating elements	N/A
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		N/A
7.3.2	Symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts ..... :		N/A
7.3.3	Type of battery and mode of insertion when applicable is marked .....:	Custom battery	N/A
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL ..... :	Not intended to be charged by service personnel	N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion).....:	No lithium batteries	N/A
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS ..... :	See Appended RM Results Table 7.3.3	N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL, marked by type and full rating at the component or by reference to ACCOMPANYING DOCUMENTS	Fuses marked	Pass
	Type ..... :	T3.15AH250V	Pass
	Voltage (V) and Current (A) rating .....:	250V 3.15A	Pass
	Operating speed (s) and Breaking capacity .....:	high	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, DB: 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1		Pass
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		Pass
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, DB: 2002 -10) marked on FUNCTIONAL EARTH TERMINALS	No functional earth terminals	N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when no HAZARD would result when interchanging connections	See Appended RM Results Table 7.3.7	N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445)		N/A
	Marking for connection to a 3-phase supply, if necessary, complies with IEC 60445		N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	“For supply connections, use wiring materials suitable for at least X °C” (where X > than max temperature measured in terminal box or wiring compartment under NORMAL USE), or equivalent, marked at the point of supply connections		N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	Marking of controls and instruments		Pass
7.4.1	The “on” & “off” positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 (IEC 60417-5007, DB: 2002-10, and IEC 60417-5008, DB: 2002-10), or		N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	The “on/off” positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 DB: 2002-10), and		Pass
	– status indicated by adjacent indicator light		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– status indicated by other unambiguous means		Pass
	The “on/off” positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 DB: 2002-10), or		N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means		Pass
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE, or	See Appended RM Results Table 7.4.2	Pass
	– an indication of direction in which magnitude of the function changes		N/A
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 31 except the base quantities listed in Table 1 expressed in the indicated units		Pass
	ISO 1000 applied for application of SI units, their multiples, and certain other units		Pass
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3	See Appended Tables 7.1.2 and 7.1.3.	Pass
7.5	Safety signs		Pass
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010	See Appended RM Results Table 7.5	Pass
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		N/A
	Specified colours in ISO 3864-1 used for safety signs..... :	Safety sign 10	Pass
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		Pass
	Safety signs including any supplementary text or symbols described in instructions for use		Pass
7.6	Symbols		Pass
7.6.1	Meanings of symbols used for marking described in instructions for use..... :	See Appended Instruction for Use.	Pass
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced		Pass
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.7	Colours of the insulation of conductors		Pass
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation		Pass
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		Pass
7.7.3	Green and yellow insulation identify only following conductors:		Pass
	– PROTECTIVE EARTH CONDUCTORS		Pass
	– conductors specified in 7.7.2		Pass
	– POTENTIAL EQUALIZATION CONDUCTORS		Pass
	– FUNCTIONAL EARTH CONDUCTORS		N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue” specified in IEC 60227-1 or IEC 60245-1	Enclosed cord	N/A
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1		Pass
7.8	Indicator lights and controls		Pass
7.8.1	Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)		Pass
	Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)		Pass
	Green indicator lights mean: Ready for use		Pass
	Other colours, if used: Meaning other than red, yellow, or green (colour, meaning) .....:		N/A
7.8.2	Red used only for emergency control		Pass
7.9	ACCOMPANYING DOCUMENTS		Pass
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description	21-22-3000 Rev 000Xb	Pass
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		Pass
	– Name or trade-name of MANUFACTURER and an address the RESPONSIBLE ORGANIZATION can be referred to .....:	CAS Medical Systems, Inc. 44 East Industrial Road Branford, CT 06405 U.S.A.	Pass
	– MODEL or TYPE REFERENCE .....:	FORE-SIGHT ELITE	Pass
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CDROM), RISK MANAGEMENT PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (for emergency operation)	See Appended RM Results Table 7.9.1	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	21-22-3000 Rev 000Xb Intended Audience	Pass
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		Pass
7.9.2	Instructions for use include the required information		Pass
7.9.2.1	– intended use of ME EQUIPMENT,	21-22-3000 Rev 000Xb Indications for Use	Pass
	– frequently used functions, and		Pass
	– known contraindication(s) to use of ME EQUIPMENT	21-22-3000 Rev 000Xb Contraindications	Pass
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	21-22-3000 Rev 000Xb Oximeter Classifications of Electrical Insulation, Symbols	Pass
	Instructions for use are in a language acceptable to the intended operator		Pass
7.9.2.2	Instructions for use include all warning and safety notices		Pass
	Warning statement for CLASS I ME EQUIPMENT indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"	IFU: 21-22-3000 Rev 00Xe.pdf Pg 13	Pass
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	21-22-3000 Rev 000Xb Warnings in Installation and Setup	Pass
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	21-22-3000 Rev 000Xb Manufacturer's Declaration of Conformity	Pass
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET indicating, "connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety"		N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	21-22-3000 Rev 000Xb Standards	Pass
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating "power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM"		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source		N/A
	Warning to remove primary batteries when ME EQUIPMENT is not likely to be used for some time when leakage from battery would result in an unacceptable RISK.....:	See Appended RM Results Table 7.9.2.4	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided.....:	No such source power	N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK.....:	See Appended RM Results Table 7.9.2.4	N/A
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	21-22-3000 Rev 000Xb Basic Operations	Pass
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such exposure can constitute an unacceptable RISK		N/A
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected		Pass
	APPLIED PARTS specified	21-22-3000 Rev 000Xb Symbols	Pass
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation	21-22-3000 Rev 00Xb Installation and Setup	Pass
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device when an APPLIANCE COUPLER or separable plug is used as isolation means to meet 8.11.1 a)	IFU: 21-22-3000 Rev 00Xe.pdf Pg 14	Pass
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation including initial control settings, and connection to or positioning of PATIENT prior to use of ME EQUIPMENT, its parts, or ACCESSORIES	21-22-3000 Rev 00Xb Basic Operations	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.9	Information provided to operate ME EQUIPMENT including explanation of controls, displays and signals, sequence of operation, connection of detachable parts or ACCESSORIES, replacement of material consumed during operation	21-22-3000 Rev 00Xb Basic Operations	Pass
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	21-22-3000 Rev 00Xb Symbols, Responding to System Conditions	Pass
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	21-22-3000 Rev 00Xb Responding to System Conditions	Pass
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	21-22-3000 Rev 00Xb Stop Monitoring Patient	Pass
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	21-22-3000 Rev 00Xb Cleaning	Pass
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	Sensors single use	Pass
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	21-22-3000 Rev 00Xb Maintenance	Pass
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	21-22-3000 Rev 00Xb Maintenance	Pass
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	IFU: 21-22-3000 Rev 00Xe.pdf	Pass
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	21-22-3000 Rev 00Xb Maintenance	Pass
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	IFU: 21-22-3000 Rev 00Xe.pdf Pg 49	Pass
	Other equipment providing power to ME SYSTEM sufficiently described (e.g. part number, RATED VOLTAGE, max or min power, protection class, intermittent or continuous service)		N/A
7.9.2.15	RISKS associated with disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified, and instructions provided on minimizing these RISKS ..... :	21-22-3000 Rev 00Xb Device Handling	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)		Pass
7.9.3	Technical description		Pass
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following:		Pass
	– information as in clause 7.2	21-22-3000 Rev 00Xb Appendix - Symbols	Pass
	– permissible environmental conditions of use including conditions for transport and storage	21-22-3000 Rev 00Xb Specifications - Operating Environment, Storage/Transport Environment	Pass
	– all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found	21-22-3000 Rev 00Xb Specifications - Measurement	Pass
	– special installation requirements such as max. permissible apparent impedance of SUPPLY MAINS	21-22-3000 Rev 00Xb General Information	Pass
	– permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling		N/A
	– a description of means of isolating ME EQUIPMENT from SUPPLY MAINS, when such means not in ME EQUIPMENT	21-22-3000 Rev 00Xb Installation and Setup Warnings	Pass
	– a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable		N/A
	– a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples	IFU: 21-22-3000 Rev 00Xe.pdf Pg 37	Pass
	"WARNING: No modification of this equipment is allowed"		Pass
	"WARNING: Do not modify this equipment without authorization of the manufacturer"		N/A
	"WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment"		N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	– information as in clause 7.2		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT		N/A
	– a brief description of ME EQUIPMENT, how it functions, and its significant physical and performance characteristics		N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		N/A
7.9.3.2	The technical description contains the following required information		Pass
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, when type and rating of fuses are not apparent from information on RATED current and mode of operation of ME EQUIPMENT.....:	See Appended RM Results Table 7.9.3.2	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure compliance with 8.11.3		N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and		Pass
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	IFU: 21-22-3000 Rev 00Xe.pdf Pg 13	Pass
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair	IFU: 21-22-3000 Rev 00Xe.pdf Pg 37	Pass
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	21-22-3000 Rev 00Xb Installation and Setup Warnings	Pass

8	PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT		—
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		Pass
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a)		Pass
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)..... :	See Appended RM Results Tables 8.1b(1), (2), (3)	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCESSIBLE PARTS determined according to 5.9		Pass
	LEAKAGE CURRENTS measured according to 8.7		Pass
8.2	Requirements related to power sources		N/A
8.2.1	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM		N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	No HAZARDOUS SITUATION other than absence of ESSENTIAL PERFORMANCE developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	See Appended RM Results Table 8.2.2	N/A
	ME EQUIPMENT connected with correct polarity did not present an unacceptable RISK		N/A
	Protective devices that can be reset by anyone without a TOOL restore correct operation on reset		N/A
8.3	Classification of APPLIED PARTS		Pass
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF		N/A
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		Pass
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF		N/A
	d) Requirements of a TYPE B APPLIED PART applied to a part in 4.6 to be subjected to requirements for an APPLIED PART (except marking)		N/A
	Requirements for a TYPE BF or CF APPLIED PART applied as in RISK MANAGEMENT PROCESS	See Appended RM Results Table 8.3d	N/A
8.4	Limitation of voltage, current or energy		Pass
8.4.1	PATIENT CONNECTIONS intended to deliver Current		N/A
	Limits in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE		N/A
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured according to Clause 8.7.4..... :	See appended Table 8.7	Pass
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA)..... :	See appended Table 8.7	Pass
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed	See Appended RM Results Table 8.4.2c	N/A
	– accessible contacts of connectors		N/A
	– contacts of fuseholders accessible during replacement of fuse		N/A
	– contacts of lampholders accessible after removal of lamp	No lampholders	N/A
	– parts inside an ACCESS COVER that can be opened without a TOOL, or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER	No such access covers	N/A
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.)..... :	See appended Table 8.4.2	N/A
	Limit of 60 V d.c applied with no more than 10% peak-to-peak ripple, and when ripple larger than specified value, 42.4 V peak limit applied (V d.c.):	See appended Table 8.4.2	N/A
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V (VA or J) ..... :	See appended Table 8.4.2	N/A
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA) ..... :	See appended Table 8.4.2	N/A
	d) Voltage and energy limits specified in c) above also applied to the following:		N/A
	– internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls using a TOOL		N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N/A
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		N/A
	Test repeated with a TOOL specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		N/A
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION		N/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnecting the plug of ME EQUIPMENT or its parts (V) ..... :	See appended Table 8.4.3	Pass
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform		Pass
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC..... :	See appended Table 8.4.3	N/A
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC..... :	See appended Table 8.4.4	N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, DB: 2002-10), and manual discharging device specified in technical description..... :		N/A
8.5	Separation of parts		Pass
8.5.1	MEANS OF PROTECTION (MOP)		Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4		Pass
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account Clause 4.6, and flow chart in Fig A.12		Pass
	Varnishing, enameling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		Pass
	Coatings and other insulation intended as a MEANS OF PROTECTION complying with IEC 60950-1:2001 considered acceptable as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION	None used a MOP	N/A
	RISK MANAGEMENT PROCESS taken into consideration for MEANS OF PATIENT PROTECTION		Pass
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		Pass
	Insulation, CREEPAGE, CLEARANCES, components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION, and failure of these parts regarded as NORMAL CONDITION		Pass
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		Pass
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6		Pass
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		Pass
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		Pass
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF PATIENT PROTECTION considered equivalent to one MEANS OF PATIENT PROTECTION	See Appended Tables 8.8.3 and 8.10	Pass
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Not used	N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :	1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	Pass
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		Pass
	– dielectric strength test of 8.8 at test voltage of Table 6; or		Pass
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		Pass
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		Pass
	– limits of Tables 13 to 16 (inclusive); or		Pass
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		Pass
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6, or		Pass
	– requirements and tests of IEC 60950-1 for protective earthing ..... :		Pass
	A Y2 capacitor complying with IEC 60384-14 and passing dielectric strength test for one MEANS OF OPERATOR PROTECTION considered equivalent to one MEANS OF OPERATOR PROTECTION..... :	See Appended Tables 8.8.3 and 8.10 None used	N/A
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF OPERATOR PROTECTION considered equivalent to two MEANS OF OPERATOR PROTECTION ..... :	See Appended Tables 8.8.3 and 8.10	Pass
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Not used	N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :	1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	Pass
	Points at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION	No such points	N/A
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION..... :		Pass
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION ..... :		Pass
8.5.2	Separation of PATIENT CONNECTIONS		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to maximum MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT at 110 % of max. MAINS VOLTAGE ..... :	See appended Table 8.7	Pass
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		Pass
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		Pass
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :		Pass
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	BF, defibrillation proof	Pass
	LEAKAGE CURRENT tests conducted per 8.7.4 ..... :	See appended Table 8.7	Pass
	Dielectric strength test conducted per 8.8.3 ..... :	See appended Table 8.8.3	Pass
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		Pass
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		Pass
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED..... :	See Appended RM Results Table 8.5.2.2	N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N/A
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 ..... :	See appended Table 8.7	N/A
	Dielectric strength test conducted per 8.8.3 ..... :	See appended Table 8.8.3	N/A
	Relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		N/A
	The RISK MANAGEMENT FILE reviewed		N/A
8.5.2.3	A connector on a PATIENT lead located at the end of the lead remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT ..... :	No patient leads	N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N/A
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, except when RISK MANAGEMENT PROCESS indicated no unacceptable RISK existed from contact with objects other than a mains socket or a flat surface:	See Appended RM Results Table 8.5.2.3	N/A
8.5.3	MAXIMUM MAINS VOLTAGE		Pass
	– MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, as well as INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V) ..... :	240 VAC	Pass
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V		N/A
	– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V) ..... :		N/A
	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V	35VDC	Pass
8.5.4	WORKING VOLTAGE		N/A
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)..... :	Certified power supply	N/A
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V) ..... :	Certified power supply	N/A
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) ..... :	See Insulation Diagram and Insulation Table Certified power supply	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	Certified power supply	N/A
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V) ..... :	Certified power supply	N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	Certified power supply	N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) ..... :	Certified power supply	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS		Pass
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART		Pass
	Possibility of an OPERATOR receiving a shock from such parts taken into consideration in RISK MANAGEMENT PROCESS	21-07-0304 and 21-07-0306 Hazard 4.1.1.8	Pass
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		Pass
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :	See Appended Table 8.5.5.1a	Pass
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS ..... :	See Appended Table 8.5.5.1b	Pass
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90% of energy delivered to this load with ME EQUIPMENT disconnected ..... :	See Appended Table 8.5.5.2	Pass
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		Pass
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		Pass
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR..... :		Pass
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside ..... :		Pass
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		Pass
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		Pass
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE :	See Appended RM Results Table 8.6.3	Pass
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop	See appended Table 8.6.4	Pass
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits..... :	See appended Table 8.6.4 & Clause 8.7	Pass
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact		N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	Plugs and sockets		Pass
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		Pass
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		Pass
	– RISK of accidental disconnection minimized in NORMAL USE		Pass
	– Terminal allows conductor to be detached without a TOOL		Pass
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		Pass
	– Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021)		Pass
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		Pass
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		Pass
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	No functional earth	N/A
8.6.9	Class II ME EQUIPMENT		N/A
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow	Not Class II	N/A
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description ..... :		N/A
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		Pass
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3 .... :	See appended Tables 8.7	Pass
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7 ..... :	See appended Tables 8.7	Pass
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		Pass
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		Pass
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		Pass
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		Pass
8.7.3	Allowable Values		Pass
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b ..... :	See appended Tables 8.7	Pass
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz ..... :	See appended Tables 8.7	Pass
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})..... :	See appended Tables 8.7	Pass
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}) ..... :	See appended Tables 8.7	Pass
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 ..... :	See appended Tables 8.7	N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device..... :	See appended Tables 8.7	Pass
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements..... :	See appended Tables 8.7	Pass
8.8	Insulation		Pass
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER-CURRENT RELEASE		Pass
	Insulation exempted from test (complies with clause 4.8)	None exempt from testing	N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		Pass
8.8.2	Distance through solid insulation or use of thin sheet material		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	Not used	N/A
	a) 0.4 mm, min, distance through insulation, or		N/A
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N/A
	– at least two layers of material, each passed the appropriate dielectric strength test, or	See appended Table 8.8.3	N/A
	– three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test	See appended Table 8.8.3	N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		N/A
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N/A
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		N/A
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		N/A
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension ..... :		N/A
	Finished component complied with routine dielectric strength tests of 8.8.3 ..... :	See appended Table 8.8.3	Pass
	Tests of Annex L not repeated since material data sheets confirm compliance ..... :	See Table 8.10 and Material Information Attachment	N/A
8.8.3	Dielectric Strength		Pass
	Solid insulating materials with a safety function withstood dielectric strength test voltages ..... :	See appended Table 8.8.3	Pass
8.8.4	Insulation other than wire insulation		Pass
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		Pass
	ME EQUIPMENT and RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests ..... :	See Appended RM Results Table 8.8.4.1	Pass
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :	Test performed	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat..... :	Test performed	Pass
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using apparatus of Fig 21	See Table 8.8.4.1	Pass
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C) ..... :	See Table 8.8.4.1	N/A
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		N/A
8.8.4.2	Resistance to environmental stress		N/A
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples		N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		Pass
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15		Pass
8.9.1.2	Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested	Not used	N/A
8.9.1.3	Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics		Pass
8.9.1.4	When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE		Pass
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m		Pass
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m) ..... :		N/A
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used to determine multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor	Not pressurized	N/A
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE		Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.6	When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		Pass
	– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :	See Insulation Diagram/Table.	Pass
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :	See Insulation Diagram/Table.	Pass
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied		Pass
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group) ..... :	See Insulation Diagram/Table.	Pass
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112 ..... :	Not evaluated	N/A
	Material of unknown group considered IIIb		Pass
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N/A
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation		Pass
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation		N/A
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions		N/A
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION		N/A
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree		N/A
8.9.1.9	Overvoltage category classification; value of MAINS TRANSIENT VOLTAGE determined from overvoltage category per IEC60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10		Pass
	V_{MT} Peak (V) ..... :	2500	Pass
	V_{MN} r.m.s (V) ..... :	250	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.10	AIR CLEARANCE for MAINS PARTS (operating on RATED MAINS VOLTAGES up to 300 V) were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE	Max 250 VAC	N/A
8.9.1.11	SUPPLY MAINS overvoltage category II applied according to IEC 60664-1		Pass
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used		N/A
	When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for Cl. 8.9 used		N/A
8.9.1.12	A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)		N/A
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		N/A
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		Pass
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I		N/A
	Table 15 column for circuits not subject to transient overvoltages applied to:		N/A
	– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and		N/A
	– circuits in INTERNALLY POWERED ME EQUIPMENT		N/A
8.9.1.13	For PEAK WORKING VOLTAGES above 1400 V peak or d.c. Table 15 not applied since all the following conditions were met:		N/A
	– CLEARANCE was at least 5 mm		N/A
	– insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or		N/A
	– a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I		N/A
	Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material		N/A
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION		Pass
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1		Pass
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied..... :	See appended Table 8.9.2 Measurements applied	N/A
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		Pass
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by molding, or there is no reduction of a distance below specified value by deformation or movement of parts		Pass
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		Pass
8.9.3	Spaces filled by insulating compound		N/A
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound were such that CLEARANCES and CREEPAGE DISTANCES don't exist	No spaces filled with insulating compound	N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted		N/A
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6 ..... :	See appended Table 8.9.3.2	N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N/A
	A winding of solvent-based enameled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N/A
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage ..... :	See appended Table 8.9.3.4	N/A
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage		N/A
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times ..... :	See appended Table 8.9.3.4	N/A
8.10	Components and wiring		Pass
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely as indicated in RISK MANAGEMENT FILE.... :	See Appended RM Results Table 8.10.1	Pass
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION ..... :	See Appended RM Results Table 8.10.2	Pass
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION as indicated in RISK MANAGEMENT FILE		Pass
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION		Pass
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS due to poor contact		Pass
8.10.3	Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as shown by measurement or using test finger	See Appended Table 5.9.2	N/A
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION		N/A
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		N/A
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		N/A
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION		N/A
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION		N/A
8.10.5	Mechanical protection of wiring		Pass
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION. :	See Appended RM Results Table 8.10.5	Pass
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION as shown by manual tests and RISK MANAGEMENT FILE		Pass
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE		N/A
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed..... :	See appended Table 8.10	N/A
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		Pass
	c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation ..... :	See appended Table 8.10	N/A
8.11	MAINS PARTS, components and layout		Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles..... :	See appended Table 8.10	Pass
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description ..... :	See appended Table 8.10	Pass
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV..... :	See appended Table 8.10	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		Pass
	e) Direction of movement of actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a) ..... :	See appended Table 8.10	Pass
	g) A fuse or a semiconductor device not used as an isolating means		Pass
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		Pass
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering		N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)		N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger of Fig 6 applied		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No multiple socket-outlets	N/A
8.11.3	POWER SUPPLY CORDS		Pass
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD		Pass
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design. 53)..... :	See appended Table 8.10	Pass
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ..... :	See appended Table 8.10	N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm^2 Cu) ..... :	18 G wire	Pass
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6..... :	See appended Table 8.10	Pass
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		N/A
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:		N/A
	– insulating material, or		N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N/A
	– metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails		N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 ..... :	See appended Table 8.11.3.5	N/A
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		N/A
8.11.3.6	POWER SUPPLY CORDS other than for STATIONARY ME EQUIPMENT protected against excessive bending at inlet opening of equipment or of MAINS CONNECTOR by means of an insulating cord guard or by means of an appropriately shaped opening		N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g) ..... :	See appended Table 8.11.3.6	N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D..... :	See appended Table 8.11.3.6	N/A
8.11.4	MAINS TERMINAL DEVICES		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection	Detachable power cord	N/A
	Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	Detachable power cord	N/A
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		N/A
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3		N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		N/A
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times		N/A
8.11.4.4	Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4		N/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a re-wirable POWER SUPPLY CORD to allow for connection of conductors, and covers fitted without damage to conductors or their insulation		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		Pass
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection per clause 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT ..... :	See appended Table 8.10 and Appended RM Results Table 8.11.5	Pass
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	portable	N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts of opposite polarity within MAINS PART, and between all parts of MAINS PART and earth, and such provisions continued within all components	Not omitted	N/A
	Effect of short-circuit fault conditions in other circuits taken into consideration before eliminating fuses or OVER-CURRENT RELEASES		N/A
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit ..... :	See appended Table 8.10	Pass
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		Pass
	Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current rating of the fuse, whichever is greater		Pass
	Justification for omission of fuses or OVER-CURRENT RELEASES is in RISK MANAGEMENT FILE	Fuses provided in the ME equipment; No omission of the fuses or over current releases	N/A
8.11.6	Internal wiring of the MAINS PART		N/A
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not less than minimum required for POWER SUPPLY CORD as in clause 8.11.3.3 (mm^2 Cu) ..... :	Certified power supply	N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents .. :	Certified power supply	N/A
	When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2	Certified power supply	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9	PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS		—
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)		Pass
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level ..... :	See Appended RM Results Table 9.2.1	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its function		N/A
	Warnings marked on ME EQUIPMENT or included in instructions for use when HAZARDS persisted after implementing all reasonable protective measures:	See provided Marking Labels	N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:		N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and protective measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20.....:	See appended Table 9.2.2.2	N/A
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13852 ..... :	See appended Table 9.2.2.2	N/A
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse		N/A
9.2.2.4	GUARDS and protective measures		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.4.1	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when GUARDS and protective measures were of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK based on results of applicable tests in 15.3 for ENCLOSURES:	See Appended Table 15.3	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that cannot be dismantled without a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open	See Appended RM Results Table 9.2.2.4.3	N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with all applicable tests as confirmed by review of RISK MANAGEMENT FILE		N/A
9.2.2.4.4	Protective measures provided in control system prevented moving parts from starting to move while in reach of persons .....:	See Appended RM Results Table 9.2.2.4.4	N/A
	– protective measures prevented TRAPPING ZONE from reach, or, when it was reached, system movement stopped once ME EQUIPMENT started to move, and in the latter case, no HAZARD or damage resulted		N/A
	– when protective measure was in a SINGLE FAULT CONDITION, and an unacceptable RISK could arise, one or more emergency stopping device(s) provided		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.2.5	Continuous activation		N/A
	TRAPPING ZONE not considered to present a MECHANICAL HAZARD where impractical to make TRAPPING ZONE inaccessible when:		N/A
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR as long as OPERATOR response to deactivate device relied upon to prevent HARM		N/A
	Manually operated movements complied with this clause since mass and velocity allowed adequate control of positioning without causing an unacceptable RISK		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) when in a SINGLE FAULT CONDITION of continuous activation system an unacceptable RISK could arise, one or more emergency stopping device(s) provided in ME EQUIPMENT .....:	See Appended RM Results Table 9.2.2.5 c)	N/A
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT, when contact with ME EQUIPMENT could result in a HAZARDOUS SITUATION, limited to allow OPERATOR control of positioning without resulting in an unacceptable RISK.....:	See Appended RM Results Table 9.2.2.6	N/A
	Over travel (stopping distance) of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
9.2.3	Other HAZARDS associated with moving parts		N/A
9.2.3.1	Controls positioned, recessed, or protected by other means and could not be accidentally actuated to result in unacceptable RISK, except when ergonomic considerations for a PATIENT with special needs require otherwise		N/A
9.2.3.2	RISK due to over travel (past range limits) of ME EQUIPMENT parts reduced to an acceptable level, and stops or other means with mechanical strength to withstand intended loading in NORMAL USE and foreseeable misuse provided limiting measure in NORMAL and SINGLE FAULT CONDITION .:	See appended Table 8.10 and Appended RM Results Table 9.2.3.2	N/A
9.2.4	Emergency stopping devices		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power :	See Appended RM Results Table 9.2.4	N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original HAZARD		N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 (symbol IEC 60417-5638, DB:2002-10) or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a protective measure, or emergency stopping, and	See Appended RM Results Table 9.2.5	N/A
	– Uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N/A
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered .....:	See Appended RM Results Table 9.3	Pass
9.4	Instability HAZARDS		Pass
9.4.1	ME EQUIPMENT, other than FIXED and hand-held, for placement on a surface did not overbalance (tip over) or move unexpectedly, to the degree that it could present an unacceptable RISK to PATIENT, or OPERATOR as tested in 9.4.2 to 9.4.4		Pass
9.4.2	Instability – overbalance		Pass
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when not specified, as in 9.4.2.2, and placed on a 10° inclined plane from horizontal consisting of a hard and flat surface (e.g., concrete floor covered with 2 to 4 mm thick vinyl material).....:	See Appended Table 9.4.2.1	Pass
9.4.2.2	Instability excluding transport		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT or its parts prepared based on a) to g), inclusive, did not overbalance when placed in different positions of NORMAL USE, except transport positions, on a 5° inclined plane from horizontal (hard and flat surface)	See Appended Table 9.4.2.2	Pass
	A warning provided, stating "Transport only under conditions described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances" when overbalance occurred during 10° inclined plane test	Passed at 10°	N/A
9.4.2.3	Instability from horizontal and vertical forces		N/A
	a) ME EQUIPMENT with a mass of 25 kg or more, other than FIXED ME EQUIPMENT for use on floor, did not overbalance due to pushing or resting		N/A
	Surfaces of ME EQUIPMENT where a RISK of overbalancing exists from pushing, leaning, resting etc., permanently marked with a CLEARLY LEGIBLE warning of the RISK (e.g., safety sign 5 of Table D.2, safety sign ISO 7010-P017)		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a force of 25% of its weight, but not more than 220 N, applied in different directions, except a direction with an upward component		N/A
	b) ME EQUIPMENT, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping, except when a legible warning of this RISK provided on ME EQUIPMENT (e.g., safety signs 6 and 7 of Table D.2, safety signs ISO 7010-P018, or ISO 7010-P019 as appropriate)		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a constant force of 800 N applied at the point of maximum moment to working surfaces, offering an foothold or sitting surface of a min 20 x 20 cm area, and at a height ≤ 1 m from the floor .....:	See Appended Table 9.4.2.3	N/A
9.4.2.4	Castors and wheels		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT (e.g., castors or wheels) did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT along a hard and flat horizontal surface did not exceed 200 N applied at a height of 1 m above floor or highest point on ME EQUIPMENT when < 1 m high, except when instructions indicated more than one person needed (N) ..... :	See Appended Table 9.4.2.4.2	N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg configured with a SAFE WORKING LOAD, moved 10 times in forward direction over a solid vertical plane obstruction with wheels impacting the obstruction at a speed of 0.4 m/s ± 0.1 m/s for manual or with max speed for motor driven MOBILE ME EQUIPMENT ..... :	See Appended Table 9.4.2.4.3	N/A
	ME EQUIPMENT went up the obstruction without overbalancing or any other unacceptable RISK as determined by examination of RISK MANAGEMENT FILE, ME EQUIPMENT and its parts ..... :	See Appended RM Results Table 9.4.2.4.3	N/A
	There was no reduction of CREEPAGE and CLEARANCES below 8.9, no access to parts exceeding limits in 8.4, and no access to moving parts capable of causing HARM, and		N/A
	– Assessment criteria in Clause 9 and 11.6 used		N/A
	– Dielectric strength test of 8.8.3 conducted to evaluate integrity of solid SUPPLEMENTARY or REINFORCED INSULATION		N/A
	– CREEPAGE DISTANCES and AIR CLEARANCES measured compared favourably with min distances in clause 8.9		N/A
	Small chips not adversely affecting protection against electric shock or moisture, disregarded		N/A
9.4.3	Instability from unwanted lateral movement (including sliding)		N/A
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control		N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position		N/A
	c) No unacceptable RISK due to unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position or worst case NORMAL USE position with SAFE WORKING LOAD, and locking device activated, on a 10° inclined hard flat surface with castors in the worst-case position		N/A
	Following initial elastic movement, creepage, and pivoting of castors, no further movement of MOBILE ME EQUIPMENT > 50 mm (in relation to inclined plane) occurred (mm) ..... :	See Appended Table 9.4.3.1	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK due to any initial movement assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
9.4.3.2	Instability excluding transport		N/A
	a) Further movement of ME EQUIPMENT (after initial elastic movement) was less than 50 mm when MOBILE ME EQUIPMENT with a SAFE WORKING LOAD positioned on a 5° inclined hard flat surface with wheel locked or braking system activated (mm).. :	See Appended Table 9.4.3.2	N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
	b) TRANSPORTABLE or STATIONARY ME EQUIPMENT for use on the floor and with a SAFE WORKING LOAD prepared as in 9.4.2.2 and placed on a horizontal plane with locking device activated and castors, when supplied, in their worst –case position		N/A
	Further movement of ME EQUIPMENT (after initial elastic movement), was no more than 50 mm when a force of 25 % of weight of unit, but less than 220 N, applied in different directions, except a direction with an upwards component, at highest point of ME EQUIPMENT but ≤ 1.5 m from floor ..... :	See Appended Table 9.4.3.2	N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
9.4.4	Grips and other handling devices		N/A
	a) ME EQUIPMENT other than PORTABLE EQUIPMENT or its part with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method, except when handling is obvious and causing HAZARDS		N/A
	Handles, when supplied, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test ..... :	See Appended Table 9.4.4	N/A
9.5	Expelled parts HAZARD		Pass
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts determined by assessment and examination of RISK MANAGEMENT FILE..... :	See Appended RM Results Table 9.5.1	Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .....:	See appended Table 8.10	N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		Pass
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK as confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and tests of 9.6.2 and 9.6.3...:	See Appended RM Results Table 9.6.1	Pass
9.6.2	Acoustic energy		Pass
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory alarm signals		Pass
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:		Pass
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:		Pass
	– 140 dB un-weighted sound pressure level for impulsive or impact acoustic energy (dB) .....:		Pass
9.6.2.2	RISK MANAGEMENT FILE examined for RISKS associated with infrasound or ultrasound, when present, addressed in RISK MANAGEMENT PROCESS	See Appended RM Results Table 9.6.2.2	N/A
9.6.3	Hand-transmitted vibration		N/A
	Means provided, except for INTENDED USE vibrations, to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values measured at points of hand contact with PATIENT or OPERATOR	No vibration	N/A
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2).....:		N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s^2) .....:		N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK		N/A
	Parts of a pneumatic or hydraulic system used as a support system, comply with 9.8		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met following requirements based on examination of RISK MANAGEMENT FILE .....:	See Appended RM Results Table 9.7.2	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:		N/A
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		N/A
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		N/A
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by examination of ME EQUIPMENT and RISK MANAGEMENT FILE, and by functional tests .....:	See Appended RM Results Table 9.7.4	N/A
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was > 50 kPa, and product of pressure and volume was more than 200 kPaI .....:	See Appended Table 9.7.5	N/A
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE .....:	See Appended RM Results Table 9.7.6	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests .....:	See Appended RM Results Table 9.7.7	N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
9.8	HAZARDS associated with support systems		N/A
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK .....:	See appended Table 8.10 and Appended RM Results Table 9.8.1	N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A
	– RISK ANALYSIS of support systems included HAZARDS from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions		N/A
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest		N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing .....:	See Appended RM Results Table 9.8.2	N/A
	When test results were part of information, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK .....:	See appended Table 8.10	N/A
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS minimize RISK of physical injuries and accidental loosening of secured joints	See Appended RM Results Table 9.8.3.1	N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance .....:	See copy of Marking Label	N/A
9.8.3.2	Part of SAFE WORKING LOAD representing mass of PATIENTS or OPERATORS is distributed on support/suspension surface representing human body as in Fig A.19		N/A
	Part of SAFE WORKING LOAD representing mass of ACCESSORIES deployed as in NORMAL USE and, when not defined, at worst case position permitted by configuration or ACCESSORIES attachment on support/suspension parts		N/A
	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR .....:	See Appended RM Results Table 9.8.3.2 a)	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and tests .....:	See appended Table 8.10	N/A
	PATIENT support/suspension system positioned horizontally in most disadvantageous position in NORMAL USE, and a mass 2 x 135 kg or twice intended person's load (the greater used), applied to foot rest over an area of 0.1 m^2 for 1 min (Kg) :	See appended Table 9.8.3.2	N/A
	Damage or deflection resulting in an unacceptable RISK did not occur on foot rest and its secured joints		N/A
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK .....:	See Appended RM Results Table 9.8.3.2 b)	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and by a test ..:	See appended Table 8.10	N/A
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass of 60 % of part of SAFE WORKING LOAD simulating PATIENT or OPERATOR, or a min 80 kg, placed on support or suspension system with centre of load 60 mm from outer edge of support or suspension system for at least one minute (Kg) .....:	See appended Table 9.8.3.2	N/A
	Deflection of support/suspension system resulting in an unacceptable RISK not occur		N/A
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE did not result in an unacceptable RISK as confirmed by following test:		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass equal to SAFE WORKING LOAD simulating PATIENT or OPERATOR dropped from 150 mm above seat area on an area of support/ suspension a PATIENT or OPERATOR can sit..... :	See appended Table 9.8.3.3	N/A
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		N/A
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided when a support system or its parts impaired by wear have a TENSILE SAFETY FACTOR ≥ to values in Table 21, rows 5 and 6, but less than 3 and 4 ....:	See Appended RM Results Table 9.8.4.1	N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD, and includes effects of SAFE WORKING LOAD when applicable		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel (movement) produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing .....:	See appended Table 8.10	N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE (e.g., a secondary cable)		N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	– Further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE ..:	See Appended RM Results Table 9.8.4.3	N/A
	– ACCOMPANYING DOCUMENTS instruct once MECHANICAL PROTECTIVE DEVICE is activated, SERVICE PERSONNEL shall be called, and MECHANICAL PROTECTIVE DEVICE must be replaced before ME EQUIPMENT can be used		N/A
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 (i.e., safety sign 7010-W001)		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE or its location relative to MECHANICAL PROTECTIVE DEVICE is obvious to service personnel		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Compliance confirmed by examination of ME EQUIPMENT, ACCOMPANYING DOCUMENTS, RISK MANAGEMENT FILE, specifications and processing of materials, and following test.....:	See appended Table 8.10	N/A
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support system parts have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 1 and 2, and are not impaired by wear .....:	See Appended RM Results Table 9.8.5	N/A
	Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 3 and 4		N/A
	Examination of ME EQUIPMENT and RISK MANAGEMENT FILE confirmed compliance		N/A

10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS		—
10.1	X-Radiation		N/A
10.1.1	X-radiation dose-rate was ≤ 36 pA/kg (5 µSv/h) (0.5 mR/h) 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation ..... :	See Table 10.1.1	N/A
	Amount of radiation measured by means of an ionizing chamber radiation monitor with an effective area of 10 cm^2 or by other instruments producing equal results		N/A
	ME EQUIPMENT operated as in NORMAL USE at most unfavourable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation		N/A
	Internal pre-set controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE (see IEC 60601-1-3 & 1.3) ..... :	See Appended RM Results Table 10.1.2	N/A
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE..... :	See Appended RM Results Table 10.2	N/A
10.3	RISK associated with microwave radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .. :	See Appended RM Results Table 10.3	N/A
10.4	Relevant requirements of IEC 60825-1:1993 applied to lasers, light emitting diodes (LEDs), and laser light barriers or similar products		N/A
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .. :	See Appended RM Results Table 10.5	N/A
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... :	See Appended RM Results Table 10.6	N/A
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 10.7	N/A
11	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS		—
11.1	Excessive temperatures in ME EQUIPMENT		Pass
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T .....:	See appended Table 11.1.1 and appended RM Results Table 11.1.1	Pass
	Surfaces of test corner did not exceed 90 °C		N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		N/A
11.1.2	Temperature of APPLIED PARTS		Pass
11.1.2.1	Temperatures, hot or cold surfaces, and when appropriate, clinical effects of APPLIED PARTS supplying heat to a PATIENT determined and documented in RISK MANAGEMENT FILE and instructions for use.....:	See appended Table 11.1.1 and appended RM Results Table 11.1.2.1	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.1.2.2	APPLIED PARTS not supplying heat to a PATIENT met Table 24 with max surface temperatures > 41 °C disclosed in instructions for use, and clinical effects regarding maturity of PATIENTS, body surface, surface pressure, medications taken, as shown in RISK MANAGEMENT FILE.....:	See appended Table 11.1.1 and appended RM Results Table 11.1.2.2	Pass
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS		N/A
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE .....:	See appended Table 11.1.3 and RM Results Table 11.1.3	N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE		N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE		Pass
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL		N/A
11.2	Fire prevention		Pass
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse and met mechanical strength tests for ENCLOSURES in 15.3		Pass
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of fire under NORMAL or SINGLE FAULT CONDITIONS when source of ignition in contact with ignitable material .....:	See appended Table 8.10	N/A
	Requirements of 13.1.1 applied to oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27.5 kPa for higher atmospheric pressures		N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT in NORMAL and SINGLE FAULT CONDITIONS under any of the following conditions . :		N/A
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE	See Appended RM Results Table 11.2.2.1	N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively..... :	See appended Table 11.2.2.1	N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :		N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... :	See Appended RM Results Table 11.2.2.1	N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3 ..... :	See appended Tables 4.11, 11.1.1 to 11.1.2.2, inclusive; and Table 13.2	N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%)..... :		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE ..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases ..... :		N/A
11.2.2.2	RISK of ignition under least favourable conditions did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT when electrical components mounted outside of ME EQUIPMENT or ME SYSTEM		N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks due to loosening or breaking, except when limited in power and energy to values in 11.2.2.1 a) 5)		N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) ..... :		N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a)..... :		N/A
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a)..... :		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas..... :		N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		N/A
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 ..... :	See Appended RM Results Table 11.3 No fire enclosure claimed metal enclosure	N/A
	Constructional requirements were met, or		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE .....:	See Appended RM Results Table 11.3	N/A
	Justification, when requirement not met .....:		N/A
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials	See appended Table 8.10	N/A
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data .....:	See appended Table 8.10	N/A
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		N/A
	b) Fire ENCLOSURE met following:		N/A
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		N/A
	2) No openings on the sides within the area included within the inclined line C in Fig 39		N/A
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and made of appropriate metal or of non-metallic materials, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a) .....:	See appended Table 8.10	N/A
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable anaesthetics (CATEGORY AP) or anaesthetics with oxidants (CATEGORY APG) comply with Annex G		N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N/A
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE .....:	See Appended RM Results Table 11.5	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		Pass
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT .....:	See Appended Table 11.6.1	Pass
11.6.2	Overflow in ME EQUIPMENT		N/A
	Liquid reservoir liable to overflow in NORMAL USE completely filled and 15 % of its capacity poured in for over 1 min, and except when restricted, TRANSPORTABLE ME EQUIPMENT tilted through an angle of 15° in least favourable direction(s), and when necessary refilled starting from position of NORMAL USE ..... :	See Appended RM Results Table 11.6.2 and Table 11.6.1	N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet..... :	See appended Table 8.7and 8.8.3	N/A
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM		Pass
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill, point of contact, and test conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT..... :	See Appended RM Results Table 11.6.3 and Table 11.6.1	Pass
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet ..... :	See appended Table 8.7and 8.8.3	Pass
11.6.4	Leakage	See 13.2.6	N/A
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :	See Appended RM Results Table 11.6.5 and Table 11.6.1	N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in a SINGLE FAULT CONDITION	See appended Table 8.7and 8.8.3	N/A
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		Pass
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected once using methods specified in instructions for use including any cooling or drying period ..... :	See Appended RM Results Table 11.6.6 and Table 11.6.1	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests, with no deterioration resulting in an unacceptable RISK present ..... :	See appended Table 8.7and 8.8.3	Pass
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER and assurance that no unacceptable RISK will occur verified by RISK MANAGEMENT FILE review ..... :	See RM Results Table 11.6.6	Pass
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11134, ISO 11135, or ISO 11137 as appropriate ..... :	See Appended RM Results Table 11.6.7	N/A
	After the test, ME EQUIPMENT complied with the appropriate dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK ..... :	See appended Table 8.7and 8.8.3, and 11.6.1	N/A
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 11.6.8	N/A
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented per ISO 10993		Pass
11.8	Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function		Pass

12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		—
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review..... :	See Appended RM Results Table 12.1	Pass
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS as confirmed by review of provided records ..... :	See Report based on IEC 60601-1-6	Pass
12.3	The need for alarm systems as a means of RISK CONTROL and RISKS associated with operation or failure of alarm system addressed in RISK MANAGEMENT PROCESS ..... :	See Report based on IEC 60601-1-8 and appended RM Results Table 12.3	Pass
12.4	Protection against hazardous output		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.1	N/A
12.4.2	When applicable, need for indication of parameters associated with hazardous output addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.2	Pass
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit designed to provide low and high-intensity outputs for different treatments addressed in RISK MANAGEMENT PROCESS, confirmed in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.3	N/A
12.4.4	When applicable, RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE..... :	See Appended RM Results Table 12.4.4	N/A
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation emitted by ME EQUIPMENT designed to produce radiation for diagnostic/therapeutic purposes		N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	RISKS associated with diagnostic X-rays addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :	See appended RM Results Table 12.4.5.2	N/A
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE..... :	See Appended RM Results Table 12.4.5.3	N/A
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.5.4	N/A
12.4.6	When applicable, RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 12.4.6	N/A

13	HAZARDOUS SITUATIONS AND FAULT CONDITIONS		—
13.1	Specific HAZARDOUS SITUATIONS		Pass
13.1.1	None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2		Pass
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		Pass
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		Pass
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3 ..... :	See appended Tables 11.1.1, 11.1.2.1, and 11.1.2.2	Pass
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3 ..... :	See appended Tables 11.1.1, 11.1.2.1, and 11.1.2.2	Pass
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded		Pass
	Limits for windings in Tables 26, 27, and 31 not exceeded		N/A
	Table 22 not exceeded in all other cases		Pass
	Temperatures measured according to 11.1.3		Pass
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:		Pass
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit, or	See appended Table 13.1.2	N/A
	– Parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation		N/A
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed..... :	See appended Table 8.7	Pass
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed ..... :	See appended Table 8.7	Pass
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS		Pass
13. 2	SINGLE FAULT CONDITIONS		Pass
13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination ..... :	See appended Table 13.2	N/A
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12 ..... :	See appended Table 13.2 and RM Results Table 13.2.6	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to room temperature		N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		N/A
13.2.13.2	ME EQUIPMENT with heating elements		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests of 13.2.13.2 b) & 13.2.13.2 c)		N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests of 13.2.13.2 b) and 13.2.13.2 c)		N/A
	a 3) other ME EQUIPMENT with heating elements met test of 13.2.13.2 b)		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) ME EQUIPMENT with heating elements tested per 11.1without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V) ..... :		N/A
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	ME EQUIPMENT with motors		N/A
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable		N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A
	b) Motor met running overload protection test of this clause when:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) ..... :		N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification) ..... :		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		N/A
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N/A
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated		N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N/A
	Motor winding temperatures did not exceed values in 13.2.10 ..... :		N/A
	Insulation Class..... :		N/A
	Maximum temperature measured (°C) ..... :		N/A
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		—
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or		N/A
	- when application of ISO 14971 showed that failure of PESS does not lead to unacceptable RISK ..... :	See Appended RM Results Table 14.1	N/A
	Every PROCESS has been followed throughout the PEMS DEVELOPMENT LIFE-CYCLE and a RECORD of PROCESS has been made available as confirmed by RISK MANAGEMENT FILE REVIEW and assessment of PROCESSES cited in this Clause		Pass
	MANUFACTURER considered the need for additional RISK CONTROL measures when unable to follow all PROCESSES identified in Clause 14 for each constituent component of PEMS as confirmed by RISK MANAGEMENT FILE review and assessment of PROCESSES cited in this Clause	No OTS or subsystems of non-medical origin used	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Assessment of PROCESSES cited in this Clause made by internal audits	audit Quality Systems Procedure QSP2016 – Internal Quality Audits QSP2016.pdf 2012 Internal Audit Summary. Notice process step 8 for risk management 2012 Internal Audit Schedule.pdf audit checklist which includes risk management and its application to PEMS Risk Management Audit Checklist.docx	Pass
14.2	Documents produced from application of Clause 14 are maintained and form a part of RISK MANAGEMENT FILE in addition to RECORDS and documents required by ISO 14971 ..... :	21-07-0303rev03.pdf Item5.5	Pass
14.3	RISK MANAGEMENT plan required by 3.5 of ISO 14971 includes reference to PEMS VALIDATION plan		Pass
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	Gemini Design Schedule 21-07-0300 Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	Gemini Design Schedule 21-07-0300 Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	Gemini Design Schedule 21-07-0300 Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	Gemini Design Schedule 21-07-0300	Pass
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	Gemini Design Schedule 21-07-0300 Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained where appropriate	QSP4002 Software Life Cycle Procedure Section 5.4.2 QSP4007, Design Verification and Validation Gemini SW Life Cycle documents; 21-07-0333, 21-07-0334, 21-07-0335, 21-07-0336	Pass
	Problem resolution system meets the prescribed criteria depending on type of product:		Pass
	– it is documented as a part of PEMS DEVELOPMENT LIFE-CYCLE		Pass
	– it allows reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE		Pass
	– it includes an assessment of each problem for associated RISKS		Pass
	– it identifies criteria that must be met for the issue to be closed		Pass
	– it identifies the action to be taken to resolve each problem		Pass
14.6	RISK MANAGEMENT PROCESS		Pass
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including NETWORK/DATA COUPLING, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS	See Appended RM Results Table 14.6.1	Pass
	In addition to the material in ISO 14971, Annex D, list of possible sources for HAZARDS associated with PEMS includes specified causes		Pass
	– failure of NETWORK/DATA COUPLING to provide characteristics necessary for PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE	No network/data coupling	N/A
	– undesired feedback [physical and data] (such as unsolicited/ out of range/ inconsistent input or input from electromagnetic interference)		Pass
	– unavailable data		Pass
	– lack of integrity of data		Pass
	– incorrect data		Pass
	– incorrect timing of data		Pass
	– unintended interactions within & among PESS		Pass
	– unknown aspects or quality of third-party software	No third party software used	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– unknown aspects or quality of third-party PESS	No third party PESS	N/A
	– lack of data security, particularly vulnerability to tampering, unintended interaction with other programs and viruses	No interaction with other programs	N/A
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 6.1 of ISO 14971 ..... :	See Appended RM Results Table 14.6.2	Pass
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem ..... :	See Appended RM Results Table 14.7	Pass
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems ..... :	See Appended RM Results Table 14.8	Pass
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:		Pass
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS	No high-integrity components	N/A
	b) fail-safe functions		Pass
	c) redundancy		Pass
	d) diversity;		Pass
	e) partitioning of functionality		Pass
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators		Pass
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS		Pass
	h) failure modes of components and their effects;		Pass
	i) common cause failures		Pass
	j) systematic failures		Pass
	k) test interval duration and diagnostic coverage		Pass
	l) maintainability		Pass
	m) protection from reasonably foreseeable misuse		Pass
	n) NETWORK/DATA COUPLING specification, when applicable	No Network/Data coupling implementation	N/A
14.9	Design is broken up into subsystems, each with a design and test specification where appropriate, and descriptive data on design environment included in RISK MANAGEMENT FILE..... :	See Appended RM Results Table 14.9	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures.....:	See Appended RM Results Table 14.10	Pass
	– milestone(s) when VERIFICATION is to be performed for each function		Pass
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		Pass
	– selection and utilization of VERIFICATION tools		Pass
	– coverage criteria for VERIFICATION		Pass
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE and requiring checks for unintended functioning of PEMS to perform and document PEMS VALIDATION	See Appended RM Results Table 14.11	Pass
	The person with overall responsibility for PEMS VALIDATION is independent of design team, and no member of a design team is responsible for PEMS VALIDATION of their own design		Pass
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE providing methods & results of PEMS VALIDATION		Pass
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	This design is not a result of an earlier design	N/A
14.13	Technical description includes the following information when PEMS is to be connected to other equipment outside control of PEMS MANUFACTURER by NETWORK/DATA COUPLING.....:	See Appended RM Results Table 14.13 device not intended to connect to Network/Data coupling	N/A
	a) characteristics of NETWORK/DATA COUPLING necessary for PEMS to achieve its INTENDED USE		N/A
	b) list of HAZARDOUS SITUATIONS resulting from a failure of NETWORK/DATA COUPLING to provide the specified characteristics addressed in RMF and ...		N/A
	Listed in technical description		N/A
	c) instructions to RESPONSIBLE ORGANIZATION containing required information and warnings		N/A
	– connection of PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS and RESPONSIBLE ORGANIZATION shall identify, analyze, and control such RISKS		N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– subsequent changes to NETWORK/DATA COUPLING introducing new RISKS and requiring new analysis; and changes to NETWORK/DATA COUPLING include:		N/A
	– The technical description shall instruct the responsible organization that changes to the network/data coupling include…		N/A
	– connection of additional items to NETWORK/DATA COUPLING		N/A
	– disconnecting items from NETWORK/DATA COUPLING		N/A
	– update of equipment connected to NETWORK/DATA COUPLING		N/A
	– upgrade of equipment connected to NETWORK/DATA COUPLING		N/A
15	CONSTRUCTION OF ME EQUIPMENT		—
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS, as confirmed by examination of RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 15.1	Pass
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance		Pass
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		Pass
15.3	Mechanical strength		Pass
15.3.1	Mold stress relief, push, impact, drop, and rough handling tests did not result in unacceptable RISK and ME EQUIPMENT displayed adequate mechanical strength		Pass
15.3.2	Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular (30mm) plane surface, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool ..... :	See Appended Table 15.3 and RM Results Table 15.3.2	Pass
	No damage resulting in an unacceptable RISK sustained as determined by examination of RISK MANAGEMENT FILE		Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.3.3	Impact test conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m ..... :	See Appended Table 15.3 and RM Results Table 15.3.3	Pass
	Test not applied to flat panel displays, platen glass of ME EQUIPMENT, or cathode ray tubes		Pass
	No damage resulting in an unacceptable RISK sustained as shown in RISK MANAGEMENT FILE		Pass
15.3.4	Drop test		Pass
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT and HAND-HELD part with SAFE WORKING LOAD allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board lying flat on a concrete or rigid base ..... :	See Appended Table 15.3	Pass
	No unacceptable RISK resulted		Pass
15.3.4.2	Sample of PORTABLE ME EQUIPMENT and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 ± 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm) ..... :	See Appended Table 15.3 and RM Table 15.3.4.2	Pass
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		Pass
15.3.5	Each sample of MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests ..... :	See Appended Table 15.3 and RM Results Table 15.3.5	N/A
	a) Ascending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s against an ascending hardwood step obstruction without the sample going over the obstruction		N/A
	b) Descending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s in order to fall over a vertical step affixed flat on a rigid base with direction of movement perpendicular to face of the step until full descent achieved		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Door frame shock test conducted on the sample by moving it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s, or for motor driven EQUIPMENT, at maximum possible speed against a hardwood vertical obstacle higher than EQUIPMENT contact point(s)		N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		N/A
15.3.6	Examination of ENCLOSURE made from molded or formed thermoplastic material indicated that material distortion due to release of internal stresses by molding or forming operations will not result in an unacceptable RISK		Pass
	Mold-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C ..... :		Pass
	No damage resulting in an unacceptable RISK		Pass
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		Pass
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		Pass
15.4	ME EQUIPMENT components and general assembly		Pass
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular ..... :	See Appended RM Results Table 15.4.1	N/A
	a) Plugs for connection of PATIENT leads cannot be connected to other outlets on same ME EQUIPMENT intended for other functions, except when RISK MANAGEMENT FILE provides proof that no unacceptable RISK could result ..... :	Unique connection design	N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable as verified by review of RISK MANAGEMENT FILE ..... :		N/A
15.4.2	Temperature and overload control devices		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could result in a HAZARDOUS SITUATION by resetting action as verified by review of RISK MANAGEMENT FILE .....:	See Appended RM Results Table 15.4.2.1 a)	N/A
	b) THERMAL CUT-OUTS with a safety function to be reset by a soldering operation affecting operating value not fitted in ME EQUIPMENT as verified by examination of design and RISK MANAGEMENT FILE:	See Appended RM Results Table 15.4.2.1 b)	N/A
	c) An independent non-SELF-RESETTING THERMAL CUT-OUT is, additionally, provided where a failure of a THERMOSTAT could constitute a HAZARD as verified by examination of design and RISK MANAGEMENT FILE .....:	See Appended RM Results Table 15.4.2.1 c)	N/A
	d) Based on design and RISK MANAGEMENT FILE review, loss of function of ME EQUIPMENT due to operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION	See Appended RM Results Table 15.4.2.1 d)	N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests:		N/A
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 1999, clauses 15, 17, J.15, and J.17 as applicable		N/A
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 .....:	See appended Table 13.2	N/A
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards		N/A
	In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	When certification based on IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function is not available, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating in both leads where a conductive connection to earth could result in overheating as verified by review of design and RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 15.4.2.1 h)	N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N/A
15.4.3	Batteries		Pass
15.4.3.1	Battery housings from which gases can escape during charging or discharging likely to result in a HAZARD ventilated to minimize RISK of accumulation and ignition as verified by review of design and RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 15.4.3.1	Pass
	Battery compartments prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as verified by examination of design and RISK MANAGEMENT FILE		Pass
15.4.3.2	Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery ..... :	See Appended RM Results Table 15.4.3.2	Pass
15.4.3.3	Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design ..... :	See Appended RM Results Table 15.4.3.3	Pass
15.4.3.4	Lithium batteries that could become a HAZARD complied with appropriate tests of IEC 60086-4	See Appended RM Results Table 15.4.3.4	N/A
	Tests of IEC 60086-4 waived on the lithium battery based on examination of design		N/A
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents when (in case of a short circuit) layout of internal wiring, cross-sectional area, rating of connected components can result in a fire ..... :	See Appended RM Results Table 15.4.3.5	Pass
	Protective device has adequate breaking capacity to interrupt the maximum fault current		Pass
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is included in RISK MANAGEMENT FILE	Fuses not omitted	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose..:	See Appended RM Results Table 15.4.4	N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position		N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational when a HAZARDOUS SITUATION could exist, except when apparent to OPERATOR from normal operating position		N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION		Pass
	Colours of indicator lights complied with 7.8.1		Pass
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE		Pass
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS when applicable as verified by review of RISK MANAGEMENT FILE.....:	See Appended RM Results Table 15.4.5	N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT		N/A
15.4.6.1	a) Actuating parts cannot be pulled off or loosened up during NORMAL USE		N/A
	b) Indication of scales (e.g., “on” “off” positions, etc.) always corresponds to position of controls with adjustment that can result in a HAZARDOUS SITUATION for PATIENT or OPERATOR while ME EQUIPMENT is in use		N/A
	c) Incorrect connection of indicating device to relevant component prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values per Table 30 applied between control knob and shaft of rotating controls for not less than 2 s, 10 times in each direction, knobs did not rotate .....:	See appended Table 15.4.6	N/A

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Tests conducted by applying an axial force of 60 N for electrical components and 100 N for other components for 1 min when an axial pull was required in NORMAL USE with no unacceptable RISK ..... :	See appended Table 15.4.6	N/A
15.4.6.2	Stops of adequate mechanical strength provided on rotating/ movable parts of controls of ME EQUIPMENT where necessary to prevent an unexpected change from max to min, or vice-versa, of the controlled parameter when this could cause a HAZARDOUS SITUATION ..... :	See appended Table 15.4.6	N/A
	Torque values in Table 30 applied 10 times in each direction to rotating controls for 2 sec ..... :	See appended Table 15.4.6	N/A
	Application of an axial force of 60 N for electrical components and 100 N for other components to rotating or movable parts of controls for 1 min when an axial pull was required in NORMAL USE ... :	See appended Table 15.4.6	N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N/A
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1		N/A
	b) Foot-operated control device supported an actuating force of 1350 N for 1 min applied over an area of 30 mm diameter in its position of NORMAL USE with no damage to device causing an unacceptable RISK ..... :		N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :		N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least IPX1 & complies with tests of IEC 60529 (IP Code) ..... :	See appended Table 11.6.1	N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6 and complies with IEC 60529 if in NORMAL USE liquids are likely to be found (IP Code) ..... :	See appended Table 11.6.1 and RM Results Table 15.4.7.3 b)	N/A
	Probability of occurrence estimated as part of RISK MANAGEMENT PROCESS		N/A
15.4.8	Aluminum wires less than 16 mm^2 in cross-sectional area are not used		Pass
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed to prevent loss of oil in any position		N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	A pressure-release device operating during NORMAL USE is, optionally, provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		N/A
15.5.1	Overheating		N/A
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 – 3 ..... :	See appended Tables 15.5.1.2 and 15.5.1.3	N/A
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		N/A
	Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests :	See appended Table 15.5.2	N/A
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ..... :	See appended Table 15.5.1.2	N/A
	Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2		N/A
15.5.1.3	Multiple overload tests conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection..... :	See appended Table 15.5.1.3	N/A
15.5.2	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION		N/A
	Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer ..... :	See appended Table 15.5.2	N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12..... :	See appended Table 8.10	N/A

16	ME SYSTEMS		—
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	See Appended RM Results Table 16.1	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	– tests performed in NORMAL CONDITION, except as specified		N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N/A
	RISK MANAGEMENT methods, optionally, used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR to determine configurations with highest RISKS and measures to ensure any configuration of ME SYSTEM will not present unacceptable RISKS		N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS are, optionally, provided in electronic format (e.g. electronic file format or CD ROM) and ME SYSTEM is capable of displaying or printing these documents		N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N/A
	c) the required information is provided:		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		N/A
	– additional safety measures to be applied during installation of ME SYSTEM		N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		N/A
	– additional measures to be applied during preventive maintenance		N/A
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor		N/A
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM		N/A
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		N/A
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM		N/A
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM		N/A
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer		N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		N/A
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		N/A
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		N/A
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements		N/A
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors, etc., without use of a TOOL operated at a voltage ≤ voltage in 8.4.2 c) supplied from a source separated from SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION		N/A
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed		N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for highest voltage occurring across SEPARATION DEVICE during a fault condition		N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :		N/A
16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION, from or between parts of ME SYSTEM within the PATIENT ENVIRONMENT, did not exceed 100 µA..... :	See appended Table 16.6.1	N/A
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, from or between parts of ME SYSTEM within PATIENT ENVIRONMENT . :	See appended Table 16.6.1	N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET did not exceed 5 mA..... :		N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values specified for ME EQUIPMENT in Tables 3 and 4 ..... :	See appended Tables 8.7 and 16.6.1	N/A
	Measurements made using a device as in clause 8.7.4.4		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
16.7	ME SYSTEM complied with applicable requirements of Clause 9 when a MECHANICAL HAZARD existed ..:	See applicable appended Tables in section 9	N/A
16.8	Interruption and restoration of relevant power connections of ME SYSTEM one at a time and all connections simultaneously did not result in a HAZARDOUS SITUATION other than interruption of its intended function		N/A
16.9	ME SYSTEM connections and wiring		N/A
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where a HAZARDOUS SITUATION could otherwise exist .....:	See Appended RM Results Table 16.9.1	N/A
	– Connectors complied with Clause 15.4.1		N/A
	– Plugs for connection of PATIENT leads could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no HAZARDOUS SITUATION could result		N/A
16.9.2	MAINS PARTS, components and layout		N/A
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 (i.e., safety sign ISO 7010-W001) visible in NORMAL USE, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6, except total impedance for ME SYSTEM was up to 400 mΩ, or higher when conditions of 8.6.4 b) met (mΩ) ..... :		N/A
	– ENCLOSURE complied with 8.4.2 d)		N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	– RATINGS of components are not in conflict with conditions of use ..... :	See appended Table 8.10	N/A
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	– POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	– Separating transformer complied with IEC 61558-2-1, except requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 were not applied..... :	See appended Table 8.10	N/A
	– Separating transformer is CLASS I		N/A
	– Degree of protection against ingress of water specified as in IEC 60529		N/A
	– Separating transformer assembly marked according to 7.2 and 7.3		N/A
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N/A
16.9.2.2	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part		N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL		N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		N/A

17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		—
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review..... :	See Appended RM Results Table 17	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :		Pass
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		Pass
ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES		—
G.2	Locations and basic requirements		N/A
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	Not Category AP or APG equipment	N/A
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH AIR occurring due to a leakage or discharge of a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE from an ENCLOSURE considered 5 to 25 cm from point of occurrence		N/A
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE contained in a completely / partly enclosed ME EQUIPMENT part and in PATIENT'S respiratory tract 5 cm from an ENCLOSURE part where leakage or discharge occurs	Not used with anesthetic mixture	N/A
G.2.4	ME EQUIPMENT or parts thereof specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR (in a location as in G.2.2) are CATEGORY AP or APG ME EQUIPMENT and complied with G.4 and G.5		N/A
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (location per G.2.2) are CATEGORY APG ME EQUIPMENT and comply with G.4 and G.6		N/A
	ME EQUIPMENT in G.2.3 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	Marking, ACCOMPANYING DOCUMENTS		N/A
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked. with a green-coloured band ≥ 2 cm wide with letters "APG" according to symbol 23 in Table D.1 :	See copies of Marking Labels Not Category APG equipment	N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A
	When above marking not possible, relevant information included in instructions for use ..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle ≥ 2 cm in diameter, with characters "AP" according to symbol 22 in Table D.1 ..... :	See copies of Marking Labels Not AP equipment	N/A
	Marking is as large as possible for the particular case		N/A
	When above marking not possible, the relevant information included in instructions for use ..... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.3	The marking according to G.3.2 and G.3.3 placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts, and not repeated on detachable parts that can only be used with the marked EQUIPMENT		N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts		N/A
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG		N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES between points of POWER SUPPLY CORD connection are according to Table 12 for one MEANS OF PATIENT PROTECTION	Not Category AP or APG equipment	N/A
	b) Connections, except those in circuits described in G.5.3 and G.6.3, protected against accidental disconnection in NORMAL USE or connection and disconnection can be performed only with a TOOL		N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD, except when circuit complied with G.5.3 and G.6.3		N/A
G.4.2	Construction details		N/A
	a) Opening of an ENCLOSURE providing protection against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL		N/A
	b) ENCLOSURE complies with requirements to minimize arcing and sparking due to penetration of foreign objects..... :	See appended Table 8.10	N/A
	– no openings on top covers of ENCLOSURE, except for openings for controls covered by control knobs		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– openings in side-covers prevented penetration of a solid cylindrical test rod of 4 mm in diameter applied in all possible directions without appreciable force		N/A
	– openings in base plates prevented penetration of a solid cylindrical test rod of 12 mm in diameter applied in all directions without appreciable force		N/A
	c) Short circuiting conductor(s) to a conductive part without presence of explosive gasses where insulation may contact a part containing a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE, ignitable gases alone, or oxygen, did not result in loss of integrity of the part, an unacceptable temperature, or other HAZARD		N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	Not Category AP or APG equipment	N/A
	– Use of antistatic materials with a limited electrical resistance as specified in G.4.3 b)..... :	See appended Table 8.10	N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor of medical room		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses and pads, castor tires, and other antistatic material complied with ISO 2882 based on measurements according to ISO 1853, ISO 2878 and ISO 23529..... :		N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N/A
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components		N/A
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5 (inclusive)	Not Category AP equipment	N/A
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
G.5.2	ME EQUIPMENT, its parts, and components in contact with gas mixtures in NORMAL USE and CONDITIONS not producing sparks and not resulting in surface temperatures above 150 °C in case of restricted or 200 °C in case of unrestricted vertical air circulation measured at 25 °C comply with G.5.1 ..... :		N/A
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1..... :		N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ..... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :		N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N/A
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2		N/A
	No extrapolation made for voltages above 242V		N/A
	U_{max}, additionally, determined using actual resistance R when the equivalent resistance R was less than 8000 Ω		N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		N/A
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open, taking into consideration MAINS VOLTAGE variations in 4.10		N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed, taking into consideration MAINS VOLTAGE variations required in 4.10		N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		N/A
	– Peak value considered when a.c. supplied		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3..... :		N/A
	Alternatively, compliance was verified by examination of design data..... :		N/A
G.5.4	External ventilation with internal overpressure		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR that might have penetrated into ENCLOSURE of ME EQUIPMENT or part removed by ventilation before EQUIPMENT energized, and penetration of such mixtures during operation was prevented by maintenance of overpressure by means of air without flammable gases, or by physiologically acceptable inert gas (e.g., nitrogen)		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa) ..... :		N/A
	Overpressure maintained at the site of potential ignition even when air or inert gas could escape through openings in ENCLOSURE necessary for normal operation of ME EQUIPMENT or its parts		N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE so that the displaced volume of air or inert gas was at least five times the volume of ENCLOSURE		N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically by means used where G.4 does not apply, or complied with G.5 when during operation overpressure dropped below 50 Pa (Pa)..... :		N/A
	d) External surface of ENCLOSURE in which internal overpressure was maintained did not exceed 150 °C in 25 °C ambient under NORMAL USE and CONDITION (°C)..... :		N/A
G.5.5	ENCLOSURES with restricted breathing		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:	No restricted breathing	N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing when it was surrounded by a FLAMMABLE AESTHETIC MIXTURE WITH AIR of a high concentration for at least 30 min without any pressure difference inside ENCLOSURE		N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h.. :		N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained when the cords were stressed by bending or pulling		N/A
	Cords are fitted with adequate anchorages to limit stresses		N/A
	After the test in G.5.4 b), an internal overpressure of 400 Pa was created and 30 pulls of the value in Table G.1 applied to each flexible cord in axial direction of cord inlet and in the least favourable direction for 1 s		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C) ..... :		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C) ..... :		N/A
G.6	CATEGORY APG ME EQUIPMENT, parts and components thereof		N/A
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION	Not Category APG equipment	N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test after attaining thermal steady state (max. 3 h) over a period of 10 min in a 12.2 % ± 0.4 ether by volume/oxygen mixture		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION ..... :		N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS ..... :		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or		N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 ..... :		N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5 ..... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :		N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N/A
	– C_{max} and L_{max} are values occurring in relevant circuit		N/A
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value taken into consideration when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		N/A
	Above requirement not applied to transformers complying with this standard		N/A
	Above requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N/A
	Temperature measurements made in accordance with 11.1, or		N/A
	U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6..... :		N/A
	Alternatively, compliance verified by comparison with design data..... :		N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 ..... :		N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	Test apparatus for flammable mixtures		N/A
	Test apparatus used was in accordance with this Clause and Fig G.7	No flammable mixtures	N/A

ANNEX L	INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION		—
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters	No insulated windings wires for use without interleaved insulation	N/A
L.2	Wire construction		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
L.3	Type Test		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified		N/A
	Temperature (°C) ..... :		N/A
	Humidity (%) ..... :		N/A
L.3.1	Dielectric strength		N/A
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 & 7, but not less than below with no breakdown:		N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 6000 V for REINFORCED INSULATION (V) ..... :		N/A
L.3.2	Flexibility and adherence		N/A
	Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1		N/A
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown		N/A
	Test voltage was at least the voltage in Tables 6 and 7but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :		N/A
L.3.3	Heat Shock		N/A
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Oven temperature based on Table L.2 (°C) ..... :		—

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2) ..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
L.3.4	Retention of electric strength after bending		N/A
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Test voltage applied between the shot and conductor.		N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2) ..... :		N/A
L.4	Tests during manufacture		N/A
L.4.1	Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3 :		N/A
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:		N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)..... :		N/A
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)		N/A
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		N/A
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION		N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.2	RM RESULTS TABLE: Risk Management Process for ME Equipment or ME Systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
3.3a	QSP1003 Rev 19 21-07-0303 Rev 03-Xa	Management Review, Section – Procedure Gemini Risk Management Plan, Section 2 - Assignment of Responsibilities and Authorities	Pass
3.5e	QSP1026 Rev 08 21-07-0303 Rev 03-Xa	Risk Management Procedure, Section 5.2 – Risk Management Plans Gemini Risk Management Plan	Pass
4.1	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.4 – Risk Analysis Gemini Risk Analysis, Section 3 - Risk Analysis	Pass
4.2	QSP1026 Rev 08 21-07-0304 Rev 01-Xa	Risk Management Procedure, Section 5.3.10 Hazard Identification, Section 3.1 – Identification of Intended Use	Pass
4.3	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.3 – Hazard Identification Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
4.4	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.5 – Initial Risk Evaluation Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
5	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.5 – Initial Risk Evaluation Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
6.1	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.6.1 – Risk Control Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
6.2	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.6.2 – Risk Control Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.2	RM RESULTS TABLE: Risk Management Process for ME Equipment or ME Systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.6.5 – Risk Control Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
6.4	QSP1026 Rev 08 21-07-0306 Rev 01-Xa	Risk Management Procedure, Section 5.7 – Residual Risk Evaluation Gemini Risk Analysis, Section 4 – List of Identified Hazards and Associated Risks	Pass
6.5	QSP1026 Rev 08 21-07-0307 Rev 01-Xa	Risk Management Procedure, Section 5.6.5, 5.7.4, 5.8.4 Section 3 – Risk Management Report	Pass
6.6	QSP1026 Rev 08 21-07-0307 Rev 01-Xa	Risk Management Procedure, Section 5.6.6 Section 3 – Risk Management Report	Pass
6.7	QSP1026 Rev 08 21-07-0307 Rev 01-Xa	Risk Management Procedure, Section 5.8.7 Section 3 – Risk Management Report	Pass
7	QSP1026 Rev 08 21-07-0307 Rev 01-Xa	Risk Management Procedure, Section 5.8.3, 5.8.4 Section 3 – Risk Management Report	Pass

4.3	TABLE: ESSENTIAL PERFORMANCE	Pass
List of ESSENTIAL PERFORMANCE functions	MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)	Remarks
Operation and annunciation of patient alarm indicators	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Accurate StO2 measurement	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Detection of equipment conditions triggering shutdown	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Signal inadequacy	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Sensor/preamp detection and management	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Resume StO2 measurement within specifications after defibrillation event	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass
Resume StO2 measurement within specifications after	21-07-0304 Rev 01-Xa Gemini Hazard Identification, Section 3.2	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.3	TABLE: ESSENTIAL PERFORMANCE		Pass
List of ESSENTIAL PERFORMANCE functions	MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)	Remarks	
external noise event			
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.			

4.3	RM RESULTS TABLE: Essential Performance		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification	Section 3.2	Pass
4.3			Pass
4.4			Pass
5			Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.5	RM RESULTS TABLE: Equivalent Safety for ME Equipment of ME System		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No alternative means of addressing risk used	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

4.6	RM RESULTS TABLE: ME Equipment or system parts contacting the patient		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification	Section 3.3	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5	No risk benefit analysis		N/A

4.7	RM RESULTS TABLE: Single Fault Condition for ME Equipment		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification	Section 3.13, Section 4	Pass
4.3			Pass
4.4	21-07-0306 Gemini Risk Analysis	Section 4	Pass

4.8	RM RESULTS TABLE: Components of ME Equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No components used outside their ratings	
4.3			
4.4			
5			
6.2			
6.3			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.8	RM RESULTS TABLE: Components of ME Equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.4			
6.5			

4.9	RM RESULTS TABLE: Use of components with high-integrity characteristics		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No high-integrity components	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

4.11	TABLE: Power Input				Pass
Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Power factor (cos φ)
Normal Operation, All 4 sensors in use	99	50	0.62	35.9	0.58
	110	50	0.57	35.5	0.57
	240	50	0.40	36.0	0.37
	264	50	0.40	36.3	0.34
	99	60	0.61	35.8	0.59
	110	60	0.56	35.4	0.57
	240	60	0.43	35.9	0.35
	264	60	0.61	36.3	0.31
Supplementary Information:					

5.1	RM RESULTS TABLE: Type Tests		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		All type tests performed	
4.3			
4.4			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

5.4 a)	RM RESULTS TABLE: Other Conditions		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification	Section 3.12	Pass
4.3			Pass
4.4			Pass

5.7	RM RESULTS TABLE: Humidity preconditioning treatment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not intended to be exposed to high humidity for extended periods	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

5.9.2	TABLE: Determination of ACCESSIBLE parts	Pass
Location	Determination method (NOTE1)	Comments
Enclosure	V	
Vent Opening	J	Did not enter
Vent Opening	U	Did not enter
Vent Opening	H	test finger did not enter
Connectors	V	
Preamp Cable	V	
Sensor	V	Type BF applied part
Supplementary information: NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

5.9.2.3	RM RESULTS TABLE: Actuating mechanisms		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No actuating mechanisms	
4.3			
4.4			
5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

5.9.2.3	RM RESULTS TABLE: Actuating mechanisms		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

7.1.2	TABLE: Legibility of Marking		Pass
Markings tested		Ambient illuminance (lx)	Remarks
Outside Markings (Clause 7.2) .....:		385	Pass
Inside Markings (Clause 7.3) .....:		N/A	No internal markings
Controls & Instruments (Clause 7.4) .....:		385	Pass
Safety Signs (Clause 7.5) .....:		385	Pass
Symbols (Clause 7.6) .....:		385	Pass

Supplementary information:

Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

7.1.3	TABLE: Durability of marking test	Pass
Characteristics of the Marking Label tested:		Remarks
Material of Marking Label .....:	Lexan* 8B35 Film	Remained Clear
Ink/other printing material or process .....:	Norcote international 88 matte series	Remained Clear
Material (composition) of Warning Label .....:	-	-
Ink/other printing material or process .....:	-	-
Other.....:	-	-

Supplementary information:

Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

7.2.2	RM RESULTS TABLE: Identification		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Product is suitably marked	
4.3			
4.4			
5			
6.4			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

7.2.5	RM RESULTS TABLE: ME EQUIPMENT powered from other equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not intended to receive power from other equipment	
4.3			
4.4			
5			
6.4			

7.2.13	RM RESULTS TABLE: Physiological effects (safety signs and warning)		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such physiological effects	
4.3			
4.4			
5			
6.3			

7.2.17	RM RESULTS TABLE: Protective packaging		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No risk in unpacking	
4.3			
4.4			
5			
6.3			
6.4			

7.3.3	RM RESULTS TABLE: Batteries		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No lithium batteries	
4.3			
4.4			
5			
6.3			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

7.3.7	RM RESULTS TABLE: Supply terminals		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No supply terminals	

7.4.2	RM RESULTS TABLE: Control devices		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.5.10.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass

7.5	RM RESULTS TABLE: Safety signs		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.1.2.2, 4.1.3.1, 4.1.3.3, 4.1.3.4, 4.1.3.5, 4.1.3.6, 4.1.7.1, 4.2.1.1, 4.2.5.1, 4.2.6.1, 4.3.1.1, 4.3.1.2, 4.3.2.1, 4.3.5.1, 4.3.6.1, 4.5.5.1, 4.5.5.6, 4.5.5.8, 4.5.5.9, 4.5.10.2, 4.7.3.1, 4.10.1.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.3			Pass

7.9.1	RM RESULTS TABLE: General accompanying documents (See Table C.4)		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.8.1.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

7.9.2.4	RM RESULTS TABLE: Electrical power source		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.10.2.1, 4.3.3.2	Pass
4.3			Pass
4.4			Pass
5			Pass
6.3			Pass

7.9.3.2	RM RESULTS TABLE: Replacement of fuses, power supply cords, other parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not permanently installed	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

8.1 b(1)	RM RESULTS TABLE: Fundamental rule of protection against electric shock - interruption of any one power-carrying conductor		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		There are no separate enclosure connection; ME equipment is part of the single enclosure	
4.4			

8.1 b(2)	RM RESULTS TABLE: Fundamental rule of protection against electric shock - unintended movement of a component		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.1.5	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk/benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.1 b(3)	RM RESULTS TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.1.5	Pass

8.2.2	RM RESULTS TABLE: Connection to an external d.c. power sources		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No external D.C. power source	
4.3			
4.4			
5			

8.3 d	RM RESULTS TABLE: Requirements of Type BF or CF Applied Parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2		See also RM Table for 4.6	

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					N/A
Test supply voltage/frequency (V/Hz)[1] ..... :						
Location From/To	Measured values					Remarks
	Vrms	Vpk or Vdc	Peak-to-peak ripple[2]	Power W/VA	Energy (J)	

Supplementary Information:

1. The input supply voltage to the ME EQUIPMENT shall be the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.
2. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.4.2 c	RM RESULTS TABLE: Accessible parts including applied parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Limits applied	
4.3			
4.4			

8.4.3	TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply									Pass
Maximum allowable voltage (V) .....:										60
Voltage measured (V)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	4.04	0.02	2.03	2.03	2.03	4.04	2.03	0.02	2.03	4.04
Plug pin 1 and plug earth pin	7.04	10.06	15.09	17.10	18.10	18.10	16.09	14.08	18.10	17.10
Plug pin 2 and plug earth pin	16.09	15.09	14.08	11.07	10.06	19.11	14.08	14.08	13.08	10.06
Plug pin 1 and enclosure	7.04	10.06	15.09	17.10	18.10	18.10	16.09	14.08	18.10	17.10
Plug pin 2 and enclosure	16.09	15.09	14.08	11.07	10.06	19.11	14.08	14.08	13.08	10.06
Maximum allowable stored charge when measured voltage exceeded 60 v (µc) ..... :										45
Calculated stored charge (µc)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 1 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 2 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 1 and enclosure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 2 and enclosure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Supplementary information:										

8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT		N/A
Maximum allowable residual voltage (V):			60 V
Maximum allowable stored charge when residual voltage exceeded 60 V :			45 µC
Description of the capacitive circuit	Measured residual	Calculated stored	

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

(i.e., accessible capacitor or circuit parts)	voltage (V)	charge (µC)	Remarks
Supplementary information:			

8.5.2.2	RM RESULTS TABLE: Type B applied parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Type BF applied part	
4.3			
4.4			
5			

8.5.2.3	RM RESULTS TABLE: PATIENT Leads		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No patient leads	
4.3			
4.4			
5			

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies				Pass
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
9	Foil underneath equipment	Sensors tied together	+	93.9	Pass
9	Foil underneath equipment	Sensors tied together	-	187.8	Pass
9	Foil on enclosure	Sensors tied together	+	93.9	Pass
9	Foil on enclosure	Sensors tied together	-	156.5	Pass
9	Monitor SIP SOP	Sensors tied together	+	125.2	Pass
9	Monitor SIP SOP	Sensors tied together	-	93.9	Pass
9	Ethernet	Sensors tied	+	125.2	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

		together			
9	Ethernet	Sensors tied together	-	156.5	Pass
9	Port A	Sensors tied together	+	125.2	Pass
9	Port A	Sensors tied together	-	156.5	Pass
9	Port B	Sensors tied together	+	93.9	Pass
9	Port B	Sensors tied together	-	187.8	Pass
9	USB	Sensors tied together	+	93.9	Pass
9	USB	Sensors tied together	-	62.6	Pass
9	USB front	Sensors tied together	+	93.9	Pass
9	USB front	Sensors tied together	-	62.6	Pass
10	Foil underneath equipment	Sensor 1 rest tied to ground	+	125.2	Pass
10	Foil underneath equipment	Sensor 1 rest tied to ground	-	219.1	Pass
10	Foil on enclosure	Sensor 1 rest tied to ground	+	250.4	Pass
10	Foil on enclosure	Sensor 1 rest tied to ground	-	156.5	Pass
10	Monitor SIP SOP	Sensor 1 rest tied to ground	+	62.6	Pass
10	Monitor SIP SOP	Sensor 1 rest tied to ground	-	219.2	Pass
10	Ethernet	Sensor 1 rest tied to ground	+	62.6	Pass
10	Ethernet	Sensor 1 rest tied to ground	-	125.2	Pass
10	Port A	Sensor 1 rest tied to ground	+	281.7	Pass
10	Port A	Sensor 1 rest tied to ground	-	219.1	Pass
10	Port B	Sensor 1 rest tied to ground	+	93.9	Pass
10	Port B	Sensor 1 rest tied to ground	-	156.5	Pass
10	USB	Sensor 1 rest tied to ground	+	250.4	Pass
10	USB	Sensor 1 rest tied to ground	-	125.2	Pass
10	USB front	Sensor 1 rest tied to ground	+	93.9	Pass

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IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
10	USB front	Sensor 1 rest tied to ground	-	125.2	Pass
10	Foil underneath equipment	Sensor 2 rest tied to ground	+	93.9	Pass
10	Foil underneath equipment	Sensor 2 rest tied to ground	-	156.5	Pass
10	Foil on enclosure	Sensor 2 rest tied to ground	+	125.2	Pass
10	Foil on enclosure	Sensor 2 rest tied to ground	-	250.4	Pass
10	Monitor SIP SOP	Sensor 2 rest tied to ground	+	125.2	Pass
10	Monitor SIP SOP	Sensor 2 rest tied to ground	-	125.3	Pass
10	Ethernet	Sensor 2 rest tied to ground	+	125.2	Pass
10	Ethernet	Sensor 2 rest tied to ground	-	219.1	Pass
10	Port A	Sensor 2 rest tied to ground	+	125.2	Pass
10	Port A	Sensor 2 rest tied to ground	-	156.5	Pass
10	Port B	Sensor 2 rest tied to ground	+	187.8	Pass
10	Port B	Sensor 2 rest tied to ground	-	93.9	Pass
10	USB	Sensor 2 rest tied to ground	+	187.8	Pass
10	USB	Sensor 2 rest tied to ground	-	187.9	Pass
10	USB front	Sensor 2 rest tied to ground	+	219.1	Pass
10	USB front	Sensor 2 rest tied to ground	-	219.1	Pass
10	Foil underneath equipment	Sensor 3 rest tied to ground	+	125.2	Pass
10	Foil underneath equipment	Sensor 3 rest tied to ground	-	313.0	Pass
10	Foil on enclosure	Sensor 3 rest tied to ground	+	187.8	Pass
10	Foil on enclosure	Sensor 3 rest tied to ground	-	219.1	Pass
10	Monitor SIP SOP	Sensor 3 rest tied to ground	+	187.8	Pass
10	Monitor SIP SOP	Sensor 3 rest tied to ground	-	187.8	Pass
10	Ethernet	Sensor 3 rest tied to ground	+	125.1	Pass
10	Ethernet	Sensor 3 rest tied to ground	-	187.7	Pass
10	Port A	Sensor 3 rest tied to ground	+	156.4	Pass

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IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
10	Port A	Sensor 3 rest tied to ground	-	125.2	Pass
10	Port B	Sensor 3 rest tied to ground	+	125.2	Pass
10	Port B	Sensor 3 rest tied to ground	-	156.4	Pass
10	USB	Sensor 3 rest tied to ground	+	125.2	Pass
10	USB	Sensor 3 rest tied to ground	-	156.5	Pass
10	USB front	Sensor 3 rest tied to ground	+	93.8	Pass
10	USB front	Sensor 3 rest tied to ground	-	125.1	Pass
10	Foil underneath equipment	Sensor 4rest tied to ground	+	156.5	Pass
10	Foil underneath equipment	Sensor 4 rest tied to ground	-	125.2	Pass
10	Foil on enclosure	Sensor 4 rest tied to ground	+	187.7	Pass
10	Foil on enclosure	Sensor 4 rest tied to ground	-	219.0	Pass
10	Monitor SIP SOP	Sensor 4 rest tied to ground	+	156.4	Pass
10	Monitor SIP SOP	Sensor 4 rest tied to ground	-	125.1	Pass
10	Ethernet	Sensor 4 rest tied to ground	+	125.1	Pass
10	Ethernet	Sensor 4 rest tied to ground	-	125.2	Pass
10	Port A	Sensor 4 rest tied to ground	+	125.2	Pass
10	Port A	Sensor 4 rest tied to ground	-	156.4	Pass
10	Port B	Sensor 4 rest tied to ground	+	125.2	Pass
10	Port B	Sensor 4 rest tied to ground	-	125.1	Pass
10	USB	Sensor 4 rest tied to ground	+	125.1	Pass
10	USB	Sensor 4 rest tied to ground	-	219.2	Pass
10	USB front	Sensor 4 rest tied to ground	+	187.8	Pass
10	USB front	Sensor 4 rest tied to ground	-	156.4	Pass
Supplementary information:					

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time			Pass
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
Sensors tied together	+	20	0	Remained 0 at all measurements made above
Supplementary information:				

8.5.5.2	TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load		Pass
Test Voltage applied to	Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy E1 as % of E2 (%)
+ sensor 1 with sensors 2, 3, and 4 of the same connected to earth	354.7	354.8	99.9
+ sensor 2 with sensors 1, 3, and 4 of the same connected to earth	353.0	355.9	99.2
+ sensor 3 with sensors 2, 1, and 4 of the same connected to earth	355.5	357.1	99.6
+ sensor 4 with sensors 2, 3, and 1 of the same connected to earth	355.3	357.2	99.5
- sensor 1 with sensors 2, 3, and 4 of the same connected to earth	311.2	319.3	97.5
- sensor 2 with sensors 1, 3, and 4 of the same connected to earth	330.2	338.7	97.4
- sensor 3 with sensors 2, 1, and 4 of the same connected to earth	336.9	337.4	99.8
- sensor 4 with sensors 2, 3, and 1 of the same connected to earth	313.5	319.3	98.2
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 Ω with ME Equipment connected; E2= Measured energy delivered to 100 Ω without ME equipment connected.			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.6.3	RM RESULTS TABLE: Protective earthing of moving parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Protective earth terminal fixed to ME chassis	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS			Pass
Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part	N/A	N/A	N/A	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part	40A/120S	-	8.2	100
ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part	N/A	N/A	N/A	200
Supplementary information:				

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks	
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
B, NC (S1=1, S5=1, S7=1, S12=1)	264	60	252.7	-	
B, SFC (S1=0, S5=1, S7=1, S12=1)	264	60	466.8	-	
A, NC (S1=1, S5=0, S7=1, S12=0)	264	60	67.9	-	
A, SFC (S1=0, S5=1, S7=1, S12=1)	264	60	128.4	-	
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC	
B, NC (S1=1, S5=1, S7=1, S12=1)	264	60	9.4	Plastic enclosure	
B, SFC (S1=1, S5=1, S7=0, S12=1)	264	60	20.9	Plastic enclosure	
A, NC (S1=1, S5=0, S7=1, S12=1)	264	60	3.2	Plastic enclosure	
A, SFC (S1=0, S5=0, S7=1, S12=0)	264	60	15.3	Plastic enclosure	
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)	
B, NC (S1=1, S5=1, S7=1, S12=1)	264	60	2.2	-	
B, SFC (S1=1, S5=0, S7=0, S12=0)	264	60	5.4	-	
A, NC (S1=1, S5=1, S7=1, S12=1)	264	60	0.9	-	
A, SFC (S1=1, S5=0, S7=0, S12=0)	264	60	1.6	-	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 uA Type CF AP: 50 uA	
B, NC (S5=1, S9=1, S13=1)	264	60	37.0	-	
B, SFC (S5=1, S9=0, S13=0)	264	60	36.6	-	
A, NC (S5=1, S9=1, S13=1)	264	60	37.4	-	
A, SFC (S5=0, S9=0, S13=0)	264	60	37.4	-	
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC(d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current)	
N/A	-	-	-	-	
N/A	-	-	-	-	

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IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 uA Type CF: N/A
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC;50 uA SFC (d.c. or a.c. current)
B, NC (S1=1, S5=0, S7=1)	264	60	1.6	One sensor tested at a time with all others tied together
B, SFC (S1=1, S5=1, S7=0)	264	60	4.5	One sensor tested at a time with all others tied together
A, NC (S1=1, S5=0, S7=1)	264	60	1.5	One sensor tested at a time with all others tied together
A, SFC (S1=1, S5=0, S7=0)	264	60	4.4	One sensor tested at a time with all others tied together
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
B, NC (S1=1, S5=1, S7=1, S12=1)	264	60	1.3	All sensors tied together
B, SFC (S1=0, S5=0, S7=1, S12=1)	264	60	1.4	All sensors tied together
A, NC (S1=1, S5=1, S7=1, S12=1)	264	60	0.9	All sensors tied together
A, SFC (S1=1, S5=1, S7=0, S12=0)	264	60	1.0	All sensors tied together
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC;1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-

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IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict

Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000uA Type CF: 100 uA
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 uA Type CF: N/A
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-
N/A	-	-	-	-

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER - Earth leakage current
TC – Touch current
P - Patient leakage current
PA – Patient auxiliary current
TP – Total Patient current
PM - Patient leakage current with mains on the applied parts
MD - Measuring device

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				Pass
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
Primary to Metal Enclosure	BI	240	-	1500	No

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Secondary to Metal Enclosure	BI	240	-	1500	No
Preamp connector to preamp enclosure	BI	240	-	1500	No
Sensor connection to Preamp enclosure	BI	240	-	1500	No
Sensor to Sensor connector	BI	240	-	1500	No
Sensor connection to Metal Enclosure	BI	240	-	1500	No
Primary to Plastic Enclosure	RI	240	-	4000	No
Sensor Connection to Primary	BI	240	-	1500	No

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		Pass
	Allowed impression diameter (mm) .....:	≤ 2 mm	—
	Force (N).....:	20	—

Part/material	Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts	75	0.6
Insulating material supporting uninsulated Mains Parts	N/A	N/A
Supplementary information:		

8.8.4.1	RM RESULTS TABLE: Mechanical strength and resistance to heat		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.1.2.5	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

8.9.2	TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4		N/A
Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1]	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
Supplementary information: Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		

Supplementary information:

[1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.4	Table: Thermal cycling tests on one sample of cemented joint (see 8.9.3.3)		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		

Supplementary information:

[1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.10	TABLE: List of critical components				Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity [1]
CAS Medical Hospital Grade Power Cord with Ferrite Bead	Feller Power Cords CCA-WESCO	Part No. 6922 CBL-PWR-SP30-FB-UK	SJT 3x 18AWG, rated 125VAC, 10A H05VV-F 32/0.2 BAx3C 250Vac,13A	UL62	UL, CSA VDE
AC Power Entry Module, Filtered	Tyco / Corcom	PE000DL6C	250VAC, 6A	UL 544, IEC 60601-1	UL, CSA, TUV
Primary Fuses (2 Provided)	Littelfuse	02153.15P	5x20mm type, T3.15AH250V, rated 250V, 3.15A slow-blow	IEC 60127	UL, CSA, TUV
Power Supply	Emerson / Astec	NPS-44M	100/250 VAC, 50/60Hz 2.5A	UL 60601-1/A2:1995	UL, CSA, TUV
Battery	Panasonic	LC-R122R2P	12V, 2.2aH, 0.33A Trickle Charge Current	UL 1989	UL
92x22mm Tube Axial Cooling Fan	NIDEC	U92T12MUA7-58 T92T12MUA7-58	12VDC, 0.25A, 3.0W, 3100RPM, 52CFM	UL 507	UL, CSA, TUV
Power Line Filter	Tyco / Corcom	3EHQ3	250VAC, 3A Medical Grade	UL60601-1	UL, CSA, TUV
F1	Littlefuse	0154002.DR	FUSEBLOCK W/2.0A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
F2,F4	Littlefuse	154.250DR	FUSEBLOCK W/.250A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
F3,F5	Littlefuse	154.125DR	FUSEBLOCK W/.125A FUSE SMD FAST, V-0	UL94, MIL-STD-202	UL, CSA
T1	HALO	TGS110-S055NCRL	ETHERNET ISOLATION TRANSFORMER, UL, 1500V, 4MM CREEPAGE	UL 60601-1/A2:1995	UL
U44,U46	Linear Technology	LTM2882CY-3#PBF	IC, Transceiver, RS232, Isolated Isolated 2500 VRMS	UL 60950,RoHS	UR
U63	RECOM	RSO-1205S/H3 RS-1205S/H3	DC-DC Converter, 9-18V in, 5V out, Isolated 3kV	Tested in end system	-

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

C280 on PCB Assy # 03-59-0402	TDK	CD85-E2GA102MYNS	Cap, Cer, 1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	IEC/EN 60384-14 IEC/EN 60065 UL 1414 CSA C22.2 No.0 & No.1	UL, VDE, CSA, BSI, SEMKO, SEV, FIMKO, DEMKO, NEMKO, IMQ
C1 on PCB assy # 03-59-0403	TDK	CD85-E2GA102MYNS	Cap, Cer, 1000pF, 20%, 250VAC, X1/Y1, Radial 0.394" LS	IEC/EN 60384-14 IEC/EN 60065 UL 1414 CSA C22.2 No.0 & No.1	UL, VDE, CSA, BSI, SEMKO, SEV, FIMKO, DEMKO, NEMKO, IMQ
Coin cell battery on PCB assy 03-59-0402	Panasonic	BR1225	Battery, Coin Cell, Lithium, 48 mAh, 12.5 mm	UL 1642	UL
U64,U65,U66,U67	Silicon Laboratories	Si8640ED-B-IS Si8640BD-B-IS	IC, Digital Isolator, Quad channel, Wide Body SOIC-16, RoHS	IEC 60950-1, 61010-1, 60601-1 (reinforced insulation)	UL, CSA, VDE
(b)(4) (b)(4) m Tape	(b)(4) (b)(4) Performance Films	(b)(4)	(b)(4) ®) i(b (b)(4) (b)(4) e, 0.0035" Thick	Tested by Intertek met 5000VAC dielectric withstand	-
(b)(4)	(b)(4)	4701-30-25035-34	(b)(4) 0.0035" thick	Tested by Intertek met 2500VAC dielectric withstand	-
Plastic enclosure	Plastic Design International	Acrylonitrile Butadiene Styrene	Acrylonitrile Butadiene Styrene	UL 94	UR
Metal enclosure	Metalmen	Aluminum 5052-H32	Aluminum 5052-H32	Tested in end system	-
Sensors	CASMEDICAL	03-05-0511	Disposable oximeter sensor	Tested in end system	-
Mylar Tape	3M™	(b)(4) (Tape 5413	(b)(4) (b)(4) Dielectric Strength: 7000 volts	UL 94 Tested by Intertek met 4000 VAC dielectric withstand	UL

Supplementary information:
1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.10.1	RM RESULTS TABLE: Fixing of components		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.1.1.1-4.1.1.7, 4.1.3.1-4.1.3.8	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

8.10.2	RM RESULTS TABLE: Fixing of wiring		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.1.5-4.1.1.7	Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

8.10.5	RM RESULTS TABLE: Mechanical protection of wiring		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.1.6, 4.1.1.7	Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.11.3.5	TABLE: Cord anchorages			Pass
Cord under test	Mass of equipment (kg)	Pull (N)	Torque Nm)	Remarks
Preamp to Monitor	0.40	30	0.1	Pass
Sensor to Preamp	0.40	30	0.1	Pass
Supplementary information:				

8.11.3.6	TABLE: Cord guard		Pass
Cord under test	Test mass	Measured curvature	Remarks
Preamp to Monitor	435 g	12.7 mm	Pass
Sensor to Preamp	250 g	9.5 mm	Pass
Supplementary information:			

8.11.5	RM RESULTS TABLE: Mains fuses and over-current releases		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		Fuses provided in the ME equipment; No omission of the fuses or over current releases	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.2.1	RM RESULTS TABLE: HAZARDS associated with moving parts - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.2.2.2	TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)			N/A
Part of body	Allowable adult gap[1], mm	Measured adult gap, mm	Allowable children gap[1], mm	Measured children gap, mm
Body	> 500		> 500	
Head	> 300 or < 120		> 300 or < 60	
Leg	> 180		> 180	
Foot	> 120 or < 35		> 120 or < 25	
Toes	> 50		> 50	
Arm	> 120		> 120	
Hand, wrist, fist	> 100		> 100	
Finger	> 25 or < 8		> 25 or < 4	

Supplementary information: No moving parts

[1] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.

9.2.2.4.3	RM RESULTS TABLE: Movable guards		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.2.2.4.4	RM RESULTS TABLE: Protective measures		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.2.2.5 c)	RM RESULTS TABLE: Continuous activation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.2.2.6	RM RESULTS TABLE: Speed of movement(s)		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.2.3.2	RM RESULTS TABLE: Over travel		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.2.4	RM RESULTS TABLE: Emergency stopping devices		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
6.6			

9.2.5	RM RESULTS TABLE: Release of patient		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.3	RM RESULTS TABLE: Hazards associated with surfaces, corners and edges		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazards 4.5.8.1, 4.5.8.2	Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

9.4.2.1	TABLE: Instability—overbalance in transport position	Pass
ME EQUIPMENT preparation	Test Condition (transport position)	Remarks
In case, laying down, wheels facing up plane	10 ° incline	Remained stable

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

In case, laying down, wheels facing down plane	10 ° incline	Remained stable
In case, on end, wheels facing up plane	10 ° incline	Remained stable
In case, on end, wheels facing down plane	10 ° incline	Remained stable
Supplementary information:		

9.4.2.2	TABLE: Instability—overbalance excluding transport position	Pass
ME EQUIPMENT preparation	Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)	Remarks
Front side facing down plane	10 ° incline	Remained stable
Right side facing down plane	10 ° incline	Remained stable
Rear side facing down plane	10 ° incline	Remained stable
Left side facing down plane	10 ° incline	Remained stable
Supplementary information:		

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces	N/A
ME EQUIPMENT preparation	Test Condition (force used, direction of force, weight of equipment, location of force	Remarks
Supplementary information:		

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion	N/A
ME EQUIPMENT preparation	Test Condition (force location and height)	Remarks
Supplementary information:		

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold	N/A
ME EQUIPMENT preparation	Test Condition (speed of movement)	Remarks
Supplementary information:		

9.4.2.4.3	RM RESULTS TABLE: Movement over a threshold		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not mobile	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position	N/A
ME EQUIPMENT Preparation	Test Condition (transport position, working load, locking device(s), caster position)	Remarks
Supplementary information:		

9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position	N/A
ME EQUIPMENT Preparation	Test Condition (working load, locking device(s), caster position, force, force location, force direction)	Remarks
Supplementary information:		

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.4.4	TABLE: Grips and other handling devices	N/A
Clause and Name of Test	Test Condition	Remarks
Supplementary information:		

9.5.1	RM RESULTS TABLE: Protective means		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.7.3.3	Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

9.6.1	RM RESULTS TABLE: Acoustic energy - General		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Rev 01-Xa Gemini Hazard Identification 21-07-0306 Rev 01-Xa Gemini Risk Analysis	Hazard 4.1.5.2	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.6.2.2	RM RESULTS TABLE: Infrasound and ultrasound energy		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No infrasound or ultrasound energy	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.7.2	RM RESULTS TABLE: Pneumatic and hydraulic parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No pneumatic or hydraulic parts	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.7.4	RM RESULTS TABLE: Pressure rating of ME equipment parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		ME equipment contains no parts using or generating working pressure	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.7.5	TABLE: Pressure vessels				N/A
Hydraulic, Pneumatic or Suitable Media and Test Pressure	Vessel Burst	Permanent Deformation	Leaks	Vessel fluid substance	Remarks
Supplementary Information: ME equipment contains no parts using or generating working pressure					

9.7.6	RM RESULTS TABLE: Pressure-control device		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		ME equipment contains no parts using or generating working pressure	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.7.7	RM RESULTS TABLE: Pressure-relief device		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		ME equipment contains no parts using or generating working pressure	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.8.1	RM RESULTS TABLE: Hazards associated with support systems - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No support systems	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.2	RM RESULTS TABLE: Tensile safety factor		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.3.1	RM RESULTS TABLE: Strength of patient or operator support or suspension systems - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No support systems	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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Clause	Requirement + Test	Result - Remark	Verdict

9.8.3.2	TABLE: PATIENT support/suspension system - Static forces			N/A
ME EQUIPMENT part or area	Position	Load	Area	Remarks
Supplementary Information: No support systems				

9.8.3.2a, b	RM RESULTS TABLE: Static forces due to loading from persons		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.3.3	TABLE: Support/Suspension System – Dynamic forces due to loading from persons			N/A
ME EQUIPMENT part or area	Position	Safe Working Load	Area	Remarks
Supplementary Information: No support systems				

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.8.4.1	RM RESULTS TABLE: Systems with mechanical protective devices - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.4.3	RM RESULTS TABLE: Mechanical protective device for single activation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

9.8.5	RM RESULTS TABLE: Systems without mechanical protective devices		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.1	TABLE: Measurement of X - radiation		N/A
Maximum allowable radiation pA/kg (µSv/h) (mR/h)		36 (5 µSv/h) (0.5 mR/h)	
Surface area under test Surface no./ Description[1]		Measured Radiation, pA/kg (µSv/h) (mR/h)	Remarks
1/ /			
2/ /			
3/ /			
4/ /			
5/ /			
6/ /			
7/ /			
8/ /			
9/ /			
10/ /			
Supplementary information: [1] Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access			

10.1.2	RM RESULTS TABLE: ME equipment intended to produce diagnostic or therapeutic X-radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce diagnostic or therapeutic X-radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

10.2	RM RESULTS TABLE: Alpha, beta, gamma, neutron & other particle radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce any particle radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

10.3	RM RESULTS TABLE: Microwave radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce microwave radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

10.5	RM RESULTS TABLE: Other visible electromagnetic radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce other radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

10.6	RM RESULTS TABLE: RISK associated with infrared radiation other than emitted by lasers and LEDs		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce qualifying infrared radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

10.7	RM RESULTS TABLE: RISK associated with ultraviolet radiation other than emitted by lasers and LEDs		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Device does not produce qualifying ultraviolet radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No. .....:	FORE-SIGHT Elite				
Test ambient (°C) .....:	25.6				
Test supply voltage/frequency (V/Hz)[4] .....:	99VAC/ 50HZ				
Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	26.6	-
Elite	3	Power Supply, Transformer Primary	155	52.2	-
Elite	4	Power Supply, Transformer Secondary	155	50.5	-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Elite	6	Power Supply, C6	105	45.5	-
Elite	7	Power Supply, Mains Wire Connector	75	33.5	-
Elite	8	Line filter	75	27.6	-
Elite	9	Appliance inlet	40	25.8	-
Elite	10	Battery	104	27.1	-
Elite	11	TGS110	70	29.5	-
Elite	12	Button Battery	80	30.8	-
Elite	13	Relay	85	42.5	-
Elite	14	Screen	48	26.3	-
Elite	15	Preamp Enclosure	48	26.3	-
Elite	17	Sensor 1	41	25.1	-
Elite	18	Sensor 2	41	24.7	-
Elite	19	Sensor 3	41	25.9	-
Elite	20	Sensor 4	41	25.6	-

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT	Pass
Model No. .....:	FORE-SIGHT Elite	
Test ambient (°C) .....:	25.7	
Test supply voltage/frequency (V/Hz)[4] .....:	99VAC/ 60HZ	

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	26.1	-

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IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
Elite	3	Power Supply, Transformer Primary	155	52.1	-
Elite	4	Power Supply, Transformer Secondary	155	50.3	-
Elite	6	Power Supply, C6	105	45.4	-
Elite	7	Power Supply, Mains Wire Connector	75	33.5	-
Elite	8	Line filter	75	27.7	-
Elite	9	Appliance inlet	40	25.9	-
Elite	10	Battery	104	27.2	-
Elite	11	TGS110	70	29.5	-
Elite	12	Button Battery	80	30.8	-
Elite	13	Relay	85	42.4	-
Elite	14	Screen	48	26.4	-
Elite	15	Preamp Enclosure	48	26.3	-
Elite	17	Sensor 1	41	25.6	-
Elite	18	Sensor 2	41	24.4	-
Elite	19	Sensor 3	41	24.7	-
Elite	20	Sensor 4	41	24.5	-

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT	Pass
Model No. .....:	FORE-SIGHT Elite	
Test ambient (°C) .....:	25.6	
Test supply voltage/frequency (V/Hz)[4] .....:	264VAC/ 50HZ	

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	26.1	-
Elite	3	Power Supply, Transformer Primary	155	55.8	-
Elite	4	Power Supply, Transformer Secondary	155	53.9	-
Elite	6	Power Supply, C6	105	44.4	-
Elite	7	Power Supply, Mains Wire Connector	75	33.0	-
Elite	8	Line filter	75	27.8	-
Elite	9	Appliance inlet	40	26.6	-
Elite	10	Battery	104	27.4	-
Elite	11	TGS110	70	29.6	-
Elite	12	Button Battery	80	30.8	-
Elite	13	Relay	85	42.5	-
Elite	14	Screen	48	26.4	-
Elite	15	Preamp Enclosure	48	26.5	-
Elite	17	Sensor 1	41	24.4	-
Elite	18	Sensor 2	41	24.4	-
Elite	19	Sensor 3	41	24.8	-
Elite	20	Sensor 4	41	24.4	-

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT	Pass
Model No. .....:	FORE-SIGHT Elite	
Test ambient (°C) .....:	26.0	
Test supply voltage/frequency (V/Hz)[4] .....:	264VAC/ 60HZ	

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	26.3	-
Elite	3	Power Supply, Transformer Primary	155	55.7	-
Elite	4	Power Supply, Transformer Secondary	155	53.6	-
Elite	6	Power Supply, C6	105	41.9	-
Elite	7	Power Supply, Mains Wire Connector	75	31.1	-
Elite	8	Line filter	75	27.8	-
Elite	9	Appliance inlet	40	26.8	-
Elite	10	Battery	104	27.5	-
Elite	11	TGS110	70	29.6	-
Elite	12	Button Battery	80	30.8	-
Elite	13	Relay	85	42.7	-
Elite	14	Screen	48	26.3	-
Elite	15	Preamp Enclosure	48	26.8	-
Elite	17	Sensor 1	41	24.4	-
Elite	18	Sensor 2	41	24.3	-
Elite	19	Sensor 3	41	24.7	-
Elite	20	Sensor 4	41	24.4	-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT	Pass
Model No. .....:	FORE-SIGHT Elite	
Test ambient (°C) .....:	24.3	
Test supply voltage/frequency (V/Hz)[4] .....:	12VDC/	

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Elite	2	Metal Enclosure	48	23.2	-
Elite	10	Battery	104	24.5	-
Elite	11	TGS110	70	25.4	-
Elite	12	Button Battery	80	24.9	-
Elite	13	Relay	85	33.8	-
Elite	14	Screen	48	24.8	-
Elite	15	Preamp Enclosure	48	24.8	-
Elite	17	Sensor 1	41	25.2	-
Elite	18	Sensor 2	41	22.8	-
Elite	19	Sensor 3	41	23.2	-
Elite	20	Sensor 4	41	25.5	-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

11.1.1	RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.1.2.6	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.2.1	RM RESULTS TABLE: Applied parts intended to supply heat to patient		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Applied parts not intended to supply heat.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.1.2.2	RM RESULTS TABLE: Applied parts not intended to supply heat to patient		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Applied part did not exceed 41°C	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.1.3	TABLE: Temperature of windings by change-of-resistance method						N/A
Temperature T of winding:	t_1 (°C)	R_1 (Ω)	t_2 (°C)	R_2 (Ω)	T (°C)	Allowed T_{max} (°C)	Insulation class
Supplementary information:							

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.3	RM RESULTS TABLE: Measurements		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Section 3.11	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5	No risk benefit analysis performed		N/A

11.2.2.1	RM RESULTS TABLE: Risk of fire in an oxygen rich environment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not used in an oxygen rich environment	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.2.2.1	TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source	N/A
Areas where sparking might cause ignition:		Remarks
1.		
2.		
3.		
5.		
6.		
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		Remarks
1.		
2.		
3.		

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.		
5.		
6.		
Test parameters selected representing worst case conditions for ME EQUIPMENT:		Remarks
Oxygen concentration (%) ..... :		
Fuel..... :		
Current (A)..... :		
Voltage (V) ..... :		
Capacitance (µF) ..... :		
Inductance or resistance (h or Ω)..... :		
No. of trials (300 Min)..... :		
Sparks resulted in ignition (Yes/No).... :		
Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.		

11.3	RM RESULTS TABLE: Constructional requirements for fire enclosures of ME equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		alternate means not used	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.5	RM RESULTS TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not intended for use in conjunction with flammable agents.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances		Pass
Clause / Test Name	Test Condition	Part under test	Remarks
11.6.3 Spillage	8 oz. of water spilled on top of the monitor, in one event lasting < 15 sec liter of water spilled on the preamp housing, in one event lasting < 30 sec	Unit	Pass
11.6.6 / Cleaning	Cleaned with 10% bleach solution per IFU	Unit	Pass
11.6.6 / Cleaning	Windex per IFU	Screen	Pass
Supplementary information:			

11.6.2	RM RESULTS TABLE: Overflow in ME equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No liquid reservoir	
4.3			
4.4			
5			

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Clause	Requirement + Test	Result - Remark	Verdict

11.6.3	RM RESULTS TABLE: Spillage on ME equipment and ME system		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification Rev 01-xc	Items 4.5.5.11, 4.5.5.12, 4.5.5.13	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5	No risk benefit analysis performed		N/A

11.6.5	RM RESULTS TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	IPX0		N/A
4.3			N/A
4.4			N/A
5			N/A

11.6.6	RM RESULTS TABLE: Cleaning and disinfection of ME equipment and ME systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.10.3.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.6.7	RM RESULTS TABLE: Sterilization of ME equipment and ME systems		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		ME equipment and its accessories are not intended to be sterilized.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.6.8	RM RESULTS TABLE: Compatibility with substances used		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No substances used	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.1	RM RESULTS TABLE: Accuracy of controls and equipment		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Section 3.6 # 5 Hazard 4.4.1.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

12.3	RM RESULTS TABLE: Alarm systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazards 4.11.1.1 – 4.11.1.3	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

12.4.1	RM RESULTS TABLE: Intentional exceeding of safety limits		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Safety limits cannot be exceeded	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.2	RM RESULTS TABLE: Indication of parameters relevant to safety		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.5.9.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

12.4.3	RM RESULTS TABLE: Accidental selection of excessive output values		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		The FORE-SIGHT is not a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments Body location does not change any settings for output of the Oximeter, but is used to improve measurement accuracy. See note in 21-07-0304 Section 3.6, sub-section 5.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.4	RM RESULTS TABLE: Incorrect output		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		See note in 21-07-0304 Section 3.6, sub-section 5 Body location does not change any settings for output of the Oximeter, but is used to improve measurement accuracy	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.5.2	RM RESULTS TABLE: Diagnostic X-ray equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not diagnostic X-ray equipment	
4.3			
4.4			
5			
6.2			
6.3			
6.4			

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Clause	Requirement + Test	Result - Remark	Verdict

12.4.5.2	RM RESULTS TABLE: Diagnostic X-ray equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.5			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

12.4.5.3	RM RESULTS TABLE: Radiotherapy equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Monitor does not provide radio therapy.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.5.4	RM RESULTS TABLE: Other ME equipment producing diagnostic or therapeutic radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Monitor does not provide diagnostic or therapeutic radiation.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.4.6	RM RESULTS TABLE: Diagnostic or therapeutic acoustic pressure		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Monitor does not provide diagnostic or therapeutic acoustic pressure.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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Clause	Requirement + Test	Result - Remark	Verdict

13.1.2	TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances	N/A

Power dissipated less than (W)..... :	15
Energy dissipated less than (J) .....:	900

Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks

Supplementary information:

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive	Pass

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Clause 8.1:	—	—
			N/A
13.2.3	Overheating of transformers per Clause 15.5:	—	—
			N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
			N/A
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
			N/A
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
			N/A
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
	Single ventilation fans locked consecutively	Unit continued to operate without overheating or exceeding temperature limits	PASS
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	Unit continued to operate without overheating or exceeding temperature limits	PASS
	Simulated blocking of filters		N/A
	Flow of a cooling agent interrupted		N/A
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
			N/A
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
		V measured =	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
		V measured =	N/A
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:		N/A
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		N/A
	Temperatures measured as specified in 11.1.3 d)		N/A
	Temperatures did not exceed limits of Table 26		N/A
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
			N/A
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
			N/A

Supplementary information:
[1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

13.2.6	RM RESULTS TABLE: Leakage of liquid		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Does not contain liquids	
4.3			
4.4			
5			
6.2			
6.3			
6.4			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.2.6	RM RESULTS TABLE: Leakage of liquid		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.5			

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Clause	Requirement + Test	Result - Remark	Verdict

14.1	RM RESULTS TABLE: Programmable electrical medical systems - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Clause 14 applied	
4.3			
4.4			
5			

14.6.1	RM RESULTS TABLE: Identification of known and foreseeable hazards		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	21-07-0306 Rev 01-Xa Gemini Risk Analysis 21-07-0334 Rev 00 Gemini NSAM Boot Life Cycle 21-07-0336 Rev 00 Gemini Main Boot Life Cycle	Software Hazards 4.1.2.1, 4.1.2.3, 4.1.3.6, 4.3.1.1, 4.3.4.1, 4.4.1.1, 4.4.1.2, 4.4.2.1, 4.4.3.1, 4.4.4.1, 4.4.4.2, 4.4.5.1, 4.4.5.2, 4.4.5.3, 4.4.6.2, 4.4.6.3, 4.4.6.4, 4.5.1.1, 4.5.1.2, 4.5.2.1, 4.5.3.1, 4.5.3.2, 4.5.4.1, 4.5.5.1, 4.5.6.1, 4.6.1.1., 4.6.1.2, 4.6.1.3, 4.6.2.1, 4.6.4.1, 4.6.5.1, 4.6.5.2, 4.6.5.4, 4.7.1.1	Pass

14.6.2	RM RESULTS TABLE: Risk control		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.1	21-07-0333 Rev 00 21-07-0334 Rev 00 21-07-0335 Rev 00 21-07-0336 Rev 00	Gemini Main App Life Cycle Gemini NSAM Boot Life Cycle Gemini NSAM Main Life Cycle Gemini Main Boot Life Cycle	Pass

14.7	RM RESULTS TABLE: Requirement specification		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	21-07-0324 Rev 00 21-07-0325 Rev 00 21-07-0326 Rev 00 21-07-0327 Rev 00	Gemini Boot SW Req Gemini Main SW Req Gemini NSAM Main Boot SW Req Gemini NSAM Main App SW Req	Pass

14.8	RM RESULTS TABLE: Architecture		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	21-07-0328 Rev 00 21-07-0329 Rev 00 21-07-0330 Rev 00 21-07-0331 Rev 01	Gemini Main Boot Architecture Gemini Main App Architecture Gemini NSAM Boot Architecture Gemini NSAM App Architecture	Pass

14.9	RM RESULTS TABLE: Design and Implementation	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2	21-07-0328 Rev 00 21-07-0329 Rev 00 21-07-0330 Rev 00 21-07-0331 Rev 01	Gemini Main Boot Architecture Gemini Main App Architecture Gemini NSAM Boot Architecture Gemini NSAM App Architecture	Pass
6.3	21-07-0333 Rev 00 21-07-0334 Rev 00 21-07-0335 Rev 00 21-07-0336 Rev 00	Gemini Main App Life Cycle Gemini NSAM Boot Life Cycle Gemini NSAM Main Life Cycle Gemini Main Boot Life Cycle	Pass

14.10	RM RESULTS TABLE: Verification		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	VeP 120017 R00-Xa	Elite Software Verification Plan	Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

14.11	RM RESULTS TABLE: PEMS validation		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	VaP 120019 Rev01	Elite Software Validation Plan	Pass

14.13	RM RESULTS TABLE: Connection of PEMS by NETWORK/DATA COUPLING to other equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		device not intended to connect to Network/Data coupling	
4.3			
4.4			
5			
6.2			
6.3			

15.1	RM RESULTS TABLE: Construction of ME equipment – Arrangements of controls and indicators of ME equipment		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Section 4.6.1.3	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5	No risk benefit analysis performed		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

15.3	TABLE: Mechanical Strength tests [1)]			Pass
Clause	Name of Test	Test conditions	Observed results/Remarks	
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No damage	
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No damage on plastic, small dent on metal	
15.3.4.1	Drop Test (hand-held)	Free fall height (m) = 1	Preamp, No damage	
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	Monitor, No damage	
15.3.5	Rough handling test	Travel speed (m/s) = N/A	N/A	
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 70	Pass	
Supplementary information: [1)]As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).				

15.3.2	RM RESULTS TABLE: Push test		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.3.5.1	Pass
4.3			Pass
4.4			Pass
5			Pass

15.3.3	RM RESULTS TABLE: Impact test		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.3.5.1	Pass
4.3			Pass
4.4			Pass
5			Pass

15.3.4.2	RM RESULTS TABLE: Portable ME equipment		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.3.5.4	Pass
4.3			Pass
4.4			Pass
5			Pass

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.3.5	RM RESULTS TABLE: Rough handling test		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not Mobile	
4.3			
4.4			
5			

15.4.1	RM RESULTS TABLE: Construction of connectors		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		All patient connections have the same functions	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

15.4.2.1 a	RM RESULTS TABLE: THERMAL CUT-OUTS and OVER-CURRENT RELEASES		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such automatic resetting devices.	
4.3			
4.4			
5			

15.4.2.1 b	RM RESULTS TABLE: THERMAL CUT-OUTS with a safety function		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such devices	
4.3			
4.4			

15.4.2.1 c	RM RESULTS TABLE: Independent non-SELF-RESETTING THERMAL CUT-OUT		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such parts	
4.3			
4.4			

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.4.2.1 d	RM RESULTS TABLE: Loss of function of ME EQUIPMENT		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such parts	
4.3			
4.4			

15.4.2.1 h	RM RESULTS TABLE: ME EQUIPMENT with tubular heating elements		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		no such tubular heating elements	
4.3			
4.4			

15.4.3.1	RM RESULTS TABLE: Housing		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.1.4.2	Pass
4.3			Pass
4.4			Pass

15.4.3.2	RM RESULTS TABLE: Connection		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.1.1.4	Pass
4.3			Pass
4.4			Pass

15.4.3.3	RM RESULTS TABLE: Protection against overcharging		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazards 4.1.2.7, 4.1.4.3	Pass
4.3			Pass
4.4			Pass

15.4.3.4	RM RESULTS TABLE: Lithium batteries		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No lithium batteries	

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Clause	Requirement + Test	Result - Remark	Verdict

15.4.3.4	RM RESULTS TABLE: Lithium batteries		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3			
4.4			

15.4.3.5	RM RESULTS TABLE: Excessive current and voltage protection		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazard 4.1.2.8	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

15.4.4	RM RESULTS TABLE: Indicators		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Apparent from normal use	
4.3			
4.4			

15.4.5	RM RESULTS TABLE: Pre-set controls		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No preset controls	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

15.4.6	TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests				N/A
Rotating control under test	Gripping diameter "d" of control knob (mm) [1]	Torque from Table 30 (Nm)	Axial force applied (N)	Unacceptable RISK occurred Yes/No	Remarks

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information: [1] Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

15.4.7.3 b	RM RESULTS TABLE: Entry of liquids		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No foot operated control devices	
4.3			
4.4			

15.5.1.2	TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION		N/A
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)[1] .:			—
RATED input frequency (Hz).....:			—

Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (when protective device did not operate)(Min)	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

Supplementary information:
[1] Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated	N/A

Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1] ..... :	
RATED input frequency (Hz)..... :	
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A)..... :	
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A)..... :	

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

Supplementary information:
[1] Loads on other windings between no load and their NORMAL USE load.
Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32.
Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7	N/A

Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
	Primary & secondary windings				
	Primary winding & frame				
	Secondary winding & frame				

Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

16.1	RM RESULTS TABLE: General requirements for ME Systems		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not an ME system	
4.3			
4.4			
5			

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS			N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (µA)	Measured TOUCH CURRENT in NORMAL CONDITION (µA)	Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)	Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
Supplementary information: Not an ME system				

16.9.1	RM RESULTS TABLE: Connection terminals and connectors		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Not an ME system	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

17	RM RESULTS TABLE: Electromagnetic compatibility of ME equipment and ME systems		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	21-07-0304 Gemini Hazard Identification 21-07-0306 Gemini Risk Analysis	Hazards 4.3.1.1, 4.3.1.2, 4.3.2.1	Pass
4.3			Pass
4.4			Pass
5			Pass
6.2			Pass
6.3			Pass
6.4			Pass
6.5		No risk benefit analysis needed	N/A

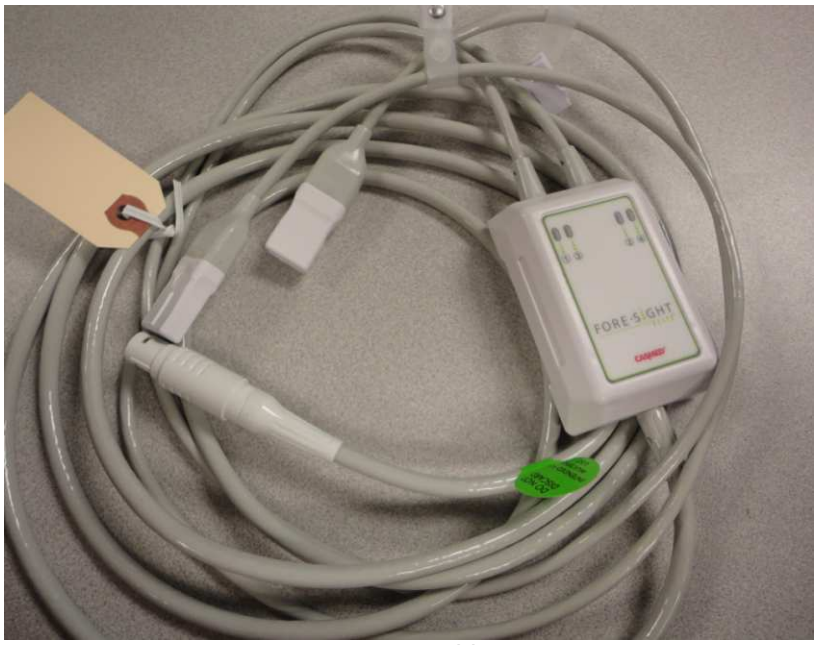
SP	TABLE: Additional or special tests conducted	N/A
Clause and Name of Test	Test type and condition	Observed results
Supplementary information:		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1
Attachment 1: Photographs of System

External view



Preamp cable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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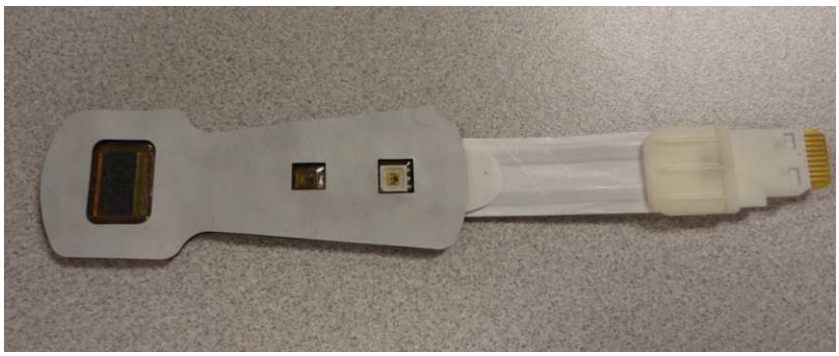
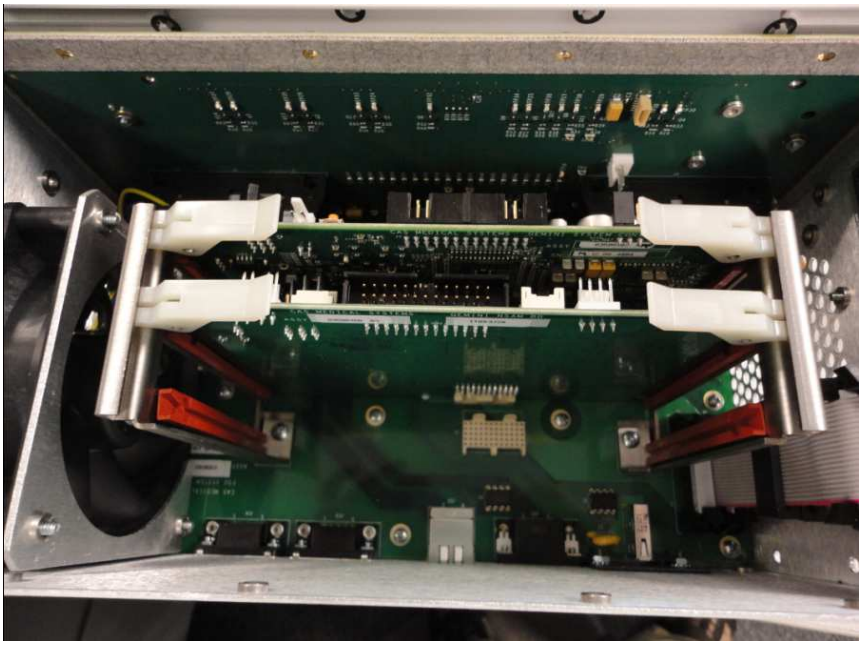
IEC 60601-1
Attachment 1: Photographs of System

Back view of sensor



Front view of sensor

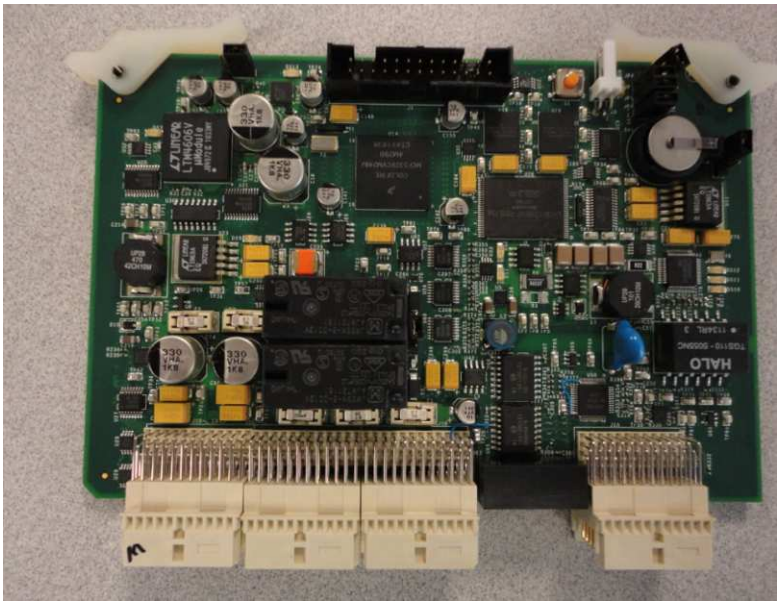


Internal View

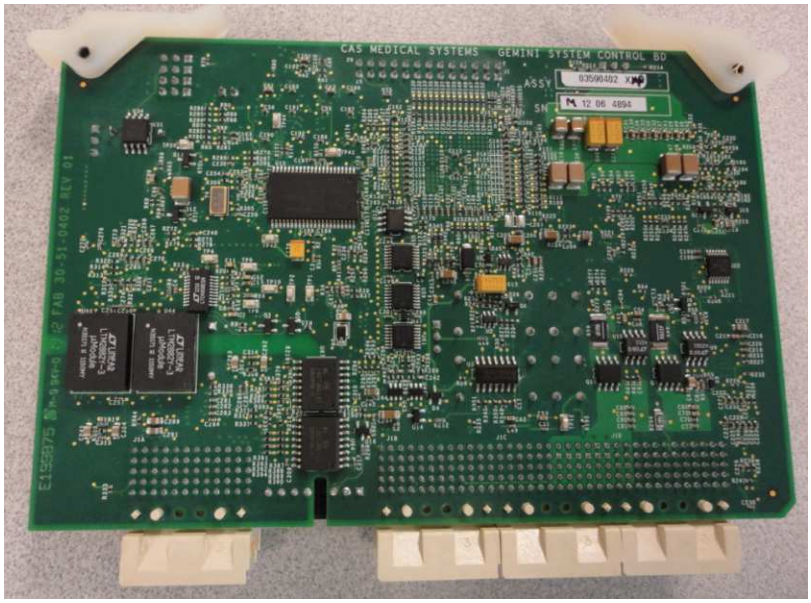
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1
Attachment 1: Photographs of System



Control board side A

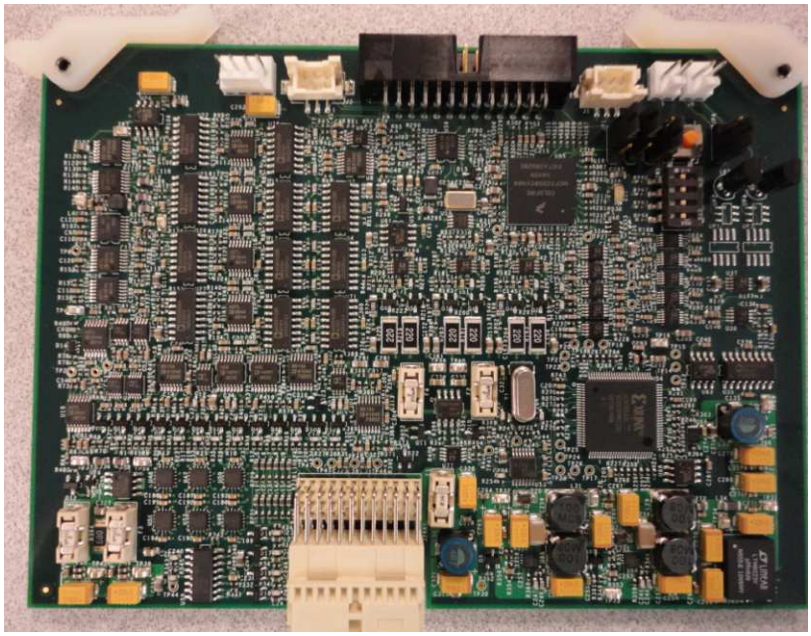


Control board side B

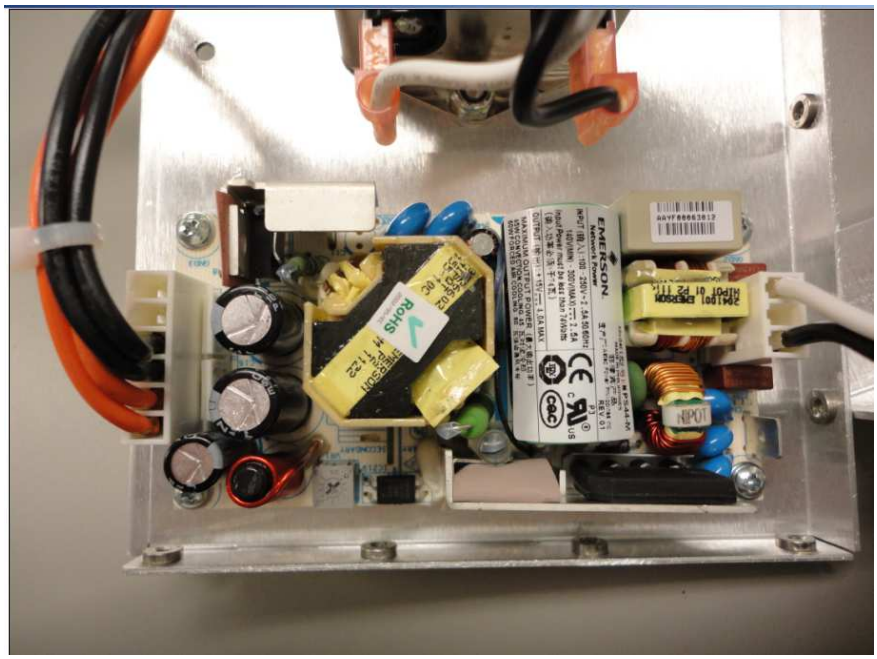
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1
Attachment 1: Photographs of System



Logic Board



Power supply

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 US NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Differences according to ..... :	National standard ANSI/AAMI ES60601-1: 2005		
Attachment Form No. ..... :	US_ND_IEC60601_1E		
Attachment Originator..... :	Underwriters Laboratories Inc.		
Master Attachment..... :	2009-08		
Copyright © 2009 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.			
4.8 b	Replacement: where there was no relevant IEC/ISO standard, the relevant US ANSI standard applied		Pass
	- when no relevant US ANSI standard existed, the requirements of this standard applied		Pass
4.10.2	Replacement: Rated voltage not exceeding 250V dc or single phase ac. or 600V poly-phase ac for ME EQUIPMENT and ME SYSTEMS up to 4kVA	240V	Pass
	Rated voltage not exceeding 600 V for all other ME EQUIPMENT and ME SYSTEMS		Pass
8.2	Addition: All FIXED ME EQUIPMENT & PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT		N/A
8.7.3 d	EARTH LEAKAGE CURRENT values are not higher than the stated values		Pass
	5 mA in NORMAL CONDITION		Pass
	10 mA in SINGLE FAULT CONDITION		Pass
8.11	Addition: PERMANENTLY CONNECTED ME EQUIPMENT provided with field wiring provision in accordance with NEC	Not permanent	N/A
	Installation of connecting cords between EQUIPMENT parts comply with NEC	No connection cord	N/A
	Cable used as external interconnection between units		Pass
	1) Exposed to abuse: Type SJT, SJTO, SJO, ST, SO, STO, or equivalent, or similar multiple-conductor appliance-wiring material,	SJT	Pass
	2) Not exposed to abuse: The cable was as in item 1) above, or		N/A
	i) Type SPT-2, SP-2, or SPE-2, or equivalent		N/A
	ii) Type SVr, SVRO, SVE, or equivalent or similar multiple-conductor appliance wiring material,		N/A

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict
	iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more,		Pass
	- enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more		Pass
	Receptacles provided as part of ME EQUIPMENT and ME SYSTEMS for use in the patient care areas of pediatric wards, rooms, or areas are Listed tamper resistant	No recepticals	N/A
	- or employ a Listed tamper resistant cover in accordance with NEC		N/A
8.11.3.2	Addition: The flexible cord is a type acceptable for the particular application,		Pass
	- and it is acceptable for use at a voltage not less than the rated voltage of the appliance		Pass
	- and has an ampacity as in NEC, not less than the current rating of the appliance		Pass

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition CA - CANADIAN NATIONAL DIFFERENCES to CAN/CSA-C22.2 No. 60601-1:08			
Differences according to.....:	Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08		
Attachment Form No. .....:	CA_ND_IEC60601_1G		
Attachment Originator .....:	CSA International		
Master Attachment .....:	2010-12		
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CA - Canadian National Differences as per CAN/CSA-C22.2 No. 60601-1:08			
1	**Scope, object and related documents**		---
1.1	**Scope**		Pass
	This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the *Canadian Electrical Code (CEC), Part I*, CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.		Pass
	NOTE 1A: *In the IEC 60601 standards series adopted for use in Canada, the Canadian-particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.*		Pass
1.3	**Collateral standards**		Pass
	Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard.		Pass
	NOTE 1: *When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards.*		Pass
1.4	**Particular standards**		Pass
	A requirement of a Canadian-particular safety standard takes precedence over this standard.		Pass
3	**Terminology and definitions**		N/A
3.41	**HIGH VOLTAGE**	Not high voltage	N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

	any voltage above 750 V, 1 050 V peak, as defined in the *Canadian Electrical Code (CEC), Part I*		N/A

4	**General requirements**		Pass
4.8	**Components of ME EQUIPMENT**		Pass
	a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; or		Pass
	NOTE 1: *For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.*		Pass
	b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied		Pass
	NOTE 2: *If there are neither requirements in this standard nor in a CSA, IEC, or ISO standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.*		Pass
4.10.2	**SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS**		Pass
	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1:		Pass
7	**ME EQUIPMENT identification, marking and documents**		Pass
7.7.1 to 7.7.5	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1		Pass
	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the *Canadian Electrical Code (CEC), Part I*, CSA C22.2 No. 21, and CSA C22.2 No. 49……..:		Pass
8	**Protection against electrical HAZARDS from ME EQUIPMENT**		Pass
8.7.3	**Allowable values**		Pass
	Allowable values shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1.		Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

8.11.3	**POWER SUPPLY CORDS**		Pass
8.11.3.2	**Types**		Pass
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be		Pass
	i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21;……..…:		N/A
	ii) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or……..:		Pass
	iii) Class II equipment having fuses on the line side/sides and neutral and may use a non-polarized attachment plug or a polarized attachment plug — CSA configuration type 1-15P shall be required and shall meet all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42. Where a polarized attachment plug is used, the POWER SUPPLY CORD shall be connected to the wiring of the EQUIPMENT on the ungrounded side of the line when any of the following devices are used in the primary circuit:…….:		N/A
	1- the centre contact of an Edison base lampholder;		N/A
	2- a single pole switch;		N/A
	3- an automatic control with a marked off position;		N/A
	4- a solitary fuse/fuse holder; or		N/A
	5- any other single pole overcurrent protective device		N/A
	b) Detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that		Pass
	i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety HAZARD to a PATIENT or OPERATOR;		Pass
	ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and		Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict
	iii) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable POWER SUPPLY CORD which could create a HAZARDOUS SITUATION		Pass
	c) A detachable POWER SUPPLY CORD shall		Pass
	i) comply with the applicable requirements of CSA C22.2 No. 21; and……..:		Pass
	ii) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than…….:		Pass
	1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT; and…..:	Not mobile equipment	N/A
	2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature)…..:		Pass
	NOTE 1A: *See CSA C22.2 No. 49 for requirements on the cord types mentioned in Sub-item 2).*		Pass
	d) Power supply cords shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:		Pass
	Connecting cords between equipment parts shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:		Pass
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		Pass
	Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……..:		Pass
9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**		N/A
9.7.5	**Pressure vessels**		N/A
	Pressure vessels shall comply with the requirements of CSA B51, as applicable……..:	No Pressure	N/A
9.7.7	**Pressure-relief device**		N/A
	A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements……..:		N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

15	**Construction of ME EQUIPMENT**		---
15.4.1	**Construction of connectors**		N/A
	bA) The point of connection of gas cylinders to EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be	No gas connections	N/A
	i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or……..:		N/A
	ii) DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359……..:		N/A
	NOTE 1A: *Users of this standard should consult the CSA Z305 series of standards, CAN/CSA-Z9170-1, CAN/CSA-Z9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke-type valve connections; and ISO 32 for colour coding.*		N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

15.4.8	**Internal wiring of ME EQUIPMENT**		Pass
	Internal wiring of ME EQUIPMENT shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……..:		Pass
16	**ME SYSTEMS**		N/A
16.1	**General requirements for the ME SYSTEMS**	Not an ME SYSTEM	N/A
	An ME SYSTEM shall provide		N/A
	- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and		N/A
	- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA, IEC, or ISO safety standards		N/A
	Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with CSA, IEC, or ISO safety standards that are relevant to that equipment.		N/A
16.9.2.1	**MULTIPLE SOCKET OUTLET**		N/A
	c) The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements……::		N/A
	- The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding		N/A
	- 1 kVA for single-phase transformers; and		N/A
	- 5 kVA for polyphase transformers The separating transformer shall also have a degree of protection not exceeding IPX4.		N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition
CH - SWITZERLAND NATIONAL DIFFERENCES to
SN EN 60601-1:06

	SWITZERLAND NATIONAL DIFFERENCES		—
4	Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7, Mercury - Annex 1.7 of SR 814.81 applies for mercury. Switches containing mercury such as thermostats, relays and level controllers are not allowed. Ordinance on chemical hazardous risk reduction SR 814.81, Annex 2.15 Batteries Annex 2.15 of SR 814.81 applies for batteries containing cadmium and mercury. Note: Ordinance relating to environmentally hazardous substances, SR 814.013 of 1986-06-09 is not longer in force and superseded by SR 814.81 of 2009-02-01 (ChemRRV).		Pass
	Supply cords of portable electrical appliances having a rated current not exceeding 10 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 6533-2:2009 Plug type 11, L + N, 250V 10A - SEV 6534-2:2009 Plug type 12, L + N + PE, 250V 10A - SEV 6532-2:2009 Plug type 15, 3L + N + PE, 250/400V 10A Supply cords of portable electrical appliances having a rated current not exceeding 16 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 5933-2:2009 Plug type 21 L + N, 250 V, 16A - SEV 5934-2:2009 Plug type 23 L + N + PE, 250 V, 16A - SEV 5932-2:2009 Plug type 25 3L + N + PE, 250/400V 16A NOTE 16 A plugs are not often used in Swiss domestic installation system. See TRF template regulatory requirements Switzerland on IECEE Website R.R. TRF templates.		Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1			
Attachment 2: Country Deviations			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 EN DIFFERENCES Medical electrical equipment, Part 1: General Requirements	
Differences according to .....:	National standard EN 60601-1:2005
Attachment Form No. .....:	EN_ND_IEC60601_1E
Attachment Originator.....:	Underwriters Laboratories Inc.
Master Attachment.....:	2009-08

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Annex ZA (normative)	Normative references to international publications with their corresponding European publications The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.		Pass
Annex ZZ (informative)	Coverage of Essential Requirements of EC Directives This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directives 90/385/EEC and 93/42/EEC. Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned. WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.		Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1
Attachment 3: Test Equipment List

TEST EQUIPMENT LIST					
Item	Equipment Type	Make	Model No.	Serial No.	Next Cal. Due
1	Weatherstation	Davis Instruments	Perception II	PE00729A02	02/14/2013
2	True RMS Multimeter	Fluke	87 V	19020163	04/23/2013
3	Articulated Test Finger Probe	E.D.&D.	TFP-01	00036	01/13/2013
4	Rigid Test Finger	Ergonomics	UFP20	ITSB-TF-001	04/02/2013
5	Test Hook	Ergonomics	601TH	SAF496	11/30/2012
6	Force Gauge	Wagner	FDK60	DSGFDK-60-B	08/25/2012
7	Programmable AC Source	QuadTech	31020A	QT31020A0067	02/20/2013
8	Power Analyzer	Extech	380801	B987393	12/05/2012
9	Digital Storage Oscilloscope	Agilent Technolgies	DSO-X 2002A	MY52013497	02/15/2013
10	Medical / ITS / Industrial switch and leakage box	Intertek	JP2	SAF720	12/28/2012
11	High Voltage Probe	Tektronix	P6015A	B040308	01/30/2013
12	10 Deg slope ramp for 601	ITS	10 Deg. Slope	SAF450	Verified
13	Digital Clinometer	Smart Tool	None	SAF235	04/12/2013
14	AC/DC Withstand Voltage Tester	Associated Research	HyPot II 3570D	A010675	03/30/2013
15	Power Analyzer	Extech	380803	10510502	10/11/2012
16	Force Gauge	Extech	475040	L621555	02/28/2013
17	Electronic Clock-Timer	Fisher Scientific	870A	20397972	11/10/2012
18	Digital Torque Gauge	Ametek (Chatillon)	DTG-100	A38712	01/13/2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1
Attachment 3: Test Equipment List

TEST EQUIPMENT LIST					
Item	Equipment Type	Make	Model No.	Serial No.	Next Cal. Due
19	Electronic Digital Caliper	Starrett	721A	04285629	09/08/2012
20	Dowel 1" dia.	ITS	Rod-1	SAF675	Verified
21	Dowel 0.875" Dia	ITS	Rod-0.875	SAF675	Verified
22	Scale Capacity 5 lb/ 2.2 kg	Sunbeam	SP5	DC:1203	05/23/2013
23	5 Foot Aluminum Ruler	C S Osborne	161	none	09/23/2012
24	Digital Lightmeter	Omega	HHLM-2	010045	02/10/2013
25	90.0% Ethanol, 9.5% Methanol and 0.5% Pyidine	ITS	Methylated Spirit	SAF648	Verified
26	Isopropyl Alcohol	ITS	Isopropyl Alcohol	SAF485	Verified
27	Electronic Clock-Timer	Fisher Scientific	870A	20397972	11/10/2012
28	Force Gauge	Wagner	FDK60	DSGFDK-60-A	09/09/2012
29	Flat Plane Pressure Probe	ITS	30 mm	SAF885	12/21/2012
30	Impact Test Ball 50mm 500gr	ED&D	ITB-01	SAF381	04/12/2013
31	Drop tube for 1M and 1.3M test	ITS	DT13	SAF565	Verified
32	Drop Test Platform (Large 50mm x 750 mm x 750 mm) used for UL335 Testing 707.5 Kg/cubic meter	ITS	SAF425	SAF425	07/25/2012
33	Data Logger	Fluke	2625A	6169601	06/25/2013
34	Thermocouple Modules (nos. 1-25)	Fluke	2620A-019	SAF067	06/25/2013
35	Laptop Computer ITS - Asset tag 17466	Compaq	NC6000	CNU45168CR	Verified
36	Sound Level Meter	Cirrus Research	CR:831C	D21956FF	01/24/2013
37	Electronic Clock-Timer	Fisher Scientific	870A	20341250	11/28/2012
38	Optical Comparitor	Finescale	OC-20	SAF220	01/13/2013

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1
Attachment 3: Test Equipment List

TEST EQUIPMENT LIST					
Item	Equipment Type	Make	Model No.	Serial No.	Next Cal. Due
39	Small Temperature/Humidity Chamber	Bryant Manufacturing	TH-5S	1207	12/02/2012
40	Chart Recorder (TH-5S)	Honeywell	DR45AT	0028Y0471539000	12/01/2012
41	Ball Pressure Tester	E.D.&D.	BPT-01	C05430462	06/19/2013
42	Ball Pressure Test Stand	E.D.&D.	BPA-01	C04430435	06/19/2013
43	Data Logger	Fluke	2625A	6593601	10/28/2012
44	Thermocouple Modules (nos. 1-25)	Fluke	2620A-100	T828S-A	10/31/2012
45	Micrometer	Mitutoyo	293-761-30	N029S	02/14/2013
46	Netbook	Gateway	LT2016U	0060150AEE81601	Verified
47	Data Acquisition/Switch Unit	Agilent	34970A	MY44060938	06/06/2013
48	20 Channel Multiplexer	Agilent	34901A	MY41135281	06/22/2013

TEST EQUIPMENT LIST					
Item	**Equipment Type**	**Make**	**Model No.**	**Serial No.**	**Next Cal. Due**
1	Weatherstation	Davis Instruments	Perception II	PE00729A02	02/14/2013
2	Impulse Tester	Compliance West	MegaPulse Defib-5P	431777	Verified
3	High Voltage Probe	Tektronix	P6015A	B041429	01/30/2013
4	Digital Storage Oscilloscope	Agilent Technolgies	DSO-X 2002A	MY52013497	02/15/2013
5	Clock/Timer 1" numbers	Sportline	Giant Timer	SAF451	02/13/2013
6	Scopemeter	Fluke	199C	DM8120327	04/26/2012
7	High Current Sourcing Milliohmeter	Hypatia	309	0480	03/27/2013

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

IEC 60601-1
Attachment 3: Test Equipment List

TEST EQUIPMENT LIST					
Item	**Equipment Type**	**Make**	**Model No.**	**Serial No.**	**Next Cal. Due**
8	Small Temperature/Humidity Chamber	Bryant Manufacturing	TH-5S	1207	12/02/2012
9	Chart Recorder (TH-5S)	Honeywell	DR45AT	0028Y0471539000	12/01/2012
10	Data Logger	Fluke	2625A	6593601	10/28/2012
11	Thermocouple Modules (nos. 1-25)	Fluke	2620A-100	T828S-A	10/31/2012
12	Optical Comparitor	Finescale	OC-20	SAF221	05/24/2013
13	Netbook	ASUS	X101CH	C3OAAS017535	Verified
14	AC Power Source	California Instr. Co	5001iLM	58545	04/13/2013
15	Data Acquistion/Switch Unit	Agilent	34970A	MY44060897	06/21/2013
16	Hipot Tester	QuadTech	Sentry Plus	S00300001101	04/12/2013
17	Medical/ITS/Industrial switch and leakage test box	ITS	JP2	SAF510	02/25/2013
18	Walk-In Humidity Chamber/Controller	Associated Env. Sys.	WR-601	8769	12/05/2012
19	Sound level meter	Simpson	886	034722	07/05/2013
20	Digital Storage Oscilloscope	Agilent Technolgies	DSO-X 2002A	MY52013497	02/15/2013
21	High Speed Si Photo Detector, 1ns Rise Time	ThorLabs Inc	DET210	SAF455	01/03/2013
22	Large 10 Degree Slope	ITS	Large 10 Deg Sect 1	SAF477	Verified
23	Hipot Tester	QuadTech	Sentry Plus	S00300001101	04/12/2013
24	Digital Multimeter	Fluke	87	66470936	12/05/2012
25	Medical/ITS/Industrial switch and leakage test box	ITS	JP2	SAF510	02/25/2013

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1
Attachment 4: CB Certificate for Power Supply

IEC IECEE CB SCHEME

Ref. Certif. No.

SG-MD-00165

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE)METHODE OC

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product Produit	Switch mode power supplies (Switch Mode Power Supply for Building-In)
Name and address of the applicant Nom et adresse du demandeur	Astec International Limited - Philippine Branch 3rd & 4th Floor, Techno Plaza One Bldg, #18 Orchard Road, Eastwood City Cyberpark, Bagumbayan 1110 Quezon City, PHILIPPINES
Name and address of the manufacturer Nom et adresse du fabricant	Astec International Limited - Philippine Branch, 3rd & 4th Floor, Techno Plaza One Bldg, #18 Orchard Road, Eastwood City Cyberpark, Bagumbayan, 1110 Quezon City, PHILIPPINES
Name and address of the factory Nom et adresse de l'usine	Astec Power Philippines Inc., Main Avenue Corner Rd "J", Cavite Export Processing Zone, Rosario, Cavite, PHILIPPINES For further information please see attachment
Rating and principal characteristics Valeurs nominales et caractéristiques principales	Rated AC Input : 100-250VAC, 50/60Hz, 2.5A Rated DC Input : 140-300V, 2.5A Rated DC Output : see test report for details Protection Class : I Degree of Protection : IPX0
Trade mark (if any) Marque de fabrique (si elle existe)	EMERSON
Model/type Ref. Réf. de type	NPS42-M, NPS43-M, NPS44-M, NPS45-M, NPS48-M
Additional information (if necessary) Information complémentaire (si nécessaire)	See Test Report for National Differences and Group Differences
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1:2005
as shown in the Test Report Ref. No. which form part of this certificate comme indiqué dans le Rapport d'essais numéro de référence qui constitue une partie de ce certificat	TÜV SÜD PSB Pte Ltd 211-300664-000

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

Date, 2012-02-06
CBS 12 01 51485 01028

(Jimmy Huang)

TÜV SÜD PSB Pte Ltd · 1 Science Park Drive · Singapore 118221

TÜV SÜD PSB Singapore

Page 1 of 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC 60601-1
Attachment 4: CB Certificate for Power Supply

IEC IECEE CB SCHEME

Ref. Certif. No.

SG-MD-00165

Additional factory information:

Name and address of the factory *Nom et adresse de l'usine*	Astec Electronics (Luoding) Co. Ltd. No. 68 Baocheng Road East, Fucheng Luoding, 527200 Guangdong, People's Republic of China Astec Electronics Co. Ltd. Emerson Industrial Park, Feng Tang Road, Fu Yong, Bao'an District, 518103 Shenzhen, Guangdong Province, People's Republic of China Astec Power Philippine Inc. 104 Laguna Boulevard, Laguna Technopark, 4026 Sta Rosa Laguna Philippines

Date, 2012-02-08
CBS 12 01 51485 01028

Signature : Jimmy Huang

TÜV SÜD PSB Pte Ltd • 1 Science Park Drive • Singapore 118221

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Page 2 of 2

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19. Performance Testing - Bench

See Clinical Section.

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20. Performance Testing – Animal

Not Applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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21. Performance Testing - Clinical

The clinical case for supporting cerebral use of the FORE-SIGHT Elite Absolute Tissue Oximeter Monitor in found in the document:

Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO2%) in Adult and Transitional Adolescent Subjects

See Attachment G

Note: The author of this section uses the term(s):

- FORE-SIGHT II Elite;
- FORE-SIGHT II;
- FS2, and
- Second Generation FORE-SIGHT

In each case this refers to the FORE-SIGHT Elite™ Absolute Tissue Oximeter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO_2%) in Adult and Transitional Adolescent Subjects

(b) (6) [redacted]

November 17, 2013

1. INTRODUCTION

1.1 Primary Objective of this 510(K) Application

This is an expanded regulatory clearance of the next generation FORE-SIGHT monitor called the FORE-SIGHT Elite Absolute Tissue Oximeter (a.k.a FORE-SIGHT II Elite to avoid confusion with the first generation FORE-SIGHT monitor) to be indicated for tissue oxygen saturation (StO2%) measurements of adult and transitional adolescent subjects using the FORE-SIGHT II Elite Large sensor.

The initial regulatory clearance (K123700) of the FORE-SIGHT Elite Absolute Tissue Oximeter was indicated for **Cerebral** tissue oxygen saturation (StO2%) measurements of adult and transitional adolescent subjects using the FORE-SIGHT II Elite Large sensor. This application expands the indication for use with **Body** or **Somatic** StO2 data validation of the FORE-SIGHT II Elite using the same Large sensor model for adults and transitional adolescents, for measurement of regional hemoglobin oxygen saturation of blood under the sensor.

Data from the Medium and Small sensors for all populations, including cerebral and somatic, will be presented in future 510(K) applications.

1.2 Proposed Indications for Use

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows: When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 Kg.

1.3. NIRS Principles –Light Interrogation of Tissues

Referring to **Figures 1 & 2**, light enters the body from a NIRS sensor light source placed on the skin. Individual photons travel on different paths because of the high light scattering characteristics of tissue; a small amount of photons reach the NIRS sensor's far light detector placed (b)(4) [redacted] FORE-SIGHT Large sensor) away from the light source. The sensor also has a near detector to detect light primarily from overlying tissues for compensation of possible overlying tissue interference. The FORE-SIGHT algorithm calculates tissue oxygen saturation (StO_2) by measuring light absorption due to oxy- and deoxy-hemoglobin at five different LED light sources at wavelengths (680, 730, 770, 805, and 870 nm). The FORE-SIGHT algorithm also compensates for background tissue light absorption and scattering, as well as skin pigmentation effects.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Figure 1: FORE-SIGHT NIRS placed on the body over a target organ with mean photon path

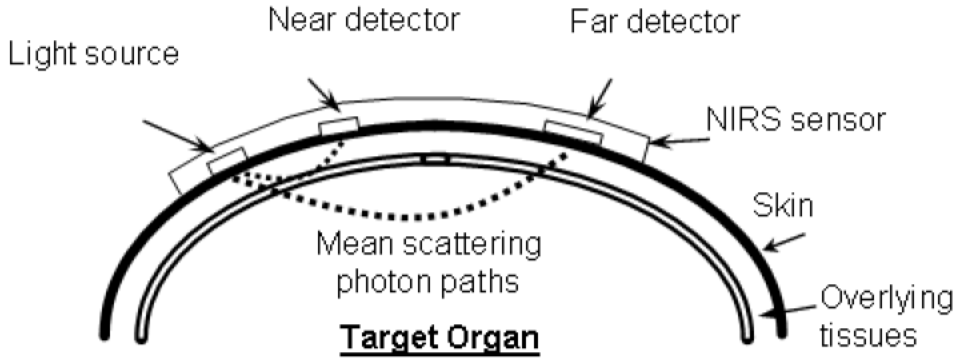
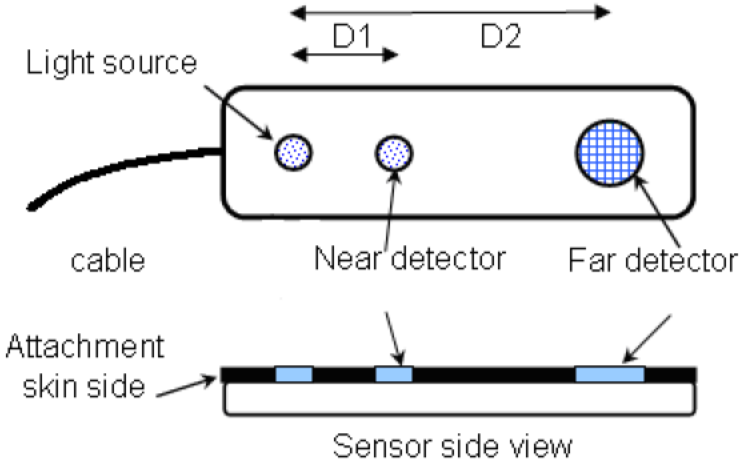


Figure 2: FORE-SIGHT Sensor design (face profile) showing placement of detectors relative to light source.



1.4. Sensor Light Interrogation Depth

As photons travel different paths and depths in tissue before reaching the NIRS sensor light detector, a banana shaped light path is formed. A general rule in NIRS sensor design is that the mean photon interrogation depth of the banana shaped light path is **½ the distance** between the sensor light source and far detector (D2 in Figure 2)[1] (Strangman et al., *Biol Psychiatry* 2002;52:679-93). When considering organ interrogation, the mean photon interrogation depth should be inside the organ to insure an adequate sample of organ tissue. Based on this information, the following table summarizes the average interrogation depths of the FORE-SIGHT sensors: For this 510(K) application, only data from adult tissue oxygen saturation application of the Large sensor will be presented.

Table 1: FORE-SIGHT sensors type and average optical photon interrogation depth

Sensor Type	Number of photodetectors	Light source to detector separation (D1 & D2)	Sensor mean photon interrogation depth in tissue (=D2 x ½)
Large	2, Near & Far detector	(b)(4) [redacted] (b)(4) [redacted]	(b)(4) [redacted]

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1.5 Primary predicate devices: FORE-SIGHT Elite Tissue Oximeter (K123700) and Nonin Model 7600 Equanox (K102715)

From FORE-SIGHT 510(k) K051257 and the latest K112820, the IFUs are as follows:

FORE-SIGHT Elite Cleared Indications for Use for Adults from K123700
The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated as follows: *When used with Large sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of adults and transitional adolescents ≥ 40 Kg.*

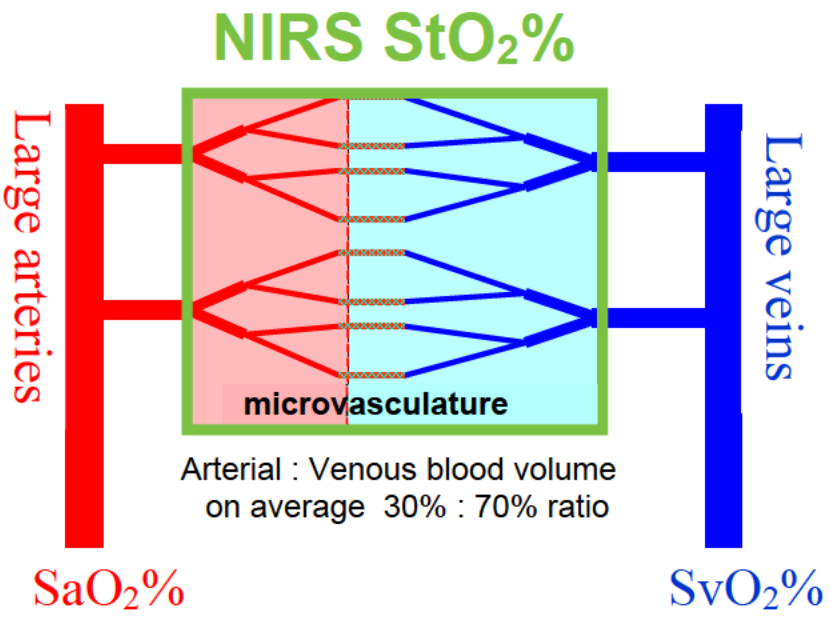
Nonin Model 7600 Equanox Cleared Indications for Use from K102715
Nonin's non-invasive Model 7600 4-Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult or pediatric patients weighting greater than 88 pounds (>40kg). It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1.6. NIRS StO_2 in Relation to Venous & Arterial Vasculature and Relative Blood Volume
Because NIRS technology mainly interrogates the microvasculature of tissue, which includes arterioles, venules, and capillaries as shown in **Figure 3**, a NIRS tissue oxygen saturation (StO_2) measurement is made on a mixture of both venous and arterial blood. The mean ratio of this mixture for brain was determined to be a 70% venous to 30% arterial blood volume[2] (Ito et al. *Ann Nucl Med* 2001;15:111-6). **The same mean ratio of 70% venous to 30% arterial blood volume applies to the whole body**[3] (Pang CC, Measurement of body venous tone. *J Pharmacol Toxicol Methods* 2000;44(2):341-60). Therefore, to validate NIRS, oxygenation measurements of both venous and arterial blood need to be considered from the venous output and arterial input of a target organ. .

For body or somatic measurements, an average adult male is made up of 42% skeletal muscle plus skin and an average adult female is made up of 36% (as a percentage of body mass)[4], therefore it is reasonable to estimate that skeletal muscle contains the same mean ratio of 70% venous to 30% arterial blood volume.

Figure 3: NIRS light interrogates the microvasculature of tissue to calculate StO_2%



1.7 Arterial and Venous Hemoglobin Oxygen Saturations of Different Organs
Referring to **Figure 4**, an organ receives oxygenated blood from one or more arteries. After the tissue of the organ extracts oxygen from the arterial blood for metabolism in the capillary bed, blood returns to the heart by one or more veins. Depending on the organ's metabolism level, the hemoglobin oxygen saturation of venous blood is typically low and can vary depending on the particular organ. Smaller veins drain into larger veins and then into the superior vena cava (SVC) or inferior vena cava (IVC) into the heart's right atrium (RA) and right ventricle (RV). Blood drawn from these locations can be called "central" venous (CV) blood, which will have an oxygen saturation somewhere in between the highest and lowest individual venous oxygen saturations of the organs. Besides the usual organs, skin and skeletal muscle metabolize oxygen significantly as well, because of the skin's large surface area and skeletal muscle's large mass relative to the rest of the body. For **brain**, arterial blood supply is primarily from the carotid arteries and the primary venous drainage is by the internal jugular vein / jugular bulb. For body / somatic locations, arterial blood supply is branched off the aorta at different places and the primary venous drainage is a central venous location around the right atrium of the heart.

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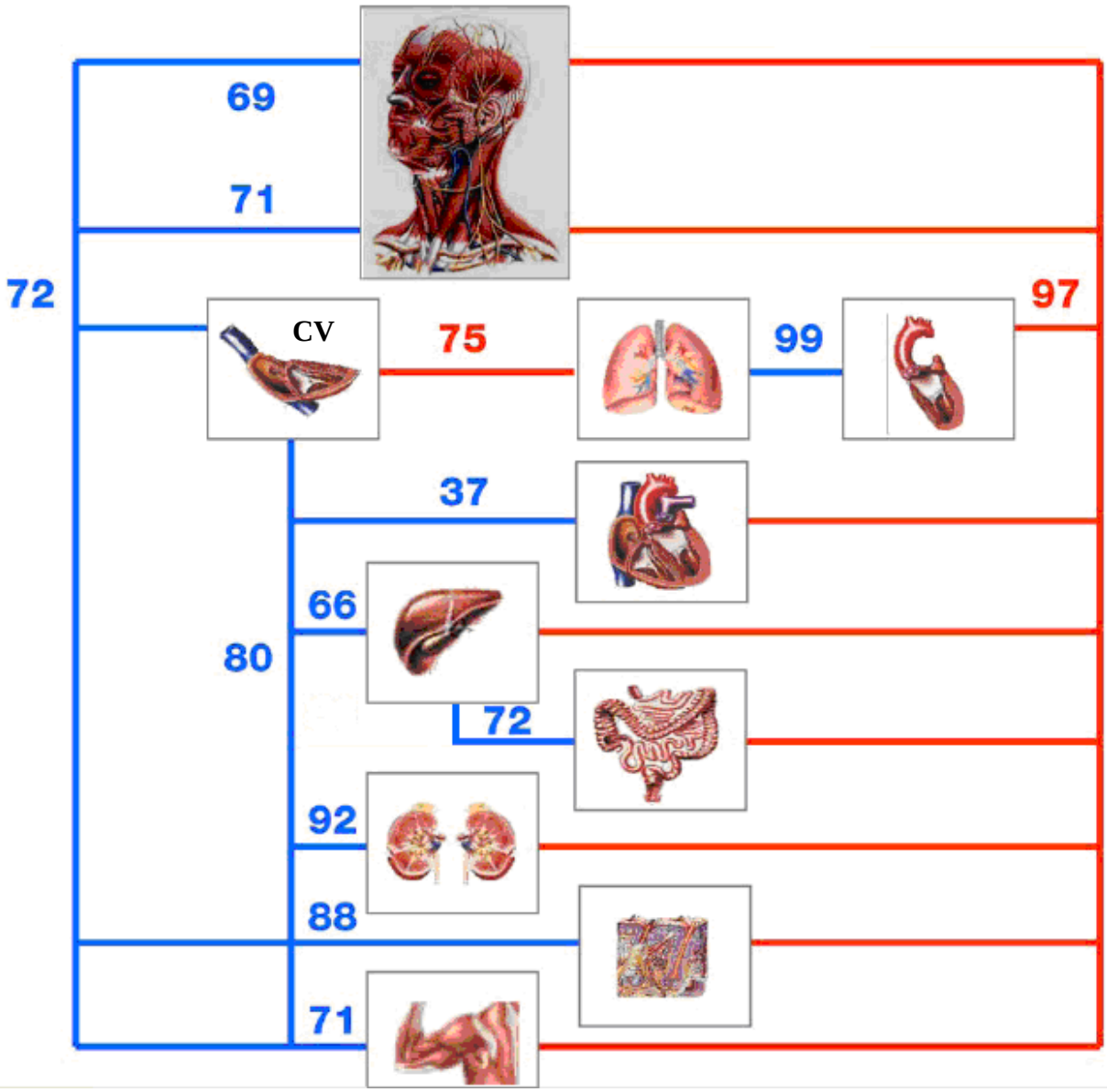
Figure 4: Arterial and venous supply to various organs with their respective hemoglobin oxygen saturation values (modified from Reinhart K in Lewis Pfeiffer (editors) : Practical Applications of Fiber Optics in Critical Care Monitoring, Springer Verlag Berlin – Heidelberg – New York 1990, pp 11-23.)[5]. The liver (or hepatic) venous oxygen saturation tends to be lower than the intestine/mesenteric portal vein oxygen saturation since the portal vein supplies low oxygenated blood to the liver.



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2. METHODS
2.1. HUMAN PROTOCOLS TO VALIDATE FORE-SIGHT SENSORS

2.2. Protocol Title:
Validation of the Second Generation of CAS Medical's FORE-SIGHT II Elite Near Infrared Spectroscopy (NIRS) Cerebral & Somatic Tissue Oxygen Saturation Sensors on Adult Subjects.

2.3 Purpose of the Study:
Primary Objectives:

1. To validate that the second generation FORE-SIGHT II Elite sensor accurately measures **Body** or **Somatic** tissue oxygen saturation (StO_2) in healthy adults and transitional adolescent adults when comparing to co-oximetry measurements of invasively drawn blood to expand the usage of FORE-SIGHT II Elite StO2 measurements for the body. The Cerebral tissue validation of the FORE-SIGHT II Elite monitor and sensor model used in this 510K application was already cleared by the FDA (K123700).
   A similar procedure for body/somatic/tissue under sensor StO2 measurements were used in predicate 510Ks: K094030 (FORE-SIGHT first generation), K112820 (FORE-SIGHT first generation), and K102715 (Nonin Equanox).

Transitional Adolescent considerations: Transitional adolescent adults (age 18-21) have been enrolled in the predicate FORE-SIGHT adult validation data submitted in previous 510(k) K123700. Based on this previous data, no special considerations are needed for transitional adolescents when validating the FORE-SIGHT II Elite monitor.

2.4 Background & Significance:
Near-infrared spectroscopy (NIRS) can be used to non-invasively estimate cerebral and somatic tissue oxygen saturation (StO_2). For brain, NIR light easily passes through skull bone and absorption of NIR light by brain tissue is dependent upon chromophores (light absorbing tissue) within the path of the transmitted light. The same is true for somatic except there is no bone in the sensor's light path. In both brain and somatic tissues the only significant chromophore is hemoglobin, which is present within both arterioles and venules. Pulse oximetry only estimates arterial oxygen saturation whereas StO_2 represents tissue oxygen saturation of the smaller blood vessels. Several continuous wave (CW) cerebral oximeters have obtained FDA 510k clearance and are currently commercially available in the USA, including the CAS Medical FORE-SIGHT device. The device has been used extensively in the clinical area of anesthesia and several recent studies have demonstrated the benefit of monitoring StO_2 in patients undergoing different surgical procedures.

The FORE-SIGHT sensor is applied to the forehead or somatic locations, preferable at larger muscle masses. The emitter and sensor are separated by a distance of (b)(4) for the Large sensor. The path of NIR light is not a straight path but instead curved ('banana-shaped'). Of the light emitted approximately 80% is dispersed by scatter, the remaining 20% is absorbed by chromophores, such as oxy- and deoxyhemoglobin. The development of the second generation sensor represents the continued efforts to improve the quality of signal processing when tissue is interrogated by NIRS.

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2.5 Design & Procedures:

This study evaluates the performance of the CAS Medical FORE-SIGHT II Elite in healthy volunteers during a controlled hypoxia sequence at steady-state $ETCO_2$ levels to measure body/somatic tissue StO_2. This protocol is very similar to validating cerebral StO2 except the venous reference is drawn from a catheter placed in the vena cava (as opposed to jugular bulb for cerebral) to obtain SvO2.

Somatic StO2 Validation

Sequence 1: Two CAS Medical FORE-SIGHT II Elite Large sensors will be placed on Flank skeletal muscle on the left or right side of the spine and on the quadriceps (Quad) muscle on the right or left leg. The monitor's values will be compared to the calculated whole body oxygen saturation derived from co-oximeter measured arterial and central venous (blood from the vena cava) oxygen saturations during the sequential desaturation study. The positions of the sensors will be alternately placed on left or right sides of the Flank and Quad so that half of the subjects will have left side StO2 measurements and the other half of the subjects will have right side StO2 measurements, depending if the subject number was odd or even.

Sequence	FORE-SIGHT II Elite Sensor type	Stepped hypoxia phases	Invasive blood draws for co-oximetry reference	Inter-Sensor body location variability test- Alternating sensor location on left & right of the body
1	FORE-SIGHT II Elite Large sensors	YES	YES	YES

Different combinations of FORE-SIGHT II Elite monitors and preamp cables, were used with different subjects to avoid monitor bias. Sensors are single use in design, so different sensors were used on each subject.

The level of oxygen within the blood will be reduced in a controlled manner by altering the inspired oxygen concentration (FiO_2) to achieve arterial oxygen saturation plateaus between 100% and 70%, measured by a finger pulse oximeter on the finger.

Each subject will be studied individually. An attending anesthesiologist will be present for each individual study. The anesthesiologist will continuously monitor subject's safety and manage the conduct of the study protocol. The subject's tolerance of the study procedures will be continually assessed and the study will be terminated by subject request or clinical discretion.

Subjects will include healthy adult volunteers who will be compensated for their participation. Written informed consent will be obtained from each subject prior to the initiation of any pre-study examination. Each subject will receive a screening health examination. Subjects will be required to fast from solid foods for 6 hours and from liquids for 2 hours prior to the study treatment in accordance with ASA guidelines. The duration of the entire clinical study is not expected to exceed 6 months, including subject recruitment, individual subject studies, and data analysis.

First, the controlled hypoxia evaluation will be conducted. The level of oxygen within the blood will be reduced in a controlled manner by the RespirAct® sequential gas delivery system (consisting of

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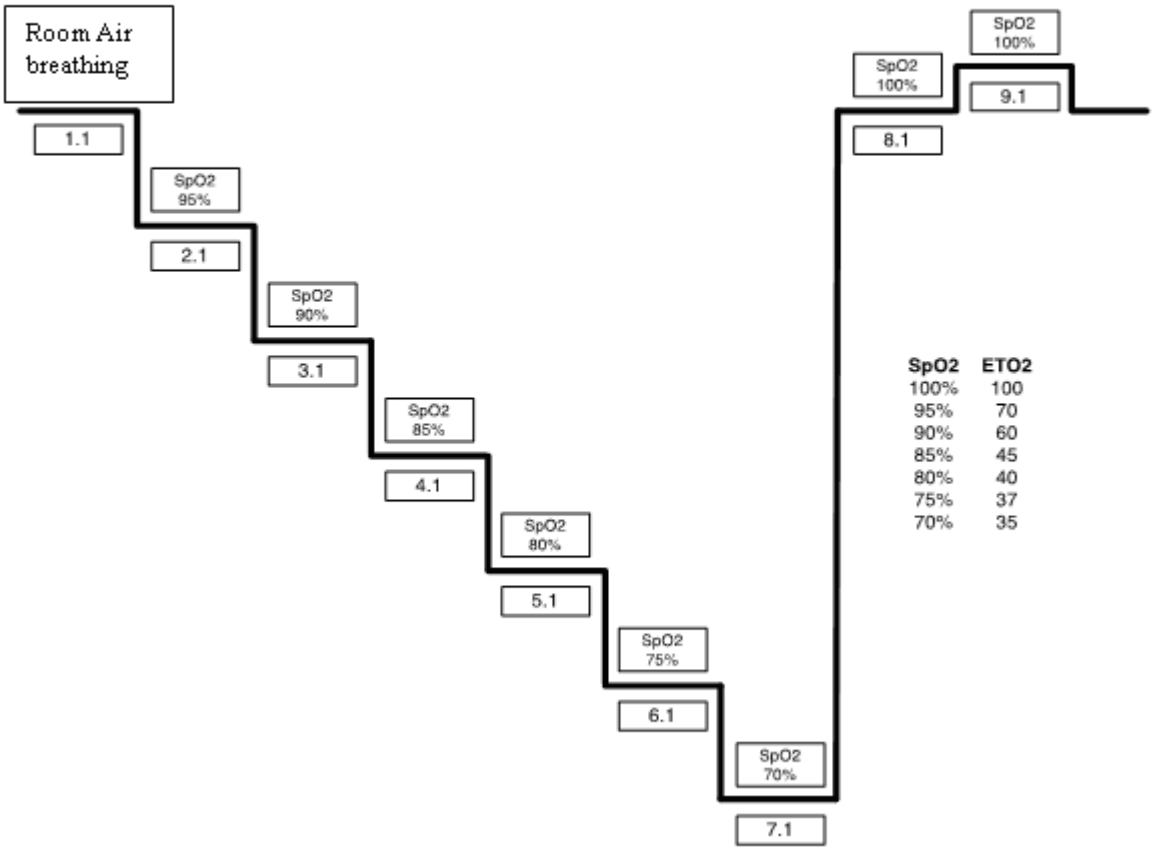
gas tanks, gas blender, facemask and control laptop with continuously displayed O_2 and CO_2) which permits control of the both the ETO_2 and ET CO_2 to reach target values. The measured ETO_2 and $ETCO_2$ equate with arterial O_2 and CO_2 (PaO_2 and $PaCO_2$ respectively). The attained PaO_2 then determines the SpO_2. One (1) Room Air and Eight (8) ETO_2 plateaus will be targeted, with resulting eight SpO_2 plateaus between 70 – 100%. Measurements and blood samples will be taken at each plateau. ECG, pulse, blood pressure, SpO_2, $ETCO_2$, and ET O_2 will be monitored throughout the study.

Prior to discharge, the subject will be given written instructions on how to contact the study doctor in the event of any concerns or adverse events. Within 48 hours of discharge, the study doctor or designee will contact the subject by phone to confirm the subject's well being and enquire to the presence of any unexpected symptoms. Following contact, the subject's participation in the study will be completed.

Figure 5: Stepped Hypoxia Sequence Protocol



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2.6 Selection of Subjects:

Advertisements will be posted around campus to recruit healthy volunteers to participate. Subject must pass study eligibility requirements prior to beginning any study treatment.

Inclusion Criteria:

1. 18 to 50 years of age, inclusive. Note transitional adolescent 18-21 year old subjects will be recruited as well.
2. Weight ≥ 40 kg and BMI of 18 to 30, inclusive
3. Does not take anticoagulants or platelet inhibitors on a regular schedule
4. Has not ingested an anticoagulant or platelet inhibitor in the 24 hour period prior to the study
5. $SpO_2 \geq 95\%$ on room air
6. Able to tolerate breathing mask apparatus
7. Expected to be able to tolerate controlled hypoxia to the levels called for in this protocol with minimal medical risk
8. Is not a resident or fellow in the Anesthesia department where study is being conducted
9. Is not an employee of sponsor company
10. Written informed consent form signed and dated by the subject

Exclusion Criteria:

Subjects with any of the conditions listed below are NOT eligible for study participation.

1. Female with positive pregnancy test
2. Beard or history of or anatomy suggestive of difficult airway
3. Hemoglobin concentration outside normal range for the clinical site
4. Platelet count outside normal range for the clinical site
5. History of cigarette smoking or currently a cigarette smoker
6. Current drug or alcohol abuse
7. History of high blood pressure or blood pressure > 140/90 at screening examination
8. Significant history of cardiac or pulmonary disease
9. Known allergy to lidocaine or heparin
10. History of sleep apnea
11. History of gastroesophageal reflux
12. ECG not within normal limits
13. History of hemoglobinopathy or coagulation abnormality, including and not limited to: sickle cell disease and/or thalassemia
14. May be placed at undue medical risk by any procedures in this protocol (e.g. arterial cannulation or hypoxia)
15. Any other condition that may, in the opinion of the investigator, increase the risk to the subject

2.7 Subject's Capacity to Give Legally Effective Consent:

All subjects will be healthy volunteers with capacity to give consent. Subjects will be excluded if they do not possess the capacity to give consent. No legally authorized representatives will be used.

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2.8 Risk/Benefit Assessment:

Risks and discomforts will be minimized through careful monitoring of the tests and procedures performed during this study to maximize safety and minimize the risks to the subject. All tests and procedures will be performed by appropriately trained staff. The CAS Medical FORE-SIGHT monitors are non-invasive devices that pose minimal risk. FORE-SIGHT employs infrared light to measure hemoglobin saturation. The trial may be stopped for safety purposes if risks associated with the use of the study device are identified. This study presents minimal risk in healthy volunteers. Controlled hypoxia will be induced by decreasing the ETO_2 in a stepwise manner. Published studies, conducted under similar conditions to those defined for this study, demonstrate that healthy subjects tolerate the mild hypoxia well and without untoward effects. This study employs methods similar to the standard protocols recommended by the FDA for testing pulse and cerebral oximeters in healthy volunteers.

As a result of participation in this study, subjects are at risk for the following:

- If the subject is highly allergic to the lidocaine, there is a risk of allergic reaction and the subject could possibly have a reaction that is severe enough to cause cardiac arrest and/or respiratory arrest.
- The other risks of this study are discomfort, tachycardia (fast heart rate), dizziness, nausea and vomiting, and the possibility of fainting (from getting needle sticks and/or breathing low oxygen). Subjects will receive standard treatment for these effects if they occur.
- Risks associated with drawing blood from the arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.
- Light headedness, headache, drowsiness, fainting, tachycardia, and hyperventilation (fast breathing rate) are the risks from breathing air for several minutes that is low in oxygen. The normal oxygen saturation for healthy individuals is greater than 96%. In a commercial airliner, the cabin pressure is set to an altitude (height) of 8,000 feet and the oxygen saturation is typically between 90 – 95%. The Federal Aviation Agency allows pilots in unpressurized airplanes to fly as high as 14,500 feet for as long as 30 minutes without supplemental oxygen. Healthy volunteers can usually tolerate an oxygen saturation of 70% and will not lose consciousness (being awake and aware) until the oxygen saturation is below 55%. This type of testing with the subject breathing air that is low in oxygen has been performed in other research studies down to an oxygen saturation of 60% without any known serious side effects. Each subject will be observed and monitored closely throughout the study by the study doctor.
- The risks of placement of the arterial catheter are bleeding, bruising, and infection, which are all rare. The radial and ulnar arteries are the two major blood vessels supplying the hand. If the color does not return immediately after release of the ulnar artery, the test is positive for potential difficulties of blood flow to the hand if a radial arterial line was present. In the event this occurs, the subject will not be allowed to continue to participate. The risks of placement of the radial and ulnar catheters are bleeding, bruising, infection, radial artery aneurysm (swelling) and loss of hand, all of which are rare.
- The risks of inserting and using any central venous (jugular vein for example) catheter placements include, but are not limited to the following:
    - Risks that do not need regimen or can be treated with medications: pain, allergic reaction to the local anesthetic, catheter migration (catheter movement from the insertion place), phlebitis (inflamed vein), nerve injury, infection, sepsis (bloodstream infection), trauma at the insertion site (redness, bleeding, blood clot, hematoma), fever, and catheter-related difficulties (insertion difficulty, leakage, blocked lines).

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  - Risks that can require surgical interventions: bleeding, hematoma (blood mass under the skin), air embolism (air bubble blocking the vein), accidental puncture of the carotid artery (supplies oxygenated blood to head and neck), hemomediastinum (blood in the space between organs in the chest), catheter embolism (catheter blocking the vein), thrombosis (blood clot in the vein), vessel perforation (puncture of the blood vessel), vascular damage (injury to blood vessel), pneumothorax (air in the chest), hydromediastinum (fluid in the space between organs in the chest) and hydrothorax (fluid in the lung membrane).
  - These complications can usually be resolved without long term problems. However, on rare occasions, some of these complications may result in permanent complications, stroke or death. In the unlikely event that such an event were to occur, the subject would be cared for by a team of health care providers including a fully trained anesthesiologist.
- The risks associated with a skull and chest x-ray are exposure to radiation. In this study, subjects will receive about the same amount of radiation as an individual would get from living in a high altitude city such as Denver for 4 weeks, or taking 8 airplane flights from New York to Los Angeles.

2.9 Data Analysis & Statistical Considerations:

2.9.1 Body/Somatic Tissue Oximetry Primary Invasive Reference Measurement: As previously described, the FORE-SIGHT II Elite Tissue Oximeter's cerebral tissue oxygen saturation (StO2) readings will be compared to the established weighted co-oximetry reference will be calculated and presented (REF CX) from the following equation:

$$\textbf{REF CX} = (0.7 \times S_vO_2) + (0.3 \times S_aO_2)$$

where S_vO_2 and S_aO_2 are the functional oxygen saturations from the blood samples drawn simultaneously from a central venous location (vena cava) and systemic arterial catheters, respectively, and measured using a co-oximeter. A similar procedure was used in predicate 510Ks: K094030 (FORE-SIGHT first generation), K112820 (FORE-SIGHT first generation), K123700 (FORE-SIGHT II), and K102715 (Nonin Equanox).

2.9.2 Sample Size Justification

This 510(k) application: 432 data points were obtained from 24 subjects where 9 data points were obtained per sensor (2 sensors used) per subject from FORE-SIGHT II Elite sensors on the Flank and Quadriceps muscle tissues.

As a reference, the number of subjects and number of data points obtained from the two Equanox sensors 8000CA (K090807) and 8004CA (K102715)[16] were compared to FORE-SIGHT II Elite cerebral and somatic applications. **Table 7** below demonstrates the comparable sample sizes of the FORE-SIGHT II Elite and Equanox data sets.

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Table 2: Comparison of sample size FORE-SIGHT II Elite and Equanox.

Model & Sensor	Number of Subjects	Number of FiO2 Plateaus (co-oximetry measurements)	Number of data points	510(K)
FORE-SIGHT II Elite *Somatic*	24	216	432 (2 sensors)*	**This application**
FORE-SIGHT II Elite Cerebral	25	225	225 (1 sensor)	K123700
Equanox 8000CA Cerebral	18	218	218 (1 sensor)[16]	K090807
Equanox 8004CA Cerebral	23	219	219 (1 sensor)[16]	K102715
FORE-SIGHT I	17	233	457 (2 sensors)**	K051257
	***NOTE**: Two sensors doubles number of data points per FiO2 plateau. **Data was also represented by left and right hemisphere sensor data, in which 16 subjects had 224 total data points for each side, while 1 subject had one sensor (contributing 9 co-oximetry measurements).			

2.9.3 Comparison of FORE-SIGHT II Elite to Co-oximetry Reference REF CX

Agreement between FORE-SIGHT II Elite and REF CX: We will use five methods to evaluate the agreement between FORE-SIGHT II Elite StO2 data vs. the reference REF CX data. The methods will include:
(1) Scatter plot of the FORE-SIGHT II Elite StO2 data vs. the reference REF CX data: visual inspection of whether the plot falls closely on the 45 degree line with the origin;
(2) Bland Altman plot (Bland and Altman, 1986)[6]: a straightforward and an intuitive approach to assess agreement by plotting the differences against the averages between two measurements;
(3) An advanced subject dependent data analysis using Deming regression (Linnet, 1993)[7]: similar to the traditional linear regression analysis but corrects the estimates of intercept and slope when both the FORE-SIGHT II Elite, and the REF CX data are subject to random errors;
(4) Traditional linear regression using Random Coefficients Model as a secondary analysis; and
(5) Concordance correlation coefficient (CCC) analysis (Lin, 1989)[8]: similar to the Pearson's correlation coefficient analysis but consists of a measure of precision multiplied by a measure of accuracy. Results between (3) Deming regression and (4) traditional linear regression will also allow visual comparison to demonstrate consistency and similarity of the two methods to compensate for any possible weaknesses of the two methods. Estimates of the regression coefficients (slope and intercept) and CCC will be presented with the 95% confidence intervals.

Regression Analysis Considerations: Because each subject has 9 data points per sensor (18 data points total), the data is not independent. Therefore the analysis will be more complex as follows.

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Deming regression assumes the reference (REF CX) is subject to measurement error. From previous 510K submissions, the FDA favors the use of Deming regression. A Deming regression line will be fitted for each subject resulting in 24 regression lines with slope and intercept for the 24 subjects. Initial Q statistic analysis showed that the estimated standard errors for the regression coefficients are not homogeneous as some subjects have larger variation than others due to subject effect (not pure instrumental random error). This factor is taken into account when we will "pool" the estimates of intercepts and slopes together. Specifically, in Step 1, the Deming regression coefficients will be determined for each subject, and then their standard errors will be determined based on the Jackknife method (Linnet 1990)[9] (Linnet 1998)[10]. In Step 2, the "Meta Analysis" technique will be used to pool these estimates together to generate a weighted average intercept and a weighted average slope (Laird and DerSimonian 1986)[11]. The pooled analysis will consider that subjects are random samples from a general population.

Random Coefficients Model is one traditional method of linear regression for subject dependent data. It assumes that each subject has his/her trajectory or inherent trend of the repeated measurements. The inherent trajectories are "high" or "low" with different steepness across subjects, suggesting that the subject-specific intercept and slope (Fitzmaurice, Laird, and Ware, 2004)[12]. The difference between Deming regression and the typical linear regression is that traditional linear regression does not assume that the reference (REF CX) is subject to measurement error.

CCC Calculation: The concordance correlation coefficient (CCC) will be used to demonstrate agreement for continuous data. It can be used in the context of multiple repeated measurements per subject, and thus is valid for this study. (Carrasco and Jover, 2003)[13]

2.9.4 Validation of Regression and CCC Analysis Methods Used

Bootstrap Validation: The regression methods (*Deming regression* and *Random Coefficients Model*) and CCC calculation will be validated by two bootstrapping methods, *Bootstrap I* and *Bootstrap II*. The Bootstrap 95% confidence interval (CI) method will be computed two different ways: "Normal" – normal approximation; and "Bias Corr" – bias-corrected percentile method.

Bootstrap I: Individual subject data will be bootstrapped without doing any moving block bootstrapping for repeated measurements within subjects. Sherman and le Cessie[14] present an 'all block bootstrap' by resampling blocks of individual subjects. They argued that, by bootstrapping these blocks, the correlation structure within each block could be maintained and the bootstrap intervals could be produced in an automatic way so that the correlation structure can be left unspecified.

Bootstrap II: We will do a second bootstrap method which does double bootstrapping for panel data (i.e., bootstrap for both subjects and time series data) based on Davison and Hinkley [15]. For this method, we will bootstrap individual subjects first and then bootstrap observations within individual subjects using the moving block method with block size 3 and overlap size 2. This is determined from the dataset, where there were 9 observations per subject where the desire block size is $n^{**(1/3)}$ which is $9^{**(1/3)}$~2 or 3[15].

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2.10 Data & Safety Monitoring:

All clinically significant adverse events will be reported to the Sponsor on the adverse event (AE) case report form (CRF). Standard of care should be implemented whenever an AE occurs to treat and/or resolve the AE and to monitor the subject. Any subject who is withdrawn from the study due to an AE shall be followed until the outcome is resolved or, in case of permanent impairment, until the event stabilizes and the overall clinical outcome has been ascertained.

An anesthesiologist will be present for the each study. An anesthesiologist will perform cannulation of the radial artery and the jugular vein. Insertion of a vena cava catheter and a radial artery catheter are low-risk procedures when performed by experienced personnel and are widely used for patient monitoring in a variety of clinical settings. The risks associated with jugular vein cannulation include infection, hematoma, and inadvertent injury to nearby structures such as the carotid artery. The latter complication will be minimized by using ultrasound image guidance for insertion of the catheter and x-ray confirmation of catheter placement. The risks associated with radial artery cannulation include infection, hematoma, and impaired blood supply to the hand. The latter complication will be minimized by using ultrasound scanning to ensure the adequacy of collateral flow before catheter insertion and by continuous oxygen saturation measurement in the hand after catheter insertion.

At the completion of the 48 hour follow-up call, a report will be generated detailing the following:

1. Cardiovascular parameters: continuous arterial systolic & diastolic blood (SBP/DBP) pressure and heart rate (HR).
2. Respiratory parameter: continuous SpO_2.
3. Blood oxygen parameters: intermittent arterial and jugular venous oxygen saturations (PaO_2 / $PjvO_2$) generated from blood gas co-oximeter analyzer (samples taken at each plateau).
4. Any adverse events reported by the PI.

Adverse events related to desaturation are most likely to present on the study day while the subject is present with the research lab. Any further adverse events are most likely to be related to arterial and jugular catheter placement and will be reported by the subject when contacted by telephone by the study staff within 48 hours of the study day.

Note that there were no adverse events reported at the completion of this study.

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3. RESULTS:

3.1 Table 3: Subject Demographics Data - Race Information: 8 White (Caucasian), 14 Black (African American), & 2 Asian subjects. Gender Information: 15 Male & 9 Female. Weight Range: 51.0 to 96.5 kg. Age range: 19 to 40 years. FORE-SIGHT II Elite Large sensors placed on Flank and Quad (quadraceps) for all subjects at alternating left and right positions depending if the subject number was odd or even.

Subject	Race	Gender	Age	Weight(Kg)	Height(m)
1	W	F	28	62.8	1.72
2	W	M	26	85.9	1.78
3	W	M	40	94.9	1.81
4	AS	M	19	81.2	1.75
5	W	F	20	66.5	1.72
6	BK	M	32	96.5	1.85
7	BK	M	27	96.4	1.96
8	BK	M	40	86.0	1.73
9	BK	M	35	90.8	1.78
10	BK	M	26	94.7	1.89
11	BK	F	38	67.7	1.56
12	BK	M	32	87.3	1.74
13	BK	M	24	95.6	1.81
14	BK	F	26	51.0	1.58
15	BK	F	19	56.0	1.57
16	BK	M	24	89.6	1.74
17	W	F	39	70.8	1.75
18	BK	F	26	69.1	1.64
19	W	M	22	74.9	1.86
20	BK	M	29	81.0	1.88
21	BK	F	19	60.3	1.59
22	W	M	20	77.6	1.84
23	W	M	19	84.1	1.90
24	AS	F	19	64.9	1.76
W=White(Caucasian); AS=Asian; & BK=Black(African American)					

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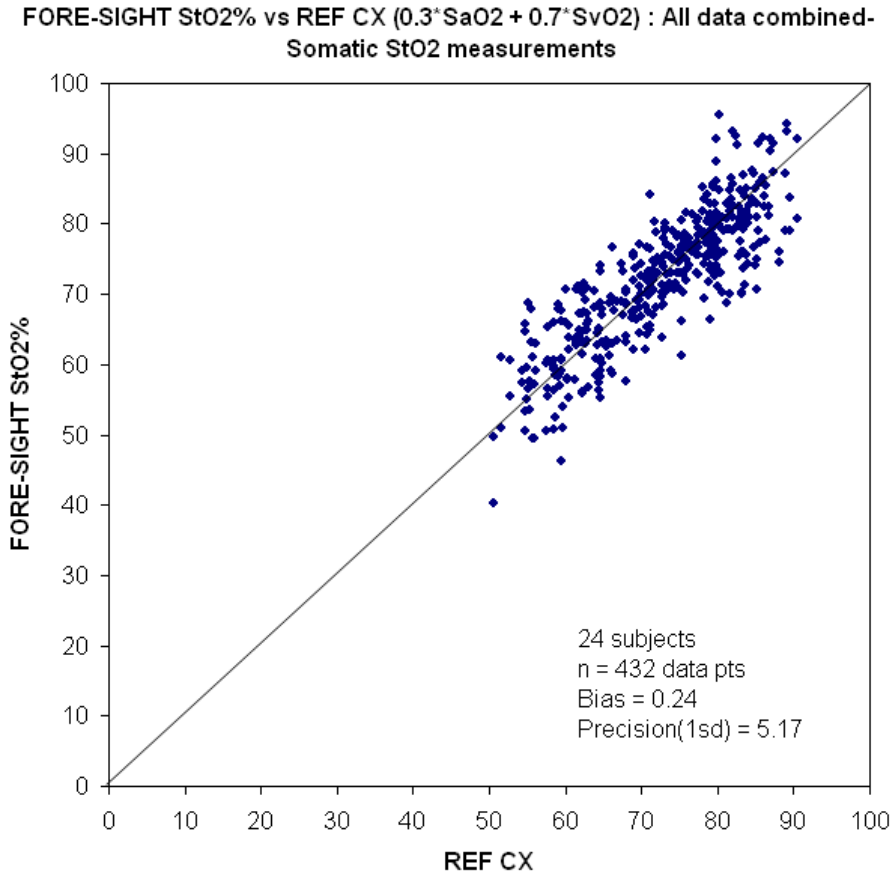
3.2 Body/Somatic FORE-SIGHT II Elite vs Co-Oximetry Reference (REF CX): Scatterplots and Bland-Altman.

Figures 6-7: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Scatter-plot and Bland-Altman plot *for all Somatic measurement data collected*



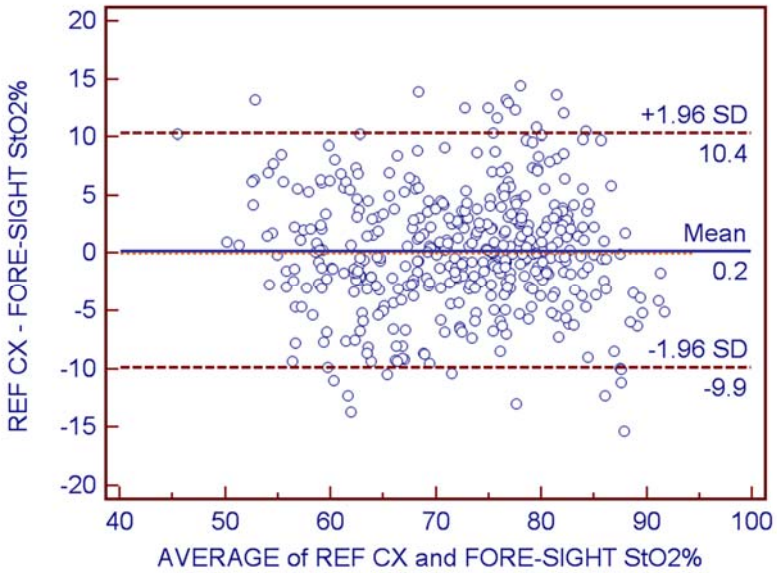


Figure 8: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Scatter-plot and Bland-Altman *with Somatic StO2 measurements of Flank and Quad data indicated*.

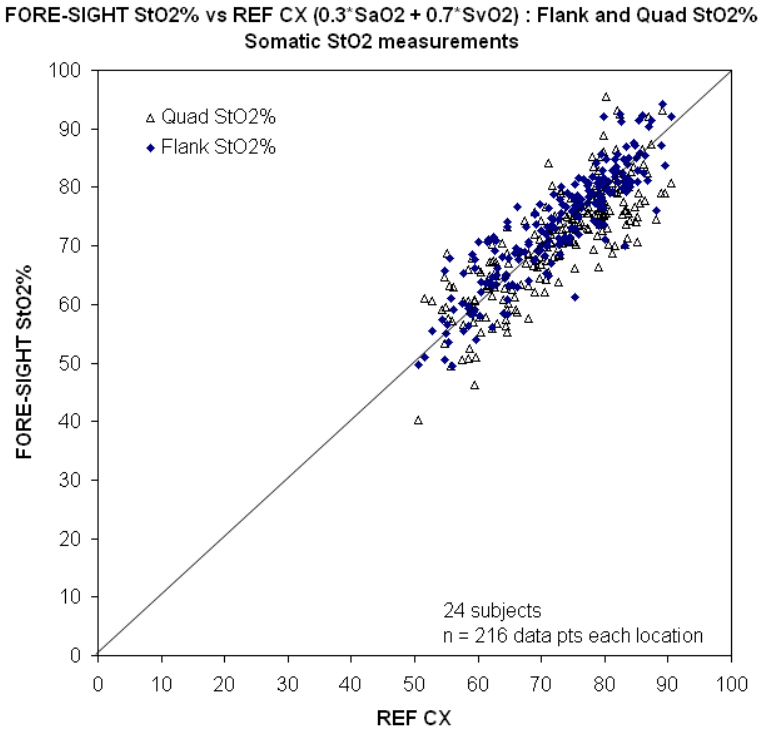
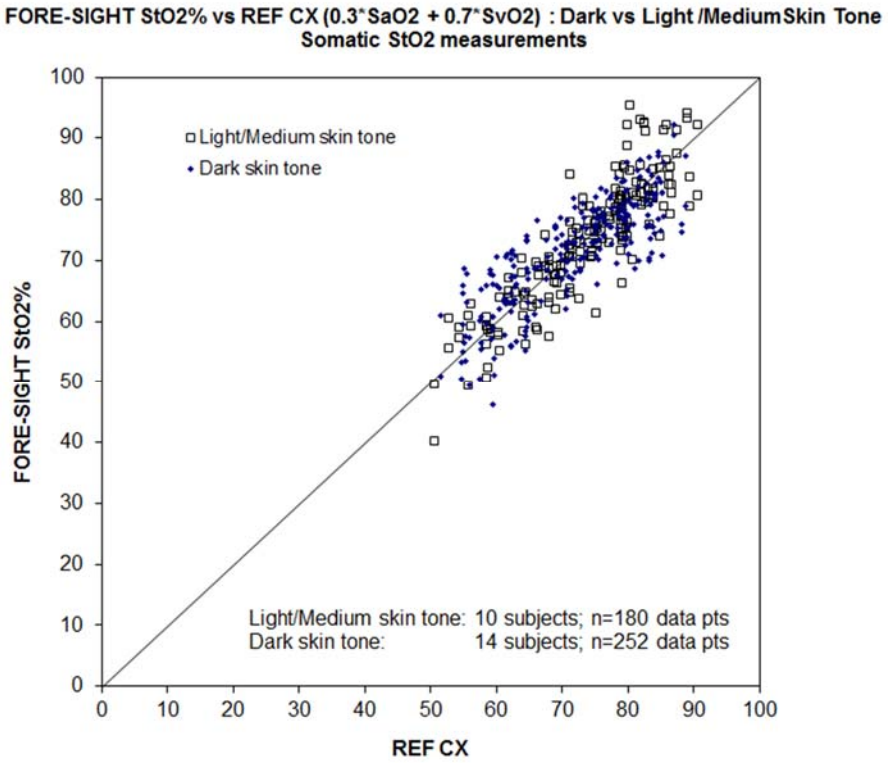


Figure 9: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Scatter-plot *with Somatic StO2 measurements of Light/Medium and Dark subject skin tones*.



3.2.1 FORE-SIGHT II Elite Somatic Tissue StO2 Bias & Precision Results Comments: Results from the Scatterplot and Bland-Altman analysis (**Figures 6-7**) shows that FORE-SIGHT II Elite StO2 Somatic tissue measurements demonstrated an overall bias ± precision (1 standard deviation) of 0.24 ± 5.17% compared to the co-oximetry reference REF CX. **Figure 8** is the same scatterplot of Figure 6 but identifies the Flank and Quad StO2 measurements. FORE-SIGHT II Elite StO2 Somatic tissue measurements from the Flank muscle tissue sensor demonstrated an overall bias ± precision (1 standard deviation) of -0.97 ± 4.29%, while the Quad muscle tissue sensor demonstrated an overall bias ± precision (1 standard deviation) of 1.45 ± 5.67%. See **Section 3.3** for Regression analysis and Bootstrap validation.

3.2.2 FORE-SIGHT II Elite Somatic Tissue StO2 Measurement Performance by Skin Tone Groups

The Light/Medium skin tone group consisted of White (Caucasian) and Asian subjects and the Dark skin tone group consisted of Black (African Americans). The bias and precision (1 standard deviation) of FORE-SIGHT II Elite StO2 vs REF CX for two skin tone groups (light/medium and dark skin tones) as demonstrated by **Table 6** and by observation in the scatterplot (**Figure 9)** clearly show consistent performance of FORE-SIGHT II Elite Somatic StO2 measurements across different skin tone types.

Table 4: Bias and precision of FORE-SIGHT II Elite StO2 vs REF CX for the two skin tone groups (light/medium and dark skin tones).

Skin Tone Groups	Subjects (n)	Data points (n)	Bias	Precision (1sd)
ALL	24	432	0.24	5.17
Light/Medium	10	180	0.33	4.92
Dark	14	252	0.18	5.35
Comparison of Light/ Medium tone vs Dark tone was not statistically significant (P = 0.76 two-tailed, t-test for means).				

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3.3 Body/Somatic FORE-SIGHT II Elite vs Co-Oximetry Reference (REF CX): Regression analysis and Bootstrap Validation Results- ALL DATA

Table 5: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Deming and Random Coefficients Model Regression, CCC, and Bootstrap I and Bootstrap II Validation. (Bootstrap sample = 200). Data from **Figure 6**.

All somatic data		Original or Bias–corrected (bootstrap) Statistic	Approx Bias	Bootstrap mean	Standard Error	Approx. Lower 95% Confidence Limit	Approx. Upper 95% Confidence Limit	Bootstrap CI Method
Deming regression - intercept	**Observed**	1.289	NA	NA	4.835	-8.188	10.765	
	Bootstrap I	1.222	0.067	1.355	4.497	-7.591	10.035	Normal
						-7.403	9.844	Bias Corr.
	Bootstrap II	2.709	-1.420	-0.131	5.180	-7.443	12.860	Normal
						-7.261	11.674	Bias Corr.
Deming regression - slope	**Observed**	0.976	NA	NA	0.065	0.849	1.102	
	Bootstrap I	0.977	-0.001	0.975	0.060	0.858	1.095	Normal
						0.862	1.086	Bias Corr.
	Bootstrap II	0.957	0.019	0.995	0.070	0.819	1.094	Normal
						0.835	1.088	Bias Corr.
Random coefficients models - intercept	**Observed**	7.632	NA	NA	3.920	-0.477	15.740	
	Bootstrap I	7.584	0.047	7.679	3.965	-0.188	15.356	Normal
						-0.189	14.977	Bias Corr.
	Bootstrap II	8.076	-0.445	7.189	4.543	-0.827	16.980	Normal
						-0.608	17.429	Bias Corr.
Random coefficients models - slope	**Observed**	0.888	NA	NA	0.053	0.777	0.998	
	Bootstrap I	0.889	-0.001	0.886	0.054	0.784	0.993	Normal
						0.783	0.989	Bias Corr.
	Bootstrap II	0.881	0.006	0.894	0.061	0.762	1.001	Normal
						0.761	1.004	Bias Corr.
Concordance Correlation Coefficient (CCC)	**Observed**	0.861	NA	NA	0.037	0.789	0.932	
	Bootstrap I	0.876	-0.015	0.846	0.055	0.767	0.984	Normal
						0.737	0.930	Bias Corr.
	Bootstrap II	0.778	0.083	0.944	0.024	0.732	0.825	Normal
						0.819	0.819	Bias Corr.

Bootstrap I : Single Bootstrapping for dependent data -- bootstrap individuals only and then sample entire block for each selected subject.
Bootstrap II: Double Bootstrapping for dependent data -- bootstrap individuals and then bootstrap observations within individuals using the moving block method with block size 3 and overlap size 2.
Bootstrap CI method: Normal – normal approximation. Bias Corr – bias-corrected percentile method.

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3.3.1 Somatic FORE-SIGHT II Elite vs Co-Oximetry Reference (REF CX): Regression analysis and Bootstrap Validation Results - FLANK muscle tissue data.

Table 6: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Deming and Random Coefficients Model Regression, CCC, and Bootstrap I and Bootstrap II Validation. (Bootstrap sample = 200). Flank muscle tissue data from **Figure 8**.

Flank		Original or Bias–corrected (bootstrap) Statistic	Approx Bias	Bootstrap mean	Standard Error	Approx. Lower 95% Confidence Limit	Approx. Upper 95% Confidence Limit	Bootstrap CI Method
Deming regression - intercept	Observed	4.676	NA	NA	4.063	-3.287	12.639	
	Bootstrap I	4.396	0.280	4.956	4.036	-3.515	12.306	Normal
						-2.034	12.638	Bias Corr.
	Bootstrap II	4.307	0.370	5.046	4.748	-4.999	13.612	Normal
						-3.309	14.870	Bias Corr.
Deming regression - slope	Observed	0.944	NA	NA	0.053	0.839	1.049	
	Bootstrap I	0.947	-0.003	0.941	0.052	0.845	1.050	Normal
						0.844	1.037	Bias Corr.
	Bootstrap II	0.948	-0.004	0.941	0.062	0.827	1.068	Normal
						0.810	1.054	Bias Corr.
Random coefficients models - intercept	Observed	6.824	NA	NA	3.701	-0.833	14.481	
	Bootstrap I	6.578	0.247	7.071	3.712	-0.699	13.854	Normal
						0.547	14.681	Bias Corr.
	Bootstrap II	6.411	0.240	7.238	4.320	-2.056	14.878	Normal
						-1.809	15.845	Bias Corr.
Random coefficients models - slope	Observed	0.915	NA	NA	0.049	0.814	1.016	
	Bootstrap I	0.918	-0.003	0.912	0.048	0.823	1.013	Normal
						0.810	0.999	Bias Corr.
	Bootstrap II	0.920	-0.005	0.910	0.057	0.809	1.031	Normal
						0.791	1.019	Bias Corr.
Concordance Correlation Coefficient (CCC)	Observed	0.803	NA	NA	0.050	0.704	0.902	
	Bootstrap I	0.823	-0.020	0.783	0.080	0.667	0.979	Normal
						0.586	0.910	Bias Corr.

Bootstrap I : Single Bootstrapping for dependent data -- bootstrap individuals only and then sample entire block for each selected subject.
Bootstrap II: Double Bootstrapping for dependent data -- bootstrap individuals and then bootstrap observations within individuals using the moving block method with block size 3 and overlap size 2.
Bootstrap CI method: Normal – normal approximation. Bias Corr – bias-corrected percentile method.

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3.3.2 Somatic FORE-SIGHT II Elite vs Co-Oximetry Reference (REF CX): Regression analysis and Bootstrap Validation Results - QUAD muscle tissue data.

Table 7: Comparison of FORE-SIGHT II Elite to Co-Oximetry Reference (REF CX) : Deming and Random Coefficients Model Regression, CCC, and Bootstrap I and Bootstrap II Validation. (Bootstrap sample = 200). Quadriceps muscle tissue (Quad) data from **Figure 8**.

QUAD		Original or Bias–corrected (bootstrap) Statistic	Approx Bias	Bootstrap mean	Standard Error	Approx. Lower 95% Confidence Limit	Approx. Upper 95% Confidence Limit	Bootstrap CI Method
Deming regression - intercept	**Observed**	5.149	NA	NA	5.186	-5.015	15.314	
	Bootstrap I	5.363	-0.214	4.936	5.273	-4.972	15.699	Normal
						-5.489	14.798	Bias Corr.
	Bootstrap II	4.638	0.511	5.661	6.481	-8.065	17.341	Normal
						-8.658	17.339	Bias Corr.
Deming regression - slope	**Observed**	0.906	NA	NA	0.068	0.773	1.039	
	Bootstrap I	0.904	0.002	0.908	0.074	0.760	1.048	Normal
						0.768	1.052	Bias Corr.
	Bootstrap II	0.914	-0.008	0.898	0.088	0.741	1.087	Normal
						0.755	1.114	Bias Corr.
Random coefficients models - intercept	**Observed**	7.940	NA	NA	5.036	-2.476	18.356	
	Bootstrap I	8.137	-0.198	7.742	4.736	-1.145	17.420	Normal
						-0.201	16.902	Bias Corr.
	Bootstrap II	7.322	0.617	8.557	5.826	-4.097	18.742	Normal
						-1.995	19.125	Bias Corr.
Random coefficients models - slope	**Observed**	0.867	NA	NA	0.070	0.724	1.011	
	Bootstrap I	0.866	0.002	0.869	0.066	0.737	0.994	Normal
						0.728	0.975	Bias Corr.
	Bootstrap II	0.875	-0.008	0.860	0.080	0.719	1.031	Normal
						0.718	1.022	Bias Corr.
Concordance Correlation Coefficient (CCC)	**Observed**	0.702	NA	NA	0.069	0.567	0.836	
	Bootstrap I	0.721	-0.019	0.683	0.077	0.569	0.872	Normal
						0.537	0.816	Bias Corr.

Bootstrap I : Single Bootstrapping for dependent data -- bootstrap individuals only and then sample entire block for each selected subject.
Bootstrap II: Double Bootstrapping for dependent data -- bootstrap individuals and then bootstrap observations within individuals using the moving block method with block size 3 and overlap size 2.
Bootstrap CI method: Normal – normal approximation. Bias Corr – bias-corrected percentile method.

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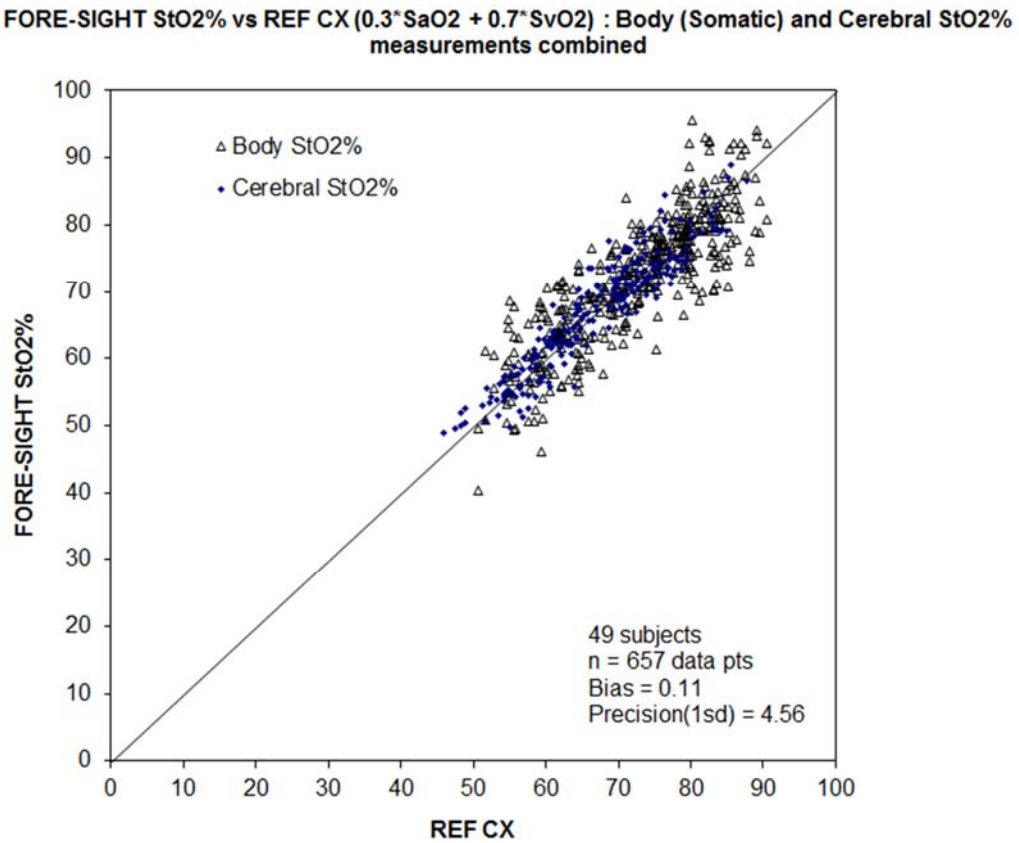
3.3.3 Regression and Bootstrap Validation Result Comments: The ***Deming Regression*** results demonstrate that the 95% confidence intervals (CI) include the desired regression coefficients of slope=1 and intercept=0 with a CCC = 0.861 for ALL DATA (**Table 5**) combined as well as Flank (**Table 6**) and Quad (**Table 7**) StO2 measurements separated. The two bootstrap validations methods Bootstrap I and Bootstrap II results also were very similar to the original *Deming Regression* results, as well to each other. The consistency of the results from the *Deming Regression* and corresponding bootstrap validation methods demonstrate the robustness of the analysis.

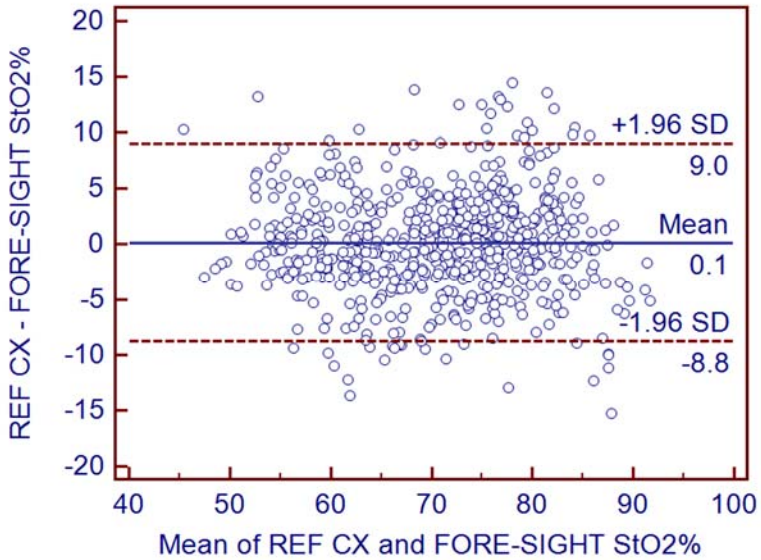
While the ***Deming Regression*** is the preferred regression method to analyze these results due to possible error in the reference measurement REF CX, the ***Random Coefficients Model*** was also used for regression analysis as a secondary analysis. The ***Random Coefficients Model*** results demonstrate that the 95% confidence intervals (CI) very nearly include the desired regression coefficients of slope=1 (>0.99 in most cases) and intercept=0 for ALL DATA (**Table 5**) combined as well as Flank (**Table 6**) and Quad (**Table 7**) StO2 measurements separated. The two bootstrap validations methods Bootstrap I and Bootstrap II results also were very similar to the original *Random Coefficients Model* results, as well to each other. Because the *Random Coefficients Model* does not consider errors in the reference measurement REF CX, which could cause some deviation of the slope and intercept, this analysis is secondary to the *Deming Regression* results.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3.4 Combination of Body /Somatic and Cerebral StO2 data to support proposed IFU

Figures 10 & 11 shows the combined FORE-SIGHT II Elite Somatic StO2 data (this application) with Cerebral StO2 (See K123700) to support our proposed IFU (See **Section 1.5**) displayed as a scatterplot and Bland-Altman plot. There were a total of 657 data points from 49 enrolled subjects (24 somatic and 25 cerebral subjects). Overall bias and precision was 0.11 ± 4.56% (1sd).





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3.5 Conclusion

The results show that FORE-SIGHT II Elite Tissue Oximeter Body/Somatic (This application) and Cerebral (K123700) StO2 measurements demonstrate a very high correlation, Deming Regression fit, and good accuracy compared to the Co-Oximetry Reference (REF CX) when using Large sensors for adult and transitional adolescent subjects ≥ 40 kg.

Table 8: Summary of Results for FORE-SIGHT II Elite Large sensors to support proposed IFU

FORE-SIGHT II Elite Large sensor StO2 measurement validation summary	**Bias ± Precision (1 standard deviation) from Bland-Altman**	**Number of subjects studied**	**Subject Population**	**Reference Document**
Body/Somatic FORE-SIGHT II Elite StO2 vs REF CX	0.24 ± 5.17%	24	Adults & Transitional Adolescents ≥ 40kg	This Application
Cerebral FORE-SIGHT II Elite StO2 vs REF CX	-0.14 ± 3.05%	25	Adults & Transitional Adolescents ≥ 40kg	K123700
Body/Somatic & Cerebral FORE-SIGHT II Elite StO2 vs REF CX	0.11 ± 4.56%	49	Adults & Transitional Adolescents ≥ 40kg	This Application combined with K123700

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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22. Risk Analysis

Risk Analysis Documentation has been updated for the changes in this submission.

- 21-07-0306 FORE-SIGHT Elite Risk Analysis
- 21-07-0307 FORE-SIGHT Elite Risk Management Summary Report

See Attachment H

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Authors: H. Triebel **Date:** 15-Oct-13

APPROVALS:

By signing this document you are giving approval to the comments, actions and outcomes documented here & on any appended pages.

10/25/2013	10/28/13	11/15/13
Marketing Product Mgr M. Aceves — Date	**Operations** G. Brocksieper — Date	**Project Leader VSM Eng** H. Triebel — Date
10/15/13	10/23/13	10/31/13
Clinical - App B. Kopotic — Date	**Quality Assurance Regulatory Affairs** R. Jeffrey — Date	**Sensor Eng** K. Duffy — Date
11/5/13	11/5/2013	See attached email for Approval 11/15/13
Service L. Hottin — Date	**R & D** J. Gamelin — Date	**Chief Medical officer** R. Mecca — Date

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Triebel, Harry

From: Mecca, Roger
Sent: Tuesday, October 15, 2013 12:12 PM
To: Triebel, Harry
Subject: Re: Update Gemini FORE-SIGHT ELITE Risk Management file docs

Ok by me

Roger S. Mecca MD
(b) (6) [redacted]

On Oct 15, 2013, at 5:35 AM, "Triebel, Harry" <Htriebel@CASMED.com> wrote:

> Roger & Bob,
>
> Attached are the latest Gemini/FORE-SIGHT ELITE Risk Management File documents, there were reviewed earlier this year and I thought I started their circulation (you both approved via email in April) but have not been released. Nothing has changes since the last emailing except to update the dates These will be needed for ELITE Project Phase 1.5 Design documentation. Please review and id acceptable print the 1st page, sign, scan and return OR simply respond to this email with your approval, I will start the process of the circulating these 3 docs internally for the remaining approvals. Thanks in advance.
>
> Harry
>
> <21-07-0304 R03.pdf>
> <21-07-0306 R03.pdf>
> <21-07-0307 R03.pdf>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Document Revision History			
Rev	**Date**	**Editor(s)**	**Reason for Change**
00	17-May-12	HT	Original release
01	13-Nov-12	HT	Updated per ITS ISO 14971 Checklist review of FORE-SIGHT project
		JG	Updated to add 4.1.1.8 for defib. hazard to operator and expanded description of ac accessories (sectio
		HT	Updated 4.1.1.1, 4.1.1.2, 4.7.3.1 & 4.1.2.8, Added 4.5.5.11, 4.5.5.12, 4.5.5.13 & 4.11.1.4
		HT	Updated 4.5.5.11 & 4.10.1.1 for fluid ingress
02	03-Dec-12	HT	Remove Age/Weight feature, update RMF documentation
			Remove sections: 4.5.1.2, 4.5.5.3, 4.5.6.4, 4.5.10.1 & 4.6.1.2
03	15-Oct-13	HT	Add 4.5.6.4 Display of valid StO2 values from a non-human tissue site.
			Add 4.3.5.5 User cuts/trims the sensor to allow it to fit on patient w/other sensors causing the integrity of the isolation layer to be compromised exposing the patient to excessive leakage current and/or damage to the system to during defibrillation.
			Change "Poorly assembled…" to "Improperly assembled…" for numerous Risks
			Update IFU in Haz ID Doc, Review/Update Risk Analysis for new IFU
			Haz ID: Change "Electronic copy" of User Manual to "Paper copy"
			Haz ID: Remove "A hard copy version of the FORE-SIGHT ELITE Warnings Guide, 21-03-0332, …"
			Remove reference to FORE-SIGHT ELITE Warning Guide 21-03-0332 & Quick Reference Guide 21-

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1. INTRODUCTION

1.1 Purpose

The document describes the Risk Analysis for the Gemini Project (Product name: FORE-SIGHT® ELITE Absolute Tissue Oximeter). The Gemini Oximeter is a medical device comprised of a Color 10.4" display, user interface controls (touchscreen) and hardware to support the acquisition of a patient's tissue oxygen concentration. The term Gemini refers to the Eng Project Name, where the term FORE-SIGHT ELITE refers to the Product Name & may be interchangeably.

1.1 Scope

This document describes the risk analysis as it applies to the FORE-SIGHT ELITE Absolute Tissue Monitor, Model 3000 Series sensors and accessories.

This analysis defines the Risk Management concepts and their documentation due to the requirement to meet the 3rd Edition of the general safety standard (60601-1:2005) as it becomes mandatory beginning in 2012. This analysis also addresses a product software update to expand the indications for use for additional tissue claims as well as the inclusion of a Video Output function. The analysis forms one part of the Risk Management process as defined in QSP1026, Risk Management Procedure.

The product's Life Cycle Phases for which each element of plan is applicable are identified as:

* Product Realization;
* Design Controls;
* Production and Distribution, and
* Post Market Surveillance.

Risk acceptability criteria are based upon: ANSI/AAMI ESES60601-1: 2005, CAN/CSAC22.2, No. 60601-1: 2008, CENELEC EN, 60601-1: 2006, - IEC 60601-1: 2005, IEC 60601-1-8: 2006, IEC 60601-1-6:2010, ISO 14971: 2007, ISO 14971: 2000 (If CB is required), FDA, Health Canada, Medical Device Directive and IEC60825-1:2007.

1.2 PHASE DESIGN

Project Gemini shall be divided into 3 Phases: Phase 1-Adult, Phase 2-Pediatric & Phase-3 Neonatal. The Risk Analysis shall attempt to capture all the Risks associated with Phase 1 design. The Risk Analysis will be updated with more actuate Phase 2 & 3 Hazard information becomes available.

2. REFERENCE DOCUMENTS

Standards:

IEC 60601-1 2nd edition Medical Electronic Equipment, Part 1: General Requirements for Safety
IEC 60601-1:2005 3rd edition General Requirements for Safety
ISO 14971:2007 Medical devices: Application of risk management to medical devices
IEC 60601-1-8:2010 Medical electrical equipment - Part 1-8: General requirements test and guidance for alarm systems in medical electrical equipment
Council Directive 93/42/EEC Concerning Medical Devices
ANSI/AAMI/IEC 62304:2005 Medical Device Software – Software Life Cycle Processes

CAS Medical Systems, Inc:

QSM1001, Quality System Manual
QSP1026, Risk Management

21-07-0301, Gemini Project Design Plan
21-07-0302, Gemini Product Specification
21-07-0303, Gemini Risk Management Plan
21-07-0306, Gemini Risk Analysis
21-07-0307, Gemini Risk Management Summary Report
21-07-0308, Gemini Usability Specifications & Requirements
21-07-0314, Gemini Large Sensor Specifications
21-07-0321, Gemini Residual Risk(s) Judged Acceptable and the Disclosure Process
21-03-0336, FORE-SIGHT ELITE Large Sensor Multilanguage DFU (Directions for Use)
21-22-3000, FORE-SIGHT ELITE Absolute Tissue Oximeter User Manual (English)

VaP/VaR 120018, Gemini/ FORE-SIGHT ELITE RMF Implementation of Mitigation Validation Plan
VaP/VaR 120019 , Gemini / FORE-SIGHT ELITE Software PEMS Validation
VaP/VaR 120020, Gemini / FORE-SIGHT ELITE Fluid Ingress Verification Plan

Mfg PS 03-58-3000 Process Sheet for 03-58-3000 Series Gemini Oximeter
Mfg PS 03-58-3008 Process Sheet for 03-58-3008 Gemini Preamp
Mfg PS 03-58-0500 Process Sheet for 03-58-0500 Series Gemini Sensors

Change Control Sheet (CCS) 03-58-3000 for Mfg PS 03-58-3000 Series Gemini Oximeter
Change Control Sheet (CCS) 03-58-3008 for Mfg PS 03-58-3008 Gemini Preamp
Change Control Sheet (CCS) 03-58-0500 for Mfg PS 03-58-0500 Series Gemini Sensors

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3. RISK ANALYSIS

3.1 Hazard Identification to Risk Analysis procedure

3.1.1 For each Gemini Hazard identified in CAS 21-07-0304, Gemini Hazard Identification, there shall be a Risk Analysis performed.

3.1.2 For each category of Hazards, the foreseeable sequence of events, hazardous situations and the Harm shall be listed. Each Hazard shall be identified present under Normal and/or Fault conditions. The associated Risk to Patient, User, Bystander, Service or Environment shall also be indicated.

3.1.3 The formal Risk Analysis procedure shall indicate the Initial Risk Evaluation, Risk Control Measures and the Residual Risk based on the Risk Control Measures using the format outlined in QSP1026 Risk Management.

3.2 Risk Evaluation (Initial)

3.2.1 For each Gemini hazard that is identified there shall be a risk estimation, which is based on the likelihood of that hazard and the severity of the consequence of that hazard.

3.2.1.1 Estimation is based on available information and data, but where the likelihood of the occurrence of harm cannot be estimated, a listing of possible consequences shall be prepared.

3.2.1.2 The likelihood of risk for the Gemini hazards shall be estimated quantitatively using the procedure outlined in QSP1026 Risk Management.

3.2.1.3 Estimation of the likelihood of harm from the Gemini may employ these approaches:

a) Use of relevant historical data;
b) Prediction of probabilities using analytical or simulation techniques;
c) Use of expert judgment.

3.2.2 The severity of risk for the Gemini hazards identified will use the qualitative descriptors outlined in QSP1026 Risk Management.

3.2.3 From the risk estimation table defined in QSP1026 Risk Management the Gemini risks shall be evaluated into three broad classes:

a. ■ **Insignificant Risk (IR)** - A negligible risk is an acceptable risk not requiring further risk control or other action;
b. ■ **Investigate Further Risk Reduction (IFRR)** - A tolerable risk if the cost of risk reduction would exceed the improved gain;
c. ■ **Unacceptable Risk (UR)** - An intolerable risk is so severe that a system in which they exist would not be tolerated.

3.3 Risk Control Measures

3.3.1 Risks identified for the Gemini shall be controlled so that the estimated risk for each identified hazard is made acceptable.

3.3.2 A risk is acceptable if the risk is less than or equal to the maximum tolerable risk and the risk is made as low as reasonably practicable. Controls, directed at the cause, can be applied to either or both, likelihood & severity.

3.3.3 One or more of the following Risk Control measures shall be employed (refer to QSP1026 Risk Management):

a. Inherently safety by design
b. Protective measures in the device or Mfg process
c. Information for safety

3.4 Risk Evaluation (Residual)

3.4.1 Identified risks for the Gemini shall be re-evaluated based upon the estimated or actual effectiveness of the Risk Control measures.
3.4.2 Residual risks, their acceptability, and effectiveness of controls used, shall be documented in the Risk Management File
3.4.3 Refer to 21-07-0321, Gemini Residual Risk(s) Judged Acceptable and the Disclosure Process

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4. LIST OF IDENTIFED HAZARDS AND ASSOCIATED RISKS

Category	4.1 Energy Hazards & Contributing Factors				
Hazard	4.1.1 Electricity				
Hazardous Situation	4.1.1.1 Improperly assembled or damaged (from fall or impact with hard object) monitor creates a broken electrical connection in Medical Device causing an electrical potential on the monitor case resulting in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	NSAM modules use 15 VDC, Chassis leakage current < 5 mA, patient leakage current < Table 3 of IEC60601-1, No exposed or access to AC components, Medical grade power supply, Fused power entry module w/fuses accessible w/o line cord, Sensor patient contact area, housing electrical components, use non-conductive plastic material, 2 points of cable retention for AC signals	Designed to meet IEC 60601-1 100% visual inspection & testing of Sensors VaR 120018, 120019	IEC 60601-1 Compliance Review of daily Sensor Visual Inspection reports Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU contains warning regarding proper operation, handling and service of medical device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.1.2 Improperly assembled or damaged (from fall or impact with hard object) monitor creates a broken electrical connection in Medical Device or patient cable allowing human contact resulting in electrical burn or associated injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	NSAM modules use 15 VDC, Chassis leakage current < 5 mA, patient leakage current < Table 3 of IEC60601-1, No exposed or access to AC components, Medical grade power supply, Fused power entry module w/fuses accessible w/o line cord, Sensor patient contact area, housing electrical components, use non-conductive plastic material	Designed to meet IEC 60601-1 100% visual inspection & testing of Sensors VaR 120018, 120019	IEC 60601-1 Compliance Review of daily Sensor Visual Inspection reports Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU contains warnings regarding proper operation, handling and service of medical device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.1.3 Broken battery connections allows shorting of battery terminals in Medical Device allowing for high DC currents resulting in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Battery wire harness connections are fully insulated & double crimped, Battery wires length design that is wire breaks at connection cannot reach other battery terminal	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

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Hazardous Situation	4.1.1.4 Mis-connected battery connections allows shorting of battery terminals allowing for high DC currents resulting in shock or affecting heart rhythm.			Risk to:	Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Battery wire harness are color coded (red-Pos., Black-Neg.), Battery only fits into battery enclosure one way, Battery board only fits into battery enclosure one way, length of battery terminals cannot be reach wrong terminals and battery & and connected battery board only fits inside battery enclosure one way	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates batteries within Battery enclosure are not user replaceable and Battery pack should only be serviced by qualified Service personnel			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.1.5 Unintended movement of cable and wires that could cause connections to loosen or accidental short circuit that results in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All wire harness connections are fully insulated & double crimped, cable connections have locking mechanism to retain connector to header, Wire harnesses are captured with tie wraps to limit movement, shrink wrap tubing is applied to solder terminals	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazardous Situation	4.1.1.6 Unintended movement of cables and wire that could damage the wire's insulation causing short circuit resulting in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All wire harnesses that pass through or are in close proximity to metal edges are protected by a chaffing guard or the wires are bundled together with a tie wraps, wire harnesses have a limited service loop to limit movement, circuits protected by fuses	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

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Hazardous Situation	4.1.1.7 Unintended movement of cable and wires during assembly (e.g. pinched cables) that could damage to the wire's insulation causing short circuit resulting in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Wire harnesses have a limited service loop to limit movement during assembly and re-assembly, all wire harnesses that pass through or are in close proximity to metal edges are protected by a chaffing guard or the wires are bundled together with a tie wrap, circuits protected by fuses	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazardous Situation	4.1.1.8 Applied parts accidentally contacted during the application of defibrillation causing possible serious injury or death.			Risk to:	Patient, User, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Applied parts and cables have minimum 500V double or re-enforced isolation, 1500V basic isolation & 5000V total isolation.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU includes warning not to touch patient during defibrillation, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	**4.1.2 Heat**				
Hazardous Situation	4.1.2.1 Improperly assembled or damaged (from fall or impact with hard object) monitor creates a broken electrical connection causing heat to be generated in Medical Device resulting in thermal injury (burns) at contact site.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All devices that produce heat are not in contact with the housing; dual means to secure wires; Sensors LEDs produce little or no heat; Max LED power is limited to 100 mW (50 µSec), Error message is indicated on display when excessive power is attempted to be delivered to LEDs output & LEDs turned off;	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp.	VaR 120018, 120019 CCS 03-58-3000 CCS 03-58-3008	Approved VP Approved PS	
	Information for Safety	DFU states that user should check Sensor before use & Sensor site periodically.	VaR 120018, 120019	Approved VP	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.2.2 Improperly assembled or damaged (from fall or impact with hard object) monitor creates a broken electrical connection allowing arcing in Medical Device causing fire or explosion in presence of flammable anesthetic gas resulting in injury or death.			Risk to:	Patient, User, Service, Bystander, Environment
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All devices that produce heat are not in contact with the housing; dual means to secure wires, Sensors LEDs produce little or no heat; Power to LEDs output is limited; Current limiting preamp.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines warning for explosion hazard in presence of flammable anesthetics, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.2.3 Sensor LED design, damaged (from fall or impact with hard object) monitor or a Software issue that allows excessive current to drive LEDs causing localized tissue injury (burn).			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensors use LEDs that produces little or no heat; Power to LEDs output is limited (current & duty cycle); Current limiting preamp.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensors; Temp measurement in Sensor will shut off LEDS if max Temp exceeded.	CCS 03-58-0500 VaR 120018, 120019	Approved PS Approved VaR	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.2.4 Thermal failure of wire and other insulation used to provide resistance to heat over the expected service life, leading to short circuiting, excessive heat or fire resulting in serious injury or death.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	PCBs, Connectors and all internal wire is UL approved with 94V0 rating, Widespread use of the product has met the Expected Service Life without any problems related to thermal failure, Medical Device monitors internal temperature and shuts down when max temp reached (less than wire rating)	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU indicates not to use damaged medical device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.2.5 Thermal failure of plastic bezel before end of expected service life of Medical Device creates an exposed electrical connection allowing for personal contact resulting in electrical shock.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Plastic enclosure uses 94V0 plastic from UL approved molder, Medical Device monitors internal temperature and shuts down when max temp reached	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU indicates not to use damaged medical device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.2.6 Applied Sensor raises the temperature under the Sensor to > 41.0℃ resulting in thermal tissue injury (heat) at Sensor site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	LED output creates little or no additional heat at sensor site, Sensor footprint is small	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines max Operating temp as 41℃ minus the max rise in temp under a Sensor	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.2.7 Batteries are subjected to over-charging that produces excessive heat that increases the ambient temperature causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Charge circuit limits amount of current to batteries, Current limiting fuse, SW monitors internal device temp-shuts down if temp exceeds max limit, Charge circuit shuts off charger if fault detected	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.2.8 Internal power source in inadequately protected against excessive current draw due to short circuit that may cause a fire resulting in thermal injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Power Entry Module fuse min rating based on power supply max current requirements, Slow blow fuse used to allow for momentary high current inrush on power up: T3.15AH250V	Fuse rating & specifications VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper rating for replacement fuse and the proper procedures for changing fuses	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.1.3 Unintended motion**				
Hazardous Situation	4.1.3.1 Medical Device is pulled by hanging connected cable(s) causing the Medical Device to move/fall resulting in contact injury, contusions, broken bones, etc.			Risk to:	Patient, User, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Rubber feet on unit; 4 meter Preamp allows routing away from travel areas; low center of gravity in enclosure.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper installation & operating procedures\Statement(s) in DFU includes risk disclosure, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.3.2 Patient with Sensor attached & Medical Device moves in opposing directions causing Sensor to pull off patient resulting in tissue injury at Sensor site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp clip use to retain Sensor/preamp at patient's location; medical grade adhesive w/only moderate retention capabilities; Limited retention force between sensor & Preamp connection.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper installation & operating procedures.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.3.3 Sensor or Preamp cable(s) become entangled around head or extremities resulting in suffocation or circulation injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Shape of Sensors & direction off side of head & away from patient's face & neck.	Visual inspection, Sensor Design	Weekly Sensor Cell defect report, Customer complaint numbers	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes that cables should be secured to prevent them from being entangled, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.3.4 Medical Device on mobile/transport device (e.g. roll stand) has wheels that contacts an object or is system is subjected to rough handling causing the device to tip and fall over resulting contact injury (contusions, broken bones, etc.)			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Design of Roll Stand has wide 5-arm base with large swivel casters; low center of gravity & mechanical method of securing monitor to Roll Stand.	Designed to meet IEC 60601-1, 21.6 Mobile Equipment 24.1 Stability	IEC 60601-1 Compliance	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper installation and operating procedures, Instructions for use of Roll Stand with monitor from Roll Stand vendor describes installation procedure, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.3.5 Failure of fixed mount (e.g., swing arm), or locking pin for mount not being engaged or unapproved mount, with Medical Device attached, causing device to fall resulting in contusions, broken bones, etc. type injuries at contact site.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Design of Wall Mount has x4 safety factor for weight; mechanical method of securing arm to Wall Mount (or pole mount) & mechanical method of securing monitor to Roll Stand.	Designed to meet IEC 60601-1, 21.6 Mobile Equipment 24.1 Stability	IEC 60601-1 Compliance	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper installation and operating procedures, Instructions for use of Wall Mount with monitor from Wall Mount vendor describes installation procedure, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazardous Situation	4.1.3.6 Patient moves/turns or loss of adhesion due to perspiration or inadequate placement causing Sensor to move from original position causing sensor to cover nose or mouth resulting in suffocation or injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Patient connected vital signs monitor should alert user to changes in physiological values; Standard Hospital practice for periodic patient surveillance; Ambient light detection to alert User; Limited retention force between sensor & Preamp connection.	Visual inspection, Sensor Design, Sampling of Hospital Practices using Tissue Oximeters, VaR 120018, 120019	Weekly Sensor Cell defect report Customer complaint numbers Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes the proper application of the Sensor & to check Sensor site every 8 hours, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.1.3.7 Preamp cable accidently pulled while the Sensor is attached to patient causing Sensor to pull off patient resulting in tissue injury at Sensor site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp clip use to retain Sensor/preamp at patient's location; Limited retention force between sensor & Preamp connection; Medical grade adhesive w/moderate retention capabilities; Standard Hospital practice for periodic patient surveillance.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes the proper application of the Sensor & to check Sensor site every 8 hours.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.3.8 Patient moves or is moved to position Sensor underneath the body which can lead to the Sensor being pressed against the patient and resulting in injury to the tissue.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor construction attempts to minimize pressure points on top of sensor	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes the proper application of the Sensor, not to allow patient to lie on sensor and to check Sensor site every 8 hours	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.3.9 Medical Device on mobile/transport device (e.g. roll stand) has wheels that contacts an object or is system is subjected to rough handling causing the device to tip and fall over causing connections to loosen or accidental short circuit that results in shock or affecting heart rhythm.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All wire harness connections are fully insulated & double crimped, cable connections have locking mechanism to retain connector to header, Wire harnesses are captured with spiral wrap to limit movement, shrink wrap tubing is applied to solder terminals	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU indicates not to use damaged medical device, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	**4.1.4 Pressure**				
Hazardous Situation	4.1.4.1 Good Batteries charging at a high rate or defective Batteries charging at a normal rate produce excessive internal pressure causing battery to fail resulting in battery burn type injury at contact site.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Batteries use relief valve devices to exhaust internal pressure, Numerous chassis venting holes & Fan allow for air exchange normal charge circuit limits amount of current to batteries, Current limiting fuse, Charge circuit shuts off charger if fault detected	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.1.4.2 Discharging, charging or overcharging internal batteries vent gas that could ignite causing fire or explosion resulting in serious injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Numerous chassis vent holes along with exhaust fan allow for air exchange, Normal charge circuit limits amount of current to batteries, Current limiting fuse, Charge circuit shuts charger off if fault detected, Battery vent regulate amount of gas released	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries, DFU indicates not to use device in presence of flammable gases	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.1.4.3 Batteries are subjected to over-charging that produce excessive internal pressure causing battery to fail releasing battery fluid resulting in battery burn (acid) type injury at contact site.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification	Fault Conditions
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Charge circuit limits amount of current to batteries, Current limiting fuse for battery charge, Charge circuit shuts charger off if fault detected	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.1.5 Acoustic Pressure**				
Hazardous Situation	4.1.5.1 Normal components or improperly assembled/damaged (from fall or impact with hard object) Medical Device causing excessive loud sounds to be generated resulting in minor hearing injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification	Normal Fault Conditions
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Unit contains mechanical parts (fan) that produces < 31 dB at 1 meter under normal temperature.	Designed to meet IEC 60601-1-2 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor.	CCS 03-58-3000	Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazardous Situation	4.1.5.2 Speaker is allowed to generate excessive loud tones resulting in minor hearing injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification	Normal Conditions
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Unit contains Speaker that produces audible tones (max volume) < 50 dB at 1 meter with user in normal position	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

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Hazard	4.1.6 Vibration				
Hazardous Situation	4.1.6.1 Medical Device damaged in rugged environment allowing loss of mechanical integrity causing shape edges and pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Small component to system mass ration, use of thread lock & mechanical locks to secure threaded fasteners	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazard	4.1.7 Magnetic fields				
Hazardous Situation	4.1.7.1 Electromagnetic components (e.g. ESU device) produce excessive magnetic fields causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Unit speaker & NSAM modules designed for minimal magnetic field emissions Power Supply and associated components UL listed	Designed to meet IEC 60601-1-2 VaR 120018, 120019	IEC 60601-1-2 compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU provides warning statement regarding ESU interference, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Category	4.2 Biological Hazards & Contributing Factors				
Hazard	4.2.1 Bio-contamination				
Hazardous Situation	4.2.1.1 Contaminated individual contacts the Medical Device or Accessories causing contamination to remain on device resulting in a bio-contamination illness.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Device & accessories are designed for easy cleaning & disinfecting; Sensor are designed for single patient use; Standard Hospital practice for decontamination and/or safe disposal of contaminated equipment.	Biocompatibility report is available & correct, VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved bio-report Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU includes procedure for proper cleaning, Sensor packaging labeling indicates single patient use, DFU indicates risk of cross contamination/infection from used sensors, DFU indicates disposal should follow local institute policies, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazard	4.2.2 Bio-incompatibility				
Hazardous Situation	4.2.2.1 Prolonged contact by sensitive individuals with Medical Device or Accessories cause a bio-incompatibility condition resulting in illness.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All patient contacts (e.g., Sensor, etc.) are not made without Latex & are tested for biocompatibility; Standard Hospital practice for periodic patient surveillance.	Biocompatibility report is available & correct, VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved bio-report Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean; new materials; no Latex.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	CAS Manufactured products include written procedure for proper cleaning & disposal; non-latex label on Sensor package.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.2.2.2 Physiological change in patient (e.g., swelling under Sensor) that makes tissue change size rigid Sensor components remain in place causing mechanical pressure resulting in tissue injury at sensor site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Smooth Sensor surface, no sharp edges on Sensor; medical grade adhesive w/only moderate retention capabilities; Sensor design bends to conform to tissue shape; Standard Hospital practice for periodic patient surveillance.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean; new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU states that user should check Sensor site periodically.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.2.3 Toxicity				
Hazardous Situation	4.2.3.1 Good Batteries charging at a high rate or defective Batteries charging at a normal rate may produce excessive internal pressure causing battery to fail resulting in injury by exposure to battery acid.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Batteries use relief valve devices to exhaust internal pressure, Numerous venting holes always allows some air flow, normal charge circuit limits amount of current to batteries, Current limiting fuse, Charge circuit shuts charger off if fault detected	Battery Design documents, Battery inspection & charge Work Procedure VaR 120018, 120019	Approved BOM Approved WP Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates proper procedures for charging & maintaining batteries	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.2.4 Allergenicity				
Hazardous Situation	4.2.4.1 Sensitive individuals repeatedly contact Medical Device or Accessories causing an allergic reaction or allergic illness.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Patient cable/Sensor, headband and all patient contacts designed using historically hypo-allergenic material	Biocompatibility report VaR 120018, 120019	Approved bio-report Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials,	Incoming inspection reports VaR 120018, 120019	Review of Incoming reports Approved VaR	
	Information for Safety	DFU indicates to examine of Sensor application surrounding area, non-latex label on Sensor packaging	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.2.5 Re- and/or cross-infection				
Hazardous Situation	4.2.5.1 Improperly cleaned or disinfected Medical Device or Accessories may allow biologic or caustic contaminants to be transferred between individuals resulting in illness or injury.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Service personnel are provided with a procedure to safely handle returned goods; Sensor is designed for single patient use; Standard hospital practice is for decontamination and/or safe disposal of contaminated equipment.	Service Procedure SVC1000, VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved Service Procedure Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU includes procedure for proper cleaning, DFU Sensor packaging labeling indicates single patient use, DFU indicates risk of cross Contamination/infection from used sensors, DFU indicates disposal should follow local institute policies, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	4.2.6 Inability to maintain hygienic safety				
Hazardous Situation	4.2.6.1 Medical Device or Accessories are incapable of being cleaned or disinfected causing in re- and / or cross-infection / contamination resulting in illness.			Risk to:	Patient, User, Service
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device, Preamp & Sensor are designed with smooth surfaces & minimal areas that cannot be readily cleaned or disinfected; Sensor are designed for single patient use; Standard Hospital practice for decontamination and/or safe disposal of contaminated equipment.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU defines the cleaning procedure for the medical device, and accessories, DFU defines single use for Sensor, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Category	**4.3 Environmental Hazards & Contributing Factors**				
Hazard	**4.3.1 Susceptibility to electromagnetic interference**				
Hazardous Situation	4.3.1.1 Medical Device is inoperable due to susceptibility of electromagnetic fields (EMC) from other devices causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply, Metal chassis; shielded Preamp & Sensor wires, Data filter attempts to eliminate noise signals, Value captured & not updated during noisy periods, sustained noisy conditions will blank numeric & recover when noise is removed.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates not to operate device in the presence of strong electromagnetic fields, DFU provides warning statement regarding EMC, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.3.1.2 Electromagnetic components (ESU device) produce excessive magnetic fields causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply, Metal chassis, shielded Preamp & Sensor wires, Standard Hospital practice for proper patient monitoring procedures, Data filter attempts to eliminate noise signals, Value captured & not updated during noisy periods, sustained noisy conditions will blank numeric & recover when noise is removed.	Designed to meet IEC 60601-1 VaR 120018, 120019 Sampling of Hospital Practices using Tissue Oximeters	IEC 60601-1 Compliance Approved VaR Compile Customer surveys	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used, DFU provides warning statement regarding EMC, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	**4.3.2 Emission of electromagnetic interference**				
Hazardous Situation	4.3.2.1 Improperly assembled or damaged (from fall or impact with hard object) devices allows excessive emission of electromagnetic fields (EMC) causing other device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply; metal chassis; shielded Preamp & Sensor wires.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU provides warning statement regarding EMC, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazard	4.3.3 Inadequate supply of power				
Hazardous Situation	4.3.3.1 Medical Device is inoperable due to low external AC supply causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply; battery backup to operate for a min of 0.5 hrs when fully charged, batteries charged whenever connected to AC.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes power supply troubleshooting guide.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.3.3.2 Medical Device is inoperable due to loss of external AC supply causing loss of device readings resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Battery backup to operate for a minimum of 1 5 hrs when fully charged, batteries charged whenever unit connected to AC	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes power supply troubleshooting guide, DFU indicates to charge batteries when Device is not in use	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.3.4 Storage or operation outside the prescribed environmental conditions				
Hazardous Situation	4.3.4.1 Medical Device is inoperable due to extreme temperature, humidity or atmospheric pressure causing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device design to operate in broadly accepted range of environmental conditions; SW monitors internal temp & adjusts fan speed accordingly; detects inoperable fan; shut device down if max temp exceeded.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines operating & storage temperatures for the medical device & accessories; Shipping label defines storage temperatures for the medical device.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.3.5 Mechanical damage				
Hazardous Situation	4.3.5.1 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor can cause electrical burns or exposure to high electrical currents resulting in injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Enclosure & accessories designed to meet mechanical requirements of standard.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU includes warning not to touch patient during defibrillation, DFU indicates not to use damaged medical device or accessories, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.3.5.2 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor causing shape edges & pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device & accessories are designed to have no sharp edges.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.3.5.3 Sensor flex circuit damaged by repeated bending back upon itself causing circuit to break & expose sharp/pointed edges & circuit contacts resulting in electrical shock and/or cut/laceration type injury.			Risk to:	Patient, User
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor flex circuit capable of being bent/folder back upon itself a min of >10 times before breaking; Sensors use 15 VDC, Chassis leakage current < 300 µA; patient leakage current < 10 µA; flex circuits conformal coated; protective flex cover on top & bottom.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor.	CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hazardous Situation	4.3.5.4 Mechanical damage to device handle due to fall or impact with hard object, causing unit to fall while attempting to be moved.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Cross hatch ribs in handle, tongue and groove seam between top and lower handle assembles, 4 points of attachment (screws) to retain handle, Increased wall thickness of handle assemblies, Handles tested to x4 load rating	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor.	CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.3.5.5 User cuts/trims the sensor to allow it to fit on patient w/other sensors causing the integrity of the isolation layer to be compromised exposing the patient to excessive leakage current and/or damage to the system to during defibrillation.			Risk to:	Patient, User, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor designed with wide foam edge, Isolation tape areas not along edge of sensor	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor.	CCS 03-58-0500	Approved PS	
	Information for Safety	Sensor DFU includes an appropriate "do not cut" symbol (e.g., scissor with a slash through it)	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.3.6 Contamination due to waste products and/or Medical Device disposal**				
Hazardous Situation	4.3.6.1 Contaminated Medical Device or Accessories are improperly disposed causing re- and/or cross-infection / contamination resulting in illness.			Risk to:	Patient, User, Service, Bystander, Environment
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	All patient contacts (e.g., Sensor, etc.) are tested for biocompatibility; Standard Hospital practice for safe disposal of contaminated equipment.	Biocompatibility report is available & correct, VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	Product produced with clean, new materials.	Incoming inspection reports	Review of Incoming reports	
	Information for Safety	DFU defines the safe disposal procedure medical device and accessories, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Category	**4.4 Hazards resulting from the incorrect output of energy and substances**				
Hazard	**4.4.1 Radiation**				
Hazardous Situation	4.4.1.1 Sensor LEDs output becomes out of specification allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Near-infrared light (690nm-880nm) LEDS are specified to be low drift, tight tolerance on LED wavelengths, Max Output Power 100 mW, Pulse time 50 us, Repetition rate < 10 Hz	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensors	CCS 03-58-3000	Approved PS	
	Information for Safety	DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.4.1.2 Sensor LEDs calibration values invalid allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Cal values stored within Sensor memory, Values need to inputted by NSAM, Checksum of Cal values must be correct in order for Sensors to be used and error message generated	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensors	CCS 03-58-3000	Approved PS	
	Information for Safety	DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used, DFU describes the Sensor Fault error message	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Category	**4.5 Hazards related to the use of the Medical Device & contributing factors**				
Hazard	**4.5.1 Inadequate labeling or operating instructions or over-complicated instructions**				
Hazardous Situation	4.5.1.1 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Body location for Sensor prominently indicated on display; Sensor body location saved.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.5.1.2 Improperly designed medical device labeling leads to an incorrect interpretation and lack of understanding resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor on body location prominently indicated on display, a Tissue Perfusion Index (TPI) shall be displayed on the main screen for each channel and values described under a Help menu. Any icons or abbreviations used are consistence with medical industry standards	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used, DFU indicates to read before operating device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.5.2 Inadequate specifications of accessories to be used with Medical Device or incompatibility with other Medical**				
Hazardous Situation	4.5.2.1 Medical Device used with inappropriate accessory allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp & Sensors connections are unique to Gemini; Software detection of connection to an approved accessory or external medical device.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the approved accessories to be used with the medical device; DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used; Medical device shipped with correct accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.5.3 Inadequate specifications of pre-use checks or specifications of service or maintenance**				
Hazardous Situation	4.5.3.1 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor on body location prominently indicated on display; Sensor body location saved.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.5.4 Used by unskilled/untrained personnel				
Hazardous Situation	4.5.4.1 Medical Device used by unskilled/untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Standard Hospital practice for proper patient monitoring procedures; TPI displayed on the main screen for each channel & value.	Sampling of Hospital Practices using Tissue Oximeters VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that only trained personnel should operate the medical device; DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used; Label stating US Federal law restricts this device to sale on or by the order of a physician.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.4.2 Medical Device used on an inappropriate type patient or in an inappropriate manner allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Body location of Sensor prominently indicated on display; Sensor body location saved.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that only trained personnel should operate medical device; DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used; US Federal law restricts this device to sale on or by order of a physician.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.5.5 Reasonable foreseeable misuse				
Hazardous Situation	4.5.5.1 Medical Device used by unskilled/untrained person allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Standard Hospital practice for proper patient monitoring procedures; TPI displayed on the main screen for each channel & value.	Sampling of Hospital Practices using Tissue Oximeters VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that only trained personnel should operate medical device, DFU indicates proper method to enter the Sensor body location, DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used, DFU indicates medical device should not be used in the presence of anesthetic gas, DFU provides warning statement regarding EMC, US Federal law restricts this device to sale on or by the order of a physician, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazardous Situation	4.5.5.2 Medical Device used with an inappropriate Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor connections are unique to Gemini; Sensor on body location prominently indicated on display; Sensor body location saved; LEDs will not turn on if incorrect Sensor attached.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the approved Sensors to be used with medical device; DFU indicates: Proper method to enter the Sensor body location; Appropriate procedure for Sensor attachment to patient; Only trained personnel should operate medical device, If measurements are in doubt alternate means to assess patient's condition should be used; Device label indicates US Federal law restricts this device to sale on or by order of a physician.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.5.3 Sensor remains on Patient & Patient is placed in MRI device that produces excessive magnetic fields causing sensor components to heat up resulting in localize tissue damage (burn).			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Active LED area of Sensor is very small, and limits the tissue area exposure; Standard Hospital practice for proper patient monitoring procedures.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that special precautions may be required if the device is placed close to a strong transmitter such as X-ray equipment, MRI devices, etc , The "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.5.4 ESU device used too close to Sensor allowing current to pass through sensor components causing the components to heat up resulting in localized tissue injury (burn).			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Active LED area of Sensor is very small, and limits the tissue area exposure; Standard Hospital practice for proper patient monitoring procedures; Dielectric isolation strength for sensor design; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	VaR 120018, 120019 , Sampling of Hospital Practices using Tissue Oximeters. CCS 03-58-0500	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates Recommended distance from an applied Sensor for proper use of ESU equipment; Read before operating device.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.5.5.5 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor can cause electrical burns or exposure to high electrical currents resulting in injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Enclosure and Sensor designed to meet mechanical requirements of standard	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use, DFU indicates not to use damaged medical device or accessories, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.5.5.6 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor causing shape edges and pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device or patient cable/Sensor are designed to have no sharp edges	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU defines inspection of medical device and accessories prior to use, DFU indicates not to use damaged medical device or accessories	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.5.7 Sensor, preamp, or monitor used near and attracted to MRI magnet causing damage to equipment, physical injury to nearby personnel or patient due to unintended motion, or injury to patient due to pull on Sensor/cabling.			Risk to:	Patient, User
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	N/A			
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that special precautions may be required if the device is placed close to a strong transmitter such as X-ray equipment, MRI devices, etc , "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazardous Situation	4.5.5.8 Sensor, preamp, or monitor stored in acceptable environment (temp & humidity) and is used before acclimated to acceptable operating environment allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	N/A			
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates to allow device to adjust to the current operating environment, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.5.5.9 Mechanical damage to device handle due to fall or impact with hard object, causing unit to fall while attempting to be moved.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Cross hatch ribs in handle, tongue and groove seam between top and lower handle assembles, 4 points of attachment (screws) to retain handle, Increased wall thickness of handle assemblies, Handles tested to x4 load rating	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor.	CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.5.10 During normal operations, liquids (8 oz. of water) may be spilled on top of the monitor, in one event lasting < 15 sec and wet internal parts that can cause exposure to high electrical currents resulting in injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supplies; No direct opening near AC components; Baffled framework on bottom of chassis allows for fluid egress.	Designed to meet IEC 60601-1 VaR 120020	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU directs user to keep all fluids away from device and to thoroughly dry device (min 1 hr) in event device gets wet, DFU indicates proper cleaning procedure when using cleaning solutions, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazardous Situation	4.5.5.11 During normal operations, liquids (1 liter of water) may be spilled on the preamp housing, in one event lasting < 30 sec and wet internal parts that can cause exposure to high electrical currents			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	NSAM modules use 15 VDC, housing electrical components use non-conductive plastic material, Cable openings use rubber grommets to limit fluid ingress	Designed to meet IEC 60601-1 VaR 120020	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU directs user to thoroughly dry device in event device gets wet (min 1 hr), DFU indicates proper cleaning procedure when using cleaning solutions, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.5.5.12 During normal operations, liquids (12 cc of water, 4cc/hr) may be dripped on the preamp housing, over a 4 hour period and wet internal parts that can cause exposure to high electrical currents resulting in injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	NSAM modules use 15 VDC, housing electrical components use non-conductive plastic material	Designed to meet IEC 60601-1 VaR 120020	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU directs user to thoroughly dry device in event device gets wet (min 1 hr), DFU indicates proper cleaning procedure when using cleaning solutions, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazard	**4.5.6 Incorrect measurement & other metrological aspects**				
Hazardous Situation	4.5.6.1 Sensor positioned improperly over wrong body location allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	A Tissue Perfusion Index (TPI) shall be displayed on the main screen for each channel & value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU & labeling define the procedure for attachment of the Sensor to the patient; DFU indicates that if measurements are in doubt alternate means to assess patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.5.6.2 Medical Device used with an inappropriate size Sensor allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Error message displayed; LEDs will not turn on if incorrect Sensor attached.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the approved Sensors to be used with the medical device; DFU & Labeling define the procedure for attachment of the Sensor to the patient; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.6.3 Software performance issue in Medical Device allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	POST & periodic system checks; Software algorithm output verified against development SW (used to obtain clinical data) output for all Sensor sizes based on body locations.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines interval for service or maintenance; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.6.4 Display of valid StO2 values from a non-human tissue site.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor off warning/alarm messages and/or StO2 invalidation when raw input levels too low, measurement values not in physiological range, or spectral characteristics not representative of tissue.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.5.7 Incompatibility with consumables/accessories/other Medical Devices				
Hazardous Situation	4.5.7.1 Medical Device used in an inappropriate manner with incompatible consumables/accessories allowing device readings to be incorrect resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Software recognition application for detection of connection to an approved medical device	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates approved for use consumables / accessories / other medical device, DFU indicates that if measurements are in doubt, alternate means to assess patient's condition should be used, Medical Device shipped with proper accessories	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.5.8 Sharp edges or points				
Hazardous Situation	4.5.8.1 Medical Device designed with shape edges and/or pinch points (external & internal) resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device exterior designed to have no sharp edges, internal sharp edges are rolled or protected with guard	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU indicates there are no user serviceable parts inside the device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.5.8.2 Medical Device is used in a manner allowing the housing to lose mechanical integrity and becomes broken causing shape edges and pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical device or patient cable/Sensor are designed to have no sharp edges	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance VaR 120018, 120019	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety	DFU defines inspection of medical device and cable/Sensor prior to use	VaR 120018, 120019 CCS 03-58-3000	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.5.9 Lack of indication of output				
Hazardous Situation	4.5.9.1 Continuous LED output to patient Sensor site causes increase of temperature at Sensor site resulting in tissue injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensors LEDs produce little or no heat, Power to LED output is limited	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes proper application of Sensor & to check Sensor site every 8 hours, DFU indicates LEDs on preamp are used as channel ID not that output LEDs are enabled	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.5.10 Inadvertent / accidental change to a control				
Hazardous Situation	4.5.10.1 Alarm Volume altered to lowest setting, allowing user to miss the Alarm tones resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Alarm Volume cannot be turned off, Lowest Alarm volume setting still audible in normal use environment, Alarm message and alarm icons visible on screen, Always visible Alarm LED	Designed to meet IEC 60601-1-8 VaR 120018, 120019	IEC 60601-1-8 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU includes statement that adjustment of alarm volume to a low level during patient monitoring may result in a hazard, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.5.10.2 Display brightness altered to lowest setting, allowing user to not see Alarm message resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Always visible Alarm LED, Alarm annunciation always includes audio tones regardless of display brightness, Brightness cannot be turned off, Lowest brightness setting still allows viewing of screen in normal use environment	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines proper operating instructions for medical device, DFU indicates to read before operating device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Category	**4.6 Inappropriate, Inadequate or over-complicated user interface**				
Hazard	**4.6.1 Mistakes & judgment errors or lapses & cognitive recall errors**				
Hazardous Situation	4.6.1.1 Medical Device presents information that are mistaken/ misinterpreted for actual values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Parameter name & units displayed adjacent to Numeric value; TPI displayed on the main screen for each channel & value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates Only skilled/trained personnel should operate the medical device; If measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.6.1.2 Arrangement of front panel controls allows user to incorrectly configure Medical Device for current type patient leading to incorrect readings and inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	User interface uses touchscreen with icons, Menu interface driven by touchscreen allow for navigation & selection; Current selections on screen are highlighted to indicate location, Feature state indicated by checkbox, numeric value or outline	VaR 120018, 120019 Usability V&V Plan 21-07-0308	Approved VaR Usability Results	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU describes display icons	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.6.2 Violations of abbreviation of instructions, procedures, etc.**				
Hazardous Situation	4.6.2.1 Abbreviations used with the Medical Device allow for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Parameter name & units displayed adjacent to Numeric value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used; Any icons or abbreviations used are consistence with medical industry standards; Translations performed by a company fluent in the target language & is familiar with Medical terminology.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.6.2.2 Abbreviations used with Medical Device DFU allow for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Translations performed by a company fluent in the target language & is familiar with Medical terminology.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used; Any icons or abbreviations used are consistence with medical industry standards.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.6.3 Complex, confusing, ambiguous or unclear device state**				
Hazardous Situation	4.6.3.1 Medical Device displays ambiguous or unclear states that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Invalid information shall be presented as dashes & messages; Limit violation & Equipment alarm messages displayed; TPI displayed on main screen for each channel & value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.6.3.2 Wrong size Sensor used on an inappropriate type/size patient allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor on body location prominently indicated on display, Sensor body location saved; TPI displayed on the main screen for each channel & value.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the pre-use checks prior to patient usage; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.6.4 Ambiguous or unclear presentation of setting, measurement or other information state				
Hazardous Situation	4.6.4.1 Medical Device displays ambiguous or unclear settings that allow misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Invalid information shall be presented as dashes & messages; Limit violation & Equipment alarm messages displayed; TPI displayed on main screen for each channel & values described in DFU; USB saved data output indicate Sensor locations & patient parameters.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.6.5 Insufficient Visibility				
Hazardous Situation	4.6.5.1 Erroneous or lack of visual information (e.g., limited viewing angle of display) on Medical Device that allows for misinterpretation of values causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Unit provides brightness adjustments for improved visibility in varying light conditions; Anti-glare coating on display lens; Wide-viewing angle LCD selected; POST & periodic Power Supply checks; Highly visible numerics & traces due to high contrast of colors.	OEM Display design documentation, VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.6.6 Insufficient Audibility				
Hazardous Situation	4.6.6.1 Lack of audible feedback on Medical Device that allows for missing Alarm conditions causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Audible output may be allowed to be turned down, and not turned off, POST Audio test; Speaker position in front of device; Visual indicators remain even if audio is muted/silenced.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used; DFU indicates to verify operation of tones via Limit testing.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Category	**4.7 Hazards arising from functional failure, maintenance & aging & contributing factors**				
Hazard	**4.7.1 Erroneous data transfer**				
Hazardous Situation	4.7.1.1 Internal data transfer is erroneous allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	POST & periodic RS232 checks; Communications between NSAM & Main ctrl board uses checksum'ed information; Invalid received data not use/displayed; Lack of continuous missing data will cause system alarm; Mfg PS 03-58-3000 Process Sheet for Gemini Monitor.	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.1.2 Calculated FS Data is collected erroneous due to a software performance issue allowing FS Data readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Software calculations for FS Data Collection are based on simple algorithms; FS Data transfer to USB Patient data file or snapshot/print feature.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.1.3 Medical Device readings are transmitted erroneously due to a software performance issue or faulty connection allowing remote readings to be incorrect causing inaccurate diagnoses resulting in wrong course of patient treatment leading to ischemic or hypoxic injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	POST & periodic RS232 checks; Serial output protocol based on documented format;	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor.	CCS 03-58-3000	Approved PS	
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.7.2 lack/delay of, or inadequate specifications for maintenance, including inadequate specification of post maintenance functional checks.				
Hazardous Situation	4.7.2.1 Medical Device readings are displayed erroneously due to lack/delay of specifications of maintenance checks allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	No NSAM user calibration required; Sensor Calibration performed at factory; POST & periodic hardware checks (Power Supply, Memory, USB, VGA & RS232).	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines the interval for pre maintenance functional checks; DFU indicates that if measurements are in doubt; alternate means to assess the patient's condition should be used; DFU indicates only authorized personnel should service medical device.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	4.7.3 Loss of electrical/mechanical integrity				
Hazardous Situation	4.7.3.1 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor can cause electrical burns or exposure to high electrical currents resulting in injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	4 Critical			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply, Fused power entry module w/fuses accessible w/o line cord, Chassis leakage current < 100 µA, patient leakage current < 10 µA, No exposed or access to AC components, rigid metal chassis; Preamp & Sensor contains only low voltage.	Designed to meet IEC 60601-1	IEC 60601-1 Compliance	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3009 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device; Preamp & Sensor prior to use; DFU indicates not to use damaged medical device or accessories, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

Hazardous Situation	4.7.3.2 Improperly assembled or damaged (from fall or impact with hard object) Medical Device housing or Sensor causing shape edges & pinch points to exist resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Designed for standard hospital environments; Medical device, Preamp & Sensor are designed to have no sharp edges.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	1 Negligible		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.7.3.3 Improperly assembled Monitor, Preamp or Sensor can cause electrical components (caps, diodes rectifiers, etc.) to be expelled resulting in cut/laceration type injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supply; Sensor, Preamp & NSAM modules use <15 VDC; No exposed components; Use of non-conductive plastic material covering; Monitor has no exposed components; Use of internal metal cage & outer plastic cover; Sensor uses soft plastic cover capable of containing expelled components.	Designed to meet IEC 60601-1 VaR 120018, 120019 100% visual inspection & testing of Sensors, Burning procedure for monitor & preamps	IEC 60601-1 Compliance Approved VaR Sensor visual reports	
	Protective measures in device or Mfg Process	Mfg PS 03-58-3000 Process Sheet for Gemini Monitor; Mfg PS 03-58-3008 Process Sheet for Gemini Preamp; Mfg PS 03-58-0500 Process Sheet for Gemini Sensors.	CCS 03-58-3000 CCS 03-58-3008 CCS 03-58-0500	Approved PS	
	Information for Safety	DFU defines inspection of medical device & accessories prior to use; DFU indicates not to use damaged medical device or accessories.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.7.4 Re-use and/or improper re-use**				
Hazardous Situation	4.7.4.1 Re-use of disposable, single-use Sensor (e.g., by user reprocessing, or non-removal of release liner on adhesive type Sensors) allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Standard Hospital practice for proper use of single use medical devices; Software recognition software for detection of connection to an approved medical device.	Sampling of Hospital Practices using Tissue Oximeters VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU & labeling defines the use of disposable Sensor; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazard	**4.7.5 Deterioration in function as a result of repeated use**				
Hazardous Situation	4.7.5.1 Medical Device controls become inoperable due to age/use & not allowing user to enter proper patient data or forced to use existing patient case allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Touchscreen has >1 million actuations in same location; POST & periodic power supply checks; User may need to start acquisition before values displayed; TPI displayed on the main screen for each channel & value.	OEM Documentation VaR 120018, 120019	Approved PN & BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines inspection of medical device prior to use.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	1 Negligible		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.7.5.2 Medical Device LCD become partially inoperable due to age/use & not allowing user to fully view patient data & causes inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	MTBF for LCD Backlight > 25,000 hrs to 50% brightness; POST & periodic power supply checks.	OEM Documentation VaR 120018, 120019	Approved PN & BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU defines inspection of medical device prior to use; DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.5.3 Medical Device calibration data incorrect that allows device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensor Flash R/W check; Redundant checksum storage of critical calibration data.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Mfg PS 03-58-0500 Process Sheet for Gemini Sensor	CCS 03-58-0500	Approved PS	
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.5.4 Patient connectors become inoperable due to age/use & mechanical insertion/extraction allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp to Sensor connectors have a minimum 750 mating cycles; Invalid computed information shall either present as dashes or a warning message.	OEM Documentation VaR 120018, 120019	Approved PN & BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety	DFU indicates that if measurements are in doubt alternate means to assess the patient's condition should be used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.7.5.5 Medical Device or Accessories warning/safety labels becomes unreadable due to cleaning over long period of time that allows for improper use of device & causes delay of treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Labels & printing specified to withstand multiple cleanings; Touchscreen & bezel assembly is designed to be limit fluid ingress; Adhesives & materials are UL approved.	OEM Documentation VaR 120018, 120019	Approved PN & BOM	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU contains explanation of markings on device	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.5.6 Patient connectors become inoperable due to age/use and mechanical insertion/extraction allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Preamp-Sensor connectors have a minimum 750 mating cycle rating, Preamp-device connectors have a minimum 5000 mating cycle rating; Invalid computed information shall either presented as dashes with warning message	OEM Documentation VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.7.5.7 Fans become inoperable due to age/use leading to an internal temp above stated environmental limits allowing device readings to be incorrect causing inaccurate diagnoses resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Fan has a rated life time of 45,000 hours; If fan stops and the internal device temp reaches a maximum threshold device will perform auto-shut off	OEM Documentation VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates that if measurements are in doubt, alternate means to assess the patient's condition should be used	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Category	**4.8 DFU provided electronically**				
Hazard	**4.8.1 Instructions for Use regarding safety not available to User**				
Hazardous Situation	4.8.1.1 User does not have access to view provided electronic copy of DFU safety instructions, that allows for improper use of device & causes delay of treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Required labeling: Fuse AC ratings, IPX & RX statement found on rear Label; Ambient light detection; SW confirmation of proper sensor w/ valid body location; Sensor generate small amount of heat.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	Warnings are provided to the user as a paper copy User Manual and Large Sensor DFU	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Category	**4.9 Replacement Parts**				
Hazard	**4.9.1 Lack of, or inadequate specifications for replacement parts**				
Hazardous Situation	4.9.1.1 Medical Device becomes inoperative due to lack of specifications of replacement parts (Lower rated fuse) allowing for delay of treatment of patient. Note: Higher rated fuse may cause delay to become inoperable with second fault (short).			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Fuse & AC ratings presented on rear Label; Warrantee void label across part seem deters user from opening device; Only Fuses are allowed to be replace by User (Biomed), no other serviceable parts.	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates that there are no user serviceable parts.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	Yes
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Category	**4.10 Fluid ingress**				
Hazard	**4.10.1 Electricity**				
Hazardous Situation	4.10.1.1 Medical Device allows fluid ingress that allows shorted AC electrical connection in Medical Device causing an electrical potential on the monitor case resulting in shock or affecting heart rhythm.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Medical Grade Power Supplies; No direct opening near AC components; Baffled framework on bottom of chassis allows for fluid egress.	Designed to meet IEC 60601-1 VaR 120018, 120019	IEC 60601-1 Compliance Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU directs user to keep all fluids away from device and to thoroughly dry device in event device gets wet (min 1 hr), DFU indicates proper cleaning procedure when using cleaning solutions, "Safety Symbol - Follow Instructions for Use" is used.	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	Statement(s) in DFU includes risk disclosure				

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Hazard	4.10.2 Battery				
Hazardous Situation	4.10.2.1 Medical Device not used (battery not charged or discharged) for extended period of time and battery leaks fluids out of Medical Device resulting in possible acid contact injury.			Risk to:	Patient, User, Service, Bystander
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Battery is re-chargeable gel type (no liquids) & can remain idle for extended periods w/o leaking, battery has self-regulating pressure relief valves-permits venting of gases only; Bottom of chassis has vent/weep holes	Battery Mfg Specifications VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	No
Disclosure	N/A				

Hazard	4.10.3 Cleaning				
Hazardous Situation	4.10.3.1 Medical Device cleaned or disinfected with solutions that causes the markings on the device to be unreadable resulting in the delay of treatment of patient.			Risk to:	User
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Fault
	Severity	2 Minor			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Labels made of UL approved material, Touchscreen made with scratch resistant material	Touchscreen & Label Specifications VaR 120018, 120019	Approved BOM Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU describes proper cleaning & disinfecting procedures, DFU indicates not to use sharp objects when touching the screen	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	No
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Category	4.11 Alarms				
Hazard	4.11.1 Annunciation failures				
Hazardous Situation	4.11.1.1 Disconnected, faulty Sensor, preamp or device causes the Medical Device to be inoperable resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal Fault
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Sensing of Sensor & Preamp connect & disconnect, Periodic Sensors & Preamp fault testing, Periodic device hardware fault testing, Fault conditions indicated & annunciated, Always visible Alarm LED	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	Full system test on Medical Device, Mfg PS 03-58-3000 Process Sheet for Gemini Monitor	VaR 120018, 120019 CCS 03-58-3000	Approved VaR Approved PS	
	Information for Safety (DFU)	DFU lists Alarm Conditions with possible causes & mitigation	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazardous Situation	4.11.1.2 Lack of notification by Medical Device of the decrease in a patient's StO2 values resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Low Alarm limits available to alert user of decrease in StO2 value, Visual & audible annunciation of Low StO2 Alarm	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates proper operation of Alarm Limit setting, DFU lists Alarm Conditions with possible causes & mitigation	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.11.1.3 Lack of notification by Medical Device of the increase in a patient's StO2 values resulting in a lack, delay or over treatment of patient.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	High Alarm limits available to alert user of increase in StO2 value, Visual & audible annunciation of High StO2 Alarm	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates proper operation of Alarm Limit setting, DFU lists Alarm Conditions with possible causes & mitigation	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Hazardous Situation	4.11.1.4 Annunciation of flashing visual Alarm conditions on screen may cause spasms and/or convulsions in people prone to seizures (e.g., epilepsy).			Risk to:	Patient, User, Service,
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	Visual Alarm Flashing conforms to IEC 60601-1-8 flash rates of alarm LEDs	VaR 120018, 120019	Approved VRs	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	N/A			
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

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Hazard	4.11.2 Limits				
Hazardous Situation	4.11.2.1 StO2 High/Low Alarm Limit selection cannot be accurately tested against the actual Patient StO2 value allowing a possible undetected change in physiological condition to exist resulting in circulatory injury.			Risk to:	Patient
Initial Risk	Probability	2 Remote		Hazard Identification Conditions	Normal
	Severity	3 Serious			
	Risk Evaluation	IFRR			
Risk Control Measures	**Type**	**Description**	Verification of Implementation	Verification of Effectiveness	
	Inherently Safe by Design	StO2 computed value & StO2 High & Low Alarm Limits have resolution of 1% High Alarm: StO2 value > High StO2 Limit Low Alarm: StO2 value < Low StO2 Limit	VaR 120018, 120019	Approved VaR	
	Protective measures in device or Mfg Process	N/A			
	Information for Safety (DFU)	DFU indicates proper operation of Alarm Limit setting, DFU lists Alarm Conditions with possible causes & mitigation	VaR 120018, 120019	Approved VaR	
Residual Risk	Probability	1 Improbable		Usability Risk	No
	Severity	2 Minor		SW Risk Controls	Yes
	Risk Evaluation	IR		DFU helps mitigate Risk	Yes
Disclosure	None - Statement(s) in DFU have been deemed sufficient				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Authors:	H. Triebel	Date:	15-Oct-13

APPROVALS:

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

10/25/2013	10/28/13	11/05/13
Marketing Product Mgr Date M. Aceves	**Operations** Date G. Brocksieper	**Project Leader VSM Eng** Date H. Triebel
10/15/13	10/23/13	11/5/13
Clinical - App Date B. Kopotic	**Quality Assurance Regulatory Affairs** Date R. Jeffrey	**Sensor Eng** Date K. Duffy
11/5/13	11/5/2013	see attached email for Approval 11/15/13
Service Date L. Hottin	**R&D** Date J. Gamelin	**Chief Medical Officer** Date R. Mecca

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Triebel, Harry

From: Mecca, Roger
Sent: Tuesday, October 15, 2013 12:12 PM
To: Triebel, Harry
Subject: Re: Update Gemini FORE-SIGHT ELITE Risk Management file docs

Ok by me

Roger S. Mecca MD
(b) (6) [redacted]

On Oct 15, 2013, at 5:35 AM, "Triebel, Harry" <Htriebel@CASMED.com> wrote:

> Roger & Bob,
>
> Attached are the latest Gemini/FORE-SIGHT ELITE Risk Management File documents, there were reviewed earlier this year and I thought I started their circulation (you both approved via email in April) but have not been released. Nothing has changes since the last emailing except to update the dates These will be needed for ELITE Project Phase 1.5 Design documentation. Please review and id acceptable print the 1st page, sign, scan and return OR simply respond to this email with your approval, I will start the process of the circulating these 3 docs internally for the remaining approvals. Thanks in advance.
>
> Harry
>
> <21-07-0304 R03.pdf>
> <21-07-0306 R03.pdf>
> <21-07-0307 R03.pdf>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Document Revision History

Rev	Date	Editor(s)	Reason for Change
00	17-May-12	HT	Original release
01	3-Nov-12	HT	Updated per ITS ISO 14971 Checklist review of FORE-SIGHT
		JG	Updated to add 4.1.1.8 Hazard Identification & Risk Analysis docs
		HT	Updated 4.1.1.1, 4.1.1.2, 4.7.3.1 & 4.1.2.8, Added 4.5.5.11, 4.5.5.12, 4.5.5.13 & 4.11.1.4
		HT	Updated 4.5.5.11 & 4.10.1.1 for fluid ingress
02	03-Dec-12	HT	Remove Age/Weight feature, update RMF documentation
			Remove sections: 4.5.1.2, 4.5.5.3, 4.5.6.4, 4.5.10.1 & 4.6.1.2
03	15-Oct-13	HT	Add 4.5.6.4 Display of valid StO2 values from a non-human tissue site.
			Add 4.3.5.5 User cuts/trims the sensor to allow it to fit on patient w/other sensors causing the integrity of the isolation layer to be compromised exposing the patient to excessive leakage current and/or damage to the system to during defibrillation.
			Change "Poorly assembled…" to "Improperly assembled…" for numerous Risks
			Update IFU in Haz ID Doc, Review/Update Risk Management Summary/Report for new IFU
			Remove reference to FORE-SIGHT ELITE Warning Guide 21-03-0332 & Quick Reference Guide 21-03-033
			Haz ID: Change "Electronic copy" of User Manual to "Paper copy"
			Haz ID: Remove "A hard copy version of the FORE-SIGHT ELITE Warnings Guide, 21-03-0332, …"

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1. INTRODUCTION

The document describes the Risk Analysis for the Gemini Project (Product name: FORE-SIGHT® ELITE Absolute Tissue Oximeter). The CAS Gemini Oximeter is a medical device comprised of a Color 10.4" display, user interface controls (touchscreen) and hardware to support the acquisition of a patient's tissue oxygen concentration. The term Gemini refers to the Eng Project Name, where the term FORE-SIGHT ELITE refers to the Product Name and may be used interchangeably.

1.1 SCOPE

This document summarizes the identified hazards and associated Risk as they apply to the Gemini Oximeter, Sensors and accessories.

This analysis defines the Risk Management concepts and their documentation due to the requirement to meet the 3rd Edition of the general safety standard (60601-1:2005) as it becomes mandatory beginning in 2012. The analysis forms one part of the Risk Management process, as defined in QSP1026.

1.2 PHASE DESIGN

Project Gemini shall be divided into 3 Phases: Phase 1-Adult, Phase 2-Pediatric and Phase 3-Neonatal. The Risk Management Summary/Report shall attempt to summarize all the Hazards and Risks associated with Phase 1 design. The Risk Management Summary/Report will be updated with more accurate as Phase 2 & 3 Hazard and Risk information becomes available.

1.3 SUMMARY

The Risk Management program consists of the Gemini Risk Management Plan (21-07-0303), the Gemini Hazard Identification document (21-07-0304), the Gemini Risk Analysis (21-07-0305) and this summary report. The Project Manager served as the project Risk Manager with team members comprised of those designated in the plan.

2. REFERENCE DOCUMENTS

Standards:

IEC 60601-1 2nd edition Medical Electronic Equipment, Part 1: General Requirements for Safety
IEC 60601-1:2005 3rd edition General Requirements for Safety
ISO 14971:2007 Medical devices: Application of risk management to medical devices
IEC 60601-1-8:2010 Medical electrical equipment - Part 1-8: General requirements test and guidance for alarm systems in medical electrical equipment
ANSI/AAMI/IEC 62304:2005 Medical Device Software – Software Life Cycle Processes
Council Directive 93/42/EEC Concerning Medical Devices

CAS Medical Systems, Inc:

QSM1001, Quality System Manual
QSP1026, Risk Management

21-07-0303, Gemini Risk Management Plan
21-07-0307, Gemini Risk Management Summary Report
21-07-0321, Gemini Residual Risk(s) Judges Acceptable and the Disclosure Process
21-03-0336, FORE-SIGHT ELITE Large Sensor Multilanguage DFU (Directions for Use)
21-22-3000, FORE-SIGHT ELITE Absolute Tissue Oximeter User Manual (English)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. REPORT

3.1 Initial Risk Evaluation & Accompanying Documents

The Directions For Use; FORE-SIGHT ELITE 21-22-3000 User Manual & 21-03-0336 Large Sensor Multilanguage DFU, shall be delivered in paper form.

The FORE-SIGHT User Manual was reviewed for consideration of information that needs to be provided as paper copy beyond the labeling on the device. All statements regarding the safe operation of the Oximeter shall be provided in a paper copy of the DFUs

Markings for all fuses and AC input range mitigate Risk 4.8.1.1 and no other marks on the device are deemed necessary.

3.2 Residual Risk Evaluation

Since the highest Residual Risk is estimated to be "Insignificant Risk", no further investigation to reduce any Risk is deemed necessary.

Refer to 21-07-0321 Gemini Residual Risk(s) Judged Acceptable and the Disclosure Process

3.3 Risk Benefit Analysis

For the reasons stated above in 3.2, No Risk Benefit Analysis in required

3.4 Risks Arising from Risk Control Measures

All existing, new or changed risks due to risk control measures, have been evaluated to not introduce any additional risks deemed significant.

Residual risks remaining, and judged acceptable (an insignificant risk) were evaluated for residual risk disclosure in the accompanying documents. All such disclosures have been made.

3.5 Evaluation of Overall Risk Acceptability and Conclusion

A review of the risks from all identified hazardous situations has been considered.

A review of the Summary of Risks outlined, in Section 4.0 of CAS 21-07-0306, Gemini Risk Analysis document indicates the highest Residual Risk Evaluation is found to be IR (Insignificant Risk).

CAS concludes that it has met is obligation to provide a safe device to its customers by reducing identified hazards to present no more than an Insignificant Risk. CAS has also evaluated the overall residual risks by the means identified in QSP1026 Section 5.8, concluding the acceptability of the product.

CAS has appropriate methods in place to obtain relevant production and post-production information applicable to, and by the means stated in the Scope section of this document

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT A

PRODUCT SPECIFICATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT B

INDICATIONS FOR USE – ODE FORMAT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number:

Device Name: FORE-SIGHT Elite™ Absolute Tissue Oximeter.

Indications for Use: The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT Oximeter is indicated for use on adults and transitional adolescents ≥ 40 kg.

Prescription Use ✔ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT C

PROPOSED LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT D

BIOCOMPATIBILITY REPORTS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT E

SOFTWARE EXHIBITS (6)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT F

SAFETY AND EMC REPORTS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT G

CLINICAL REPORT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT H

RISK ANALYSIS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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January 9, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Regarding: K133879 – Administrative Review Errors

To Whom It May Concern:

This letter and the accompanying documents will address the (3) noted deficiencies during the administrative review of our submission brought to our attention on January 7, 2014. Note that per the instruction of the reviewer there is a newly added section to the eCopy document. This response letter and its referenced attachments are in VOL_010.

Reference	Criteria / Deficiency	FDA has requested	CASMED reply
Organizational Elements (question # 3)	All pages of the submission are numbered.	Resubmit with all pages numbered.	Some of the automatic numbering was obscured. As requested, and clarified by the reviewer (1/10/13) there are page numbers on all pages, including the newly added sections.
Section F. Shelf Life (question # 28)	Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	Please provide a summary of methods used to establish that device performance is not adversely affected by aging or include a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	It has been established that device performance is not adversely affected by aging and as such there is no overall effect on safety and effectiveness. A study was conducted verifying that conclusion. Storage conditions are a part of the study. Attached to this reply is the study See VeP & VeR 110023.
Section H. Software (question # 33)	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has	While your submission includes some information from the Software Guidance Document, it does not clearly identify the Software Requirements Specification, Software Design Specification, Revision Level history, and Unresolved Anomalies. Please	Part of our reply is to identify where the requirements are in documents already provided. There are (2) additional documents included here as well. The Software Requirements Specification are found in the following (2) documents: - Vol 005, PDF 002, Doc #21-07-0325 & - Vol 005, PDF 003, Doc # 21-07-0327. The Software Design Specifications are found in the following (2) documents:

CAS Medical Systems, Inc.
44 East Industrial Road, Branford CT 06405, USA
Tel: (203) 488 6056 • Toll Free: (800) 227 4414 • Fax: (203) 488 9438
www.casmed.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	provided an alternative approach with a rationale.	amend your submission to include this information.	- Vol 005, PDF 004, Doc #21-07-0329 & - Vol 006, PDF 005, Doc #21-07-0231. The missing Revision Level History can be found in new document 21-07-0339 rev. 11 "Project Gemini – Software Revision History". The missing Unresolved Anomalies can be found in new document(s) "What's in This Release" 15-06-0284 version 1.1.1. and 15-06-0283 version 2.0.0.

We hope the information provided will satisfy the questions raised and this submission can move to the next phase.

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs.

CAS Medical Systems, Inc.
44 East Industrial Road, Branford CT 06405, USA
Tel: (203) 488 6056 • Toll Free: (800) 227 4414 • Fax: (203) 488 9438
www.casmed.com

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Title: Gemini Sensors: Accelerated Aging Storage Test Verification Plan

Author: P. Tala 31-Mar-2011

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approved by:

Validation Engineer	P. Tala	06.17.13 Date
Project Engineer	M. Dalene	6/17/13 Date
Engineering	K. Duffy	6/18/13 Date
VP R & D	J. Gamelin	6/18/2013 Date
Mktg Product Manager	M. Aceves	6/21/2013 Date
Quality Assurance Regulatory Affairs	R. Jeffrey	6/19/13 Date

FINAL

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Table of Contents

1.0 INTRODUCTION 3
2.0 SCOPE 3
3.0 REFERENCE DOCUMENTS 3
4.0 LIST OF EQUIPMENT 3
5.0 DATA SHEETS 4
6.0 TEST PROCEDURES 5
6.1 INITIAL VISUAL & FUNCTIONAL INSPECTION 5
6.2 ACCELERATED SHELF STORAGE TESTING 5
6.3 POST ADHESIVE TEST 8
6.4 DIELECTRIC STRENGTH TEST 8
6.5 LEAKAGE TEST 9
7.0 SUMMARY 11

Tables

Table 1: Standard Guide for Accelerated Aging (from ASTM F1980-02) 6
Table 2: Kits Visual & Functional Inspection after Accelerated 6 Months Shelf Life Conditioning 7
Table 3: Kits Visual & Functional Inspection after Accelerated 12 Months Shelf Life Conditioning 7
Table 4: Kits Visual & Functional Inspection after Accelerated 18 Months Shelf Life Conditioning 7
Table 5: Kits Visual & Functional Inspection after Accelerated 24 Months Shelf Life Conditioning 7
Table 6: Alcohol Prep Pad & Adhesiveness Test 8
Table 7: Sensors Dielectric Test Results 9
Table 8: Patient Leakage current 10

OIETA

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1.0 Introduction

The purpose of this document is to detail the validation of the design requirements for the FORE-SIGHT Elite Large Sensors Construction (CAS PN: 03-05-0511) as well as the FORE-SIGHT Elite Large Sensors Packaging Kit (CAS PN: 01-07-1103 & 01-07-2103). This Verification Plan is designed to verify that construction, assembly process and Packaging meets the safety, performance and efficacy requirements of the Storage and Transport Environmental Specifications outline in "Project Gemini Product Specifications – 21-07-0302" and in 21-07-0314 "Gemini Large Sensor Specifications".

Following major test requirement will be validated:

- Components Verification: Test and verify all components in the sensors are functional and behave within the specified range after being subjected to an Accelerated Aging Test.

2.0 Scope

This Verification procedure applies only to the FORE-SIGHT Elite Large Sensors and packaging as it pertains to the safety, performance and efficacy requirements of the Storage and Environmental Specification
The Large Sensors (03-05-0511, Initial release, 20 samples), contained within Sensor Kits (01-07-1103 & 01-07-2103) will be used in this Verification.

3.0 Reference Documents

- CAS 21-07-0302 - Gemini Product Specification
- CAS 21-07-0314 – Gemini Large Sensor Specifications
- CAS QSP 1026 – Risk Management
- CAS QSP4001 – Product Design Procedure
- CAS QSP4007 – Design Verification and Validation
- CAS WP3460 – FORE-SIGHT Elite Sensor Test Procedure
- ASTM F1980-02 Standard Guide for Accelerated Aging
- IEC 60601-1:2005 3rd edition – General Requirements for Safety

4.0 List of Equipment

- Gemini Tissue Oximeter: SN ENG 06
  - NSAM Boot loader software 15-06-0282 Ver. 0.1.4b
  - NSAM Application software 15-06-0283 Ver. 0.7.6e
  - Main Boot loader software 15-06-0284 Ver. 0.6.0A
  - Main Application software 15-06-0285 Ver. 0.6.0D

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- CAS 15-06-0335 – FORE-SIGHT ELITE Sensors: Calibration & Final Test Software Rev 1.0
- IBM PC running Windows Excel
- CAS 93-04-0191 – FS-Elite Sensor Test fixture
- CAS 03-05-0511 – FS-Elite Large Sensor
- Hospital Grade AC Power Cord
- FORE-SIGHT Elite Large Sensors: Single Kits (01-07-1103)
- FORE-SIGHT Elite Shipping Boxes for Single Kits (01-07-2103)
- FORE-SIGHT Elite Preamp Assembly (01-06-3100) SN: 0065
- Environmental Chamber WATLOW SN F1-533 Cal Date 12-6-14

The UUT for this Validation Plan are FORE-SIGHT Elite Large Sensors

ID: 982	ID: 988	ID: 996	ID: 980
ID: 983	ID: 989	ID: 1001	ID: 981
ID: 984	ID: 990	ID: 1002	ID: 997
ID: 985	ID: 991	ID: 1004	ID: 995
ID: 987	ID: 993	ID: 1005	ID: 978

5.0 Data Sheets

5.1 Pass/Fail Criteria

This Verification Plan will be complete when all Test Procedure Data sheets referenced on the following pages have passed and all tests completed. The following rules shall be followed for the Data Sheets:

- Checking and signing the Data Sheets results will be done in black ink only.
- The word **PASS** in the associated _____ will be used to identify when a Data Sheet step was successfully been verified. The word **FAIL** in the associated _____ will be used to identify when a Data Sheet step was unsuccessfully been verified. All Data Sheet steps must be filled in.
- Data Sheet step failures and discrepancies are to be marked red. Failures will be initialed and dated. Discrepancies will be lined out and the correction inserted next to the error with the person's initials and date.
- All performance reports and Verification Plan discrepancies will be reviewed and their resolution approved prior to releasing product or accessory.

OFDM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.0 Test Procedures

6.1 Initial Visual & Functional Inspection

a) Prior to Environmental conditioning, verify proper operation of the Fore-Sight Large Sensors to be tested.
b) Using the Fore-Sight Large Sensors Final Test Procedure (WP3460).
c) Verify all Sensors pass the visual and functionality tests. PASS (Do not use any sensor that failed any of the tests)
d) Place the FORE-SIGHT Elite Large Sensors together with the Alcohol Prep Pad (02-04-0132) in Large Sensor Pouches (01-07-1103).
e) Verify all Pouches are properly sealed. PASS (do not use any kits that are not sealed completely). PASS
f) Place the Sensor Kits, together with the other accessories inside their regular Shipping boxes (01-07-2103).
g) Close and seal the boxes.

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

6.2 Accelerated Shelf Storage Testing

Per ASTM F1980-02 Accelerated aging tests will be performed to document shelf Life and expiration Time for products. Temperature selection should be chosen to avoid failure conditions such as deformation due to melting. As the Sensor Kit contain various kind of materials, only the most common (recommended by the ASTM 1980-02 or ISO 11607) Aging Factor of 2.0 will be used.

Following the Chart in **Table 1**, the accelerated testing will be performed at 50°C. The temperature will remain at this level for **13** Weeks to simulate the minimal specification of 2.0 years shelf Storage The Relative Humidity will be set to 50%.

a) Place one Shipping Box containing 20 pouches into an environmental chamber at room temperature & humidity.
b) Slowly (20°C/ hour) change the temperature and humidity in the chamber to:
   Temperature: 50°C (+/– 2°C)
   Relative Humidity: 50%, non–condensing
c) Once the temperature and humidity are reached, leave the Sensor Kits in the chamber for 92 Days. (Samples may be pulled out of the chamber if chamber is needed. Records days or hours out and extend the test duration)
d) Pull out 5 pouches from the Box at the predetermined intervals (23 days simulating 6 Months).
e) Let the pouches stand for at least two hours at room Temperature before any further testing begins.

Test Performed By (signature): EM Date of Test: 6-19-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Aging Temp	Ambient Temp	Formula			Days to Age 1 Year at Ambient	Weeks to Age 1 Year at Ambient
		Days in the Year		Aging Factor		
40	23	365	%	$2^{1.7}$	112.3	16
45	23	365	%	$2^{2.2}$	79.5	11.4
50	20	365	%	$2^{3.0}$	45.6	6.5
	23		%	$2^{2.7}$	56.1	8.0
	25		%	$2^{2.5}$	64.5	9.2
55	20	365	%	$2^{3.5}$	32.3	4.6
	23		%	$2^{3.2}$	39.7	5.7
	25		%	$2^{3.0}$	45.6	6.5
60	20	365	%	$2^{4.0}$	22.8	3.3
	23		%	$2^{3.7}$	28.0	4.0
	25		%	$2^{3.5}$	32.3	4.6
65	20	365	%	$2^{4.5}$	16.1	2.3
	23		%	$2^{4.2}$	19.8	2.8
	25		%	$2^{4.0}$	22.8	3.3

Table 1: Standard Guide for Accelerated Aging (from ASTM F1980-02)

f) Verify all pouches are in a good visual condition. PASS
g) Verify the Indication for Use on each pouch are still perfectly legible. PASS
h) Verify every Large Sensor pouch could be opened without excessive force. PASS
i) Verify the Sensors do not present any sign of damages. PASS (Take pictures in case of damages)
j) Verify the release liners on the sensors do not present any folds or other damages PASS
k) Verify the Logo printed on top of the Poron Foam is intact PASS
l) Verify there is no ink transfer to package or parts. PASS
m) Using the Large Sensors Final Test Procedure (WP3460). Verify the Sensors pass all Visual and Functional Tests then fill in **Table 2** to **Table 5**.
n) Verify proper operation of the Fore-Sight Large Sensors once connected to a FORE-SIGHT Elite Monitor PASS (Using an optical simulator & without removing the Release Liner)
o) Verify after the 24 Months simulation all labels around the Shipping box are still legible and intact. PASS
p) Verify the Multilingual IFU (21-03-0336) sheets is in good condition and legible. PASS

Test Performed By (signature): [signature] Date of Test: 6-18-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ID #	Pouches		Sensors		Comments
	Visual	IFU	Visual	Functional	
982	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
989	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
983	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
982	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
988	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	

Table 2: Kits Visual & Functional Inspection after Accelerated 6 Months Shelf Life Conditioning

ID #	Pouches		Sensors		Comments
	Visual	IFU	Visual	Functional	
984	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
985	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
990	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
991	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
993	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	

Table 3: Kits Visual & Functional Inspection after Accelerated 12 Months Shelf Life Conditioning

ID #	Pouches		Sensors		Comments
	Visual	IFU	Visual	Functional	
980	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
978	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
997	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
995	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
981	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	RAN FUNCTIONAL 2X

Table 4: Kits Visual & Functional Inspection after Accelerated 18 Months Shelf Life Conditioning

ID #	Pouches		Sensors		Comments
	Visual	IFU	Visual	Functional	
996	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	SLIGHT LEFTING
1001	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
1005	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
1004	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	
1002	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐	

Table 5: Kits Visual & Functional Inspection after Accelerated 24 Months Shelf Life Conditioning

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

Test Performed By (signature): [signature] Date of Test: 6-18-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.3 Post Adhesive Test

a) Using a set of three sensors that were freshly foamed for comparison purposes
b) Clean a test volunteer skin using the alcohol prep pad included in the individual sensors packaging before applying the test sensor on the skin.
c) Clean a similar part of the body (e.g. Left/Right forehead) with a fresh alcohol prep pad that has not been stressed before applying one of the fresh sensor.
d) Verify both prep pad could similarly clean the skin. PASS
e) Verify both sensors could easily be applied to the skin. PASS (Allow sensor to remain in position for 30minutes)
f) Lift off both sensors using the same procedure.
g) Verify both sensors could easily/similarly be removed from the subject's skin. PASS

Sensor ID	Alcohol Prep Pad	Sensor Affixing	Sensor Removal
6Months Shelf Life Conditioning			
987	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
989	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
983	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
12 Months Shelf Life Conditioning			
984	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
990	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
993	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
18 Months Shelf Life Conditioning			
980	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
978	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
997	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
24 Months Shelf Life Conditioning			
996	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
1001	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐
1005	P ☑ F ☐	P ☑ F ☐	P ☑ F ☐

Table 6: Alcohol Prep Pad & Adhesiveness Test

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS or FAIL

6.4 Dielectric Strength Test

a) Following the conditioning, perform the dielectric strength test on two Sensors
b) Test Station Settings:
   Frequency = 60 Hz
   Max Voltage = 3,750 VDC
   Ramp = 60 sec
   Dwell = 60 sec
c) Wrap the Patient contact area of the sensor in Aluminum foil.

Test Performed By (signature): [signature] Date of Test: 6-18-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications?

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d) Connect the Aluminum foil to the negative on the Test Station
e) Short the Leads of the USB connector to pull all leads on the same plane. The board mount female plug will be used to short the leads and the sensor male USB lead will be connected to the female plug.
f) Connect the USB lead to the positive side of the Test Station.
g) Press Start.

CAUTION: DO NOT TOUCH THE SENSOR OR ANY CONNECTED ELEMENT WHILE HIGH VOLTAGE IS APPLIED

h) Verify there are no Flashover or breakdown during the Ramp part of the Test PASS
i) Verify there are no Flashover or breakdown during the Dwelling part of the Test PASS
j) Record the failing voltages (if applicable) as well as the measure currents (Dwelling phase) in **Table 7** below.

Sensor ID #	Test Result	Sensor ID #	Test Result
6 Months Shelf Life Conditioning		**12 Months Shelf Life Conditioning**	
#4 982	Voltage: 3.75KDC Current: ~20 P ☑ F ☐	991	Voltage: Current: P ☑ F ☐
#5 988	Voltage: 3.75KDC Current: 6-18-13 P ☑ F ☒	985	Voltage: Current: P ☑ F ☐
18 Months Shelf Life Conditioning		**24 Months Shelf Life Conditioning**	
995	Voltage: Current: P ☑ F ☐	1004	Voltage: Current: P ☑ F ☐
981	Voltage: Current: P ☑ F ☐	1002	Voltage: Current: P ☑ F ☐

Table 7: Sensors Dielectric Test Results

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

6.5 Leakage Test

a) Following the conditioning & the dielectric strength test, perform the leakage test on all Sensors that have passed the dielectric strength test
b) Using an Electrical Safety Analyzer. With a FORE-SIGHT Elite Monitor on a non-conductive surface, measure the leakage current with reference to the StO_2 Sensors (See **Sec 4.4** Patient Leakage of **WP3466 FORE-SIGHT ELITE Product** Safety Test Procedure).
c) Record the Leakage Currents into **Table 8**
d) Verify the leakage current is less than 200 μA:

Test Performed By (signature): Em Date of Test: 6-18-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications?

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Sensor ID	Patient Leakage Current	Pass/ Fail	Sensor ID	Patient Leakage Current	Pass/ Fail
6 Months Shelf Life Conditioning			**12 Months Shelf Life Conditioning**		
982	0 µA	P ☑ F ☐	991	0 µA	P ☑ F ☐
988	0 µA	P ☑ F ☐	985	0 µA	P ☑ F ☐
18 Months Shelf Life Conditioning			**24 Months Shelf Life Conditioning**		
995	0 µA	P ☑ F ☐	1004	0 µA	P ☑ F ☐
981	0 µA	P ☑ F ☐	1002	0 µA	P ☑ F ☐

Table 8: Patient Leakage current

PASS/FAIL CRITERIA:
PASS: All verify statements are filled with Pass.
FAIL: Any of the verify statements filled with Fail.
TEST RESULTS (circle one): PASS -or- FAIL

OIETA

Test Performed By (signature): Em Date of Test: 6-18-13
Comments-Test Plan Deviations-Monitor H/W or S/W Modifications?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.0 Summary

All Tests were applicable & performed

No Incident, Defect or Variance noted

Performed by: [illegible] Date: 09.05.13

Attached

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Test Performed By (signature): [illegible] Date of Test: 09.05.13

Comments-Test Plan Deviations-Monitor H/W or S/W Modifications?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Author: P. Tala 05-Sep-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals:

Validation Engineer	P. Tala	09-05-13 Date
Project Engineer	M. Dalene	9/6/13 Date
Engineering	K. Duffy	9/5/13 Date
VP R & D	J. Gamelin	9/6/2013 Date
Mktg Product Manager	M. Aceves	9/12/2013 Date
Quality Assurance Regulatory Affairs	R. Jeffrey	9/9/13 Date

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Table of Contents

1. INTRODUCTION 3
1.1 PURPOSE 3
1.2 SCOPE 3
1.3 REFERENCE DOCUMENTS 3
1.4 ACRONYM 3
2. SUMMARY OF TESTING PERFORMED 3
3. DEFECTS, VARIANCES AND INCIDENTS 3
4. COMPREHENSIVE ASSESSMENT 4
5. EVALUATION 4
APPENDIX A 4

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1. INTRODUCTION

1.1 PURPOSE

This Verification Report summarizes the testing performed on the Gemini Sensors: Accelerated Aging Storage Test per VeP 110023. For information on the Gemini Sensors: Accelerated Aging Storage Test, refer to the attached Verification plan (APPENDIX A).

1.2 SCOPE

This document refers only to the verification that was performed during the execution of the Gemini Sensors: Accelerated Aging Storage Test Plan. Refer to VeP 110023 (APPENDIX A) for details on the scope of this testing.

1.3 REFERENCE DOCUMENTS

- VeP 110023 – Gemini Sensors: Accelerated Aging Storage Test Plan

1.4 ACRONYM

- VeP Verification Plan
- VeR Verification Report

2. SUMMARY OF TESTING PERFORMED

The following tests were conducted per VeP 110023.

Test	Description	Pass / Fail	Comments
6.1	Initial Visual & functional Inspection	PASS	
6.2	Accelerated Shelf Storage Testing	PASS	
6.3	Post Adhesive Test	PASS	
6.4	Dielectric Strength Test	PASS	
6.5	Leakage Test	PASS	

All data sheets corresponding to each test have been completed and are included in APPENDIX A of this report.

3. DEFECTS, VARIANCES AND INCIDENTS

No defects, variances or incidents were noted in any of tests.

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4. COMPREHENSIVE ASSESSMENT

The testing performed fully exercised the Storage capabilities of the FORE-SIGHT Elite Large Sensors in the Packaging Kits (CAS PN: 01-07-1103 & 01-07-2103) configuration under accelerated aging conditioning.

No additional hazards or concerns were identified in the testing.

No additional hazards or concerns were identified in the testing.

5. EVALUATION

All tests were applicable and performed.

All Tests passed:

The FORE-SIGHT Elite Large Sensors (CAS PN: 03-05-0511) within the Packaging Kits (CAS PN: 01-07-1103 & 01-07-2103), have proven to be resistant against typical accelerated Shelf Storage hazards over **2** years and therefore determined to meet the safety, performance and efficacy requirements of the Storage Environmental Specifications

APPENDIX A

VeP 110023

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CASMED®	Document Number 21-07-0339	Rev 11

Title: Project Gemini - Software Revision History

Author: H. Triebel 16-Dec-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals:

Project Leader — Harry Triebel — 12/16/13 Date

REVISION HISTORY

Rev	Date	Editor(s)	Reason for Change
00	14-Nov-12	HMT	Initial Release
01	08-Feb-13	HMT	Main App & Bootloader Release: 0.3.5E NSAM App Release: 7.3d
02	14-Feb-13	HMT	Main App & Bootloader Release: 0.3.6
03	25-Mar-13	HMT	Gemini Package Release: 0.1.A, Package 0.1.0B • Main App & Bootloader Release: 0.3.6A, 3.6B, 3.6C • NSAM App Release: 7.3.e, 7.3f, 7.3.g
04	17-May-13	HMT	Gemini Package Release: 0.1.0C, 0.2.0A, 0.3.0A, 0.3.0B, 0.3.0C, 0.3.0D • NSAM App Release: 0.7.3.e, 0.7.3f, 0.7.3.g, 0.7.4.b, 0.7.4d, 0.7.4h • Main Bootloader Release: 0.3.6A, 3.6B, 3.6C, 0.5.0C, 0.5.0D • Main Mfg Bootloader Release: 0.3.0B, 0.3.0C, 0.3.0D • Main App Release: 0.3.6A, 3.6B, 3.6C, 0.5.0C, 0.5.0D
05	01-Jul-13	HMT	Gemini Package Release: 0.3.0E, 0.3.0F, 0.3.0G, 0.3.1G, 0.3.2G • NSAM App Release: 0.7.5b, 0.7.5.c, 0.7.5.d, 0.7.6a • Main Bootloader Release: 0.5.0E, 0.5.0F, 0.5.0G, 0.5.1G, 0.5.2G • Main Mfg Bootloader Release: 0.3.0E, 0.3.0F, 0.3.0G, 0.3.1G, 0.3.2G • Main App Release: 0.5.0E, 0.5.0F, 0.5.0G , 0.5.1G, 0.5.2G
06	08-Aug-13	HMT	Gemini Package Release: 0.4.0A, 0.4.0B, 0.4.0C, 0.4.0D • NSAM App Release: 0.7.6e, 0.7.6i, 0.7.6j • Main Bootloader Release: 0.6.0A • Main Mfg Bootloader Release: 0.4.0A, 0.4.0B • Main App Release: 0.6.0A, 0.6.0B, 0.6.0C, 0.6.0D
07	19-Aug-13	HMT	Gemini Package Release: 1.0.0 • NSAM Bootloader Release: 1.0.0 • NSAM App Release: 1.0.0 • Main Bootloader Release: 1.0.0 • Main Mfg Bootloader Release: 1.0.0 • Main App Release: 1.0.0

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Rev	Date	Editor(s)	Reason for Change
08	26-Aug-13	HMT	Gemini Package Release: 1.0.1 • Main Bootloader Release: 1.0.1 • Main Mfg Bootloader Release: 1.0.1 • Main App Release: 1.0.1 • NSAM App Release: 1.0.2
09	30-Aug-13	HMT	Gemini Package Release: 1.0.2 • Main App Release: 1.0.2
10	09-Dec-13	HMT	US & OUS Software will be incorporated into US SW. A SW switch will allow OUS Features to be enabled in Mfg & Srv (password protected). Gemini Package Release: 1.1.0 • Main Bootloader Release: 1.1.0 • Main Mfg Bootloader Release: 1.1.0 • Main App Release: 1.1.0 • NSAM App Release: 2.0.0
11	16-Dec-13	HMT	Fix minor issues with V1.1.0c build (not released to production only V&V) Gemini Package Release: 1.1.1 • Main App Release: 1.1.1 • NSAM App Release: 2.0.0

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TABLE OF CONTENT

1. INTRODUCTION 3
2. REFERENCES 4
3. SPECIFICATIONS 5
   3.1 NSAM Bootloader Releases (Newest to Oldest): 5
   3.2 NSAM Application Releases (Newest to Oldest): 6
   3.3 NSAM Mfg Test Application Releases (Newest to Oldest): 11
   3.4 Main Bootloader Releases (Newest to Oldest): 12
   3.5 Main Mfg Bootloader Releases (Newest to Oldest): 21
   3.6 Main Application Releases (Newest to Oldest): 25
   3.7 Spectrum SCM Change Request (CR) for Gemini Builds (Newest to Oldest): 40

1. INTRODUCTION

This document lists the Revision History associated with the Gemini Project Software. The Gemini Software is divided into the following PN:

Gemini Software Description	CAS PN	Current Ver
NSAM Bootloader	15-06-0282	1.0.0
NSAM Application	15-06-0283	2.0.0
NSAM Mfg Test Application	15-06-0338	1.0.0
Main Bootloader	15-06-0284	1.1.0
Main Mfg Bootloader	15-06-0333	1.1.0
Main Application	15-06-0285	1.1.1
Gemini Software Description	**CAS PN**	**Current Ver**
Software Update Package	15-06-0339	1.1.1

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2. REFERENCES

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005
- CAS QSM1001 - Quality System Manual
- CAS QSP1026 - Risk Management
- CAS QSP4001 - Product Design Procedure
- CAS QSP4002 - Software Life Cycle Procedure
- CAS QSP4004 - System Performance Report (SPR), Product Request (PR) Procedure
- CAS GEMINI Product Profile
- CAS GEMINI Marketing Requirements
- 21-07-0324 Gemini Main Bootloader Software Requirements
- 21-07-0325 Gemini Main Application Software Requirements
- 21-07-0326 Gemini NSAM Bootloader Software Requirements
- 21-07-0327 Gemini NSAM Application Software Requirements
- 21-07-0328 Gemini Main Bootloader Software Architecture & Specification
- 21-07-0329 Gemini Main Application Software Architecture & Specification
- 21-07-0330 Gemini NSAM Bootloader Software Architecture & Specification
- 21-07-0331 Gemini NSAM Application Software Architecture & Specification
- 21-07-0333 Gemini Main Bootloader Software Life Cycle Worksheet
- 21-07-0334 Gemini Main Application Software Life Cycle Worksheet
- 21-07-0335 Gemini NSAM Bootloader Software Life Cycle Worksheet
- 21-07-0336 Gemini NSAM Application Software Life Cycle Worksheet
- 21-07-0337 Gemini Software Level of Concern Document
- 21-07-0338 Gemini Software V&V History

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3. SPECIFICATIONS

3.1 NSAM Bootloader Releases (Newest to Oldest):

Associated Release(s): Gemini NSAM Bootloader	Ver: 1.0.0
Release Notes: SCM NSAM 1.0.0 Build & Package 1.0.0 • All versions set to V1.0.0, Corrected spelling errors. (986)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM Bootloader	Ver: 1.4b
Release Notes: SCM NSAM 0.7.5d Build & Package 0.3.0F • NSAM - Main & boot NSAM Flash update failure (691)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM Bootloader	Ver: 1.4a
Release Notes: NSAM 0.3.5 Build • Initial Release	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

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3.2 NSAM Application Releases (Newest to Oldest):

Associated Release(s): Gemini NSAM App **Ver: 2.0.0**

Release Notes: SCM NSAM 2.0.0 Build & Package 1.1.0

- Add for MFG ability to get the 1 wire device S/N (1033)
- (b)(4) [redacted]
- Account for the 1 wire temperature NSAM offsets & Code Cleanup (1043)
- Enable the Enhanced AGC, allow higher dynamic range for the gains (1044)
- Adjust high Ambient Light Threshold (1048)
- Enhance the Bovie Filter (1049)

(b)(4) [redacted]

- Add Adult Somatic IFU, adjust Adult Cerebral TPI Levels (1079)
- (b)(4) [redacted], Adjust Low Thb levels, High Ambient Light (1093)
- Ignore Low brain 690nm values & do not include in spectral window calculation of "Sensor Off" (1140)

SPR	Description (Refer to QSP1026 for Risk Assessment)

Associated Release(s): Gemini NSAM App **Ver: 1.0.2**

Release Notes: SCM NSAM 1.0.2 Build & Package 1.0.1

- Spikes above "High Ambient Light" will reset "Ambient Light" de-bouncing/warning (993)
- NSAM - LPF Ambient light (1006)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 1.0.0**

Release Notes: SCM NSAM 1.0.0 Build & Package 1.0.0

- All versions set to V1.0.0, Corrected spelling errors. (986)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.6j**

Release Notes: SCM NSAM 0.7.6j Build & Package 0.6.0D

- (b)(4) [redacted]

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.6i**

Release Notes: SCM NSAM 0.7.6i Build & Package 0.6.0C

- Enhance AGC (881)
- Sensor off enhancement (962)
- Disable AGC Enhancements, Default MFG build setting (970)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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Associated Release(s): Gemini NSAM App	Ver: 0.7.6e
Release Notes: SCM NSAM 0.7.6e Build & Package 0.6.0A • Add Authentication code to sensor 1 Wire (882) • Low THB Warning on super outlier (897)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.6a
Release Notes: SCM NSAM 0.7.6a Build & Package 0.3.2G • Support Preamp Offsets. (476)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.5f
Release Notes: SCM NSAM 0.7.5f Build & Package 0.3.0G • Hitting SAM reset switch during SAM boot update leaves SAM inoperable (791) • Detect presence of SAM Mfg build on SAM (793) • NSAM - Invalidate Sto2 for "Signal Out of range" (811)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.5d
Release Notes: SCM NSAM 0.7.5d Build & Package 0.3.0F • NSAM - Main & boot NSAM Flash update failure (691) • Increase High Temperature Threshold, Lower Brain Low signal Thresholds, Lower high Ambient Light Threshold (762) • Hitting SAM reset switch during SAM boot update leaves SAM inoperable (791)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.5b
Release Notes: SCM NSAM 0.7.5b Build & Package 0.3.0E • Overriding Monitor PD values (721) • Flash Update failure patch (723)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.4h
Release Notes: SCM NSAM 0.7.4h Build & Package 0.3.0D • Turn off LEDs of an invalid sensor (687) • StO2 out of range will sometimes not report an error. 2. Add NSAM ADC offsets (689) • MFG features enhance sensor calibration and support diagnostics info for the NSAM test (692) • TOP Lock / outlier decision after a certain period of time in the case (697)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**

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N/A	

Associated Release(s): Gemini NSAM App	**Ver: 0.7.4d**
Release Notes: SCM NSAM 0.7.4b Build & Package 0.3.0C • Since the LED drive is lower on phantoms to avoid saturation, monitor signals can be lower than the thresholds used for "Signal out of range". (652) • The problem floated with a problematic hardware (bad cable) but triggered a vulnerability that if from some reason reading of the 2nd page of the sensor calibration params failed it will not retry to read it. (653) • Updated new “sensor off” thresholds after reviewing the current IRBs data, the older thresholds made the algorithm too sensitive to “sensor off” producing false alarms in the middle of a valid deep cooling DHCA case, resulting in a false message and a recalculation of TOP. (661)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	**Ver: 0.7.4b**
Release Notes: SCM NSAM 0.7.4b Build • As a temporary way to record the S/N of the sensors used in the IRBs the S/N read from the sensor's 1 wire will be output as "Generic_1" field in the scientific data. Pay attention that value will be represented as a float number. (623) • Added Sensor Off detection, logic to recalculate TOP and (477) • Sensor Off was not debounced properly for the sake of recalculating TOP (642)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	**Ver: 0.7.3.h**
Release Notes: SCM Gemini Package 0.1.0C Build • Don't allow the HOST task to start before the channels have been initialized (592) • Sensor test fixture option - use default temperature offset (587) • NSAM - Update 1-Wire first block with type Descriptor (494)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	**Ver: 0.7.3.g**
Release Notes: SCM Gemini Package 0.1.0B Build • Potential fix for the "incorrect sensor size" on the 1 Wire detect of a sensor. (556)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	**Ver: 0.7.3.f**
Release Notes: SCM Gemini Package 0.1.0A Build • Remap channel ordering (544) • Averaging of StO_2 values (551)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

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Associated Release(s): Gemini Main Bootloader **Ver: 0.7.3e**

Release Notes: SCB Gemini 0.7.3e Build

- Numerous bug fixes, interim release

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.3.d**

Release Notes: SCM Gemini 0.3.5.D Build

- Support for 1-wire information for sensors (421)
- Corrected out of range or other errors being displayed when preamp/sensor disconnected (427)

(b)(4) [redacted]

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.3a**

Release Notes: SCM Gemini 0.3.5.B Build

- Support new 1-wire for preamp (411)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.2T**

Release Notes: SCM Gemini 0.3.5.A Build

- Support new Preamps with extra LED to indicate sensor connection (347)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.2S**

Release Notes: SCM 0.3.5 Build

- Ambient light threshold temporarily set very high (354)
- AGC hysteresis (373)
- When brain PD is out of range AGC adjusts LED current (373)
- If gain is out of range for 14 seconds begin TOP calculations (373)
- Workaround For LED switch HW problem (346)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.1X**

Release Notes: SCM 0.3.4 Build

- Update to match LV version 110 (FDA RC1)
- Don't start TOP calculation until first stage of AGC converges

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

- Lock AGC while calculating Top
- Switch to AGC monitor after Top is done
- Added / modified signal alerts
- Added Physio check to verify high enough total Hb
- $St0_2$ results will be shown as soon as they are stable after starting TOP, not only after Top is done.
- Added another outlier check Top2_730 > 200
- Fixed Failsafe 1 to not be "sticky" if triggered once
- Added Exception / Junk data to the “TestData.C”
- Added a Sequence Number to the NSAM <-> SCB comm.

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.5.1X**

Release Notes: SCM 0.3.3 Build

- Added/updated a few routines to enable sensor calibration fixture
- Removed a few unused parameters in the sensor structure
- Added an indication whether TOP is active to enable sync the calculation with LV

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.4.5X**

Release Notes: SCM 0.3.2 Build

- New Algorithm (V109)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.4.4X**

Release Notes: SCM 0.3.1 Build

- Implement new algorithm (C1x & C4x) "running in parallel
- Removed Age / Weight
- Added TOP730 Top690 Check relevant calculations
- A few additions to support preamp and sensor calibration fixture
- Updated proceeded data structure

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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3.3 NSAM Mfg Test Application Releases (Newest to Oldest):

Associated Release(s): Gemini NSAM Mfg Test App	Ver: 1.0.0
Release Notes: SCM MFG NSAM 1.0.0 Build & Package 1.0.0 • All versions set to V1.0.0, Corrected spelling errors. (986)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

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3.4 Main Bootloader Releases (Newest to Oldest):

Associated Release(s): Gemini Main Bootloader	Ver: 1.1.0
Release Notes: Package 1.1.0 Build & Gemini Package 1.1.0 Build	
• Touch screen calibration range check (1026) • Adjust Ambient light upper threshold for NSAM test (1030) • diag -ext in shell does not work in manufacturing boot loader (1060) • Addition of a manufacturing test for verifying 1 wire checksums (1098)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 1.0.1
Release Notes: Package 1.0.1 Build & Gemini Package 1.0.1 Build	
• Correct package version update in the boot loader. (1016)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 1.0.0
Release Notes: Package 1.0.0 Build & Gemini Package 1.0.0 Build	
• All versions set to V1.0.0, Corrected spelling errors. (986)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.6.0A
Release Notes: Package 0.6.0A Build & Gemini Package 0.4.0A Build	
• Begin a system shutdown immediately if voltage is under 10.8. (891) • Added additional elements to NVRAM for future use. • Engineering password made to match Fore-Sight (ACCESS1). (896) • Once a shutdown error is logged it is cleared to avoid future error reporting. (898) • Add touch screen play back with random variation. (904) • Add a monitor feature to the shell touch screen (touch -monitor). (905) • Ensure no huge sleep times in touch screen playback (touch -play). (906) • Add ability to activate SAM and related tasks in the boot loader. • Shell command is "datastart". (900) • Set the first time started time in the "system operation" section of NVRAM. (901) • Force package information update in NVRAM even when no update is necessary. (902) • Remove display of IP address from boot loader. (895)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.5.2G
Release Notes: Package 0.5.2G Build & Gemini Package 0.5.2G Build	
• Engineering dialog in Boot screen shall be password protected (873)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

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Associated Release(s): Gemini Main Bootloader	Ver: 0.5.1G

Release Notes: Package 0.5.1G Build & Gemini Package 0.5.1G Build

- Bug Fix - Remove next button on button bar for manufacturing. (821)
- New boot up image with trade mark (845)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.5.0G

Release Notes: Package 0.5.0G Build & Gemini Package 0.5.0G Build

- Bug Fix - SCB BootLoader about doesn't display NSAM BootLoader version when NSAM main is not available (770)
- Bug Fix - Detect presence of SAM manufacturing build on SAM (793)
- Cleaner package updater messages (806)
- Crisper and nicer looking icons (767)
- Remove power down button hysteresis / fixed power down lockup problems (803)
- Core dump file no longer being saved at power down (803)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.5.0F

Release Notes: Package 0.5.0F Build & Gemini Package 0.5.0F Build

- Bug Fix - Date & time improperly changed during software updates (570)
- Extended core dump - now saves audit and error logs (748)
- Extended shell command for testing "dm -tdssize" to create faster use of patient storage (739)
- Shell command "usbdir" indicates if there is a stick present in the front/back (549)
- Core on shutdown to USB stick is in the format core-date-time.txt
- (e.g. core-06042013-085037.txt) (759)
- Default IP address will now be 192.168.10.90 to accommodate manufacturing (763)
- Bug Fix - Package on the USB stick was not always correctly being detected (761)
- Bug Fix - Package updater starts before SAM is booted and does arbitrary update of SAM
- Last line of package dialog (SAM Main) had no associated colors (673)
- If a halt file is detected on a USB stick (boothalt.cas) the system plays a
- double beep and does not proceed to main (761)
- Configure TCP/IP address dialog (744)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.5.0E

Release Notes: Package 0.5.0E Build & Gemini Package 0.5.0E Build

- Core dump function to snap shot the state of the system (708, 711)
- If a memory stick is present a "core.txt" file is saved on system power down (takes approx 4-5 seconds) (733)
- SAM manager and related tasks are no longer started in the boot loader. (707)

SPR	Description (Refer to QSP1026 for Risk Assessment)

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N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.5.0D**

Release Notes: Package 0.5.0D Build & Gemini Package 0.5.0D Build

- Bug Fix - Audio Volume set to zero without apparent reason / loss of sync with led/sound alarms (527, 569)
- Bug Fix - Change in the ports dialog will eventually crash the system (695)
- Bug Fix - Intermittent GUI hangs and does not recognize button up for several seconds. (705)
- Added more audit trail information on the main application starting up and shutting down (703)
- Bug Fix - Default parameters in the shell were being set to zero (676)
- Bug Fix - Battery temperature sensor was not appearing in the system temperature table (207)
- New shell command to dump OS health manager information (702)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.5.0C**

Release Notes: Package 0.5.0C Build & Gemini Package 0.5.0C Build

- 1-wire power test is now part of the POST (656)
- Package updater moved from the engineering sub-menu to the main bar (650)
- Likely cause of many network related crashes has been fixed (629)
- Adjustment to system task priorities to reduce system hang problems (644)
- The logs now display the task name along with the task ID (648)
- System temperature monitoring is now distributed across time instead of a single block (649)
- Modified code to handle system shutdown more gracefully (657)
- Additional MQX debug information added to the shell (669)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.5.0B**

Release Notes: Package 0.5.0B Build

- Kernel logging debug tool - engineering use (634, 639)
- Fully implement validity test of SAM data on the SCB. (633, 637)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.5.0A**

Release Notes: SCB Gemini 0.4.0A Build

- Port to Numonyx / 512K NVRAM (608, 620, 621)
- First cut implementation of SAM values system test - needs update with more parameters (561)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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Associated Release(s): Gemini Main Bootloader	Ver: 0.4.0A
Release Notes: SCB Gemini 0.4.0A Build • Major architectural change - running fully out of RAM instead of partially out of FLASH (605) • Package update system (601)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6E
Release Notes: SCB Gemini 0.3.6E Build • Bug Fix - sometimes systems took too much time to shutdown (589) • Limited display of logs from the boot loader (576)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6D
Release Notes: SCB Gemini 0.3.6D Build • Button bar now displays icons with language independent text at the bottom (545, 578, 583) • VGA and alarm LEDs should be turned off at shutdown - VGA turned on at power up (566)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6C
Release Notes: SCB Gemini 0.3.6C Build • Command in shell "log" combines the error and audit trails in time order (499) • Shell contains commands to switch between human and machine mode (510) • Allow pollute blocks to be turned on/off via the shell (510) • Improper shutdown is logged (517) • Ability to create and playback macros from the shell (524) • Jump to the main application in the event of an improper system power down (crash) • Don't play preamp/sensor sounds on quick recovery (531, 534)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6B
Release Notes: SCB Gemini 0.3.6B Build • Numerous bug fixes, interim release	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6A
Release Notes: SCB Gemini 0.3.6A Build • Display of screen occurs earlier in the power up cycle (489)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**

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N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.6**

Release Notes: SCB Gemini 0.3.6 Build

- Hold of the power button for 15 seconds in the boot will reset various parts of NVRAM. (474, 484)
- When the reset takes place a triple beep is played.
- Key section resets include the touch screen calibration, network, possibly detected system errors
- Preliminary GUI configuration of serial ports for VueLink/scientific outputs (447, 470)
  Note: That the baud rates are currently unrestricted
- First cut of the Philips VueLink - numbers and sensor connect/disconnect are displayed (395)
  Note: Other SAM and system errors are currently not sent to the Philips
- Event list now display the correct OR list (468)
- Graphing has been refactored (466)
- New graph displays "pen" at the current value on the right side of the screen
- Graph allows through touch screen to reconfigure graph windows on the fly (472)
- SAM allows for case simulation data - only available through the shell (471)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.5E**

Release Notes: SCB Gemini 0.3.5E Build

- RTC battery fault - SPR 711 (365)
- Task analysis and control from shell (448)
- Display of "..." with spaces in boot loader to indicate detected errors (446)
- Searchable help in shell (456)
- NVRAM setting to prevent OS health manager from resetting system (459)
- Allow reset of NVRAM sections (460)
- Change boot loader to indicate "Fore-Sight Elite" not "Gemini" (461)
- Increased OS health manager error logging (462)

SPR	Description (Refer to QSP1026 for Risk Assessment)
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing.

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.5D**

Release Notes: SCB Gemini 0.3.5D Build

- Temporarily increase timeout of PEG from 10 to 30 seconds (451)
- Correct display of dashes instead of numeric on the main screen (450)
- Minor corrections to the GUI (441)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Associated Release(s): Gemini Main Bootloader	**Ver: 0.3.5C**

Release Notes: SCB Gemini 0.3.5C Build

- Shows 2 graphs (403)
- Graph colors match numeric values (404)
- Graph spike starting/ending at zero has been fixed (406)
- Added the ability to allow login as engineering for Paul to be able to see all body locations (399)
- Added acknowledge of disconnected sensor/preamps using the alarm button (369)
- Graphs did not start until a patient was modified (409)
- New button bar icons - white on black (410)
- Date/time now select text month - use of new ok/cancel icons (413)
- Boot allows flash of successive elements from the USB stick (416)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	**Ver: 0.3.5B**

Release Notes: SCB Gemini 0.3.5B Build

- Shows 2 graphs (403)
- Graph colors match numeric values (404)
- Graph spike starting/ending at zero has been fixed (406)
- Added the ability to allow login as engineering for Paul to be able to see all body locations (399)
- Added acknowledge of disconnected sensor/preamps using the alarm button (369)
- Graphs did not start until a patient was modified (409)
- New button bar icons - white on black (410)
- Date/time now select text month - use of new ok/cancel icons (413)
- Boot allows flash of successive elements from the USB stick (416)

SPR	Description (Refer to QSP1026 for Risk Assessment)
710	**Not all Audio and Visual Alarms removed after Condition cleared**: It was noted that at certain occasions the Yellow or Red Alarm LED, the Yellow or Red Background on the system or channel message area and the High or Medium Priority Alarm Audio are not always removed after the condition (e.g. Low or Depleted Battery) has been cleared. Only the Alarm text message was removed. Same was observed with certain channel alarm conditions such as "External Interference". Issue is only cleared if the Unit is power cycled or if a new alarm is initiated.

Associated Release(s): Gemini Main Bootloader	**Ver: 0.3.5A**

Release Notes: SCB Gemini 0.3.5A Build

- Corrected problem with the interpretation of incorrect locations for the touch screen (305 / SPR 708)
- A number of corrections to the patient configuration dialog including making it modal (396)
- This version has all body locations available (401)

SPR	Description (Refer to QSP1026 for Risk Assessment)
708	**Incorrect Interpretation of Geographical Location of Entries on the Touch**

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	Screen: User touches one location of the touchscreen in order to activate or select a specific Menu or Submenu. It was noted in certain occasions that either a different location become activated or a different action is performed (e.g. the Views selections will open up if the silence key is pressed while the View menu is open)

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.5**

Release Notes: SCB 0.3.5 Build

- TPI value no longer starts at full bars - now zero bars (352)
- NVRAM now supports cross version changes (366, 367)
- New button bar with next page capability (371)
- Refactored list boxes for brightness, volume etc. (370, 389)
- Events are now sent out to the scientific data stream (386)
- View time is now saved and restored from NVRAM (392)
- Ability to flash SCB boot loader (378)
- Refactor of boot loader to have look of main application (374)
- Use of new patient/alarm limits configuration dialog (382)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.4**

Release Notes: SCB 0.3.4 Build

- Unified build of NSAM and SCB code
- A variety of NSAM algorithm changes
- Addition of a PC utility to verify scientific output
- Resolution of SPRs 709, 711
- Addition of error, audit, and service log accessible via telnet
- Brightness and volume displayed via a list box
- Added cleanscreen command to the telnet shell
- Login to the telnet shell with "machine9" changes to machine friendly mode

SPR	Description (Refer to QSP1026 for Risk Assessment)
709	**Set Audio Volume not automatically implemented:** The newly selected Audio volume is not always automatically implemented. It is sometimes necessary to enable or disable the Audio Silence for the new volume settings to be implemented.
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing. **Note/Mitigation**: Last Date & Time are also saved into the system Flash that will keep them unless the System Battery and AC are disconnected from the Unit. The User is instructed to/how set the Time and Date if the last setting was lost.

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.3**

Release Notes: SCB 0.3.3 Build

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- Audio is now played for plugging in the preamp and sensor
- Provide for scientific output only when $St0_2$ is valid
- $St0_2$ values are now rounded - NOT truncate
- Dialog boxes are now modal
- Use of a new generic "button bar" - should be transparent to the user
- New NSAM error message for low sensor temperature

SPR	Description (Refer to QSP1026 for Risk Assessment)	
708	**Incorrect Interpretation of Geographical Location of Entries on the Touch Screen**: User touches one location of the touchscreen in order to activate or select a specific Menu or Submenu. It was noted in certain occasions that either a different location become activated or a different action is performed (e.g. the Views selections will open up if the silence key is pressed while the View menu is open)	
	Probability	Occasional
	Severity	Minor
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
709	**Set Audio Volume not automatically implemented**: The newly selected Audio volume is not always automatically implemented. It is sometimes necessary to enable or disable the Audio Silence for the new volume settings to be implemented.	
	Probability	Frequent
	Severity	Negligible
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
710	**Not all Audio and Visual Alarms removed after Condition cleared**: It was noted that at certain occasions the Yellow or Red Alarm LED, the Yellow or Red Background on the system or channel message area and the High or Medium Priority Alarm Audio are not always removed after the condition (e.g. Low or Depleted Battery) has been cleared. Only the Alarm text message was removed. Same was observed with certain channel alarm conditions such as "External Interference". Issue is only cleared if the Unit is power cycled or if a new alarm is initiated.	
	Probability	Occasional
	Severity	Minor
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing or defect	
	Probability	Frequent
	Severity	Negligible
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released

Associated Release(s): Gemini Main Bootloader Ver: 0.3.2

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Release Notes: SCB 0.3.2 Build

- Double beep is once again playing at boot up time
- The UI is more resilient to fast keyboard touches - crashes have been prevented
- Access to the boot loader screen is now working
- Audio "click" is available when pressing buttons in the boot loader
- Audio is now played for plugging in the pre-amp and sensor

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader Ver: 0.3.1

Release Notes: SCB 0.3.1 Build

- Boot loader "bios" screen now displays the boot loader and main application version
- Bug fix: Audio "buzz" on start of the main application has been removed
- Shell touch screen playback now can be looped N times with a specified delay between loops
- Implemented loop back for DUARTs
- Clean screen feature partially implemented as a potential product feature
- New function in the shell to get and set parameters - prelude for manufacturing
- Dialog boxes in the main application now work without memory leaks or major problems
- Traces now display data. Limitation for now is that it is restricted to about 18 hours of data and does not persist through power cycles
- Scientific binary output is now provided through the DUART ports based on configuration in NVRAM. (Currently no GUI for this configuration.)
- Changes to the numeric key pad. Now includes a cancel button.
- A preliminary key “click” has been implemented only in the boot GUI. This plays key click in between any alarm being played. This is very preliminary and does not always sound correct.

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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3.5 Main Mfg Bootloader Releases (Newest to Oldest):

Associated Release(s): Gemini Main Bootloader — Ver: 1.1.0

Release Notes: Package 1.1.0 Build & Gemini Package 1.1.0 Build

- Touch screen calibration range check (1026)
- Adjust Ambient light upper threshold for NSAM test (1030)
- diag -ext in shell does not work in manufacturing boot loader (1060)
- Addition of a manufacturing test for verifying 1 wire checksums (1098)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader — Ver: 1.0.1

Release Notes: Package 1.0.1 Build & Gemini Package 1.0.1 Build

- Bug Fix - Fix "diag -ext." - shell version 1.0.2 (1010)
- Correct package version update in the boot loader (1016)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader — Ver: 1.0.0

Release Notes: Package 1.0.0 Build & Gemini Package 1.0.0 Build

- All versions set to V1.0.0, Corrected spelling errors. (986)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader — Ver: 0.4.0B

Release Notes: Package 0.4.0B Build & Gemini Package 0.4.0B Build

- Add the ability to wipe the system clean in the manufacturing boot loader using file wipesys.cas (944)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader — Ver: 0.4.0A

Release Notes: Package 0.4.0A Build & Gemini Package 0.4.0A Build

- Begin a system shutdown immediately if voltage is under 10.8 (891)
- Added additional elements to NVRAM for future use
- Engineering password made to match Fore-Sight (ACCESS1) (896)
- Once a shutdown error is logged it is cleared to avoid future error reporting (898)
- Add touch screen play back with random variation (904)
- Add a monitor feature to the shell touch screen (touch-monitor) (905)
- Ensure no huge sleep times in touch screen playback (touch-play) (906)
- Add ability to activate SAM and related tasks in the boot loader
- Shell command is "datastart" (900)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Associated Release(s): Gemini Main Bootloader **Ver: 0.3.2G**

Release Notes: Package 0.3.2G Build & Gemini Package 0.3.2G Build

- Engineering dialog in Boot screen shall be password protected (873)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader **Ver: 0.3.1G**

Release Notes: SCB Main Mfg Boot 0.3.1G Build & Gemini Package 0.5.01G Build

- Bug Fix - Remove next button on button bar for manufacturing. (821)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader **Ver: 0.3.0G**

Release Notes: SCB Main Mfg Boot 0.3.0G Build & Gemini Package 0.3.0G Build

- Bug Fix - Detect presence of SAM manufacturing build on SAM (793)
- Crisper and nicer looking icons (767)
- Remove power down button hysteresis / fixed power down lockup problems (803)
- Core dump file no longer being saved at power down (803)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader **Ver: 0.3.0F**

Release Notes: SCB Main Mfg Boot 0.3.0F Build & Gemini Package 0.3.0F Build

- Bug Fix - Date & time improperly changed during software updates (570)
- Extended core dump - now saves audit and error logs (748)
- Extended shell command for testing "dm -tdssize" to create faster use of patient storage (739)
- Shell command "usbdir" indicates if there is a stick present in the front/back (549)
- Core on shutdown to USB stick is in the format core-date-time.txt
- (e.g. core-06042013-085037.txt) (759)
- Default IP address will now be 192.168.10.90 to accommodate manufacturing (763)
- Configure TCP/IP address dialog (744)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader **Ver: 0.3.0E**

Release Notes: SCB Main Mfg Boot 0.3.0E Build & Gemini Package 0.3.0E Build

- Core dump function to snap shot the state of the system (708, 711)
- If a memory stick is present a "core.txt" file is saved on system power down (takes approx 4-5 seconds) (733)
- Bug Fix - Cannot update boot loader from software package upgrade (718)
- SAM manager and related tasks are no longer started in the boot loader. (707, 728)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader **Ver: 0.3.0D**

Release Notes: SCB Main Mfg Boot 0.3.0D Build & Gemini Package 0.3.0D Build

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- Changed the splash screen (696)
- Bug Fix - Default parameters in the shell were being set to zero (676)
- Bug Fix - Battery temperature sensor was not appearing in the system temperature table (207)
- New shell command to dump OS health manager information (702)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.3.0C

Release Notes: SCB Main Mfg Boot 0.3.0C Build & Gemini Package 0.3.0C Build

- 1-wire power test is now part of the POST (656)
- Package updater moved from the engineering sub-menu to the main bar (650)
- Likely cause of many network related crashes has been fixed (629)
- Adjustment to system task priorities to reduce system hang problems (644)
- The logs now display the task name along with the task ID (648)
- System temperature monitoring is now distributed across time instead of a single block (649)
- Modified code to handle system shutdown more gracefully (657)
- Additional MQX debug information added to the shell (669)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.3.0B

Release Notes: SCB Main Mfg Boot 0.3.0B Build & Gemini Package 0.3.0B Build

- Kernel logging debug tool - engineering use (634, 639)
- Fully implement validity test of SAM data on the SCB. (633, 637)
- Different displayed image on splash screen - request to avoid confusion (643)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.3.0A

Release Notes: SCB Main Mfg Boot 0.3.0A Build

- Port to Numonyx / 512K NVRAM (608, 620, 621)
- First cut implementation of SAM values system test - needs update with more parameters (561)
- Bug fix - Eratic silence alarm count down - sometimes 1, 2, or 3 seconds between updates (584)
- Bug fix - VueLink reset problem (571)
- Language selection and graph layout now saved in NVRAM (615)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.2.0A

Release Notes: SCB Main Mfg Boot 0.2.0A Build

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- Bug fix - Problems with alarm limits dialog (609)
- Numerous user interface changes (610, 613)
- Start/Stop text now appears on the STS start/stop toggle button (612)
- Major architectural change - running fully out of RAM instead of partially out of FLASH (605)
- Package update system (601)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.7.3h

Release Notes: SCB Main Mfg Boot 0.1.0C Build

- New manufacturing build (586, 593)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.2.3

Release Notes: SCB Main Mfg Boot 0.2.3 Build

- No password is required to start the shell and starts in machine mode (510)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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3.6 Main Application Releases (Newest to Oldest):

Associated Release(s): Gemini Main US App **Ver: 1.1.1**

Release Notes: SCB Gemini 1.1.1 Build & SCB Gemini Package 1.1.1 Build

- Add toggling bitmap Checkbox to Engineering settings dialog (1142)
- Add klog tools to Engineering Dialog (1163)
- Bug Fix - Caution - Investigational Device not displayed when engineering body locations are enabled (1129)
- Bug Fix - In Italian "View" 24 Hour selection is 1Ore, should be 24 Ore (SPR 762-2) (1136)
- Bug Fix - In 4 C4 CAS protocol crash when baud rate is selected. (SPR 761) (1145)
- Bug Fix - Numeric Field "Current Value" sometimes blank after fast boot (SPR 764) (1147)
- Bug Fix - Remove active case from USB save list (SPR 758 & 760) (1148)
- Bug Fix - Change STS statistics to match CSV (1149)
- Bug Fix - Text for sensor over/under temperature not appearing in CSV event. (1150)
- Bug Fix - Clicking the Ref value does not toggle the Ref line on graph (1151)
- Bug Fix - Event Mark vertical dotted line (SPR 754) (1153)
- Bug Fix - Dutch under STS & other string fixes(SPR 762-1) (1158)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 1.1.0**

Release Notes: SCB Gemini 1.1.0 Build & SCB Gemini Package 1.1.0 Build

- Sensor Off Tissue and StO2 Value (928)
- Addition of languages including Russian. (multiple CRs)
- Russian Cyrillic keyboard. (1029)
- Implement adaptive fan speed based on internal temperatures. (1021, 1080)
- 4 Channel ATE and CSV. (1008)
- Ports no longer require a system reset. (827)
- Special file on the USB stick "eng1984.cas" automatically starts the network. (1047)
- Shell - 1-wire serial memory tests (command "serm"). (1045)
- Create secondary level of reporting NSAM issues to the user. (1052, 1053)
- Entering Biomed password will display Button bar with Language and defaults (1054)
- Add confirm dialog to Stop STS data (1058)
- Adjust priorities and error messages (1062)
- Change Brightness settings scale (1064)
- CAS/ATE Remap Unstable Signal status (1071)
- Add Patient ID to USB File Name (1073)
- Add one decimal digit to Cumulative Sat Below Thresh & Reg O2 % Ranges (1067)
- Add scientific mode to all users. (1075)
- Different body locations available in OUS (1077)
- Add translation for Ports -> scientific. (1081)
- Add automatically generated events based on special NSAM conditions. (1061)
- Add languages to USB patient file (1095)
- Bug Fix - Correct redraw speed of numeric fields after display of events -

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Still may occur but is vastly improved (746)

- Bug Fix - Rapid changes in Settings-View causes crash. (1038)
- Bug Fix - External Interference causes the Numeric field to go blank instead of dashes. (1041)
- Bug Fix - Monitor reset if Factory Defaults activated (1003, 827)
- Bug Fix - Correct underlying alarm led and audio problems. (1057)
- Bug Fix - Pressed Events, then OR then screen froze showing just bottom 3 options (949)
- Bug Fix - Rapid switching between Event button and Undo button causes crash (965)
- Bug Fix - Possibility to delete more than the last Event entered. (1000)
- Bug Fix - USB File - need to add a decimal digit precision to STS data (1094)
- Bug Fix - ICU Event list "Reposition Patient" should be Green Event after "Prostaglandin" (1096)

SPR	Description (Refer to QSP1026 for Risk Assessment)
758	Active case total duration time. (CR 1148)
760	Active cases saved to the USB (CR 1148)
764	System Reset & StO2 Numerics on Display (CR 1147)

Associated Release(s): Gemini Main US App Ver: 1.0.2

Release Notes: SCB Gemini 1.0.2 Build & SCB Gemini Package 1.0.2 Build

- Package 1.0.1 (1014)
- Bug Fix - Spelling incorrect for "Venous Return Down". (1017)

SPR	Description (Refer to QSP1026 for Risk Assessment)
748	Main App - Incorrect spelling of Event “Venous Return Down” (CR 1017)

Associated Release(s): Gemini Main US App Ver: 1.0.1

Release Notes: SCB Gemini 1.0.1 Build & SCB Gemini Package 1.0.1 Build

- Package 1.0.1 (1014)
- SPR 739 - New update to Events: Reposition head/heart etc. (1001)
- SPR 742 - Fix STS output problems. (992)
- Bug Fix - Increase the size of Help About for French and make month text. (978)
- Bug Fix - Sto2 seems to be truncated and not rounded (988)
- SPR 740 - ECLs off event is attached to ECL's On and saves to USB wrong (1004)
- SPR 744 - Correct mapping of Faulty Clock Battery SPR744 (1007)

SPR	Description (Refer to QSP1026 for Risk Assessment)
742	STS Cumulative Saturation Value Calculation (CR 992)
739	Missing Event Marks from OP & ICU Listing (CR 1001)
740	Incorrect Event saved to the USB (CR 1004)
744	Correct mapping of Faulty Clock Battery (1007)

Associated Release(s): Gemini Main US App Ver: 1.0.0

Release Notes: SCB Gemini 1.0.0 Build & SCB Gemini Package 1.0.0 Build

- All versions set to V1.0.0, Corrected spelling errors. (986)

SPR	Description (Refer to QSP1026 for Risk Assessment)

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

737	No Time/Date change Prompt
738	NSAM Board Communication Failure Detection (CR 997)
739	Missing Event Marks from OP & ICU Listing (CR # 998)
740	Incorrect Event saved to the USB (CR 999)
741	Possibility to delete more than the last Event entered (CR 1000)
744	Faulty Clock Battery Error on ATE (CR 990)
742	STS Cumulative Saturation Value Calculation (CR 992)

Associated Release(s): Gemini Main US App **Ver: 0.6.0D**

Release Notes: SCB Gemini 0.6.0D Build & SCB Gemini Package 0.4.0D Build

- CAS ATE Protocol and 2-Minute Audio Disabled State. (948)
- Power up with active VueLink connection (824)
- Change Help Dialogs, Fix Strings & Events (971)
- Force restart after port config change (975)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.6.0C**

Release Notes: SCB Gemini 0.6.0C Build & SCB Gemini Package 0.4.0C Build

- Bug Fix - The Alarm Audio and/or visual is not cleared after the condition has been removed. (701)
- Bug Fix - Red LED switching from flashing to frozen state and back to flashing. (915)
- Bug Fix - Previous Reference Value on Numerics Display right after Channel Activation (943)
- Bug Fix - System crash during second Patient File saving (953)
- Bug Fix - The “g” in the “Saving… %” & “Saving…Done” overwritten by line below (960)
- Bug Fix - StO_2 Values Differences between Values on Display and on ATE/IntelliBridge Devices (954)
- Bug Fix - STS Stop Key update (952)
- Bug Fix - Crash when pressing OK twice to cancel a case save USB (967)
- Add "Do not remove USB" to case save dialog (946)
- ATE/CSV Alarm State update (955)
- German, Italian, Russian, Spanish, Dutch Translation (947)
- Fix plain text Ch, Hrs, L/R icon, and other strings (950)
- STS Warning at end of STS Data Collection (951)
- Capture boot exception into NVRAM "fatal error" location. (959)
- Baud Rate Selection on CAS ATE and CSV Output (961)
- New Sensor Off remapping of warnings (963)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.6.0B**

Release Notes: SCB Gemini 0.6.0B Build & SCB Gemini Package 0.4.0B Build

- Begin a system shutdown immediately if voltage is under 10.8 (891)

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- Slight (20%) improvement in USB save speed (942)
- Bug Fix - Hitting exit during Save Case to USB causes crash (825)
- Bug Fix - Language is lost at reboot (934)
- Bug Fix - Incorrect IntelliBridge/VueLink Communication Error Message (935)
- Bug Fix - USB Data Saving Progress Status now completes correctly (925)
- Bug Fix - Event Mark Line not removed after New Patient (920)
- Move Scientific output to engineering mode ONLY. (913)
- Display IP address when TCP/IP button is pressed (914)
- Patient is not saved if the case is 30 seconds or less (918)
- STS is now output for saved cases to the USB (917)
- Add French Translation (927)
- Patient File deletion - Confirmation dialog added (929)
- Data Collection prevented until 1 valid channel (940)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.6.0A**

Release Notes: SCB Gemini 0.6.0A Build & SCB Gemini Package 0.4.0A Build

- Begin a system shutdown immediately if voltage is under 10.8 (891)
- Added additional elements to NVRAM for future use
- Engineering password made to match Fore-Sight (ACCESS1) (896)
- Once a shutdown error is logged it is cleared to avoid future error reporting (898)
- Add touch screen play back with random variation (904)
- Add a monitor feature to the shell touch screen (touch-monitor) (905)
- Ensure no huge sleep times in touch screen playback (touch-play) (906)
- Add ability to activate SAM and related tasks in the boot loader
- Shell command is "datastart" (900)
- Prevent new channels from being tracked after starting STS data (892)
- Modify new patient dialog setting to 30 minutes (899)
- Selecting the same item on a list box initiates no change (894)
- STS On/Off button: Remove image jitter (907)
- Remove grey "STS data" from top of main screen when disabled (908)
- Changed "Cannot save current case" to "USB file error" (911)
- Increase size of text boxes at top of MainScreen (912)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.2G**

Release Notes: SCB Gemini 0.5.2G Build & SCB Gemini Package 0.3.2G Build

- Engineering dialog in Boot screen shall be password protected (873)
- Update Patient Data Flow operation (852, 889)
- Display "Faulty Serial Port" if VueLink/Intellibridge communication lost (862, 864)
- Add title to Events dialogs. OR Events, ICU, Vascular, NICU (866)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

- Change "FS Data" in title bar to "STS Data" (846)
- Title Bar Launch Dialogs for ID, View & Time (867)
- Display of channels w/unused body locations in STS View (833)
- Update events as per marketing changes (870)
- Make number in numeric field launch Patient Setup Dialog (834)
- Display state of the batter (on AC or various levels of discharge) (868, 858, 874, 877, 879, 884)
- Update Factory Default dialog Title & Text (848)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.1G**

Release Notes: SCB Gemini 0.5.1G Build & SCB Gemini Package 0.3.1G Build

- Bug Fix - Remove next button on button bar for manufacturing. (821)
- New VueLink/IntelliBridge condition messages to handle (831)
- Bug Fix - Selection of body location from numeric field causes error. (828)
- Bug Fix - Add "investigation use only" message at exit of Engineering screen if any alarm is disabled. (840)
- Fix spacing and size of Alpha keypad (826)
- On alpha keypad the remaining characters is not initialized (829)
- Change dialog text when asking for new patient after body location change (832)
- Change USB to File icon in Setup->Files menu. (838)
- Change order of Events button bar to “OR ICU Vascular” (839)
- Round corners of Silence and Home icons (842)
- Reduce size of backspace key in Alpha keypad (843)
- When using keyboard for password, hide char entry (830)
- Use white image background on body location icons when rendered on white (837)
- When Ref button touched, draw all corresponding dashed reference lines
- Mainscreen New patient dialog Title is: “New Patient” text is “Start a new patient?” (863)
- Change title of Engineer setting from “Demo” to “Engineer Settings” (863)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0G**

Release Notes: SCB Gemini 0.5.0G Build & SCB Gemini Package 0.3.0G Build

- Bug Fix - New patient and default confirmations "OK" now work correctly (766)
- Bug Fix - Numeric field font is too big in 4 channel mode (771)
- Bug Fix - Display view time was not updating on the main screen. (775)
- Bug Fix - Minor cosmetic fix - move Patient ID down a few pixels in Main screen. (785)
- Bug Fix - Intellibridge was not working, baud rate selections were not taking effect. (794)
- Bug Fix - Setting year in date/time dialog sets the date to 4 digits. (807)
- Bug Fix - Transition from 2 channel CSV to off causes system crash. (809)
- Bug Fix - UNDO of a selected event leaves dashed lines on multi-graphs. (789)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

- Bug Fix - Occasional RTC loss of time and date (473)
- Bug Fix - NSAM Bootloader & Main Software download without NSAM Module (449)
- Ability to use touch screen test scripts (805)
- ATE is now available as a port selection (782)
- New patient is not started if the user presses OK but the date has not changed (795)
- 4 event categories are now available - ICU, OR, Vascular, (NICU - disabled) (769)
- Added high/low limit violations to the exported file data (773)
- Added new/continue patient timers & prompting (772)
- Disable greying out and dynamic area under curve feature. (776)
- Alarm delay now available (777, 778, 779)
- Minimal functionally ATE is available - sends out a continuous stream in ATE format (738)
- Patient setup dialog - replace bitmap numbers with text and add column titles (781)
- Re-order time date dialog to Day-Month-Year and add warning text (787)
- Remove unused USB icons and FS icon (790)
- Add 4 blank help screens as place holders (796)
- Engineering configuration allowing disable of audio and visual alarms (800)
- New backspace icon (810)
- Event marks are placed onto the trace after a power cycle (808)
- Crisper and nicer looking icons (767)
- Remove power down button hysteresis / fixed power down lockup problems (803)
- Core dump file no longer being saved at power down (803)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0F**

Release Notes: SCB Gemini 0.5.0F Build & SCB Gemini Package 0.3.0F Build

- Bug Fix - Date & time improperly changed during software updates (570)
- Extended core dump - now saves audit and error logs (748)
- Extended shell command for testing "dm -tdssize" to create faster use of patient storage (739)
- Shell command "usbdir" indicates if there is a stick present in the front/back (549)
- Core on shutdown to USB stick is in the format core-date-time.txt
- (e.g. core-06042013-085037.txt) (759)
- Default IP address will now be 192.168.10.90 to accommodate manufacturing (763)
- Bug Fix - Existing patient setup cancel improperly allowed changes to stick in memory (740)
- Bug Fix - Sto2 data is now being saved to the USB memory stick (741)
- Bug Fix - TCP activation can only be pressed once (751)
- Bug Fix - Gap in data records no longer occurs (572)
- Core dump button under password now dumps the core to any USB stick (748)
- New body location prompts the user if they want to start a new patient (752)
- New patient button prompts with an "Are you sure?" dialog (755)
- Reference value resets on new patient (756)

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

- Display "Investigational unit" based on NVRAM settings - audio/led disabled, body locations (760)
- Display saving to USB percentage progress with more detail (758)

(NOTE: New patient is broken in this version and will be fixed in the next version that will be available shortly. However, this version can still be used for button testing, package update testing, and testing the newly available features.)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0E**

Release Notes: SCB Gemini 0.5.0E Build & SCB Gemini Package 0.3.0E Build

- Core dump function to snap shot the state of the system (708, 711)
- If a memory stick is present a "core.txt" file is saved on system power down (takes approx 4-5 seconds) (733)
- Bug Fix - Grid lines are no longer displayed (710)
- Manufacturing default can now be activated from the setup menu (694, 698)
- Network no longer automatically starts in the main application - turned ON in password/setup button bar (714)
- Fore-Sight 2 Channel CSV (700, 712)
- Restructure of GUI components / password is now alpha keyboard (722)
- Add investigational use text when in entering special system modes - currently in password/setup button bar entry (729)
- Add "Silence" to alarm button, some icons updated to be much nicer (719)
- Expanded data storage to include space for alarm events (674)
- When no StO2 data is being acquired data is not being saved to memory (735)
- Shell command available "sam -sto2on <N>" when N is the seconds of preamp disconnect cycle simulation - useful for testing (735)

Known Issues in this release

- Pressing cancel on the patient setup still takes values that were changed
- Saving patient data to the USB stick does not save the data

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0D**

Release Notes: SCB Gemini 0.5.0D Build & SCB Gemini Package 0.3.0D Build

- Likely cause of many network related crashes has been fixed (629)
- Bug Fix - Audio Volume set to zero without apparent reason / loss of sync with led/sound alarms (527, 569)
- Bug Fix - Change in the ports dialog will eventually crash the system (695)
- Bug Fix - Intermittent GUI hangs and does not recognize button up for several seconds. (705)
- Added more audit trail information on the main application starting up and shutting down (703)
- Bug Fix - Default parameters in the shell were being set to zero (676)
- Bug Fix - Battery temperature sensor was not appearing in the system temperature table

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(207)
- New shell command to dump OS health manager information (702)
- Remove quick event from events button bar. (679)
- Touching limits launches patient setup dialog & remove outline of limits when selected. (680)
- Add in color coordination of events with circles on graph (681, 683)
- Add single event UNDO to events button bar (685)
- For events use background color instead of text color (686)
- Add information to the about dialog box. (682)
- Update the alpha numeric keyboard - added space bar, cleaned up look (699)
- First cut of case management storage/delete to USB stick (684)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0C**

Release Notes: SCB Gemini 0.5.0C Build & SCB Gemini Package 0.3.0C Build
- Likely cause of many network related crashes has been fixed (629)
- Adjustment to system task priorities to reduce system hang problems (644)
- The logs now display the task name along with the task ID (648)
- System temperature monitoring is now distributed across time instead of a single block (649)
- Modified code to handle system shutdown more gracefully (657)
- Additional MQX debug information added to the shell (669)
- Display the correct percentage ranges on the STS dialog (626)
- Disallow selection by use to ALL channels to unused - one must remain a valid body location (630)
- Display software package version and installation date in the about box under help (645)
- Numeric keypad now auto-completes when a valid value is entered (e.g. alarm limit) (659)
- Patient ID input (651)
- Serial port configuration baud rates are now restricted (655)
- Modified setup button bar order, minor mods to STS dialog (662)
- Bug Fix - Color was not set back to black after a system error resolved (660)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0B**

Release Notes: SCB Gemini 0.5.0B Build & SCB Gemini Package 0.3.0B Build
- Random crash with scientific serial steam enabled frequency reduced (632)
- Kernel logging debug tool - engineering use (634, 639)
- Fully implement validity test of SAM data on the SCB. (633, 637)
- Data management to accommodate Numonyx flash (606)
- Add handling for new NSAM messages related to Sensor Off and Sensor Lifting (635)
- Display of about box that shows package number (636)
- Add password-protected button bar for service/developer actions (625)

SPR	Description (Refer to QSP1026 for Risk Assessment)

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N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0A**

Release Notes: SCB Gemini 0.5.0A Build & SCB Gemini Package 0.3.0A Build

- Port to Numonyx / 512K NVRAM (608, 620, 621)
- First cut implementation of SAM values system test - needs update with more parameters (561)
- Bug fix - Eratic silence alarm count down - sometimes 1, 2, or 3 seconds between updates (584)
- Bug fix - VueLink reset problem (571)
- Language selection and graph layout now saved in NVRAM (615)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.4.0A**

Release Notes: SCB Gemini 0.4.0A Build & SCB Gemini Package 0.2.0A Build

- Bug fix - Problems with alarm limits dialog (609)
- Numerous user interface changes (610, 613)
- Start/Stop text now appears on the STS start/stop toggle button (612)
- Major architectural change - running fully out of RAM instead of partially out of FLASH (605)
- Package update system (601)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6E**

Release Notes: SCB Gemini 0.3.6E Build & SCB Gemini Package 0.1.0C Build

- Bug Fix - sometimes systems took too much time to shutdown (589)
- Bug Fix - Selecting port with port menu crash (588)
- Bug Fix - exit of patient setup can cause system crash (585)
- Bug Fix - exit of empty numeric dialog box causes a crash (594)
- Bug Fix - backspace works properly in password dialog (520)
- Improved performance of the screen drawing (579, 599)
- Event items are now shown in color on the list box (591, 598)
- Items that are the current value in list boxes (e.g. brightness) are now highlighted in green (603)
- STS Toggle button now works - FSData shows up on "status" bar (602)

SPR	Description (Refer to QSP1026 for Risk Assessment)
717	Exit of patient setup can cause system crash.

Associated Release(s): Gemini Main US App **Ver: 0.3.6D**

Release Notes: SCB Gemini 0.3.6D Build & SCB Gemini Package 0.1.0B Build

- Button bar now displays icons with language independent text at the bottom (545, 578, 583)
- VGA and alarm LEDs should be turned off at shutdown - VGA turned on at power up (566)
- Bug fix - lost REF values switching from 4 to 2 channels (567)

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- Various GUI updates (573)
- Bug fix - alarm messages lost when screen is reconfigured 2 <-> 4 channels (567)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6C**

Release Notes: SCB Gemini 0.3.6C Build & SCB Gemini Package 0.1.0A Build

- Graphs on the screen can be combined/split using the touchscreen (480)
- Channel errors and warnings used with VueLink (498)
- Bug fix - drop of a blank event when the cancel button is used on the dialog (509)
- StO_2 data is now stored in NVRAM - graph is maintained through power cycles (513)
- Dialog boxes are automatically centered (526)
- Normalize the look of all list dialog boxes (529)
- Modify power down to be more user responsive - adjust down hysteresis, blank screen after push in power button (535)
- Add in basic Gemini statistics & STS dialog (532, 533, 540, 546)
- Possible improvement in the "crash" issue - possible decreased incidence (557)
- Tie in of numeric regions to display reference, limits, AUT
- Tie in of STS start/stop into gathering statistics (521, 542. 562)
- Change various GUI screens for consistency (558)
- Increased font for Numeric Field
- Standardized key size on NumericKeyPad to match (future) alpha numeric
- Changed OK/Cancel button to same size on NumericKeyPad, PatientSetup, DateTimeDlg, and SerialPortDlg.
- Corrected title color to white on STSviewDlg and centered text and spreadsheets.
- Bug Fix - Boot would crash after a long while (501)
- Bug Fix - Fix rounding errors in SctO2 (454)
- Transfer of data and management of flash extending recording to approximately 24 days. (538)
- (This version of software is a short transition to multiple patients)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6B**

Release Notes: SCB Gemini 0.3.6B Build

- Numerous bug fixes, interim release

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6A**

Release Notes: SCB Gemini 0.3.6A Build

- Corrected VueLink file to allow display of graphs on the Philips monitor (487)
- Bug fix to the serial stream user interface (488)
- Display of screen occurs earlier in the power up cycle (489)
- Display of event marks including touch of event mark on graph to show the text of the

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event mark (483)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6**

Release Notes: SCB Gemini 0.3.6 Build

- Log files are synced to the file system in a background task (439)
- Increased monitoring of system performance that is records to the error log (467)
- Preliminary GUI configuration of serial ports for VueLink/scientific outputs (447, 470)
  Note: That the baud rates are currently unrestricted
- First cut of the Philips VueLink - numbers and sensor connect/disconnect are displayed (395)
  Note: Other SAM and system errors are currently not sent to the Philips
- Event list now display the correct OR list (468)
- Graphing has been refactored (466)
- New graph displays "pen" at the current value on the right side of the screen
- Graph allows through touch screen to reconfigure graph windows on the fly (472)
- SAM allows for case simulation data - only available through the shell (471)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.5E**

Release Notes: SCB Gemini 0.3.5E Build

- RTC battery fault - SPR 711 (365)
- Task analysis and control from shell (448)
- Display of "..." with spaces in boot loader to indicate detected errors (446)
- Searchable help in shell (456)
- NVRAM setting to prevent OS health manager from resetting system (459)
- Allow reset of NVRAM sections (460)
- Change boot loader to indicate "Fore-Sight Elite" not "Gemini" (461)
- Increased OS health manager error logging (462)

SPR	Description (Refer to QSP1026 for Risk Assessment)
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing.

Associated Release(s): Gemini Main US App **Ver: 0.3.5D**

Release Notes: SCB Gemini 0.3.5D Build

- Temporarily increase timeout of PEG from 10 to 30 seconds (451)
- Correct display of dashes instead of numeric on the main screen (450)
- Minor corrections to the GUI (441)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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Associated Release(s): Gemini Main US App	**Ver: 0.3.5C**

Release Notes: SCB Gemini 0.3.5C Build

- Shows 2 graphs (403)
- Graph colors match numeric values (404)
- Graph spike starting/ending at zero has been fixed (406)
- Added the ability to allow login as engineering for Paul to be able to see all body locations (399)
- Added acknowledge of disconnected sensor/preamps using the alarm button (369)
- Graphs did not start until a patient was modified (409)
- New button bar icons - white on black (410)
- Date/time now select text month - use of new ok/cancel icons (413)
- Boot allows flash of successive elements from the USB stick (416)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App	**Ver: 0.3.5B**

Release Notes: SCB Gemini 0.3.5B Build

- Shows 2 graphs (403)
- Graph colors match numeric values (404)
- Graph spike starting/ending at zero has been fixed (406)
- Added the ability to allow login as engineering for Paul to be able to see all body locations (399)
- Added acknowledge of disconnected sensor/preamps using the alarm button (369)
- Graphs did not start until a patient was modified (409)
- New button bar icons - white on black (410)
- Date/time now select text month - use of new ok/cancel icons (413)
- Boot allows flash of successive elements from the USB stick (416)

SPR	Description (Refer to QSP1026 for Risk Assessment)
710	**Not all Audio and Visual Alarms removed after Condition cleared**: It was noted that at certain occasions the Yellow or Red Alarm LED, the Yellow or Red Background on the system or channel message area and the High or Medium Priority Alarm Audio are not always removed after the condition (e.g. Low or Depleted Battery) has been cleared. Only the Alarm text message was removed. Same was observed with certain channel alarm conditions such as "External Interference". Issue is only cleared if the Unit is power cycled or if a new alarm is initiated.

Associated Release(s): Gemini Main US App	**Ver: 0.3.5A**

Release Notes: SCB Gemini 0.3.5A Build

- Corrected problem with the interpretation of incorrect locations for the touch screen (305 / SPR 708)
- A number of corrections to the patient configuration dialog including making it modal (396)
- This version has all body locations available (401)

SPR	Description (Refer to QSP1026 for Risk Assessment)
708	**Incorrect Interpretation of Geographical Location of Entries on the Touch**

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	Screen: User touches one location of the touchscreen in order to activate or select a specific Menu or Submenu. It was noted in certain occasions that either a different location become activated or a different action is performed (e.g. the Views selections will open up if the silence key is pressed while the View menu is open)

Associated Release(s): Gemini Main US App **Ver: 0.3.5**

Release Notes: SCB 0.3.5 Build

- TPI value no longer starts at full bars - now zero bars (352)
- NVRAM now supports cross version changes (366, 367)
- New button bar with next page capability (371)
- Refactored list boxes for brightness, volume etc. (370, 389)
- Events are now sent out to the scientific data stream (386)
- View time is now saved and restored from NVRAM (392)
- Ability to flash SCB boot loader (378)
- Refactor of boot loader to have look of main application (374)
- Use of new patient/alarm limits configuration dialog (382)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.4**

Release Notes: SCB 0.3.4 Build

- Unified build of NSAM and SCB code
- A variety of NSAM algorithm changes
- Addition of a PC utility to verify scientific output
- Resolution of SPRs 709, 711
- Addition of error, audit, and service log accessible via telnet
- Brightness and volume displayed via a list box
- Added cleanscreen command to the telnet shell
- Login to the telnet shell with "machine9" changes to machine friendly mode

SPR	Description (Refer to QSP1026 for Risk Assessment)
709	**Set Audio Volume not automatically implemented:** The newly selected Audio volume is not always automatically implemented. It is sometimes necessary to enable or disable the Audio Silence for the new volume settings to be implemented.
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing. **Note/Mitigation**: Last Date & Time are also saved into the system Flash that will keep them unless the System Battery and AC are disconnected from the Unit. The User is instructed to/how set the Time and Date if the last setting was lost.

Associated Release(s): Gemini Main US App **Ver: 0.3.3**

Release Notes: SCB 0.3.3 Build

- Audio is now played for plugging in the preamp and sensor

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- Provide for scientific output only when $St0_2$ is valid
- $St0_2$ values are now rounded - NOT truncate
- Dialog boxes are now modal
- Use of a new generic "button bar" - should be transparent to the user
- New NSAM error message for low sensor temperature

SPR	Description (Refer to QSP1026 for Risk Assessment)	
708	**Incorrect Interpretation of Geographical Location of Entries on the Touch Screen**: User touches one location of the touchscreen in order to activate or select a specific Menu or Submenu. It was noted in certain occasions that either a different location become activated or a different action is performed (e.g. the Views selections will open up if the silence key is pressed while the View menu is open)	
	Probability	Occasional
	Severity	Minor
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
709	**Set Audio Volume not automatically implemented**: The newly selected Audio volume is not always automatically implemented. It is sometimes necessary to enable or disable the Audio Silence for the new volume settings to be implemented.	
	Probability	Frequent
	Severity	Negligible
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
710	**Not all Audio and Visual Alarms removed after Condition cleared**: It was noted that at certain occasions the Yellow or Red Alarm LED, the Yellow or Red Background on the system or channel message area and the High or Medium Priority Alarm Audio are not always removed after the condition (e.g. Low or Depleted Battery) has been cleared. Only the Alarm text message was removed. Same was observed with certain channel alarm conditions such as “External Interference”. Issue is only cleared if the Unit is power cycled or if a new alarm is initiated.	
	Probability	Occasional
	Severity	Minor
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing or defect	
	Probability	Frequent
	Severity	Negligible
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released

Associated Release(s): Gemini Main US App **Ver: 0.3.2**

Release Notes: SCB 0.3.2 Build

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- Double beep is once again playing at boot up time
- The UI is more resilient to fast keyboard touches - crashes have been prevented
- Access to the boot loader screen is now working
- Audio "click" is available when pressing buttons in the boot loader
- Audio is now played for plugging in the pre-amp and sensor

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.1**

Release Notes: SCB 0.3.1 Build

- Boot loader "bios" screen now displays the boot loader and main application version
- Bug fix: Audio "buzz" on start of the main application has been removed
- Shell touch screen playback now can be looped N times with a specified delay between loops
- Implemented loop back for DUARTs
- Clean screen feature partially implemented as a potential product feature
- New function in the shell to get and set parameters - prelude for manufacturing
- Dialog boxes in the main application now work without memory leaks or major problems
- Traces now display data. Limitation for now is that it is restricted to about 18 hours of data and does not persist through power cycles
- Scientific binary output is now provided through the DUART ports based on configuration in NVRAM. (Currently no GUI for this configuration.)
- Changes to the numeric key pad. Now includes a cancel button.
- A preliminary key “click” has been implemented only in the boot GUI. This plays key click in between any alarm being played. This is very preliminary and does not always sound correct.

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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3.7 Spectrum SCM Change Request (CR) for Gemini Builds (Newest to Oldest):

SCM Build: Package 1.1.1	
CR Number	**Description** (newest to oldest, except release CR)
Gemini001164	Package 1.1.1
Gemini001163	Add klog tools to Engineering Dialog
Gemini001160	OUS Configuration & Body Location (SPR 765)
Gemini001159	GUI Strings Translation (SPR 763)
Gemini001158	Dutch under STS & other string fixes(SPR 762-1)
Gemini001156	Reference Value: Horizontal dotted line not toggling (SPR 757)
Gemini001155	STS Data Calculation (SPR 756)
Gemini001154	NSAM Auto Event Mark on USB (SPR 755)
Gemini001153	Event Mark vertical dotted line (SPR 754)
Gemini001151	Clicking the Ref value does not toggle the Ref line on graph
Gemini001150	(b)(4) [redacted]
Gemini001149	Change STS statistics to match CSV
Gemini001148	Remove active case from USB save list (SPR 758 & 760)
Gemini001147	Numeric Field "Current Value" sometimes blank after fast boot (SPR 764)
Gemini001146	Remove unused Arial 14 point Narrow font (not used)
Gemini001145	In 4 CH CAS protocol, crash when baud rate is selected. (SPR 761)
Gemini001142	Add toggling bitmap Checkbox to Engineering settings dialog
Gemini001140	NSAM - Ignore Low brain 690nm values & do not include in spectral window calculation of "Sensor Off"
Gemini001136	In Italian "View" 24 Hour selection is 1Ore, should be 24 Ore (SPR 762-2)
Gemini001129	Caution - Investigational Device not displayed when engineering body locations are enabled

SCM Build: Package 1.1.0	
CR Number	**Description** (newest to oldest, except release CR)
Gemini001122	Package 1.1.0
Gemini001135	In Dutch "Pre induction base line ..." 1st char not Capitalized
Gemini001134	Help About Dialog: Serial number spacing is wrong.
Gemini001132	Add lookup string by language to PEG
Gemini001131	Russian events appear as "junk" in CSV file
Gemini001130	Russian keyboard problems.
Gemini001128	Text cosmetic changes
Gemini001127	Invalid login does not display dialog box.
Gemini001126	Minor format change of event output in the shell.
Gemini001125	Save Patient data to USB broke in Russian
Gemini001124	Do not display NSAM specific events.
Gemini001123	Silence not centered in Dutch
Gemini001121	Bug fix to event list display
Gemini001120	SensorLocation: Spacing missing between “Ch 2” and “Emplacement”.
Gemini001119	Saving...Done on save to usb missing ... if not English
Gemini001118	CAS/ATE - Add Model Number for OUS
Gemini001117	Help about dialog not correct. Overlap and gaps.
Gemini001116	Undefined users do not always give "Bad password" message

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Gemini001115	Engineering mode does not show all body icons when in Non US mode
Gemini001114	Correct Formatting in STS Data in USB file
Gemini001112	Correct Almost black to black in body location icons
Gemini001111	STS state does not persist when changing button bars
Gemini001110	Translation dead string removal, updates and corrections
Gemini001108	Setting Password in Russian displays ASCII keypad
Gemini001107	Message "Caution - Investigational Device" does not work correctly.
Gemini001105	German translations: Seconds and Minutes not consistent
Gemini001104	Reset body icons to L/R brain when changing between US/OUS
Gemini001103	Change "Service" button to "Biomed"
Gemini001101	Update Spanish translations using Eng-Spa GUI_Rev1MA file
Gemini001100	When logging in as "Service", all body locations are displayed
Gemini001099	Ports streams mismatch in NVRAM
Gemini001098	Create Mfg serial memory test for all 1st blocks
Gemini001097	Fix PN in Help -> "Sensor Selection" screen
Gemini001096	ICU Event list "Reposition Patient" should be Green Event after "Prostaglandin
Gemini001095	Add languages to USB patient file
Gemini001094	USB File - need to add a decimal digit precision to STS data
Gemini001093	NSAM - Adjust Sensor Off Temp,, Adjust Low Thb levels, High Ambient Light
Gemini001092	Update German, Russian & Dutch strings
Gemini001091	Correct formatting for ThresholdSaturationCell
Gemini001090	Update Spanish translations
Gemini001089	Center Right/Left above pics in body location dialog
Gemini001088	Update French translations
Gemini001087	Adjust sensor location dialog size and location
Gemini001086	Unit Test CheckSystemStatus Battery Low fails
Gemini001084	Body location dialog not centered
Gemini001083	Restore the CheckNSAMStatus Unit Test Functionality
Gemini001082	Cosmetic & stability fix. Ports dialog border & Baud text overwriting
Gemini001081	Add translation for Ports -> scientific.
Gemini001080	Modify temperature/fan algorithm slightly
Gemini001079	NSAM - Add Adult Somatic IFU, adjust Adult Cerebral TPI Levels
Gemini001078	Modify one wire CRC logic for old/new
Gemini001077	Add body location icons when In OUS mode
Gemini001076	Minor cleanup CurrentSystemUser and MainScreen
Gemini001075	Add scientific mode to all users.
Gemini001074	Change isOUS flag to isOS for Outside US logic
Gemini001073	Add Patient Id to USB File Name
Gemini001072	Add streaming capability to time and date objects.
Gemini001071	CAS/ATE Remap Unstable Signal status
Gemini001070	NSAM - Do not invalidate 1 wire type when getting 1 wire S/N (MFG build)
Gemini001068	Add string utility functions.
Gemini001067	STS - Add one decimal digit to Cumulative Sat Below Thresh & Reg O2 % Ranges

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Gemini001066	STS Button loses state on screen switch.
Gemini001065	Add White Background body location images
Gemini001064	Change Brightness settings scale
Gemini001063	Update Dutch strings
Gemini001062	Adjust priorities and error messages
Gemini001061	Add automatically generated events based on special NSAM conditions.
Gemini001060	diag -ext in shell does not work in manufacturing boot loader
Gemini001059	Change shell name from Gemini to Fore-Sight Elite
Gemini001058	Add confirm dialog to Stop STS data
Gemini001057	Correct underlying alarm led and audio problems.
Gemini001056	(b)(4) [redacted]
Gemini001055	
Gemini001054	Entering Biomed password will display Button bar with Language and defaults
Gemini001053	Create Unit test of one wire Serial memory
Gemini001052	Create secondary level of reporting NSAM issues to the user.
Gemini001051	Refactor binary file code.
Gemini001050	NSAM - MFG build doesn't build
Gemini001049	NSAM - Enhance the Bovie Filter
Gemini001048	NSAM - Adjust high Ambient Light Threshold
Gemini001047	Special file on the USB stick automatically starts the network.
Gemini001046	Code clean up.
Gemini001045	Create serial memory tests
Gemini001044	NSAM - Enable the Enhanced AGC, allow higher dynamic range for the gains
Gemini001043	NSAM - Account for the 1 wire temperature NSAM offsets & Code Cleanup
Gemini001042	(b)(4) [redacted]
Gemini001041	External Interference causes the Numeric field to go blank instead of dashes
Gemini001040	Change action when time exceeds high limit
Gemini001039	Change checkout type in SharedGui
Gemini001038	Rapid changes in Settings-View causes crash
Gemini001037	Change level of memory warning reporting level.
Gemini001035	Clean up Peg wbx file
Gemini001034	Add Dutch string updates
Gemini001033	NSAM - Add for MFG ability to get the 1 wire device S/N
Gemini001032	Minor code cleanup.
Gemini001030	Adjust Ambient light upper threshold for NSAM test
Gemini001029	Add Cyrillic keypad. Update strings in some languages
Gemini001028	Modify PEG to group Do Not Translate strings
Gemini001027	Create new SIDs for events to Group them
Gemini001026	Touch screen calibration range check.
Gemini001024	Minor code cleaning.
Gemini001023	Add integer to hex string functions.
Gemini001022	Add new Italian strings to PEG and correct help screen punctuation

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini001021	Implement adaptive fan speed based on internal temperatures.
Gemini001020	STS Data field too small
Gemini001019	Add Russian Language, Update Russian keypad
Gemini001013	Fix problems noted in CR 990
Gemini001008	Add commands specific to 4 channel ATE/CAS protocol
Gemini001003	Monitor reset if Factory Defaults activated
Gemini001000	Possibility to delete more than the last Event entered
Gemini000965	Rapid switching between Event button and Undo button causes crash
Gemini000949	Event Menu Freeze
Gemini000928	Sensor Off Tissue and StO2 Value
Gemini000827	Serial Stream Crash when configuring a second port
Gemini000746	Correct redraw speed of numeric fields
Gemini000667	Modify TaskClassBase management of pool and queue

SCM Build: Package 1.0.2

CR Number	**Description** (newest to oldest, except release CR)
Gemini001018	Package 1.0.2
Gemini001017	Spelling incorrect for "Venous Return Down"

SCM Build: Package 1.0.1

CR Number	**Description** (newest to oldest, except release CR)
Gemini001014	Package 1.0.1
Gemini000978	Increase the size of Help About for French and make month text
Gemini000979	Add Russian key pad
Gemini000983	Correct image palettes
Gemini000987	Correct underlying code for snapshot functionality
Gemini000988	Sto2 seems to be truncated and not rounded
Gemini000989	Add 4 Channel CSV serial stream output
Gemini000990	Add 4 Channel ATE/CAS serial stream output
Gemini000991	Minor shell typos
Gemini000992	Fix STS output problems
Gemini000993	NSAM - Spikes above "High Ambient Light" will reset ""Ambient Light" de-bouncing / warning
Gemini001001	New update to Events: Reposition head/heart etc.
Gemini001004	ECLs off event is attached to ECL's On and saves to USB wrong
Gemini001006	NSAM - LPF Ambient light
Gemini001007	Correct mapping of Faulty Clock Battery SPR744
Gemini001010	diag -ext response has changed
Gemini001015	Add audit trail events for channel and system errors
Gemini001016	Correct package version update in the boot loader

SCM Build: Package 1.0.0

CR Number	**Description** (newest to oldest, except release CR)
Gemini000986	Package 1.0.0

SCM Build: Package 0.4.0.D

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CR Number	Description (newest to oldest, except release CR)
Gemini000976	Package 0.4.0D
Gemini000977	Recover lost code
Gemini000975	Force restart after port config change
Gemini000973	(b)(4) [redacted]
Gemini000971	Change Help Dialogs, Fix Strings & Events
Gemini000948	CAS ATE Protocol and 2-Minute Audio Disabled State
Gemini000824	Power up with active VueLink connection

SCM Build: Package 0.4.0.C

CR Number	Description (newest to oldest, except release CR)
Gemini000945	Package 0.4.0C
Gemini000970	NSAM - Disable AGC Enhancements, Default MFG build setting
Gemini000969	Increase stack size for USB and Flasher task.
Gemini000967	Crash when pressing OK twice to cancel a case save USB
Gemini000966	Translation String length tweaks
Gemini000963	New Sensor Off remapping of warnings
Gemini000962	NSAM - Sensor off enhancement
Gemini000961	Baud Rate Selection on CAS ATE and CSV Output
Gemini000960	The “g” in the “Saving… %” & “Saving…Done” overwritten by line below
Gemini000959	Add Boot exception handling
Gemini000958	Use simple printf to clean up some USB output code.
Gemini000957	Add improved performance sprintf.
Gemini000956	Alarm strings Translation Switch
Gemini000955	ATE/CSV Alarm State update
Gemini000954	StO2 Values Differences between Values on Display and on ATE/IntelliBridge Devices
Gemini000953	System crash during second Patient File saving
Gemini000952	STS Stop Key update
Gemini000951	STS Warning at end of STS Data Collection
Gemini000950	Fix plain text Ch, Hrs, L/R icon, and other strings
Gemini000947	Add German, Italian, Russian, Spanish, Dutch Translation
Gemini000946	Add "Do not remove USB" to case save dialog
Gemini000943	Previous Reference Value on Numerics Display right after Channel Activation
Gemini000923	Defaults Menu only Partially Implemented
Gemini000915	Red LED Alarm Flashing Rate
Gemini000881	NSAM - Enhance AGC
Gemini000701	LED & Audio remains after condition clears

SCM Build: Package 0.4.0.B

CR Number	Description (newest to oldest, except release CR)
Gemini000945	Package 0.4.0B
Gemini000944	Add the ability to wipe the system clean in the manufacturing boot loader.
Gemini000942	Improve USB save performance.
Gemini000940	Data Collection prevented until 1 valid channel
Gemini000935	Incorrect IntelliBridge/VueLink Communication Error Message

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000934	Language is lost at reboot
Gemini000933	Increase size of Patient Setup Hi/Low limit buttons for 5 French
Gemini000929	Patient File deletion - Confirmation Screen/Menu Missing
Gemini000927	Add French Translation to PEG
Gemini000925	USB Data Saving Progress Status
Gemini000921	STS allowed to start without Patient Data
Gemini000920	Event Mark Line not removed after New Patient
Gemini000918	Patient File not saved after switching to a new Patient
Gemini000917	STS Feature only working for current cases
Gemini000916	Patient Files deleted/lost after Time & Date change
Gemini000914	Display IP address when TCP/IP button is pressed.
Gemini000913	Move Scientific output to engineering mode ONLY.
Gemini000825	Hitting exit during Save Case to USB causes crash.

SCM Build: Package 0.4.0.A

CR Number	**Description** (newest to oldest, except release CR)
Gemini000903	Package 0.4.0A
Gemini000882	NSAM - Add Authentication code to sensor 1 Wire
Gemini000891	Amend battery shutdown
Gemini000892	Prevent new channels from being tracked after starting STS data
Gemini000894	Modify Gemini button list selection
Gemini000895	Remove display of IP address from boot loader
Gemini000896	Modify NVRAM configuration
Gemini000897	NSAM - Low THB Warning on super outlier
Gemini000898	Clear shutdown error detected
Gemini000899	Modify new patient dialog setting to 30 minutes
Gemini000900	Add ability to activate SAM and related tasks in the boot loader
Gemini000901	Set first time started time in NVRAM
Gemini000902	Force package information update in NVRAM even when no update is necessary
Gemini000904	Add touch screen play back with random variation
Gemini000905	Add a monitor feature to the shell touch screen
Gemini000906	Add cap in sleep time in touch screen playback
Gemini000907	STS On/Off button: Remove image jitter
Gemini000908	Remove grey "STS data" from top of main screen when disabled
Gemini000909	Ensure negative number does not occur in touch screen playback
Gemini000910	Occasional crash with initial new patient dialog at boot-up time
Gemini000911	Change "Cannot save current case" to USB file error
Gemini000912	Increase size of text boxes at top of MainScreen

SCM Build: Package 0.3.2G

CR Number	**Description** (newest to oldest, except release CR)
Gemini000885	Package 0.3.2G
Gemini000337	Unit test involving RTC failed in the Windows environment
Gemini000476	NSAM - Support Preamp Offsets
Gemini000724	Remove unused stings in PEG
Gemini000833	Display of channels w/unused body locations in STS View

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Gemini000834	Make number in numeric field launch Patient Setup Dialog
Gemini000844	Update USB output
Gemini000846	Change "FS Data" in title bar to "STS Data"
Gemini000848	Update Factory Default dialog Title & Text
Gemini000852	Update Patient Data Flow operation
Gemini000858	Add Battery state icons
Gemini000862	Add flag to indicate connection status
Gemini000864	Add display of any external port communication errors
Gemini000865	Remove unused GUI colors. Fix R brain color
Gemini000866	Add title to Events dialogs. OR Events, ICU, Vascular, NICU
Gemini000867	Title Bar Launch Dialogs for ID, View & Time
Gemini000868	Add processing of battery state
Gemini000869	USB Case Management: Update dialog boxes
Gemini000870	Update events as per marketing changes
Gemini000871	Change STs/FS icon to STS
Gemini000872	Ports dialog shall not update configuration if no user changes made
Gemini000873	Engineering dialog in Boot screen shall be password protected
Gemini000874	Update battery thresholds
Gemini000875	Restart Accumulations with New Patient plus other display enhancements
Gemini000876	Minor changes to Event Lists
Gemini000877	Add new battery icons
Gemini000878	Change language from Swedish to Dutch
Gemini000879	Update battery behavior
Gemini000880	Remove factory default button
Gemini000883	Fix Alarm Suppress color
Gemini000884	Change battery level logic
Gemini000886	Home button appears gray. Change back to green
Gemini000887	Normalize colors, fix greens
Gemini000888	Add "Factory Defaults" button
Gemini000889	Improve startup of system with new patient dialog
Gemini000890	Modify saved patient information to USB

SCM Build: Package 0.3.1G

CR Number	Description (newest to oldest, except release CR)
Gemini000841	Package 0.3.1G
Gemini000821	Remove next button on button bar for manufacturing
Gemini000826	Fix spacing and size of Alpha keypad. Add missing image files
Gemini000828	Selection of body location from numeric field causes error
Gemini000829	On alpha keypad the remaining characters is not initialized
Gemini000830	When using keyboard for password, hide char entry
Gemini000831	New VueLink/IntelliBridge condition messages to handle
Gemini000832	Change dialog text when asking for new patient after body location change
Gemini000836	Minor code cleanup
Gemini000837	Use white image background on body location icons when rendered on white
Gemini000838	Change USB to File icon in Setup->Files menu

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Gemini000839	Change order of Events button bar to “OR ICU Vascular”
Gemini000840	Add "investigation use only" message at exit of Engineering screen if any alarm is disabled
Gemini000842	Round corners of Silence and Home icons
Gemini000843	Reduce size of backspace key in Alpha keypad
Gemini000845	Change Splash Screen to TM (trade mark)
Gemini000849	When Ref button touched, draw all corresponding dashed reference lines
Gemini000863	Update various GUI text strings

SCM Build: Package 0.3.0G

CR Number	**Description** (newest to oldest, except release CR)
Gemini000797	Package 0.3.0G
Gemini000449	NSAM Bootloader & Main Software download without NSAM Module
Gemini000473	Occasional RTC loss of time and date
Gemini000490	Not Responsive Power switch Button
Gemini000595	No Event Marks on trace after Power cycle
Gemini000727	Transition from 2 channel CSV to off causes system crash
Gemini000737	Peg wbx updates for clean XLIF translation file
Gemini000738	Continue with ATE Implementation
Gemini000753	Have new patient confirmation dialog ask "New Patient?"
Gemini000754	Replace the TCP/IP message box with a Gemini dialog based message box
Gemini000766	Correct new patient action
Gemini000767	Add crisper button bar images
Gemini000768	Slight refactor of the network dialog
Gemini000769	Add more events
Gemini000770	SCB BootLoader about won't display NSAM BootLoader version when NSAM main is not available
Gemini000771	Font too Big in Numeric Field 4 ch mode
Gemini000772	Add new/continue patient timers & prompting
Gemini000773	Add fields to data file export
Gemini000774	Data file export cleanup
Gemini000775	Display view time was not updating on the main screen
Gemini000776	Disable greying out and dynamic area under curve feature
Gemini000777	Add alarm delay to NVRAM
Gemini000778	Add alarm limits to the business layer
Gemini000779	Add alarm delay to the user interface
Gemini000780	Allow Util message box to use string ID's
Gemini000781	Remove bitmap numbers in patient setup. Add header
Gemini000782	Add ATE Commands
Gemini000783	Move events strings and dialog to shared GUI
Gemini000785	Move Patient ID down in Main screen
Gemini000786	Add code to allow external modules access event string and color information
Gemini000787	Re-order time date dialog to Day-Month-Year
Gemini000788	Allow clearing/setting of package in NVRAM from the shell
Gemini000789	UNDO of a selected event leaves dashed lines on multi-graphs
Gemini000790	Remove unused USB icons and FS icon

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000791	Hitting SAM reset switch during SAM boot update leaves SAM inoperable
Gemini000793	Detect presence of SAM Mfg build on SAM
Gemini000794	Correct problems with VueLink/IntelliBridge
Gemini000795	Do not cancel current patient if time not changed
Gemini000796	Launch help dialogs when help buttons pressed. Phase 1: No content
Gemini000798	Fix code refactoring problems
Gemini000799	Correct touch play back feature in shell
Gemini000800	Add button to Eng Mode to turn off alarms
Gemini000801	NSAM - Main version bump
Gemini000802	Modify vascular event list
Gemini000803	Remove power button hysteresis
Gemini000804	Temporarily remove NICU event button
Gemini000805	Add touch screen scripts
Gemini000806	Package Updater display items
Gemini000807	Setting year in date/time dialog sets the date to 4 digits
Gemini000808	Add events to output data file
Gemini000809	Transition from 2 channel CSV to off causes system crash
Gemini000810	New battery and backspace icons. Icons updated true black background
Gemini000811	NSAM - Invalidate Sto2 for "Signal Out of range"
Gemini000812	Change Help-About Foresight logo
Gemini000813	Broke Win32 build when fixing flash update issues
Gemini000814	Add content to help dialogs
Gemini000816	Remove unique ID from Case Mgmt dialog
Gemini000817	Remove Russian from Language dialog. Change view dialog to one column
Gemini000818	Change cancel icon to wide on baud dialog. Fix L icon to black
Gemini000820	Fix BL unit test

SCM Build: Package 0.3.0F

CR Number	**Description** (newest to oldest, except release CR)
Gemini000764	Package 0.3.0F
Gemini000765	NSAM - Bump Bootloader version
Gemini000763	Default IP address change
Gemini000762	NSAM - Increase High Temperature Threshold, Lower Brain Low signal Thresholds, Lower high Ambient Light Threshold
Gemini000761	Stop in boot loader if trigger file is detected on USB stick
Gemini000760	Display investigational unit based on NVRAM settings
Gemini000759	Have core file dump at shut down save with date/time format
Gemini000758	Increase usability of Save to File progress reporting
Gemini000757	Decrease CPU utilization of the OS health manager
Gemini000756	Reset reference on a new patient
Gemini000755	Add "Are you sure?" to the new patient button
Gemini000752	Ask if new patient if different body location
Gemini000751	Allow network to only be started once. Provide better user feedback
Gemini000750	Minor text change
Gemini000749	DataManager cleanup and refactoring
Gemini000748	Extend core dump to include audit and error logs

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000747	Create a start-up thread
Gemini000745	Activate special investigation mode text
Gemini000744	Add TCP-IP address dialog
Gemini000743	Fix redraw speed of numeric fields
Gemini000741	Fix saving of case to file to save data
Gemini000740	Exiting patient setup with cancel still allows changes to stick
Gemini000739	Add ability to modify TimeDataStore size for testing
Gemini000736	Move FlashUpdateDialog from Mfg and Boot to Shared Dir
Gemini000691	NSAM - Main & boot NSAM Flash update failure
Gemini000673	Package updater starts before SAM is booted and does arbitrary update of SAM
Gemini000596	Reference values on Numerics area right after Channel Reactivation
Gemini000572	Gap in Data Records
Gemini000570	Time & Date changed during Software upgrade
Gemini000549	Add USB detect stick to the shell

SCM Build: Package 0.3.0E

CR Number	Description (newest to oldest, except release CR)
Gemini000725	Package 0.3.0E
Gemini000735	Prevent invalid data entries from being saved in data stores
Gemini000734	Fix TimeDataStoreCollection unit test
Gemini000733	Save core file to any present USB memory stick instead of NVRAM
Gemini000731	Make flash update dialog a shared GUI entity
Gemini000729	Add investigational use text when in entering special system modes
Gemini000728	Do not start SAM in the manufacturing build
Gemini000726	Center alpha dialog box
Gemini000723	NSAM - Flash Update failure
Gemini000722	Modify various UI components to return values
Gemini000721	NSAM - Overriding Monitor PD values
Gemini000719	Various GUI related changes
Gemini000718	Cannot update boot loader from manufacturing build
Gemini000717	Add ATE Serial Protocol & UI
Gemini000715	Create a Shared PEG GUI wbx project to share dialogs between projects
Gemini000714	Add button to turn TCP-IP on. Set it off by default
Gemini000713	USB. MQX error on usb drive removal
Gemini000712	Add Events to CSV Serial Stream
Gemini000711	Add information to core dump
Gemini000710	Grid lines appear when graph layout changes
Gemini000709	Case Table related cleanup
Gemini000708	Core dump diagnostic feature
Gemini000707	Do not start SAM and data tasks in boot
Gemini000700	Add Simple CSV Serial Output Stream
Gemini000698	Add "Are you sure" dialog
Gemini000694	Add manufacturing default
Gemini000674	Increase size of data elements to store alarms
Gemini000624	Improve graph update timing

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SCM Build: Package 0.3.0D	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000706	Package 0.3.0D
Gemini000705	GUI hangs and does not register button up for several seconds. Intermittent
Gemini000704	Modify stack sizes to accommodate log and debug
Gemini000703	Add audit trail information to the main application
Gemini000702	Add OS Health manager dump from shell
Gemini000699	GUI updates, Alpha keypad
Gemini000697	NSAM - TOP Lock / outlier decision after a certain period of time in the case
Gemini000696	Change manufacturing splash screen
Gemini000695	Memory crash problem - Change in serial stream
Gemini000693	Add Asserts to fopen in serial stream based entities
Gemini000692	NSAM - MFG features enhance sensor calibration and support diagnostics info for the NSAM test
Gemini000689	NSAM - 1.Sto2 out of range will sometimes not report an error. 2. Add NSAM ADC offsets
Gemini000688	Modify set date/time
Gemini000687	NSAM - Turn off LEDs of an invalid sensor
Gemini000686	Set event list background color instead of text color
Gemini000685	Add UNDO to event list
Gemini000684	Add case management dialog
Gemini000683	Make event mark circles match the event code color
Gemini000682	Add information to the about dialog box
Gemini000681	Draw in filled circle on graph
Gemini000680	Modify touch of numeric area
Gemini000679	Remove quick event
Gemini000678	Auto detection of USB with SW package
Gemini000677	Problems updating SCB boot in the package updater
Gemini000676	Default parameters in shell are being set to zero
Gemini000672	Remove set task error if fopen fails and fix any fopen that fails to check null
Gemini000666	Improve efficiency of PegString
Gemini000646	Add Case Table
Gemini000569	Alarm Audio not always on during System Alarm state
Gemini000550	Closing the command window with a shell session causes the system to crash
Gemini000527	Audio Volume set to zero without apparent reason
Gemini000207	Add battery one wire back into the one wire table

SCM Build: Package 0.3.0C	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000671	Package 0.3.0C
Gemini000670	Modify task stack sizes
Gemini000669	Add additional debug information to the MQX kernel
Gemini000668	PEG ICON fix body locations
Gemini000665	Increase PegString buffers to prevent memory errors
Gemini000664	Fix GeminiTextButton constructor
Gemini000663	Fix Peg colors. Remove transparent icon from button bar

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Gemini000662	GUI updates: STS dialog, etc.
Gemini000661	NSAM - Adjust Sensor Off parameters and behavior
Gemini000660	System Message background color remains non-black when error clears
Gemini000659	Numeric Key pad -Auto close on valid data
Gemini000658	Shell error
Gemini000657	Address various system shutdown issues
Gemini000656	Add in 1-wire power test in POST
Gemini000655	Modify Serial dialog to add new stream protocol
Gemini000653	NSAM - Enable a retry in reading the sensor 1 -wire 2nd page
Gemini000652	NSAM - Lower thresholds for Monitor PD levels with Phantoms
Gemini000651	Add Keypad for patient ID input
Gemini000650	Move Update Package from Eng Mode bar to first Boot bar, first item
Gemini000649	Modify temperature monitoring to be more distributed in time
Gemini000648	Display task name along with ID when logging
Gemini000647	Add Transparent Icons to button bar
Gemini000645	Fix Boot update: Add Software Version Package to Help button
Gemini000644	Adjust system stack, poll rate, etc. to avoid system problems
Gemini000641	Add basic output of patient data to file
Gemini000638	Copy NSAM *.txt files to the Binaries Directory after build
Gemini000630	System crash if all channels are set to "Unused"
Gemini000629	Occasional system crashes related to network traffic
Gemini000626	Incorrect STS Percentiles Range Distribution

SCM Build: Package 0.3.0B

CR Number	**Description** (newest to oldest, except release CR)
Gemini000640	Package 0.3.0B
Gemini000643	Change image displayed on manufacturing build
Gemini000642	NSAM - Fix debouncing in Sensor Off for recalculating TOP
Gemini000639	Enhance kernel logging in the shell
Gemini000637	Change Data limits of the NSAM test
Gemini000636	Add Software Version Package to Help button
Gemini000635	Add handling for new NSAM messages related to Sensor Off and Sensor Lifting
Gemini000634	Add kernel logging function to shell
Gemini000633	Fully implement validity test of SAM data on the SCB
Gemini000632	Random Crash with scientific serial steam enabled
Gemini000627	Modify task stack sizes
Gemini000625	Add password-protected button bar for service/developer actions
Gemini000623	NSAM - Add sensor S/N to scientific data
Gemini000606	Modify data management for Numonyx
Gemini000477	NSAM - Sensor on / off detection

SCM Build: NSAM 0.7.4d

CR Number	**Description** (newest to oldest, except release CR)
Gemini000662	NSAM - Lower thresholds for Monitor PD levels with Phantoms
Gemini000661	NSAM - Adjust Sensor Off parameters and behavior
Gemini000653	NSAM - Enable a retry in reading the sensor 1 -wire 2nd page

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SCM Build: NSAM 0.7.4b	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000642	NSAM - Fix debouncing in Sensor Off for recalculating TOP
Gemini000623	NSAM - Add sensor S/N to scientific data
Gemini000477	NSAM - Sensor on / off detection

SCM Build: Package 0.3.0A	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000619	Ensure NVRAM elements are valid
Gemini000618	Document NVRAM debug facility
Gemini000617	Fix Boot to build with PackageUpdate dialog
Gemini000615	Save graph layout and Language to NVRAM on user change. Restore at start.
Gemini000608	Add Numonyx M29W128GL flash device driver
Gemini000607	Fix Boot and Manufacturing builds for RAM release
Gemini000584	Alarm silence countdown
Gemini000571	System Resets due to VueLink Connection
Gemini000561	Create a validity test of SAM data on the SCB.

SCM Build: Package 0.2.0A	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000616	Package 0.2.0A
Gemini000614	Add graph channel layout and grids to NVRAM.
Gemini000613	GUI: Ch 2 and 4 text, swap Body icons, etc
Gemini000612	Add State aware Start and Stop to STS button on button bar
Gemini000610	Correct colors in PEG builder.
Gemini000609	A second dialog for alarm limit numerics sometimes appears.
Gemini000605	Move all code to run from RAM
Gemini000601	Implement package update system

SCM Build: Package 0.1.0C	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000604	Package 0.1.0C
Gemini000603	Allow highlight of list box items.
Gemini000602	Add toggle state persistence to button bar buttons. Second phase
Gemini000599	Event dialog box does not redraw numeric fields.
Gemini000598	Add set of individual colors to button list dialog.
Gemini000594	NumericKeyPad does not handle empty entry properly
Gemini000593	Add support to srecordchecksum for new SAM app part numbers
Gemini000592	NSAM - Don't allow the HOST task to start before the channels have been initialized
Gemini000591	Rework Gemini button base class.
Gemini000590	Add lightweight debug info system
Gemini000589	Investigate long shutdown time on some systems
Gemini000588	Selecting the port selection within Port menu causing a system crash (SPR 716)
Gemini000587	NSAM - Sensor test fixture option - use default temperature offset

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SCM Build: Package 0.1.0B	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000580	Package 0.1.0B
Gemini000583	Change button bar bitmaps to allow text at bottom
Gemini000582	Change FlexBus Chip Selects to be inputs
Gemini000578	Add text strings for button bar
Gemini000577	Fix graph crash when big gap in data at startup
Gemini000575	Fix data delivery and display with multiple TimeDataStores
Gemini000574	Alarm message is lost when screen is reconfigured 2 <-> 4 channel
Gemini000573	GUI updates
Gemini000568	Numeric key pad does not work.
Gemini000567	Ref values lost after switching from 4 to 2 channels
Gemini000566	System Alarm LED & VGA left on during shutdown sequence
Gemini000564	Add toggle state persistence to button bar buttons
Gemini000545	Modify the button bar to display text on the bottom of the icons.

SCM Build: Package 0.1.0A	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000563	Package 0.1.0A
Gemini000565	Temporary patch to handle power off gaps in graphs
Gemini000562	Add touch zone to NumericField to launch patient setup dialog
Gemini000560	Add package number to NVRAM
Gemini000559	Clean up namespace dependencies
Gemini000558	Change various GUI screens for consistency
Gemini000557	Increase task priority of spawn manager to improve performance
Gemini000556	NSAM - TOP 690/730 outlier transition / detection
Gemini000555	Modify STS dialog spreadsheets to be more narrow
Gemini000554	Set STS threshold to 75% of the starting value
Gemini000553	Create calls to manage patient data in flash memory
Gemini000551	NSAM - Averaging of StO_2 Values
Gemini000548	Large dialog box was being improperly displayed centered on the screen
Gemini000547	Increase log delta time from 4 to 6 digits
Gemini000546	Add more information to Gemini statistics
Gemini000544	NSAM - Remap channels to accommodate Mt. Sinai IRB channel ordering
Gemini000543	Modify PEG spread sheet object to disable display of scroll bars
Gemini000542	Ref / AUT wiring through UI
Gemini000540	Add fields to STS Dialog
Gemini000539	Combine logic in PegUtil for setNumericValue with comma
Gemini000538	Add transfer of data from NVRAM to flash
Gemini000537	Modify PEG to support screen snapshot
Gemini000535	Modify power down process to be more user responsive
Gemini000534	Improve main application start up
Gemini000533	Add STS dialog
Gemini000532	Add in collection of case statistics
Gemini000531	Jump to main from boot quickly in the event of a power down incorrectly.
Gemini000530	Clean up main screen code

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Gemini000529	Normalize how list dialogs are displayed
Gemini000528	Modify system files to support PEG languages
Gemini000526	Auto center dialogs.
Gemini000525	fix a few drawing issues in graph
Gemini000524	Create shell macros facility
Gemini000523	Add cleanup for each task when system is powering down
Gemini000521	Clean up patient info to UI wiring
Gemini000518	Change task priorities to accommodate serial input
Gemini000517	Save improper power down into the error log
Gemini000514	Fix log merging changes to compile under Windows build
Gemini000513	Move data store from RAM to NVRAM
Gemini000512	Add error logging to serial loopback
Gemini000511	Allow pollute blocks to be turned on/off dynamically via the shell.
Gemini000510	Add machine to human mode command in shell.
Gemini000509	Cancel on event drop menu still drops an event.
Gemini000508	Adjust new priority scheme (see description)
Gemini000507	Change warning levels for memory health.
Gemini000506	PEG startup sync code broke manufacturing build
Gemini000503	Ports Configuration Setting
Gemini000501	Fix Boot to not run out of memory
Gemini000499	Provide mechanism for intermingled ErrorLog and AuditLog data
Gemini000498	Add Channel Errors and Warnings for VueLink
Gemini000480	Implement 4-channel overlay and controls
Gemini000478	Add language support
Gemini000454	StO_2 on graph is being truncated and not rounded

SCM Build: Gemini 0.3.6C	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000548	Large dialog box was being improperly displayed centered on the screen.
Gemini000546	Add more information to Gemini statistics
Gemini000543	Modify PEG spread sheet object to disable display of scroll bars.
Gemini000540	Add fields to STS Dialog
Gemini000539	Combine logic in PegUtil for setNumericValue with comma
Gemini000537	Modify PEG to support screen snapshot
Gemini000535	Modify power down process to be more user responsive
Gemini000534	Improve main application start up
Gemini000533	Add STS dialog
Gemini000532	Add in collection of case statistics
Gemini000531	Jump to main from boot quickly in the event of a power down incorrectly
Gemini000530	Clean up main screen code
Gemini000529	Normalize how list dialogs are displayed
Gemini000528	Modify system files to support PEG languages
Gemini000526	Auto center dialogs
Gemini000525	fix a few drawing issues in graph
Gemini000524	Create shell macros facility

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000523	Add cleanup for each task when system is powering down
Gemini000521	Clean up patient info to UI wiring
Gemini000518	Change task priorities to accommodate serial input
Gemini000517	Save improper power down into the error log
Gemini000514	Fix log merging changes to compile under Windows build
Gemini000513	Move data store from RAM to NVRAM
Gemini000512	Add error logging to serial loopback
Gemini000511	Allow pollute blocks to be turned on/off dynamically via the shell
Gemini000510	Add machine to human mode command in shell
Gemini000509	Cancel on event drop menu still drops an event
Gemini000508	Adjust new priority scheme (see description)
Gemini000506	PEG startup sync code broke manufacturing build
Gemini000499	Provide mechanism for intermingled ErrorLog and AuditLog data
Gemini000498	Add Channel Errors and Warnings for VueLink

SCM Build: Gemini 0.3.6B

CR Number	**Description** (newest to oldest, except release CR)
Gemini000504	0.3.6B Release notes
Gemini000505	run checkmessage in samman in debug build
Gemini000493	Reorder task priorities
Gemini000500	Block peg task until RTC is read
Gemini000481	Make sure logging classes clean up varargs in all return paths

SCM Build: Gemini 0.3.6A

CR Number	**Description** (newest to oldest, except release CR)
Gemini000492	0.3.6A Release notes
Gemini000496	Test graph startup
Gemini000488	Serial Stream baud/protocol not saving correctly
Gemini000483	Make the event markers work
Gemini000489	Have the screen display earlier in the boot sequence
Gemini000491	For debugging, make graph optional (conditional compile)
Gemini000495	Fix Windows app build errors relating to SerialSpawnManager
Gemini000497	Fix the array of Win32 compiler warnings in pegStringArray
Gemini000475	Create message distribution mechanism
Gemini000487	Change the VueLink Specification File
Gemini000486	Add new strings and remove obsolete strings in PEG

SCM Build: Gemini 0.3.6

CR Number	**Description** (newest to oldest, except release CR)
Gemini000482	0.3.6 Release notes
Gemini000485	Make shell access to NVRAM numbered sections sync'd
Gemini000484	Add 15 second power button hold of reset into the manufacturing build
Gemini000479	fix warnings in GeminiButtonListDialog in windows build
Gemini000474	Power button press and hold in boot loader to reset NVRAM
Gemini000472	Implement on-the-fly graph layout changes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000471	Add in case simulation data
Gemini000470	Protocol and Baud dialog: Add Correct Header and show selected values
Gemini000469	Modify Build to Fix Problem
Gemini000468	First Event list shall display OR events
Gemini000467	Update error logging
Gemini000466	Clean up graph object
Gemini000447	Add GUI serial port configuration
Gemini000439	Create flash file access task
Gemini000426	High Pitch Tones while On Battery
Gemini000408	Slow plug in of preamp causes 2nd preamp to show disconnect
Gemini000395	Add Philips VueLink DataStream handler
Gemini000387	Add VueLinkConverter to Tools
Gemini000265	Graph data does not start at right hand side of graph

SCM Build: Gemini 0.3.5E

CR Number	**Description** (newest to oldest, except release CR)
Gemini000465	0.3.5E Release notes
Gemini000462	Add OS health manager problems to the error log
Gemini000461	Change boot loader text of "Gemini" to "Fore-Sight Elite"
Gemini000460	Allow of reset of sections of NVRAM from the shell
Gemini000459	Create system setting that will prevent the OS health manger from rebooting
Gemini000458	Add RTC-SRAM Battery Health Monitor - SPR # 711
Gemini000456	Allow for display of help by search in the shell
Gemini000448	Add task class analysis and control from the shell
Gemini000446	Add system error detection code to be displayed in the boot loader
Gemini000365	RTC battery fault not displayed - SPR # 711

SCM Build: Gemini 0.3.5D

CR Number	**Description** (newest to oldest, except release CR)
Gemini000452	0.3.5D Release notes
Gemini000455	Events size too big
Gemini000453	Bug fixes, Added boot delay, Fix GUI artifacts
Gemini000451	Temporarily increase peg task timeout
Gemini000450	Numeric Field does not always work
Gemini000445	Correct shell help
Gemini000441	GUI updates

SCM Build: Gemini 0.3.5C

CR Number	**Description** (newest to oldest, except release CR)
Gemini000442	0.3.5C Release notes
Gemini000444	Minor fix to Windows build
Gemini000443	Remove obsolete MainConfigWindow.cpp from the windows project
Gemini000440	Button bar blank when no bitmap is used (as in boot mode)
Gemini000438	Make greater use of error log and audit trail

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Gemini000437	Clean-up before create file access task
Gemini000435	Audio Volume not matching set Volume level - SPR #710
Gemini000432	Date Auto Correct without warning
Gemini000431	Create a shell tool to detect threads
Gemini000430	Add display of error messages in the shell
Gemini000429	Out of Range Issue with Preamp or Sensor disconnected
Gemini000428	Account for monitor ADC offsets while calculating sensor temp
Gemini000427	Clear alarms / signal warnings when a channel has been invalidated
Gemini000425	Color themes: Unify Gemini code with PEG
Gemini000424	Fix (so far inconsequential) typo in duart init structure
Gemini000423	Allow SAM communications to lag more before triggering restart strategy
Gemini000422	Add header to numeric keypad, Clean up old Limits logic
Gemini000421	Support updated 1-Wire information for sensors
Gemini000420	Create a manufacturing build application
Gemini000418	Remove 5% selection from Brightness and Volume dialogs
Gemini000397	Add file support to CircularBuffer
Gemini000325	Not all Audio and Visual Alarms removed after Condition cleared - SPR # 710
Gemini000319	Enhance AuditLog tracking of Preamp and Sensor connects/disconnects
Gemini000303	Investigate spontaneously created task

SCM Build: Gemini 0.3.5B

CR Number	**Description** (newest to oldest, except release CR)
Gemini000417	0.3.5B Release notes
Gemini000416	Fix boot to allow entry to multiple update dialogs
Gemini000415	Add diagnostic audit logs to (maybe) help track down crash
Gemini000414	Code change to set graph colors crashes win win32 build
Gemini000413	Add month to time date, Add header to keypad, Clean up
Gemini000412	GuiUnitTest will not build, Remove include ForeSightTextButton.h
Gemini000411	Support new 1-wire parameters for the preamp
Gemini000410	Change button bar bitmaps: Black background
Gemini000409	Graphs don't start until patient setup is modified
Gemini000407	Untangle header files, Remove global from SensorLocation
Gemini000406	Graph traces start with a spike from bottom of graph to initial value
Gemini000404	main screen graph colors should match sensor location color
Gemini000403	Main graph only shows 1 graph (2 channels)
Gemini000402	Create class to maintain the current system user
Gemini000400	Flashing SCB boot via shell interface does not work
Gemini000399	Add Warning/Info Dialog
Gemini000369	Dismissing Sensor or Preamp Disconnected Errors

SCM Build: Gemini 0.3.5A

CR Number	**Description** (newest to oldest, except release CR)
Gemini000401	0.3.5A Release notes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000396	Make Body Location dialog modal
Gemini000394	Add user configuration to NVRAM
Gemini000311	Add in facility for touch screen press and hold
Gemini000305	Touch screen touch event is sometimes incorrect - SPR # 708

SCM Build: 0.3.5

CR Number	Description (newest to oldest, except release CR)
Gemini000393	0.3.5 Release notes
Gemini000392	Have the view time persist over power cycles
Gemini000390	fix windows build
Gemini000389	Save GUI information into NVRAM
Gemini000388	Automate registration of class foundation classes
Gemini000386	Tie events into the serial stream
Gemini000384	Add the ability to use icons and set selected items in a button list dialog box
Gemini000383	firmware download to SAM from HyperTerminal doesn't work
Gemini000382	Add new Patient Setup dialog
Gemini000381	Fixes to SCB Main after refactoring
Gemini000380	Modify Main project files to build release mode correctly
Gemini000379	Add multi-line capability to GeminiButton
Gemini000378	Implement ability to field-update SCB boot
Gemini000377	update srecordchecksum
Gemini000376	Minor code clean up
Gemini000375	Boot's win32 build is broken
Gemini000374	Modify Boot module to use ButtonBar
Gemini000372	Minor code clean up
Gemini000371	Modify ButtonBar to provide 'Next' button
Gemini000370	Modify Button List Dialog
Gemini000367	Modify NVRAM saves to provide cross-version compatibility
Gemini000366	Modify NVRAM layout to support cross-module variables
Gemini000363	Document serial output setup procedure
Gemini000362	Fix bugs in SCB boot SAM updater code
Gemini000358	check in srecordchecksum executable
Gemini000352	TPI value at startup when sensor is not connected is at max
Gemini000350	Consolidate custom controls and buttons

SCM Build: 0.3.4

CR Number	Description (newest to oldest, except release CR)
Gemini000359	0.3.4 Release notes
Gemini000364	Delay communication to NSAM to fix auto start bug
Gemini000361	Temporarily remove RTC Oscillator check
Gemini000360	Fix SystemErrorCodes to properly activate alarms
Gemini000357	Add NVRAM disable of LED alarm
Gemini000356	Allow non-cerebral sensor locations
Gemini000355	Refactor GeminiButtonListDialog

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Gemini000348	Plug in of sensor and preamps produces no audio
Gemini000345	Add "Change Brightness" Dialog
Gemini000343	Add requested fields to scientific binary output
Gemini000342	NSAM comm recovery gets in the way of NSAM flashing
Gemini000340	Add full screen touch analysis for use by diagnostics
Gemini000339	Make SCB and NSAM image checksums stored in same relative location
Gemini000336	Unit test for FixedSizeQueue and CircularBuffer failed
Gemini000332	Add functionality to Read/Write 1 wire memory chips
Gemini000331	Test Xon Xoff for serial output stream over DUART
Gemini000330	Modify ButtonBar to meet new UI requirements
Gemini000328	Change Alarm Pulse durations to match 60601-1-8
Gemini000327	Create generic button list window
Gemini000326	Set Audio Volume not automatically implemented - SPR # 709
Gemini000324	Write a C++ utility to verify Scientific output sequence numbers and checksums
Gemini000322	Fix last check-in for RTC alarm
Gemini000321	Delay slightly between channels in scientific output to allow LV to keep up
Gemini000320	Enable Flash Filesystem
Gemini000317	Add RTC-SRAM Battery Health Monitor - SPR # 711
Gemini000315	Add diagnostic data collection to SamManager communication errors
Gemini000314	Update NSAM boot task
Gemini000301	Add Error, Audit, and Service Logging
Gemini000290	Clarify changes made for CR 233
Gemini000284	Adding binary file language support to PEG
Gemini000249	Create a single build for the NSAM and SCB
Gemini000247	Rework building of the NSAM boot loader and main application to match the SCB
Gemini000070	Develop a machine readable version of the shell

SCM Build: 0.3.3

CR Number	**Description** (newest to oldest, except release CR)
Gemini000299	0.3.3 Release notes
Gemini000318	Modify audio play based on ITS 0.2.1
Gemini000313	Add compile switch to create a boot loader that is in serial pass-through mode
Gemini000309	Add Messages for new NSAM error conditions
Gemini000308	Add in new NSAM mappings
Gemini000307	Modify MQX serial I/O to allow a blocking read or write to be abandoned
Gemini000306	SAM task stopped working
Gemini000302	Modify Button-Bar to highlight buttons along selection path
Gemini000298	Correct ITS Issues with version 0.2.0
Gemini000297	Breaking out PEG modules for Unit Testing and Using Custom Widgets
Gemini000296	Round the $St0_2$ value
Gemini000294	Speed up start of data acquisition at startup

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Gemini000293	Scientific output data becomes static when $St0_2$ is not valid
Gemini000292	Add version number to unit tests
Gemini000291	Touch screen events appear to be sometimes incorrect
Gemini000289	Refactor button bar design
Gemini000288	Clean up Sound-Manager
Gemini000287	Migrate dialogs to being modal

SCM Build: 0.3.2

CR Number	Description (newest to oldest, except release CR)
Gemini000281	0.3.2 Release notes
Gemini000286	Allow registered buttons to receive presses while in modal dialog
Gemini000285	Clean up Data-Manager code
Gemini000283	Change audio tones for system sounds to play at their own volume
Gemini000279	Startup beep does not play
Gemini000278	don't emit serial stream data for invalid channels
Gemini000275	Fast tap on the main menu does not work
Gemini000266	Access to boot loader screen no longer works
Gemini000258	Improve SAM communication
Gemini000256	Add in a fixed queue template

SCM Build: 0.3.1

CR Number	Description (newest to oldest, except release CR)
Gemini000215	0.3.1 Release notes
Gemini000277	Fix crash on start of Main App
Gemini000276	Get Release Build to complete building
Gemini000274	Scientific output debug data was left on
Gemini000273	Prevent invalid SAM readings from being displayed as 0
Gemini000272	Display of "RETRY" on patient window
Gemini000270	NSAM is losing power between boot loader and main application
Gemini000269	NumericKeyPad does not handle a 1 keystroke entry appropriately
Gemini000267	Adjust Patient Setup dialog to fix issues
Gemini000264	Change default baud of external ports to 115200
Gemini000263	Start $St0_2$ graph automatically at startup
Gemini000262	Start Serial-Stream-Manager tasks automatically at startup
Gemini000261	Improvements to external loopback DUART test
Gemini000260	Scientific Output Build
Gemini000259	Ensure build steps happen in proper order
Gemini000257	Migrate graph x-axis from using Date-Time to Abs-Date-Time
Gemini000255	Create single port DUART loop back test
Gemini000254	Minor Windows build changes
Gemini000253	Adjust Scientific output format
Gemini000252	Make cosmetic changes to Peg-Date & Time-Bar
Gemini000251	Correct timer for alarm suppression
Gemini000250	Implement scientific serial output

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Gemini000248	Create a higher level build for the SCB
Gemini000246	Sensor calibration, Top Active flag
Gemini000245	Track down excessive CPU spikes
Gemini000244	Implement binary serial stream output test code
Gemini000243	initialize Duart ports (baud rate from NVRAM)
Gemini000242	Add new larger images
Gemini000240	DUART driver documentation
Gemini000239	Add ability to play sounds with alarms
Gemini000238	Create software documentation area for the SCB
Gemini000236	Remove obsolete Duart support files
Gemini000235	Create standalone Windows unit test facility
Gemini000234	Update diagnostic shell commands to new shell structure
Gemini000233	Improve Usability of Numeric Key Pad
Gemini000232	Eliminate old I^2C interface
Gemini000231	Duart performance is slow
Gemini000230	Add functions to set and get system configuration parameters via the shell
Gemini000229	Remove Status-Bar and Graph-Scroll-Bar from Data-Time-Graph
Gemini000228	Adjust code to match the latest NSAM code
Gemini000227	Additional changes for new Algorithm
Gemini000226	Minor name changes in the shell & suspend OS health manager during m-test command
Gemini000225	New Algorithm (V1.09)
Gemini000224	Touch screen play back loop
Gemini000223	Implement Data-Store objects
Gemini000222	Clean up date/time object and scroll bar
Gemini000220	Set images in main to RLE
Gemini000216	Enable ability from shell to stop/start the SAM manager and SAM feeder
Gemini000214	Exit the clean screen when it has been mostly cleaned
Gemini000213	Remove Timer for Graph Updates
Gemini000212	Modify New Patient dialog to meet new UI requirements
Gemini000211	Add clean screen facility
Gemini000210	Remove quick cases from the system
Gemini000209	Download of code from TFTP server reset in the middle
Gemini000208	Features in the shell cause a system reset
Gemini000206	Audio buzz on application start
Gemini000205	Update how the SAM timing and graph updates function
Gemini000203	Use of a modal dialog box causes the health manager to kill the PEG
Gemini000202	Simplify Multi-Button implementation and usage by clients
Gemini000201	Add display of version information to the boot loader
Gemini000195	Update Duart driver
Gemini000190	Add unit tests for graph

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

CASMED®	What's In This Release		
P/N 15-06-0285	**Description** FS-ELITE Main Application	**Ver** 1.1.1	**Date** 16-Dec-13

1.0 Programming Notes:

Value of Unused bytes:	0xFFFF
File Name:	15-06-0285_SCBMain_1.1.1_0d73ab5c.S19
16-bit Checksum:	0x0d73ab5c

2.0 New/Changed Features:

The following are New/Changes Features associated with this release:

- Addition of languages including Russian (CR multiple CRs)
- 4 Channel ATE and CSV (CR 1008)
- Different body locations available in OUS (CR 1077)
- Implement adaptive fan speed based on internal temperatures (CR 1021, 1080)
- Entering Biomed password will display Button bar with Language and defaults (CR 1054)
- Add confirm dialog to Stop STS data (CR 1058)
- Change Brightness settings scale (CR 1064)
- Adjust priorities and error messages (CR 1062)
- Ports no longer require a system reset (CR 827)
- Add languages to USB patient file (CR 1095)

3.0 Improvements:

The following are Improvements associated with this release:

- Add toggling bitmap Checkbox to Engineering settings dialog (CR 1142)
- Add klog tools to Engineering Dialog (CR 1163)
- Caution - Investigational Device not displayed when engineering body locations are enabled (CR 1129)
- In 4 C4 CAS protocol crash when baud rate is selected. (SPR 761) (CR 1145)
- Change STS statistics to match CSV (CR 1149)
- (b)(4) [redacted]
- Clicking the Ref value does not toggle the Ref line on graph (1151)
- Sensor Off Tissue and StO_2 Value (CR 928)
- Russian Cyrillic keyboard (CR 1029)
- Special file on the USB stick "eng1984.cas" automatically starts the network (CR 1047)
- Shell - 1-wire serial memory tests (CR command "serm") (CR 1045)
- Create secondary level of reporting NSAM issues to the user (CR 1052, 1053)
- CAS/ATE Remap Unstable Signal status (CR 1071)
- Add Patient ID to USB File Name (CR 1073)
- Add one decimal digit to Cumulative Sat Below Thresh & Reg O2 % Ranges (CR 1067)
- Add scientific mode to all users (CR 1075)
- Add translation for Ports -> scientific (CR 1081)
- Add automatically generated events based on special NSAM conditions (CR 1061)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CASMED®	What's In This Release		
P/N 15-06-0285	**Description** FS-ELITE Main Application	**Ver** 1.1.1	**Date** 16-Dec-13

- Correct redraw speed of numeric fields after display of events - Still may occur but is vastly improved (CR 746)
- Rapid changes in Settings, e.g., View causes crash (CR 1038)
- External Interference causes the Numeric field to go blank instead of dashes (CR 1041)
- Monitor reset if Factory Defaults activated (CR 1003, 827)
- Correct underlying alarm led and audio problems (CR 1057)
- Pressed Events, then OR then screen froze showing just bottom 3 options (CR 949)
- Rapid switching between Event button and Undo button causes crash (CR 965)
- Possibility to delete more than the last Event entered (CR 1000)
- USB File - need to add a decimal digit precision to STS data (CR 1094)
- ICU Event list "Reposition Patient" should be Green Event after "Prostaglandin" (CR 1096)

4.0 Software Fixes:

The following are Software Fixes associated with this release:

- SPR 762-2 - In Italian "View" 24 Hour selection is 1Ore, should be 24 Ore (CR 1136)
- SPR 761 - In 4 C4 CAS protocol crash when baud rate is selected (CR 1145)
- SPR 764 - Numeric Field "Current Value" sometimes blank after fast boot (CR 1147)
- SPR 758 & 760 - Remove active case from USB save list (CR 1148)
- SPR 754 - Event Mark vertical dotted line (CR 1153)
- SPR 762-1 - Dutch under STS & other string fixes (CR 1158)

5.0 Hardware Changes:

There are no Hardware Changes associated with this release known at this time.

6.0 Incompatibilities:

There are no Incompatibilities associated with this release known at this time.

7.0 Dependencies:

The following are SW Dependencies of Main Application, 15-06-0285 V1.1.1 associated with this release:

- Main Bootloader, 15-06-0284 V1.1.0

8.0 Idiosyncrasies:

The following is a list of known Idiosyncrasies associated with this release:

None

Each has been examined and determined to have the following risk assessment:

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

CASMED®	What's In This Release		
P/N 15-06-0283	**Description** FS-ELITE NSAM Application	**Ver** 2.0.0	**Date** 16-Dec-13

1.0 Programming Notes:

Value of Unused bytes:	0xFFFF
File Name:	15-06-0283_SamMain_2.0.0_033cf6dc.S19
16-bit Checksum:	0x033cf6dc

2.0 New/Changed Features:

The following are New/Changes Features associated with this release:

- Enhance the Bovie Filter (1049)
- Add Adult Somatic IFU, adjust Adult Cerebral TPI Levels (1079)
- Enable the Enhanced AGC, allow higher dynamic range for the gains (1044)

3.0 Improvements:

The following are Improvements associated with this release:

- Add for MFG ability to get the 1 wire device S/N (1033)
- (b)(4) [redacted]
- Account for the 1 wire temperature NSAM offsets & Code Cleanup (1043)
- Adjust high Ambient Light Threshold (1048)
- (b)(4) [redacted]
- (b)(4) [redacted]
- Adjust Sensor Off Temp, Adjust Low Thb levels, High Ambient Light (1093)
- Ignore Low brain 690nm values & do not include in spectral window calculation of "Sensor Off" (1140)

4.0 Software Fixes:

There are no Software Fixes associated with this release known at this time.

5.0 Hardware Changes:

There are no Hardware Changes associated with this release known at this time.

6.0 Incompatibilities:

There are no Incompatibilities associated with this release known at this time.

7.0 Dependencies:

The following are SW Dependencies of NSAM Application, 15-06-0283 V 2.0.0 associated with this release:

- NSAM Bootloader, 15-06-0282 V1.0.0
- Main Application, 15-06-0285 V1.1.1

8.0 Idiosyncrasies:

The following is a list of known Idiosyncrasies associated with this release:

None

Each has been examined and determined to have the following risk assessment:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

K133879/S002

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January 28, 2014

FDA CDRH DMC
JAN 29 2014
Received

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Regarding: K133879/S002 – eCopy hold – replacement eCopy.

To whom it may concern:

This letter and the accompanying eCopy should correct the error preventing eCopy loading into the system. The eCopy is an exact duplicate of the paper copy.

We have created new volume numbering (VOL_001_Reply to eCopy Hold Letter) with this letter and the original content which remains unchanged. The document structure and location for all documents is as follows:

VOL_001, PDF 001 – This letter;

Architecture Design Chart:

VOL_001, PDF 002 – "Gemini Main Application Software Architecture Design Chart" (21-07-0365) New document;
VOL_001, PDF 003 – "Gemini NSAM Application Software Architecture Design Chart" (21-07-0367) New document;

Software Design Specification:

VOL_001, PDF 004 – "Gemini Main Application Software Design Specification" (21-07-0329) Revised document;
VOL_001, PDF 005 – "Gemini NSAM Application Software Design Specification" (21-07-0331) Revised document;

Revision Level History:

VOL_001, PDF 006 – "Project Gemini – Software Revision History" (21-07-0339) Existing document;

Unresolved Anomalies:

VOL_001, PDF 007 – "What's in This Release – FS Elite Main Application" (15-06-0285 v. 1.1.1) Existing document;
VOL_001, PDF 008 – "What's in This Release – FS Elite NSAM Application" (15-06-0283 v.2.0.0) Existing document;

Note – The project name for this device was Gemini. Documents may contain this name. Elite is the product name. They are one and the same.

We hope the information provided will satisfy the questions raised and this submission can move to the next phase.

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs.

CAS Medical Systems, Inc.
44 East Industrial Road, Branford CT 06405, USA
Tel: (203) 488 6056 • Toll Free: (800) 227 4414 • Fax: (203) 488 9438
www.casmed.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

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K133879/S2

January 24, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

FDA CDRH DMC
JAN 27 2014
Received

Regarding: K133879/S001 – Administrative Review Errors

To Ms. Nathalie Yarkony:

This letter and the accompanying documents will address the (1) noted deficiency during the administrative review of our submission brought to our attention on January 23, 2014. The eCopy is an exact duplicate of the paper copy.

The # 33check list comment stated:

While your submission includes some information from the Software Guidance Document, it does not clearly identify the Software Design Specification (SDS), Revision Level history, and Unresolved Anomalies. Please amend your submission to include this information.

Our reply:

We have created a new volume (VOL_011_Reply to Administrative RTA#2) to contain this response. The document structure and location for all documents is as follows:

VOL_011, PDF 001 – This letter;

Architecture Design Chart:

VOL_011, PDF 002 – "Gemini Main Application Software Architecture Design Chart" (21-07-0365) New document;
VOL_011, PDF 003 – "Gemini NSAM Application Software Architecture Design Chart" (21-07-0367) New document;

Software Design Specification:

VOL_011, PDF 004 – "Gemini Main Application Software Design Specification" (21-07-0329) Revised document;
VOL_011, PDF 005 – "Gemini NSAM Application Software Design Specification" (21-07-0331) Revised document;

Revision Level History:

VOL_011, PDF 006 – "Project Gemini – Software Revision History" (21-07-0339) Existing document;

Unresolved Anomalies:

VOL_011, PDF 007 – "What's in This Release – FS Elite Main Application" (15-06-0285 v. 1.1.1) Existing document;
VOL_011, PDF 008 – "What's in This Release – FS Elite NSAM Application" (15-06-0283 v.2.0.0) Existing document;

Note – The project name for this device was Gemini. Documents may contain this name. Elite is the product name. They are one and the same.

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We hope the information provided will satisfy the questions raised and this submission can move to the next phase.

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs.

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January 28, 2014

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Center for Devices and Radiological Health
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10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Regarding: K133879/S002 – eCopy hold – replacement eCopy.

To whom it may concern:

This letter and the accompanying eCopy should correct the error preventing eCopy loading into the system. The eCopy is an exact duplicate of the paper copy.

We have created new volume numbering (VOL_001_Reply to eCopy Hold Letter) with this letter and the original content which remains unchanged. The document structure and location for all documents is as follows:

VOL_001, PDF 001 – This letter;

Architecture Design Chart:

VOL_001, PDF 002 – "Gemini Main Application Software Architecture Design Chart" (21-07-0365) New document;
VOL_001, PDF 003 – "Gemini NSAM Application Software Architecture Design Chart" (21-07-0367) New document;

Software Design Specification:

VOL_001, PDF 004 – "Gemini Main Application Software Design Specification" (21-07-0329) Revised document;
VOL_001, PDF 005 – "Gemini NSAM Application Software Design Specification" (21-07-0331) Revised document;

Revision Level History:

VOL_001, PDF 006 – "Project Gemini – Software Revision History" (21-07-0339) Existing document;

Unresolved Anomalies:

VOL_001, PDF 007 – "What's in This Release – FS Elite Main Application" (15-06-0285 v. 1.1.1) Existing document;
VOL_001, PDF 008 – "What's in This Release – FS Elite NSAM Application" (15-06-0283 v.2.0.0) Existing document;

Note – The project name for this device was Gemini. Documents may contain this name. Elite is the product name. They are one and the same.

We hope the information provided will satisfy the questions raised and this submission can move to the next phase.

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

CASMED®	Document Number	Rev
	21-07-0365	00

Title: Gemini Main Application Software Architecture Design Chart

Author: R. Bystrianyk 18-Nov-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals: Main Software Eng 1-24-14 Date

Engineering 24-Jan-14 Date

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REVISION HISTORY

Rev	Date	Editor(s)	Reason for Change
01	18-Nov-13	RB, HT	Original release

TABLE OF CONTENTS

1. INTRODUCTION 3
   1.0 PURPOSE OF DOCUMENT 3
   1.1 SCOPE OF DOCUMENT 3
2. REFERENCE DOCUMENTS 3
3. SPECIFICATIONS 4
   3.0 MAIN APPLICATION SOFTWARE ARCHITECTURE 4

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

1. Introduction

1.0 Purpose of Document

This Document exists for the purposes of:

a) Defining the Architecture of the design of Project Gemini's Main Application Software;

1.1 Scope of Document

This document covers the Software Architecture of the Project Gemini's Main Application software.

2. Reference Documents

- 21-07-0301 Project Gemini Design Plan
- 21-07-0302 Project Gemini Product Specification
- 21-07-0306 Project Gemini Risk Analysis
- 21-07-0312 Project Gemini GUI Specifications
- 21-07-0317 Project Gemini Eng/Mfg/Srv GUI Specifications
- 21-07-0323 Project Gemini Software Icons Specifications
- 21-07-0325 Project Gemini Main Application Software Requirement Specifications (SRS)
- 21-07-0329 Project Gemini Main Application Software Design Specifications (SDS)
- 21-07-0334 Project Gemini Main Application Software Life Cycle Worksheet
- 21-07-0337 Project Gemini Software Level of Concern Document
- 21-07-0338 Project Gemini Software V&V History
- 21-07-0339 Project Gemini Software Revision History

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

3. Specifications

3.0 Main Application Software Architecture

Figure 1 below, is a top level view of the main blocks in the Main Application software.

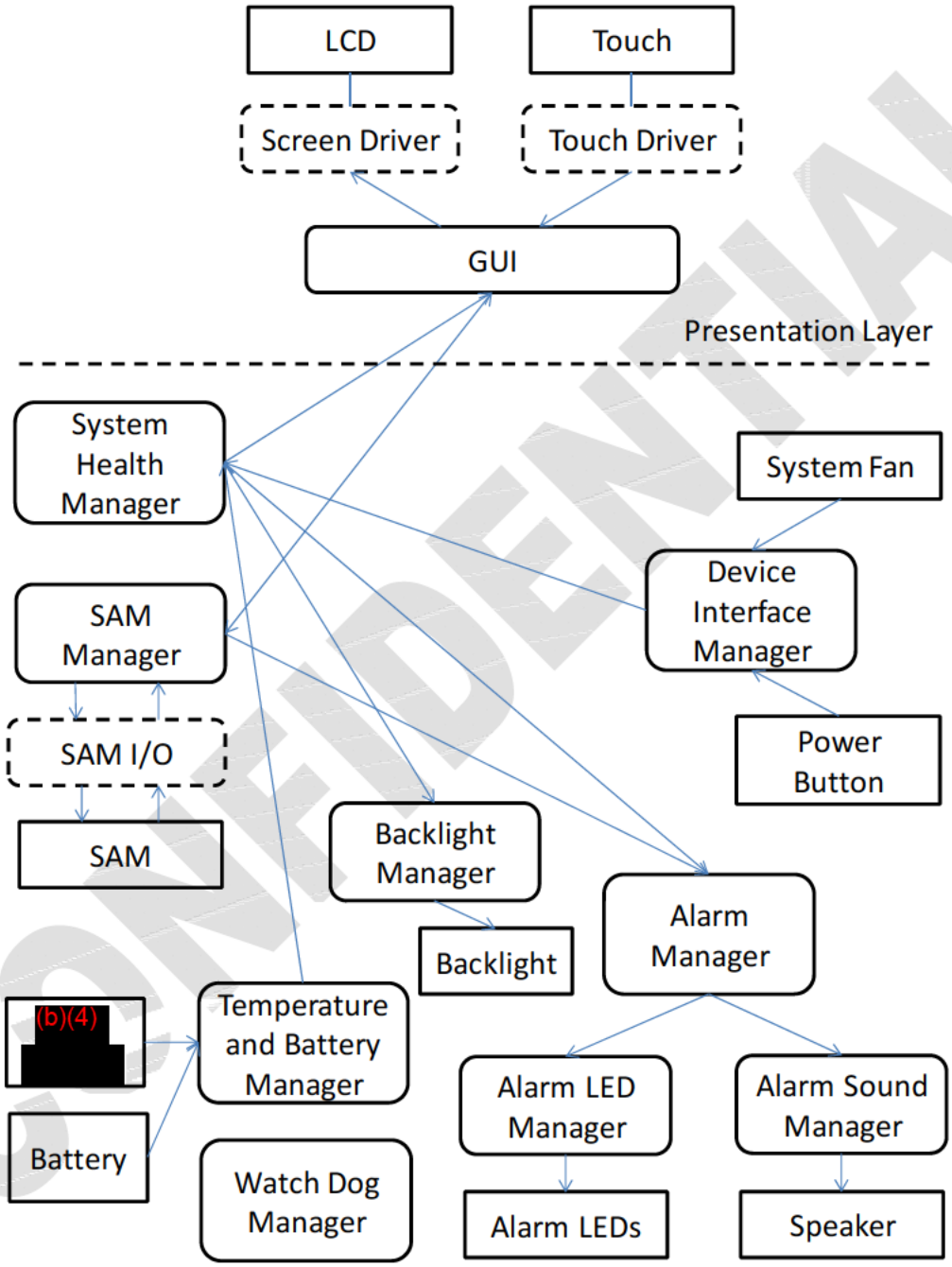

Figure 1 – Gemini Main Application Architecture

Refer to 21-07-0329, Gemini Main Application Software Design Specifications for specific information regarding the Main Application.

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CASMED®	Document Number	Rev
	21-07-0367	00

Title: Gemini NSAM Application Software Architecture Design Chart

Author: M. Kenigsztein 24-Jan-14

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals: NSAM Software Eng 1/24/17 Date

Engineering 24-Jan-14 Date

ORIGINAL

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REVISION HISTORY

Rev	Date	Editor(s)	Reason for Change
00	24-Jan-14	MK	Initial Release

TABLE OF CONTENTS

1 INTRODUCTION 3

1.1 PURPOSE OF DOCUMENT 3

1.2 SCOPE OF DOCUMENT 3

2 REFERENCE DOCUMENTS 3

3 SPECIFICATIONS 4

3.1 NSAM APPLICATION SOFTWARE ARCHITECTURE 4

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

1 INTRODUCTION

1.1 Purpose of Document

This Document exists for the purposes of:

a) Defining the Architecture of the design of Project Gemini's NSAM Application Software;

1.2 Scope of Document

This document covers the Software Architecture of the Project Gemini's NSAM Application software.

2 Reference Documents

- 21-07-0301 Project Gemini Design Plan
- 21-07-0302 Project Gemini Product Specification
- 21-07-0306 Project Gemini Hazard Identification
- 21-07-0327 Project Gemini NSAM Application Software Requirement Specifications (SRS)
- 21-07-0331 Project Gemini NSAM Application Software Design Specifications (SDS)
- 21-07-0336 Project Gemini NSAM Application Software Life Cycle Worksheet
- 21-07-0337 Project Gemini Software Level of Concern Document
- 21-07-0338 Project Gemini Software V&V History
- 21-07-0339 Project Gemini Software Revision History

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3 Specifications

3.1 NSAM Application Software Architecture

Diagram 1 below, is a top level view of the main blocks in the NSAM application software

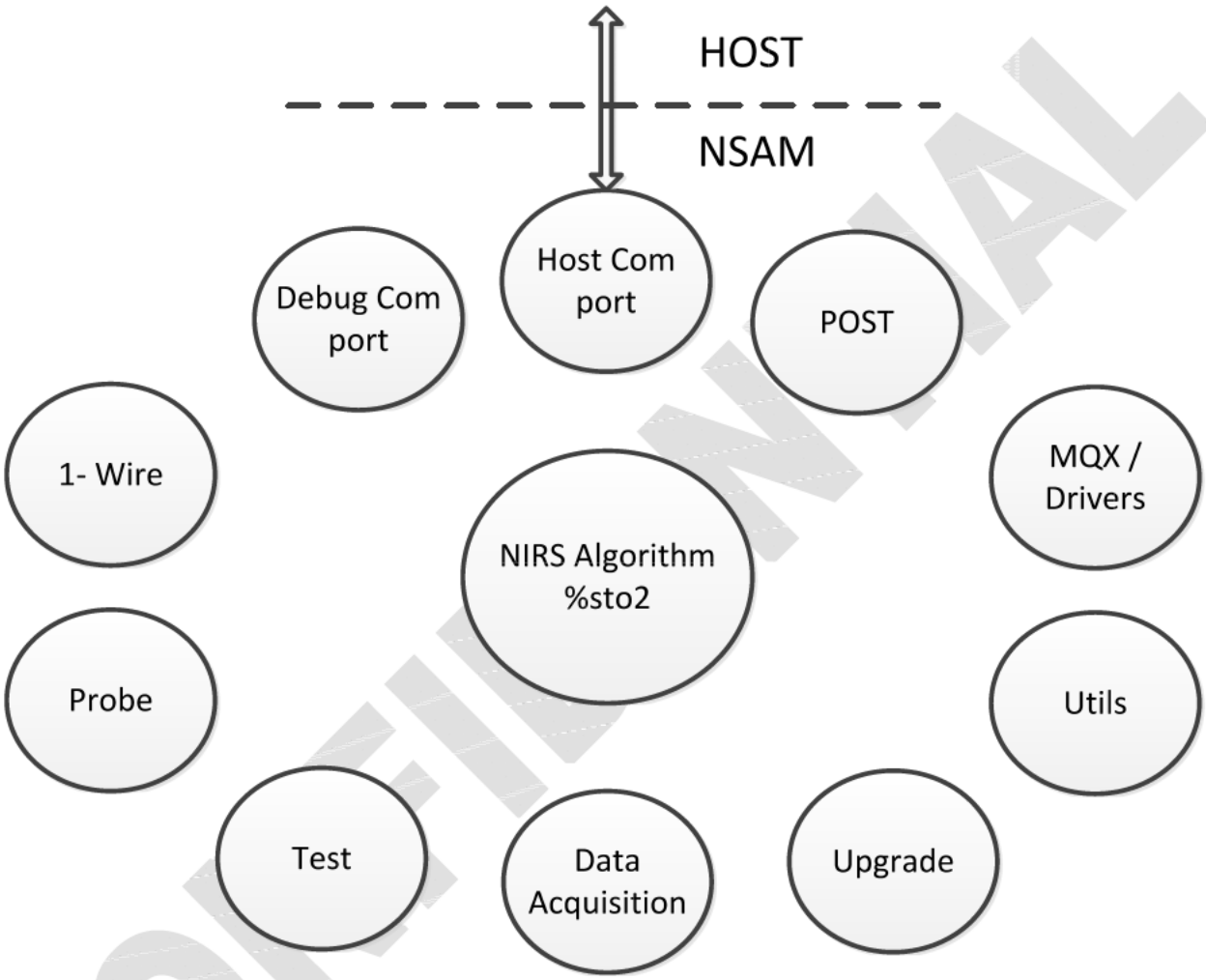

Diagram 1: Top level blocks

The main duty of the NSAM main application is to execute the NIRS algorithm and to calculate the percentage of the oxygen saturation in a specific tissue.

The software can monitor up to 4 channels (sensors) in real time. Each sensor is comprised of 5 near IR LEDs and two photodiodes.

Approximately every 100 milliseconds, new samples are available for each channel to be processed, these samples are being averaged and once every 1.5 – 2 seconds per channel the NIRS algorithm is being executed to calculate the %sto2.

Refer to 21-07-0331, Gemini NSAM Application Software Design Specifications for specific information regarding the SNAM Application.

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

CASMED®	Document Number	Rev
	21-07-0329	02

Title: Gemini Main Application Software Design Specifications (SDS)

Author: R. Bystrianyk 24-Jan-14

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals: Main Software Eng — Date 1-24-14

Engineering — Date 24-Jan-14

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REVISION HISTORY

Rev	Date	Editor(s)	Reason for Change
00	31-Jul-13	RB	Original release
01	18-Nov-13	RB, HT	Update to include requirements for latest DFU (Adult Skeletal Muscle), new Section 3.1.2
02	24-Jan-14	RB, HT	Change title to SDS, create & reference new Main Bootloader Software Architecture Design Chart

TABLE OF CONTENTS

1. Introduction 3
   1.0 Purpose of Document 3
   1.1 Scope of Document 3
2. Reference Documents 3
3. Specifications 4
   3.0 Main Application Software Architecture 4
   3.1 Main Software Modules 4
      3.1.1 GUI (Graphical User Interface) 4
      3.1.2 SAM (Signal Acquisition Module) 5
      3.1.3 SAM I/O (Signal Acquisition Module Input/Output) 5
      3.1.4 Alarm LED Manager 5
      3.1.5 Alarm Sound Manager 6
      3.1.6 Alarm Manager 6
      3.1.7 System Health Manager 6
      3.1.8 Temperature and Battery Manager 6
      3.1.9 Device Interface Manager 6
      3.1.10 Watch Dog Manager 7

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

1. Introduction

1.0 Purpose of Document

This Document exists for the purposes of:

a) Defining the requirements of the design of Project Gemini's Main Application Software;

1.1 Scope of Document

This document covers the Software Architecture and Specifications of the Project Gemini's Main Application software.

2. Reference Documents

- 21-07-0301 Gemini Design Plan
- 21-07-0302 Gemini Product Specification
- 21-07-0306 Gemini Risk Analysis
- 21-07-0312 Gemini GUI Specifications
- 21-07-0317 Gemini Eng/Mfg/Srv GUI Specifications
- 21-07-0323 Gemini Software Icons Specifications
- 21-07-0325 Gemini Main Application Software Requirement Specifications (SRS)
- 21-07-0334 Gemini Main Application Software Life Cycle Worksheet
- 21-07-0337 Gemini Software Level of Concern Document
- 21-07-0338 Gemini Software V&V History
- 21-07-0339 Gemini Software Revision History
- 21-07-0365 Gemini Main Application Software Architecture Design Chart

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3. Specifications

3.0 Main Application Software Architecture

Refer to 21-07-0365, Gemini Main Application Software Architecture Design Chart for specific information regarding the Main Application Software Architecture

3.1 Main Software Modules

The Gemini Main Application provides the front-end user interface for system control and display of StO_2 and related information. The software is architected under the auspices of a multitasking operating system. The various tasks each perform specific and separate dedicated functions.

The following task diagram depicts the software architecture. The various hardware components are depicted as rectangles and include the LCD, touch screen, alarm LEDs, speaker, SAM (Signal Acquisition Module), temperature sensors, battery, power button, and system fan. Tasks are represented by rectangles with rounded borders and interfaces are represented by dash-lined rectangles with rounded borders.

3.1.1 GUI (Graphical User Interface)

The GUI portion of the system interfaces with the touch screen to receive inputs and the LCD to display information to the user. The primary information that is displayed is:

- StO_2 values for up to 4 sensor channels
  - ✓ Refer to Hazards/Risks 4.5.1.1, 4.5.1.2, 4.5.1.3, 4.5.3.1, 4.5.4.1, 4.5.4.2, 4.5.5.1, 4.5.5.2, 4.5.5.3, 4.5.6.1, 4.5.6.2, 4.5.6.3, 4.5.10.1, 4.6.3.2 & 4.7.5.1 - Body location for Sensor prominently indicated on display; Patient's Age, Weight & Sensor on body location saved.
  - ✓ Refer to Hazards/Risks 4.5.1.3, 4.5.4.1, 4.5.5.1, 4.6.5.1, 4.6.3.1, 4.6.3.2, 4.6.4.1 & 4.7.5.1 - A Tissue Perfusion Index (TPI) shall be displayed on the main screen for each channel & value
  - ✓ Refer to Hazard/Risk 4.6.3.1, 4.7.5.4 & 4.7.5.6 - Invalid information shall be presented as dashes & messages
- Sensor alarms for up to 4 sensor channels
  - ✓ Refer to Hazards/Risks 4.6.3.1, 4.6.4.1 & 4.11.1.2 - Equipment alarm messages displayed
- StO_2 Alarm limits for up to 4 sensor channel
  - ✓ Refer to Hazards/Risks 4.6.3.1, 4.6.4.1 & 4.11.1.2 - Limit violation alarm messages displayed
- StO_2 Trace values for up to 4 sensor channels
  - ✓ Refer to Hazards/Risks 4.6.2.1& 4.6.4.1 - Parameter name & units displayed in trace area
- System alarms
  - ✓ Refer to Hazards/Risks 4.6.3.1, 4.6.4.1, 11.1.1, 4.11.1.2, 4.11.1.3& 4.11.2.1- Equipment alarm messages displayed

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The GUI is the presentation portion of the system and is highly separated from the decision making and other elements of the system. The presentation layer contains the components that implement and display the user interface and manage user interaction. This layer includes controls for user input and display.

The GUI receives inter-task messages from other system elements to display relevant information such as StO_2 values, sensor alarms, etc. This divided architecture allows to the Business Layer Logic (BLL) that handles items such as alarm priorities to be independently unit tested and verified apart from any user interface.

The GUI also can receive user input via the touch screen that can affect other components in the system. For example, the mute button provides for mute/unmute functionality that changes the audio output within the alarm sound manager.

- ✓ Refer to Hazard/Risk 4.6.1.3 - User interface uses touchscreen with icons, Menu interface driven by touchscreen allow for navigation & selection

3.1.2 SAM (Signal Acquisition Module)

The SAM task's responsibility is to provide for communication with the SAM board. The Main Application exists in a master-slave relationship with the SAM. Each message the Main Application sends to the SAM receives a response. There are no unsolicited messages generated by the SAM. Message integrity is handled by the SAM I/O layer. Phase 1.0 included Adult Cerebral (left and right Brain) body location messages. Phase 1.5 included Adult Skeletal Muscle (left and right Arm, Flank & Leg) body location messages.

Status and data messages are interpreted by the SAM task to provide the front-end GUI presentation layer with simple display messages. The SAM task takes key information from the status provided by the SAM and utilizes a Business Layer Logic (BLL) to determine alarming levels. Alarm levels are provided to the Alarm LED and Alarm Sound tasks so they can provide visual and audio alarm information.

- ✓ Refer to Hazard/Risk 4.7.1.1 - Communications between NSAM & Main ctrl board uses checksum'ed information; Invalid received data not use/displayed;

3.1.3 SAM I/O (Input/Output)

The SAM I/O layer handles message integrity to and from the SAM board via a serial communication pathway. All messages are provided with a checksum to ensure that all messages are free of transmission errors. In the event of a transmission error the event is logged. Repeat transmission errors result in a user displayed system alert indicating a system problem. Due to the physical nature of the interface (serial communication over a backplane – no cabling) no transmission errors have been detected to date.

3.1.4 Alarm LED Manager

The Alarm LED Manager's responsibility is to display the appropriate color LED at a defined blink pattern based on the currently queued alarm levels. Other elements of the system set or clear alarm levels in the Alarm LED manager. The Alarm LED manager maintains all alarm requests and displays a high priority alarm blink rate over all other priority alarms. When there are no high priority alarms then the medium priority alarm link rate is used and so forth. This separated approach allows other elements of the system to be independent of the implementation of the color and blink rate of alarm levels.

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- ✓ Refer to Hazard/Risk 4.5.10.2, 4.11.1.1, 4.11.1.2, 4.11.1.3 & 4.11.2.1 - Always visible Alarm LED

3.1.5 Alarm Sound Manager

The Alarm Sound Manager is similar to the Alarm LED manager in that it processes set and clear alarm levels from other elements in the system. It is responsible for producing the correct series of notes based on the currently active alarm level. Like the Alarm LED manager the Alarm Sound Manager maintains a queue of alarm levels and plays the appropriate alarm sound.

- ✓ Refer to Hazards/Risks 4.5.10.2, 4.5.10.3, 4.6.6.1, 4.11.1.1, 4.11.1.2, 4.11.1.3 & 4.11.2.1 - Alarm Volume cannot be turned off, Lowest Alarm volume setting still audible in normal use environment

3.1.6 Alarm Manager

The Alarm Manager provides for coordination of alarm state between the Alarm LED Manager and the Alarm Sound Manager.

- ✓ Refer to Hazards/Risks 4.5.10.2, 4.5.10.3, 4.11.1.1, 4.11.1.2, 4.11.1.3 & 4.11.2.1- Alarm message and alarm icons visible on screen

3.1.7 System Health Manager

This component monitors information from the rest of the system to determine any system wide problems that may exist. Any problems that are detected are prioritized in order of importance for reporting to the front end and alarm manager.

- ✓ Refer to Hazards/Risks 4.1.2.3, 4.1.2.4, 4.1.2.5, 4.1.2.7, 4.3.4.1 & 4.7.5.7 - Medical Device monitors internal temperature and shuts down when max temp reached.
- ✓ Refer to Hazards/Risks 4.5.6.4, 4.6.5.1, 4.6.6.1, 4.7.2.1, 4.7.5.1 & 4.7.5.2 - POST & periodic system checks
- ✓ Refer to Hazard/Risk 4.7.1.1 - Lack of continuous missing NSAM data will cause system alarm;

3.1.8 Temperature and Battery Manager

This task periodically examines the state of the various temperature sensors within the system and the state of the system battery. This information is provided to the System Health Manger.

- ✓ Refer to Hazards/Risks 4.1.2.3, 4.1.2.4, 4.1.2.5, 4.1.2.7 & 4.3.4.1 - Medical Device monitors internal temperature and shuts down when max temp reached

3.1.9 Device Interface Manager

The Device Interface Manager interfaces to a number of hardware elements within the system. It monitors the power switch to determine when the user wishes to turn the system off. The power switch is under software control to enable an orderly shutdown of the system. This task also monitors the system fan to determine if there has been a fan fault. This information is reported to the System Health Manager.

- ✓ Refer to Hazard/Risk 4.5.2.1, 4.5.7.1 & 4.7.4.1 - Software recognition application for detection of connection to an approved medical device
- ✓ Refer to Hazard/Risk 4.6.4.1 & 4.7.1.2 - USB saved data output indicate Sensor locations & patient parameters.

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3.1.10 Watch Dog Manager

The Gemini hardware provides for a watch dog that if not regularly serviced will automatically reset the system. The Watch Dog Manager periodically services the watch dog unless certain conditions occur within the system that necessitates a forced shutdown of the system. This type of action is a failsafe to absolutely ensure that the system software never enters a state where it is nonresponsive. The Watch Dog Manager monitors the following:

- The health of the other tasks in the system detecting if any task has stopped functioning.
- The state of the power switch. If the power switch is off and the system has failed to turn off within 30 seconds

3.1.11 Backlight Manager

The Backlight Manager provides for coordination of intensity setting of the GUI selection with the actual brightness of the backlight for the LCD

- ✓ Refer to Hazards/Risks 4.5.10.3 & 4.6.5.1 - Brightness cannot be turned off, lowest brightness setting still allows viewing of screen in normal use environment

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CASMED®	Document Number	Rev
	21-07-0331	03

Title: Gemini NSAM Application Software Design Specifications (SDS)

Author: M. Kenigsztein 24-Jan-14

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals: NSAM Software Eng 1/24/14 Date

Engineering 24-Jan-14 Date

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REVISION HISTORY

Rev	Date	Editor(s)	Reason for Change
00	25-Jun-12	MK	Initial Release
01	02-Aug-12	MK	Added risk mitigation details
02	18-Nov-13	MK, HT	Update to include requirements for latest DFU (Adult Skeletal Muscle), update Section 3.1.1
03	24-Jan-14	MK, HT	Change title to SDS, create & reference new Main Bootloader Software Architecture Design Chart

TABLE OF CONTENTS

1 Introduction 3
1.1 Purpose of Document 3
1.2 Scope of Document 3
2 Reference Documents 3
3 Specifications 4
3.1 NSAM Application Software Architecture 4
3.1.1 Host Com port 4
3.1.2 Debug Com port 4
3.1.3 POST 4
3.1.4 MQX / Drivers 4
3.1.5 Utils 5
3.1.6 Upgrade 5
3.1.6.1 NSAM Application Bootloader Update 5
3.1.6.2 NSAM Application Upgrade 5
3.1.7 Data Acquisition 6
3.1.8 Test 7
3.1.9 Probe 7
3.1.10 1- Wire 7
3.1.11 NIRS Algorithm 7

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1 INTRODUCTION

1.1 Purpose of Document

This Document exists for the purposes of:

a) Defining the requirements of the design of Project Gemini's NSAM Application Software;

1.2 Scope of Document

This document covers the Software Architecture and Specifications of the Project Gemini's NSAM Application software.

2 Reference Documents

- 21-07-0301 Gemini Design Plan
- 21-07-0302 Gemini Product Specification
- 21-07-0306 Gemini Hazard Identification
- 21-07-0327 Gemini NSAM Application Software Requirement Specifications (SRS)
- 21-07-0336 Gemini NSAM Application Software Life Cycle Worksheet
- 21-07-0337 Gemini Software Level of Concern Document
- 21-07-0338 Gemini Software V&V History
- 21-07-0339 Gemini Software Revision History
- 21-07-0367 Gemini NSAM Application Software Architecture Design Chart

TAL

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3 Specifications

3.1 NSAM Application Software Architecture

Refer to 21-07-0366, Gemini NSAM Application Software Architecture Design Chart for specific information regarding the NSAM Application Software Architecture.

The main duty of the NSAM main application is to execute the NIRS algorithm and to calculate the percentage of the oxygen saturation in a specific tissue.

The software can monitor up to 4 channels (sensors) in real time. Each sensor is comprised of 5 near IR LEDs and two photodiodes.

Approximately every 100 milliseconds, new samples are available for each channel to be processed, these samples are being averaged and once every 1.5 – 2 seconds per channel the NIRS algorithm is being executed to calculate the %sto2.

3.2 Host Com port

The NSAM Application will have the capability to serially output real-time channel information on a dedicated channel to the Host. This real-time output shall be requested by the host to be sent periodically (Host control). Additional information from the Host may be received at any time. The NSAM Application shall echo back all received information to the Host. The Host will set each channel with an appropriate Body Location: Phase 1: Adult Cerebral (Left or Right Brain), Phase 1.5: Adult Cerebral (Left or Right Brain) or Adult Skeletal Muscle (Left or Right Arm, Flank or Leg). The host and the NSAM will work in a Master- Slave architecture where the NSAM will reply to the host requests but will generally not imitate a request from the host. All the communication between the Host and the NSAM will have a checksum to validate the communication is genuine and is free from errors – Refer to Hazard/Risk 4.4.6.3.

3.3 Debug Com port

The NSAM Application will have the capability to serially output embedded information on a dedicated Debug channel. This information may be used to assist developers in verifying proper operation of the NSAM code. This output may be disabled in the NSAM Application release build and is not accessible to the user. The NSAM J4 header will have the basic UART connections to support this channel (no HW flow control option).

3.4 POST

The NSAM Application shall perform any POSTs required to support the proper operation of the NSAM Board. POST will include functions such as checking the power supply rails, NSAM board temperatures, ADC offsets, 1-Wire communication - Refer to Hazard/Risk 4.4.6.3.

3.5 MQX / Drivers

The NSAM Application will run underneath the Freescale MQX RTOS, MQX is a full featured real time operating system that provides the ability to create libraries that can be customized and create the necessary BSP (board support package) and PSP (processor support package). The MQX provides real time scheduling, synchronization and task services together with setting up different HW drivers and controls like the serial communication, I2C and ADCs.

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3.6 Utils

Collection of different auxiliary functions like CRC / checksum, and debug defines.

3.7 Upgrade

This functional unit will be responsible to update /reprogram either the NSAM Bootloader code or the NSAM main application code:

3.7.1 NSAM Application Bootloader Update

The NSAM Application shall have the capability to reprogram (Download) the NSAM Bootloader. The NSAM Application shall perform the following to re-program the NSAM Bootloader:

- The Main Application shall detect the NSAM Bootloader file on a USB Memory stick – Must have proper file name & extension, as well as a NSAM Bootloader version that is different than the currently installed NSAM Bootloader.
- Once the "start download" procedure is initiated by the User, the NSAM Application shall first reprogram the Power-On vector address to point to the start of the NSAM Application code.
- The Main Application will serially send information to the NSAM Application to re-program the NSAM Bootloader FLASH memory with the information provided in the new NSAM Bootloader Application USB file.
- Once the NSAM Application has re-programmed the NSAM Bootloader, the NSAM Application will verify the NSAM Bootloader Checksum.
- If the NSAM Bootloader's Checksum is correct, the NSAM Application will re-program the Power-On vector address to point to the start of the NSAM Bootloader code.
- If the NSAM Bootloader's Checksum is incorrect, a message may appear in the NSAM Bootloader download screen.
- The Main Application will record in the System Log that the NSAM Bootloader has been re-programmed along with the NSAM Bootloader Checksum pass/fail state.
- With the next power cycle, the NSAM Application will eventually start and if the Power-On vector address does not point to the start of the NSAM Bootloader code, the NSAM Application shall report this state to the Main Application. The Main Application will record in the System Log that the NSAM Bootloader Checksum failed.

If the NSAM Bootloader Checksum is determined to be incorrect (NSAM Bootloader code corrupt) no visual or audible Alarm shall be generated.

3.7.2 NSAM Application Upgrade

The NSAM Application shall have the capability to reprogram a new version of the NSAM main application code. The NSAM Application shall perform the following to start this procedure:

- The Main Application shall detect the NSAM main application file on a USB Memory stick – Must have proper file name & extension, as well as a NSAM main application version that is different than the currently installed NSAM main application.

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- Once the "start download" procedure is initiated by the User, the NSAM Application shall first reprogram set a flag in the flash memory to indicate that an NSAM application reprogramming is required.
- Once the flash flag has been written the NSAM application will jump to the reset vector that will cause the NSAM to reset and jump to the Bootloader.
- From that point the Bootloader will take over as described in 21-07-0330.

3.8 Data Acquisition

As described before approximately every 100 milliseconds, new samples are available for each channel to be processed. The near and far photodiodes channels and the ambient light in each sensor are being sampled using high precision ADCs while the monitor channel, temperature of the sensor, temperature of the NSAM board and board power rails are being sampled by the internal processor ADCs. The acquisition sequence which comprises of firing each individual LEDs and measuring the reflected IR for each LED on the near, far and monitor photodiodes is controlled by a CPLD on the NSAM board. The task of the NSAM is to be able to respond to the HW interrupts initiated by the CPLD (every ~ 24 milliseconds) aggregate the data / process the data and set up the next iteration LED currents and photodiodes gains.

Diagram 1 describes the SW data acquisition process:

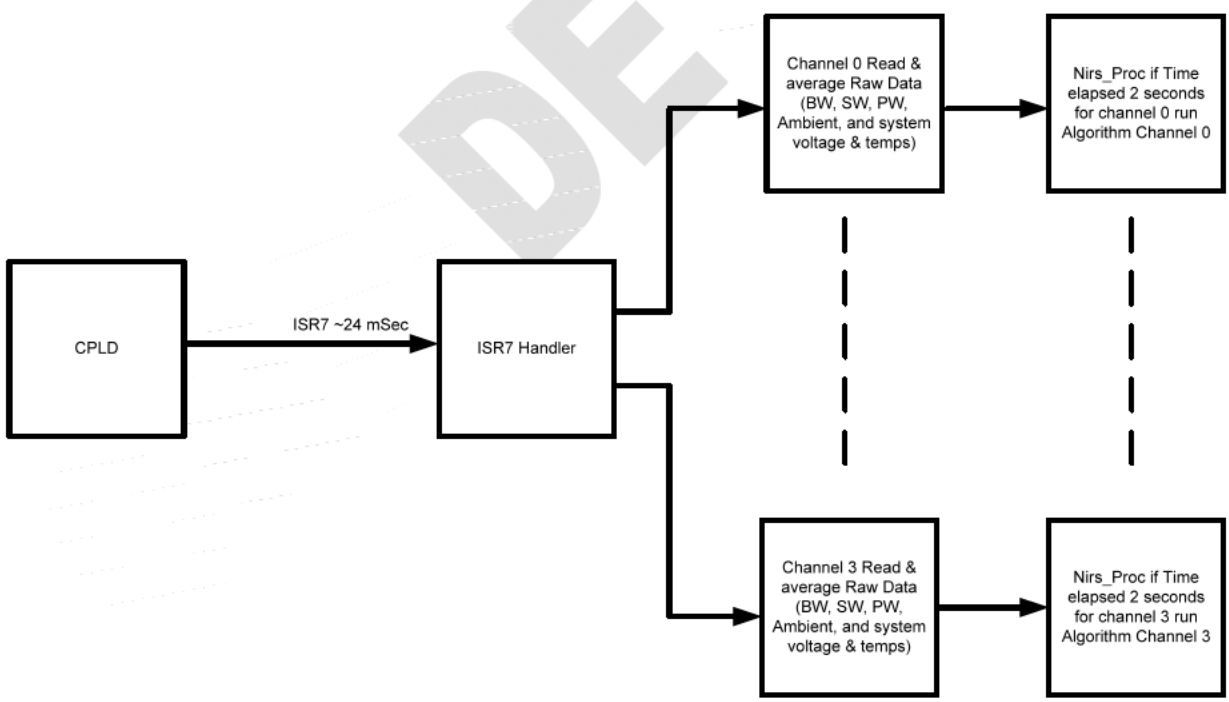

Diagram 1: Data Acquisition process

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3.9 Test

This functional unit is meant to verify different blocks of the application, particularly verification of the NIRS algorithm blocks. Testing is done by setting the application to a test mode and feeding a known / previously captured raw data clinical samples while verifying the output of the blocks compared to the algorithmic development tool (NI Lab view 7.1)

3.10 Probe

Detection of pre amplifiers and / or sensor connect and disconnect will be performed in this functional unit. Also it will read / write the different EEPROM 1 – Wire chips in the sensor and preamp.

3.11 1- Wire

Different HW components in the system will have different kinds of Maxim 1-Wire ICs, the sensors, preamps and the NSAM board will each have a dedicated 1Kbit or 4Kbit EEPROM that can store usage or calibration data to be used by the NSAM application / NIRS algorithm. The preamp LEDs will be controlled by a 1-Wire switch IC as well. This block will be responsible to implement and expose commands to communicate with these devices.

3.12 NIRS Algorithm

The NIRS algorithm needs to have prior knowledge of some usage scenarios, patient parameters and specific calibration parameters that are stored in the sensor EEPROM prior to executing the NIRS algorithm. Diagram 2 represents the major parameters that are needed:

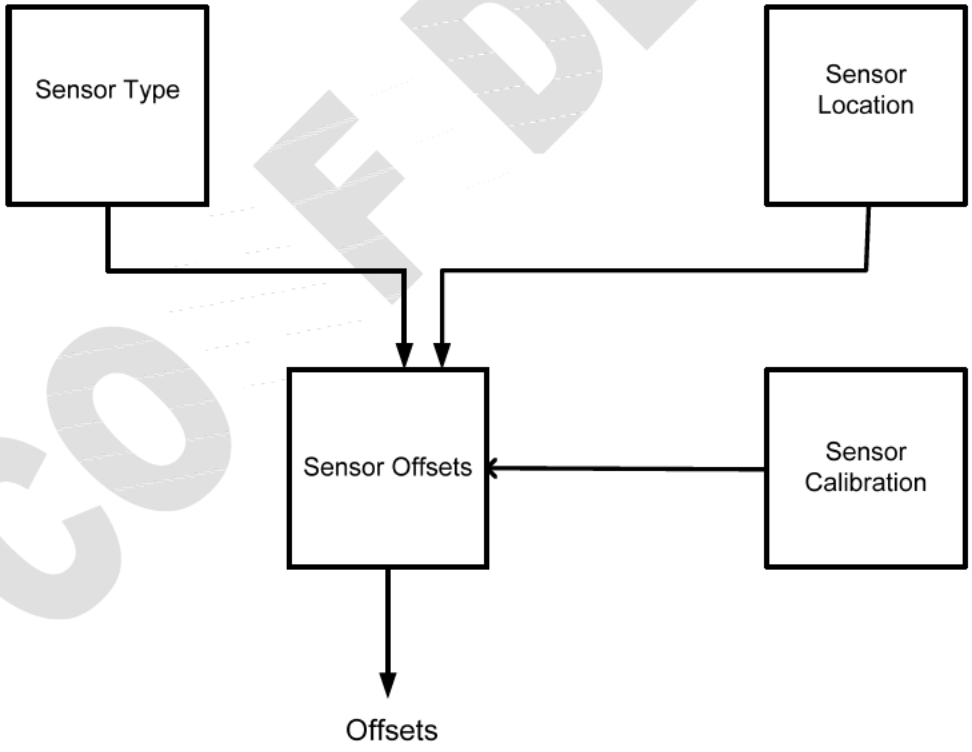

Diagram 2: Sensor Calibration

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(b)(4)

[redacted]

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CASMED®	Document Number 21-07-0339	Rev 11

Title: Project Gemini - Software Revision History

Author: H. Triebel 16-Dec-13

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals:

Project Leader — Harry Triebel — 12/16/13 Date

REVISION HISTORY

Rev	Date	Editor(s)	Reason for Change
00	14-Nov-12	HMT	Initial Release
01	08-Feb-13	HMT	Main App & Bootloader Release: 0.3.5E NSAM App Release: 7.3d
02	14-Feb-13	HMT	Main App & Bootloader Release: 0.3.6
03	25-Mar-13	HMT	Gemini Package Release: 0.1.A, Package 0.1.0B • Main App & Bootloader Release: 0.3.6A, 3.6B, 3.6C • NSAM App Release: 7.3.e, 7.3f, 7.3.g
04	17-May-13	HMT	Gemini Package Release: 0.1.0C, 0.2.0A, 0.3.0A, 0.3.0B, 0.3.0C, 0.3.0D • NSAM App Release: 0.7.3.e, 0.7.3f, 0.7.3.g, 0.7.4.b, 0.7.4d, 0.7.4h • Main Bootloader Release: 0.3.6A, 3.6B, 3.6C, 0.5.0C, 0.5.0D • Main Mfg Bootloader Release: 0.3.0B, 0.3.0C, 0.3.0D • Main App Release: 0.3.6A, 3.6B, 3.6C, 0.5.0C, 0.5.0D
05	01-Jul-13	HMT	Gemini Package Release: 0.3.0E, 0.3.0F, 0.3.0G, 0.3.1G, 0.3.2G • NSAM App Release: 0.7.5b, 0.7.5.c, 0.7.5.d, 0.7.6a • Main Bootloader Release: 0.5.0E, 0.5.0F, 0.5.0G, 0.5.1G, 0.5.2G • Main Mfg Bootloader Release: 0.3.0E, 0.3.0F, 0.3.0G, 0.3.1G, 0.3.2G • Main App Release: 0.5.0E, 0.5.0F, 0.5.0G , 0.5.1G, 0.5.2G
06	08-Aug-13	HMT	Gemini Package Release: 0.4.0A, 0.4.0B, 0.4.0C, 0.4.0D • NSAM App Release: 0.7.6e, 0.7.6i, 0.7.6j • Main Bootloader Release: 0.6.0A • Main Mfg Bootloader Release: 0.4.0A, 0.4.0B • Main App Release: 0.6.0A, 0.6.0B, 0.6.0C, 0.6.0D
07	19-Aug-13	HMT	Gemini Package Release: 1.0.0 • NSAM Bootloader Release: 1.0.0 • NSAM App Release: 1.0.0 • Main Bootloader Release: 1.0.0 • Main Mfg Bootloader Release: 1.0.0 • Main App Release: 1.0.0

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Rev	Date	Editor(s)	Reason for Change
08	26-Aug-13	HMT	Gemini Package Release: 1.0.1 • Main Bootloader Release: 1.0.1 • Main Mfg Bootloader Release: 1.0.1 • Main App Release: 1.0.1 • NSAM App Release: 1.0.2
09	30-Aug-13	HMT	Gemini Package Release: 1.0.2 • Main App Release: 1.0.2
10	09-Dec-13	HMT	US & OUS Software will be incorporated into US SW. A SW switch will allow OUS Features to be enabled in Mfg & Srv (password protected). Gemini Package Release: 1.1.0 • Main Bootloader Release: 1.1.0 • Main Mfg Bootloader Release: 1.1.0 • Main App Release: 1.1.0 • NSAM App Release: 2.0.0
11	16-Dec-13	HMT	Fix minor issues with V1.1.0c build (not released to production only V&V) Gemini Package Release: 1.1.1 • Main App Release: 1.1.1 • NSAM App Release: 2.0.0

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TABLE OF CONTENT

1. INTRODUCTION 3
2. REFERENCES 4
3. SPECIFICATIONS 5
   3.1 NSAM Bootloader Releases (Newest to Oldest): 5
   3.2 NSAM Application Releases (Newest to Oldest): 6
   3.3 NSAM Mfg Test Application Releases (Newest to Oldest): 11
   3.4 Main Bootloader Releases (Newest to Oldest): 12
   3.5 Main Mfg Bootloader Releases (Newest to Oldest): 21
   3.6 Main Application Releases (Newest to Oldest): 25
   3.7 Spectrum SCM Change Request (CR) for Gemini Builds (Newest to Oldest): 40

1. INTRODUCTION

This document lists the Revision History associated with the Gemini Project Software. The Gemini Software is divided into the following PN:

Gemini Software Description	CAS PN	Current Ver
NSAM Bootloader	15-06-0282	1.0.0
NSAM Application	15-06-0283	2.0.0
NSAM Mfg Test Application	15-06-0338	1.0.0
Main Bootloader	15-06-0284	1.1.0
Main Mfg Bootloader	15-06-0333	1.1.0
Main Application	15-06-0285	1.1.1
Gemini Software Description	**CAS PN**	**Current Ver**
Software Update Package	15-06-0339	1.1.1

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2. REFERENCES

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005
- CAS QSM1001 - Quality System Manual
- CAS QSP1026 - Risk Management
- CAS QSP4001 - Product Design Procedure
- CAS QSP4002 - Software Life Cycle Procedure
- CAS QSP4004 - System Performance Report (SPR), Product Request (PR) Procedure
- CAS GEMINI Product Profile
- CAS GEMINI Marketing Requirements
- 21-07-0324 Gemini Main Bootloader Software Requirements
- 21-07-0325 Gemini Main Application Software Requirements
- 21-07-0326 Gemini NSAM Bootloader Software Requirements
- 21-07-0327 Gemini NSAM Application Software Requirements
- 21-07-0328 Gemini Main Bootloader Software Architecture & Specification
- 21-07-0329 Gemini Main Application Software Architecture & Specification
- 21-07-0330 Gemini NSAM Bootloader Software Architecture & Specification
- 21-07-0331 Gemini NSAM Application Software Architecture & Specification
- 21-07-0333 Gemini Main Bootloader Software Life Cycle Worksheet
- 21-07-0334 Gemini Main Application Software Life Cycle Worksheet
- 21-07-0335 Gemini NSAM Bootloader Software Life Cycle Worksheet
- 21-07-0336 Gemini NSAM Application Software Life Cycle Worksheet
- 21-07-0337 Gemini Software Level of Concern Document
- 21-07-0338 Gemini Software V&V History

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3. SPECIFICATIONS

3.1 NSAM Bootloader Releases (Newest to Oldest):

Associated Release(s): Gemini NSAM Bootloader	Ver: 1.0.0
Release Notes: SCM NSAM 1.0.0 Build & Package 1.0.0 • All versions set to V1.0.0, Corrected spelling errors. (986)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM Bootloader	Ver: 1.4b
Release Notes: SCM NSAM 0.7.5d Build & Package 0.3.0F • NSAM - Main & boot NSAM Flash update failure (691)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM Bootloader	Ver: 1.4a
Release Notes: NSAM 0.3.5 Build • Initial Release	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

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3.2 NSAM Application Releases (Newest to Oldest):

Associated Release(s): Gemini NSAM App **Ver: 2.0.0**

Release Notes: SCM NSAM 2.0.0 Build & Package 1.1.0

- Add for MFG ability to get the 1 wire device S/N (1033)
- (b)(4) [redacted]
- Account for the 1 wire temperature NSAM offsets & Code Cleanup (1043)
- Enable the Enhanced AGC, allow higher dynamic range for the gains (1044)
- Adjust high Ambient Light Threshold (1048)
- Enhance the Bovie Filter (1049)
- (b)(4) [redacted]
- (b)(4) [redacted]
- Add Adult Somatic IFU, adjust Adult Cerebral TPI Levels (1079)
- (b)(4) [redacted], Adjust Low Thb levels, High Ambient Light (1093)
- Ignore Low brain 690nm values & do not include in spectral window calculation of "Sensor Off" (1140)

SPR	Description (Refer to QSP1026 for Risk Assessment)

Associated Release(s): Gemini NSAM App **Ver: 1.0.2**

Release Notes: SCM NSAM 1.0.2 Build & Package 1.0.1

- Spikes above "High Ambient Light" will reset "Ambient Light" de-bouncing/warning (993)
- NSAM - LPF Ambient light (1006)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 1.0.0**

Release Notes: SCM NSAM 1.0.0 Build & Package 1.0.0

- All versions set to V1.0.0, Corrected spelling errors. (986)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.6j**

Release Notes: SCM NSAM 0.7.6j Build & Package 0.6.0D

- (b)(4) [redacted]

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.6i**

Release Notes: SCM NSAM 0.7.6i Build & Package 0.6.0C

- Enhance AGC (881)
- Sensor off enhancement (962)
- Disable AGC Enhancements, Default MFG build setting (970)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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Associated Release(s): Gemini NSAM App	Ver: 0.7.6e
Release Notes: SCM NSAM 0.7.6e Build & Package 0.6.0A	
• Add Authentication code to sensor 1 Wire (882) • Low THB Warning on super outlier (897)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.6a
Release Notes: SCM NSAM 0.7.6a Build & Package 0.3.2G	
• Support Preamp Offsets. (476)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.5f
Release Notes: SCM NSAM 0.7.5f Build & Package 0.3.0G	
• Hitting SAM reset switch during SAM boot update leaves SAM inoperable (791) • Detect presence of SAM Mfg build on SAM (793) • NSAM - Invalidate Sto2 for "Signal Out of range" (811)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.5d
Release Notes: SCM NSAM 0.7.5d Build & Package 0.3.0F	
• NSAM - Main & boot NSAM Flash update failure (691) • Increase High Temperature Threshold, Lower Brain Low signal Thresholds, Lower high Ambient Light Threshold (762) • Hitting SAM reset switch during SAM boot update leaves SAM inoperable (791)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.5b
Release Notes: SCM NSAM 0.7.5b Build & Package 0.3.0E	
• Overriding Monitor PD values (721) • Flash Update failure patch (723)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini NSAM App	Ver: 0.7.4h
Release Notes: SCM NSAM 0.7.4h Build & Package 0.3.0D	
• Turn off LEDs of an invalid sensor (687) • StO2 out of range will sometimes not report an error. 2. Add NSAM ADC offsets (689) • MFG features enhance sensor calibration and support diagnostics info for the NSAM test (692) • TOP Lock / outlier decision after a certain period of time in the case (697)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.4d**

Release Notes: SCM NSAM 0.7.4b Build & Package 0.3.0C

- Since the LED drive is lower on phantoms to avoid saturation, monitor signals can be lower than the thresholds used for "Signal out of range". (652)
- The problem floated with a problematic hardware (bad cable) but triggered a vulnerability that if from some reason reading of the 2nd page of the sensor calibration params failed it will not retry to read it. (653)
- Updated new “sensor off” thresholds after reviewing the current IRBs data, the older thresholds made the algorithm too sensitive to “sensor off” producing false alarms in the middle of a valid deep cooling DHCA case, resulting in a false message and a recalculation of TOP. (661)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.4b**

Release Notes: SCM NSAM 0.7.4b Build

- As a temporary way to record the S/N of the sensors used in the IRBs the S/N read from the sensor's 1 wire will be output as "Generic_1" field in the scientific data. Pay attention that value will be represented as a float number. (623)
- Added Sensor Off detection, logic to recalculate TOP and (477)
- Sensor Off was not debounced properly for the sake of recalculating TOP (642)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.3.h**

Release Notes: SCM Gemini Package 0.1.0C Build

- Don't allow the HOST task to start before the channels have been initialized (592)
- Sensor test fixture option - use default temperature offset (587)
- NSAM - Update 1-Wire first block with type Descriptor (494)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.3.g**

Release Notes: SCM Gemini Package 0.1.0B Build

- Potential fix for the "incorrect sensor size" on the 1 Wire detect of a sensor. (556)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.3.f**

Release Notes: SCM Gemini Package 0.1.0A Build

- Remap channel ordering (544)
- Averaging of StO_2 values (551)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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Associated Release(s): Gemini Main Bootloader **Ver: 0.7.3e**

Release Notes: SCB Gemini 0.7.3e Build

- Numerous bug fixes, interim release

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.3.d**

Release Notes: SCM Gemini 0.3.5.D Build

- Support for 1-wire information for sensors (421)
- Corrected out of range or other errors being displayed when preamp/sensor disconnected (427)
- (b)(4) [redacted]
- [redacted]

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.3a**

Release Notes: SCM Gemini 0.3.5.B Build

- Support new 1-wire for preamp (411)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.2T**

Release Notes: SCM Gemini 0.3.5.A Build

- Support new Preamps with extra LED to indicate sensor connection (347)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.2S**

Release Notes: SCM 0.3.5 Build

- Ambient light threshold temporarily set very high (354)
- AGC hysteresis (373)
- When brain PD is out of range AGC adjusts LED current (373)
- If gain is out of range for 14 seconds begin TOP calculations (373)
- Workaround For LED switch HW problem (346)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.7.1X**

Release Notes: SCM 0.3.4 Build

- Update to match LV version 110 (FDA RC1)
- Don't start TOP calculation until first stage of AGC converges

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- Lock AGC while calculating Top
- Switch to AGC monitor after Top is done
- Added / modified signal alerts
- Added Physio check to verify high enough total Hb
- $St0_2$ results will be shown as soon as they are stable after starting TOP, not only after Top is done.
- Added another outlier check Top2_730 > 200
- Fixed Failsafe 1 to not be "sticky" if triggered once
- Added Exception / Junk data to the “TestData.C”
- Added a Sequence Number to the NSAM <-> SCB comm.

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.5.1X**

Release Notes: SCM 0.3.3 Build

- Added/updated a few routines to enable sensor calibration fixture
- Removed a few unused parameters in the sensor structure
- Added an indication whether TOP is active to enable sync the calculation with LV

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.4.5X**

Release Notes: SCM 0.3.2 Build

- New Algorithm (V109)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini NSAM App **Ver: 0.4.4X**

Release Notes: SCM 0.3.1 Build

- Implement new algorithm (C1x & C4x) "running in parallel
- Removed Age / Weight
- Added TOP730 Top690 Check relevant calculations
- A few additions to support preamp and sensor calibration fixture
- Updated proceeded data structure

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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3.3 NSAM Mfg Test Application Releases (Newest to Oldest):

Associated Release(s): Gemini NSAM Mfg Test App	Ver: 1.0.0
Release Notes: SCM MFG NSAM 1.0.0 Build & Package 1.0.0 • All versions set to V1.0.0, Corrected spelling errors. (986)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

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3.4 Main Bootloader Releases (Newest to Oldest):

Associated Release(s): Gemini Main Bootloader	Ver: 1.1.0
Release Notes: Package 1.1.0 Build & Gemini Package 1.1.0 Build	
• Touch screen calibration range check (1026) • Adjust Ambient light upper threshold for NSAM test (1030) • diag -ext in shell does not work in manufacturing boot loader (1060) • Addition of a manufacturing test for verifying 1 wire checksums (1098)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 1.0.1
Release Notes: Package 1.0.1 Build & Gemini Package 1.0.1 Build	
• Correct package version update in the boot loader. (1016)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 1.0.0
Release Notes: Package 1.0.0 Build & Gemini Package 1.0.0 Build	
• All versions set to V1.0.0, Corrected spelling errors. (986)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.6.0A
Release Notes: Package 0.6.0A Build & Gemini Package 0.4.0A Build	
• Begin a system shutdown immediately if voltage is under 10.8. (891) • Added additional elements to NVRAM for future use. • Engineering password made to match Fore-Sight (ACCESS1). (896) • Once a shutdown error is logged it is cleared to avoid future error reporting. (898) • Add touch screen play back with random variation. (904) • Add a monitor feature to the shell touch screen (touch -monitor). (905) • Ensure no huge sleep times in touch screen playback (touch -play). (906) • Add ability to activate SAM and related tasks in the boot loader. • Shell command is "datastart". (900) • Set the first time started time in the "system operation" section of NVRAM. (901) • Force package information update in NVRAM even when no update is necessary. (902) • Remove display of IP address from boot loader. (895)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.5.2G
Release Notes: Package 0.5.2G Build & Gemini Package 0.5.2G Build	
• Engineering dialog in Boot screen shall be password protected (873)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Associated Release(s): Gemini Main Bootloader	Ver: 0.5.1G

Release Notes: Package 0.5.1G Build & Gemini Package 0.5.1G Build

- Bug Fix - Remove next button on button bar for manufacturing. (821)
- New boot up image with trade mark (845)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.5.0G

Release Notes: Package 0.5.0G Build & Gemini Package 0.5.0G Build

- Bug Fix - SCB BootLoader about doesn't display NSAM BootLoader version when NSAM main is not available (770)
- Bug Fix - Detect presence of SAM manufacturing build on SAM (793)
- Cleaner package updater messages (806)
- Crisper and nicer looking icons (767)
- Remove power down button hysteresis / fixed power down lockup problems (803)
- Core dump file no longer being saved at power down (803)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.5.0F

Release Notes: Package 0.5.0F Build & Gemini Package 0.5.0F Build

- Bug Fix - Date & time improperly changed during software updates (570)
- Extended core dump - now saves audit and error logs (748)
- Extended shell command for testing "dm -tdssize" to create faster use of patient storage (739)
- Shell command "usbdir" indicates if there is a stick present in the front/back (549)
- Core on shutdown to USB stick is in the format core-date-time.txt
- (e.g. core-06042013-085037.txt) (759)
- Default IP address will now be 192.168.10.90 to accommodate manufacturing (763)
- Bug Fix - Package on the USB stick was not always correctly being detected (761)
- Bug Fix - Package updater starts before SAM is booted and does arbitrary update of SAM
- Last line of package dialog (SAM Main) had no associated colors (673)
- If a halt file is detected on a USB stick (boothalt.cas) the system plays a
- double beep and does not proceed to main (761)
- Configure TCP/IP address dialog (744)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.5.0E

Release Notes: Package 0.5.0E Build & Gemini Package 0.5.0E Build

- Core dump function to snap shot the state of the system (708, 711)
- If a memory stick is present a "core.txt" file is saved on system power down (takes approx 4-5 seconds) (733)
- SAM manager and related tasks are no longer started in the boot loader. (707)

SPR	Description (Refer to QSP1026 for Risk Assessment)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.5.0D**

Release Notes: Package 0.5.0D Build & Gemini Package 0.5.0D Build

- Bug Fix - Audio Volume set to zero without apparent reason / loss of sync with led/sound alarms (527, 569)
- Bug Fix - Change in the ports dialog will eventually crash the system (695)
- Bug Fix - Intermittent GUI hangs and does not recognize button up for several seconds. (705)
- Added more audit trail information on the main application starting up and shutting down (703)
- Bug Fix - Default parameters in the shell were being set to zero (676)
- Bug Fix - Battery temperature sensor was not appearing in the system temperature table (207)
- New shell command to dump OS health manager information (702)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.5.0C**

Release Notes: Package 0.5.0C Build & Gemini Package 0.5.0C Build

- 1-wire power test is now part of the POST (656)
- Package updater moved from the engineering sub-menu to the main bar (650)
- Likely cause of many network related crashes has been fixed (629)
- Adjustment to system task priorities to reduce system hang problems (644)
- The logs now display the task name along with the task ID (648)
- System temperature monitoring is now distributed across time instead of a single block (649)
- Modified code to handle system shutdown more gracefully (657)
- Additional MQX debug information added to the shell (669)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.5.0B**

Release Notes: Package 0.5.0B Build

- Kernel logging debug tool - engineering use (634, 639)
- Fully implement validity test of SAM data on the SCB. (633, 637)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.5.0A**

Release Notes: SCB Gemini 0.4.0A Build

- Port to Numonyx / 512K NVRAM (608, 620, 621)
- First cut implementation of SAM values system test - needs update with more parameters (561)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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Associated Release(s): Gemini Main Bootloader	Ver: 0.4.0A

Release Notes: SCB Gemini 0.4.0A Build

- Major architectural change - running fully out of RAM instead of partially out of FLASH (605)
- Package update system (601)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6E

Release Notes: SCB Gemini 0.3.6E Build

- Bug Fix - sometimes systems took too much time to shutdown (589)
- Limited display of logs from the boot loader (576)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6D

Release Notes: SCB Gemini 0.3.6D Build

- Button bar now displays icons with language independent text at the bottom (545, 578, 583)
- VGA and alarm LEDs should be turned off at shutdown - VGA turned on at power up (566)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6C

Release Notes: SCB Gemini 0.3.6C Build

- Command in shell "log" combines the error and audit trails in time order (499)
- Shell contains commands to switch between human and machine mode (510)
- Allow pollute blocks to be turned on/off via the shell (510)
- Improper shutdown is logged (517)
- Ability to create and playback macros from the shell (524)
- Jump to the main application in the event of an improper system power down (crash)
- Don't play preamp/sensor sounds on quick recovery (531, 534)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6B

Release Notes: SCB Gemini 0.3.6B Build

- Numerous bug fixes, interim release

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.6A

Release Notes: SCB Gemini 0.3.6A Build

- Display of screen occurs earlier in the power up cycle (489)

SPR	Description (Refer to QSP1026 for Risk Assessment)

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N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.6**

Release Notes: SCB Gemini 0.3.6 Build

- Hold of the power button for 15 seconds in the boot will reset various parts of NVRAM. (474, 484)
- When the reset takes place a triple beep is played.
- Key section resets include the touch screen calibration, network, possibly detected system errors
- Preliminary GUI configuration of serial ports for VueLink/scientific outputs (447, 470)
  Note: That the baud rates are currently unrestricted
- First cut of the Philips VueLink - numbers and sensor connect/disconnect are displayed (395)
  Note: Other SAM and system errors are currently not sent to the Philips
- Event list now display the correct OR list (468)
- Graphing has been refactored (466)
- New graph displays "pen" at the current value on the right side of the screen
- Graph allows through touch screen to reconfigure graph windows on the fly (472)
- SAM allows for case simulation data - only available through the shell (471)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.5E**

Release Notes: SCB Gemini 0.3.5E Build

- RTC battery fault - SPR 711 (365)
- Task analysis and control from shell (448)
- Display of "..." with spaces in boot loader to indicate detected errors (446)
- Searchable help in shell (456)
- NVRAM setting to prevent OS health manager from resetting system (459)
- Allow reset of NVRAM sections (460)
- Change boot loader to indicate "Fore-Sight Elite" not "Gemini" (461)
- Increased OS health manager error logging (462)

SPR	Description (Refer to QSP1026 for Risk Assessment)
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing.

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.5D**

Release Notes: SCB Gemini 0.3.5D Build

- Temporarily increase timeout of PEG from 10 to 30 seconds (451)
- Correct display of dashes instead of numeric on the main screen (450)
- Minor corrections to the GUI (441)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Associated Release(s): Gemini Main Bootloader	Ver: 0.3.5C

Release Notes: SCB Gemini 0.3.5C Build

- Shows 2 graphs (403)
- Graph colors match numeric values (404)
- Graph spike starting/ending at zero has been fixed (406)
- Added the ability to allow login as engineering for Paul to be able to see all body locations (399)
- Added acknowledge of disconnected sensor/preamps using the alarm button (369)
- Graphs did not start until a patient was modified (409)
- New button bar icons - white on black (410)
- Date/time now select text month - use of new ok/cancel icons (413)
- Boot allows flash of successive elements from the USB stick (416)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.5B

Release Notes: SCB Gemini 0.3.5B Build

- Shows 2 graphs (403)
- Graph colors match numeric values (404)
- Graph spike starting/ending at zero has been fixed (406)
- Added the ability to allow login as engineering for Paul to be able to see all body locations (399)
- Added acknowledge of disconnected sensor/preamps using the alarm button (369)
- Graphs did not start until a patient was modified (409)
- New button bar icons - white on black (410)
- Date/time now select text month - use of new ok/cancel icons (413)
- Boot allows flash of successive elements from the USB stick (416)

SPR	Description (Refer to QSP1026 for Risk Assessment)
710	**Not all Audio and Visual Alarms removed after Condition cleared**: It was noted that at certain occasions the Yellow or Red Alarm LED, the Yellow or Red Background on the system or channel message area and the High or Medium Priority Alarm Audio are not always removed after the condition (e.g. Low or Depleted Battery) has been cleared. Only the Alarm text message was removed. Same was observed with certain channel alarm conditions such as "External Interference". Issue is only cleared if the Unit is power cycled or if a new alarm is initiated.

Associated Release(s): Gemini Main Bootloader	Ver: 0.3.5A

Release Notes: SCB Gemini 0.3.5A Build

- Corrected problem with the interpretation of incorrect locations for the touch screen (305 / SPR 708)
- A number of corrections to the patient configuration dialog including making it modal (396)
- This version has all body locations available (401)

SPR	Description (Refer to QSP1026 for Risk Assessment)
708	**Incorrect Interpretation of Geographical Location of Entries on the Touch**

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	Screen: User touches one location of the touchscreen in order to activate or select a specific Menu or Submenu. It was noted in certain occasions that either a different location become activated or a different action is performed (e.g. the Views selections will open up if the silence key is pressed while the View menu is open)

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.5**

Release Notes: SCB 0.3.5 Build

- TPI value no longer starts at full bars - now zero bars (352)
- NVRAM now supports cross version changes (366, 367)
- New button bar with next page capability (371)
- Refactored list boxes for brightness, volume etc. (370, 389)
- Events are now sent out to the scientific data stream (386)
- View time is now saved and restored from NVRAM (392)
- Ability to flash SCB boot loader (378)
- Refactor of boot loader to have look of main application (374)
- Use of new patient/alarm limits configuration dialog (382)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.4**

Release Notes: SCB 0.3.4 Build

- Unified build of NSAM and SCB code
- A variety of NSAM algorithm changes
- Addition of a PC utility to verify scientific output
- Resolution of SPRs 709, 711
- Addition of error, audit, and service log accessible via telnet
- Brightness and volume displayed via a list box
- Added cleanscreen command to the telnet shell
- Login to the telnet shell with "machine9" changes to machine friendly mode

SPR	Description (Refer to QSP1026 for Risk Assessment)
709	**Set Audio Volume not automatically implemented:** The newly selected Audio volume is not always automatically implemented. It is sometimes necessary to enable or disable the Audio Silence for the new volume settings to be implemented.
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing. **Note/Mitigation**: Last Date & Time are also saved into the system Flash that will keep them unless the System Battery and AC are disconnected from the Unit. The User is instructed to/how set the Time and Date if the last setting was lost.

Associated Release(s): Gemini Main Bootloader **Ver: 0.3.3**

Release Notes: SCB 0.3.3 Build

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- Audio is now played for plugging in the preamp and sensor
- Provide for scientific output only when $St0_2$ is valid
- $St0_2$ values are now rounded - NOT truncate
- Dialog boxes are now modal
- Use of a new generic "button bar" - should be transparent to the user
- New NSAM error message for low sensor temperature

SPR	Description (Refer to QSP1026 for Risk Assessment)	
708	**Incorrect Interpretation of Geographical Location of Entries on the Touch Screen**: User touches one location of the touchscreen in order to activate or select a specific Menu or Submenu. It was noted in certain occasions that either a different location become activated or a different action is performed (e.g. the Views selections will open up if the silence key is pressed while the View menu is open)	
	Probability	Occasional
	Severity	Minor
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
709	**Set Audio Volume not automatically implemented**: The newly selected Audio volume is not always automatically implemented. It is sometimes necessary to enable or disable the Audio Silence for the new volume settings to be implemented.	
	Probability	Frequent
	Severity	Negligible
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
710	**Not all Audio and Visual Alarms removed after Condition cleared**: It was noted that at certain occasions the Yellow or Red Alarm LED, the Yellow or Red Background on the system or channel message area and the High or Medium Priority Alarm Audio are not always removed after the condition (e.g. Low or Depleted Battery) has been cleared. Only the Alarm text message was removed. Same was observed with certain channel alarm conditions such as "External Interference". Issue is only cleared if the Unit is power cycled or if a new alarm is initiated.	
	Probability	Occasional
	Severity	Minor
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing or defect	
	Probability	Frequent
	Severity	Negligible
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released

Associated Release(s): Gemini Main Bootloader Ver: 0.3.2

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Release Notes: SCB 0.3.2 Build

- Double beep is once again playing at boot up time
- The UI is more resilient to fast keyboard touches - crashes have been prevented
- Access to the boot loader screen is now working
- Audio "click" is available when pressing buttons in the boot loader
- Audio is now played for plugging in the pre-amp and sensor

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader Ver: 0.3.1

Release Notes: SCB 0.3.1 Build

- Boot loader "bios" screen now displays the boot loader and main application version
- Bug fix: Audio "buzz" on start of the main application has been removed
- Shell touch screen playback now can be looped N times with a specified delay between loops
- Implemented loop back for DUARTs
- Clean screen feature partially implemented as a potential product feature
- New function in the shell to get and set parameters - prelude for manufacturing
- Dialog boxes in the main application now work without memory leaks or major problems
- Traces now display data. Limitation for now is that it is restricted to about 18 hours of data and does not persist through power cycles
- Scientific binary output is now provided through the DUART ports based on configuration in NVRAM. (Currently no GUI for this configuration.)
- Changes to the numeric key pad. Now includes a cancel button.
- A preliminary key “click” has been implemented only in the boot GUI. This plays key click in between any alarm being played. This is very preliminary and does not always sound correct.

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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3.5 Main Mfg Bootloader Releases (Newest to Oldest):

Associated Release(s): Gemini Main Bootloader — Ver: 1.1.0

Release Notes: Package 1.1.0 Build & Gemini Package 1.1.0 Build

- Touch screen calibration range check (1026)
- Adjust Ambient light upper threshold for NSAM test (1030)
- diag -ext in shell does not work in manufacturing boot loader (1060)
- Addition of a manufacturing test for verifying 1 wire checksums (1098)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader — Ver: 1.0.1

Release Notes: Package 1.0.1 Build & Gemini Package 1.0.1 Build

- Bug Fix - Fix "diag -ext." - shell version 1.0.2 (1010)
- Correct package version update in the boot loader (1016)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader — Ver: 1.0.0

Release Notes: Package 1.0.0 Build & Gemini Package 1.0.0 Build

- All versions set to V1.0.0, Corrected spelling errors. (986)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader — Ver: 0.4.0B

Release Notes: Package 0.4.0B Build & Gemini Package 0.4.0B Build

- Add the ability to wipe the system clean in the manufacturing boot loader using file wipesys.cas (944)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Bootloader — Ver: 0.4.0A

Release Notes: Package 0.4.0A Build & Gemini Package 0.4.0A Build

- Begin a system shutdown immediately if voltage is under 10.8 (891)
- Added additional elements to NVRAM for future use
- Engineering password made to match Fore-Sight (ACCESS1) (896)
- Once a shutdown error is logged it is cleared to avoid future error reporting (898)
- Add touch screen play back with random variation (904)
- Add a monitor feature to the shell touch screen (touch-monitor) (905)
- Ensure no huge sleep times in touch screen playback (touch-play) (906)
- Add ability to activate SAM and related tasks in the boot loader
- Shell command is "datastart" (900)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Associated Release(s): Gemini Main Bootloader	Ver: 0.3.2G
Release Notes: Package 0.3.2G Build & Gemini Package 0.3.2G Build	
• Engineering dialog in Boot screen shall be password protected (873)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Mfg Bootloader	Ver: 0.3.1G
Release Notes: SCB Main Mfg Boot 0.3.1G Build & Gemini Package 0.5.01G Build	
• Bug Fix - Remove next button on button bar for manufacturing. (821)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Mfg Bootloader	Ver: 0.3.0G
Release Notes: SCB Main Mfg Boot 0.3.0G Build & Gemini Package 0.3.0G Build	
• Bug Fix - Detect presence of SAM manufacturing build on SAM (793)	
• Crisper and nicer looking icons (767)	
• Remove power down button hysteresis / fixed power down lockup problems (803)	
• Core dump file no longer being saved at power down (803)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Mfg Bootloader	Ver: 0.3.0F
Release Notes: SCB Main Mfg Boot 0.3.0F Build & Gemini Package 0.3.0F Build	
• Bug Fix - Date & time improperly changed during software updates (570)	
• Extended core dump - now saves audit and error logs (748)	
• Extended shell command for testing "dm -tdssize" to create faster use of patient storage (739)	
• Shell command "usbdir" indicates if there is a stick present in the front/back (549)	
• Core on shutdown to USB stick is in the format core-date-time.txt	
• (e.g. core-06042013-085037.txt) (759)	
• Default IP address will now be 192.168.10.90 to accommodate manufacturing (763)	
• Configure TCP/IP address dialog (744)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Mfg Bootloader	Ver: 0.3.0E
Release Notes: SCB Main Mfg Boot 0.3.0E Build & Gemini Package 0.3.0E Build	
• Core dump function to snap shot the state of the system (708, 711)	
• If a memory stick is present a "core.txt" file is saved on system power down (takes approx 4-5 seconds) (733)	
• Bug Fix - Cannot update boot loader from software package upgrade (718)	
• SAM manager and related tasks are no longer started in the boot loader. (707, 728)	
SPR	**Description (Refer to QSP1026 for Risk Assessment)**
N/A	

Associated Release(s): Gemini Main Mfg Bootloader	Ver: 0.3.0D
Release Notes: SCB Main Mfg Boot 0.3.0D Build & Gemini Package 0.3.0D Build	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- Changed the splash screen (696)
- Bug Fix - Default parameters in the shell were being set to zero (676)
- Bug Fix - Battery temperature sensor was not appearing in the system temperature table (207)
- New shell command to dump OS health manager information (702)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.3.0C

Release Notes: SCB Main Mfg Boot 0.3.0C Build & Gemini Package 0.3.0C Build

- 1-wire power test is now part of the POST (656)
- Package updater moved from the engineering sub-menu to the main bar (650)
- Likely cause of many network related crashes has been fixed (629)
- Adjustment to system task priorities to reduce system hang problems (644)
- The logs now display the task name along with the task ID (648)
- System temperature monitoring is now distributed across time instead of a single block (649)
- Modified code to handle system shutdown more gracefully (657)
- Additional MQX debug information added to the shell (669)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.3.0B

Release Notes: SCB Main Mfg Boot 0.3.0B Build & Gemini Package 0.3.0B Build

- Kernel logging debug tool - engineering use (634, 639)
- Fully implement validity test of SAM data on the SCB. (633, 637)
- Different displayed image on splash screen - request to avoid confusion (643)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.3.0A

Release Notes: SCB Main Mfg Boot 0.3.0A Build

- Port to Numonyx / 512K NVRAM (608, 620, 621)
- First cut implementation of SAM values system test - needs update with more parameters (561)
- Bug fix - Eratic silence alarm count down - sometimes 1, 2, or 3 seconds between updates (584)
- Bug fix - VueLink reset problem (571)
- Language selection and graph layout now saved in NVRAM (615)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.2.0A

Release Notes: SCB Main Mfg Boot 0.2.0A Build

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- Bug fix - Problems with alarm limits dialog (609)
- Numerous user interface changes (610, 613)
- Start/Stop text now appears on the STS start/stop toggle button (612)
- Major architectural change - running fully out of RAM instead of partially out of FLASH (605)
- Package update system (601)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.7.3h

Release Notes: SCB Main Mfg Boot 0.1.0C Build

- New manufacturing build (586, 593)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main Mfg Bootloader Ver: 0.2.3

Release Notes: SCB Main Mfg Boot 0.2.3 Build

- No password is required to start the shell and starts in machine mode (510)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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3.6 Main Application Releases (Newest to Oldest):

Associated Release(s): Gemini Main US App **Ver: 1.1.1**

Release Notes: SCB Gemini 1.1.1 Build & SCB Gemini Package 1.1.1 Build

- Add toggling bitmap Checkbox to Engineering settings dialog (1142)
- Add klog tools to Engineering Dialog (1163)
- Bug Fix - Caution - Investigational Device not displayed when engineering body locations are enabled (1129)
- Bug Fix - In Italian "View" 24 Hour selection is 1Ore, should be 24 Ore (SPR 762-2) (1136)
- Bug Fix - In 4 C4 CAS protocol crash when baud rate is selected. (SPR 761) (1145)
- Bug Fix - Numeric Field "Current Value" sometimes blank after fast boot (SPR 764) (1147)
- Bug Fix - Remove active case from USB save list (SPR 758 & 760) (1148)
- Bug Fix - Change STS statistics to match CSV (1149)
- Bug Fix - (b)(4) [redacted]
- Bug Fix - Clicking the Ref value does not toggle the Ref line on graph (1151)
- Bug Fix - Event Mark vertical dotted line (SPR 754) (1153)
- Bug Fix - Dutch under STS & other string fixes(SPR 762-1) (1158)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 1.1.0**

Release Notes: SCB Gemini 1.1.0 Build & SCB Gemini Package 1.1.0 Build

- Sensor Off Tissue and StO2 Value (928)
- Addition of languages including Russian. (multiple CRs)
- Russian Cyrillic keyboard. (1029)
- Implement adaptive fan speed based on internal temperatures. (1021, 1080)
- 4 Channel ATE and CSV. (1008)
- Ports no longer require a system reset. (827)
- Special file on the USB stick "eng1984.cas" automatically starts the network. (1047)
- Shell - 1-wire serial memory tests (command "serm"). (1045)
- Create secondary level of reporting NSAM issues to the user. (1052, 1053)
- Entering Biomed password will display Button bar with Language and defaults (1054)
- Add confirm dialog to Stop STS data (1058)
- Adjust priorities and error messages (1062)
- Change Brightness settings scale (1064)
- CAS/ATE Remap Unstable Signal status (1071)
- Add Patient ID to USB File Name (1073)
- Add one decimal digit to Cumulative Sat Below Thresh & Reg O2 % Ranges (1067)
- Add scientific mode to all users. (1075)
- Different body locations available in OUS (1077)
- Add translation for Ports -> scientific. (1081)
- Add automatically generated events based on special NSAM conditions. (1061)
- Add languages to USB patient file (1095)
- Bug Fix - Correct redraw speed of numeric fields after display of events -

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Still may occur but is vastly improved (746)

- Bug Fix - Rapid changes in Settings-View causes crash. (1038)
- Bug Fix - External Interference causes the Numeric field to go blank instead of dashes. (1041)
- Bug Fix - Monitor reset if Factory Defaults activated (1003, 827)
- Bug Fix - Correct underlying alarm led and audio problems. (1057)
- Bug Fix - Pressed Events, then OR then screen froze showing just bottom 3 options (949)
- Bug Fix - Rapid switching between Event button and Undo button causes crash (965)
- Bug Fix - Possibility to delete more than the last Event entered. (1000)
- Bug Fix - USB File - need to add a decimal digit precision to STS data (1094)
- Bug Fix - ICU Event list "Reposition Patient" should be Green Event after "Prostaglandin" (1096)

SPR	Description (Refer to QSP1026 for Risk Assessment)
758	Active case total duration time. (CR 1148)
760	Active cases saved to the USB (CR 1148)
764	System Reset & StO2 Numerics on Display (CR 1147)

Associated Release(s): Gemini Main US App Ver: 1.0.2

Release Notes: SCB Gemini 1.0.2 Build & SCB Gemini Package 1.0.2 Build

- Package 1.0.1 (1014)
- Bug Fix - Spelling incorrect for "Venous Return Down". (1017)

SPR	Description (Refer to QSP1026 for Risk Assessment)
748	Main App - Incorrect spelling of Event “Venous Return Down” (CR 1017)

Associated Release(s): Gemini Main US App Ver: 1.0.1

Release Notes: SCB Gemini 1.0.1 Build & SCB Gemini Package 1.0.1 Build

- Package 1.0.1 (1014)
- SPR 739 - New update to Events: Reposition head/heart etc. (1001)
- SPR 742 - Fix STS output problems. (992)
- Bug Fix - Increase the size of Help About for French and make month text. (978)
- Bug Fix - Sto2 seems to be truncated and not rounded (988)
- SPR 740 - ECLs off event is attached to ECL's On and saves to USB wrong (1004)
- SPR 744 - Correct mapping of Faulty Clock Battery SPR744 (1007)

SPR	Description (Refer to QSP1026 for Risk Assessment)
742	STS Cumulative Saturation Value Calculation (CR 992)
739	Missing Event Marks from OP & ICU Listing (CR 1001)
740	Incorrect Event saved to the USB (CR 1004)
744	Correct mapping of Faulty Clock Battery (1007)

Associated Release(s): Gemini Main US App Ver: 1.0.0

Release Notes: SCB Gemini 1.0.0 Build & SCB Gemini Package 1.0.0 Build

- All versions set to V1.0.0, Corrected spelling errors. (986)

SPR	Description (Refer to QSP1026 for Risk Assessment)

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

737	No Time/Date change Prompt
738	NSAM Board Communication Failure Detection (CR 997)
739	Missing Event Marks from OP & ICU Listing (CR # 998)
740	Incorrect Event saved to the USB (CR 999)
741	Possibility to delete more than the last Event entered (CR 1000)
744	Faulty Clock Battery Error on ATE (CR 990)
742	STS Cumulative Saturation Value Calculation (CR 992)

Associated Release(s): Gemini Main US App **Ver: 0.6.0D**

Release Notes: SCB Gemini 0.6.0D Build & SCB Gemini Package 0.4.0D Build

- CAS ATE Protocol and 2-Minute Audio Disabled State. (948)
- Power up with active VueLink connection (824)
- Change Help Dialogs, Fix Strings & Events (971)
- Force restart after port config change (975)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.6.0C**

Release Notes: SCB Gemini 0.6.0C Build & SCB Gemini Package 0.4.0C Build

- Bug Fix - The Alarm Audio and/or visual is not cleared after the condition has been removed. (701)
- Bug Fix - Red LED switching from flashing to frozen state and back to flashing. (915)
- Bug Fix - Previous Reference Value on Numerics Display right after Channel Activation (943)
- Bug Fix - System crash during second Patient File saving (953)
- Bug Fix - The “g” in the “Saving… %” & “Saving…Done” overwritten by line below (960)
- Bug Fix - StO_2 Values Differences between Values on Display and on ATE/IntelliBridge Devices (954)
- Bug Fix - STS Stop Key update (952)
- Bug Fix - Crash when pressing OK twice to cancel a case save USB (967)
- Add "Do not remove USB" to case save dialog (946)
- ATE/CSV Alarm State update (955)
- German, Italian, Russian, Spanish, Dutch Translation (947)
- Fix plain text Ch, Hrs, L/R icon, and other strings (950)
- STS Warning at end of STS Data Collection (951)
- Capture boot exception into NVRAM "fatal error" location. (959)
- Baud Rate Selection on CAS ATE and CSV Output (961)
- New Sensor Off remapping of warnings (963)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.6.0B**

Release Notes: SCB Gemini 0.6.0B Build & SCB Gemini Package 0.4.0B Build

- Begin a system shutdown immediately if voltage is under 10.8 (891)

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

- Slight (20%) improvement in USB save speed (942)
- Bug Fix - Hitting exit during Save Case to USB causes crash (825)
- Bug Fix - Language is lost at reboot (934)
- Bug Fix - Incorrect IntelliBridge/VueLink Communication Error Message (935)
- Bug Fix - USB Data Saving Progress Status now completes correctly (925)
- Bug Fix - Event Mark Line not removed after New Patient (920)
- Move Scientific output to engineering mode ONLY. (913)
- Display IP address when TCP/IP button is pressed (914)
- Patient is not saved if the case is 30 seconds or less (918)
- STS is now output for saved cases to the USB (917)
- Add French Translation (927)
- Patient File deletion - Confirmation dialog added (929)
- Data Collection prevented until 1 valid channel (940)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.6.0A**

Release Notes: SCB Gemini 0.6.0A Build & SCB Gemini Package 0.4.0A Build

- Begin a system shutdown immediately if voltage is under 10.8 (891)
- Added additional elements to NVRAM for future use
- Engineering password made to match Fore-Sight (ACCESS1) (896)
- Once a shutdown error is logged it is cleared to avoid future error reporting (898)
- Add touch screen play back with random variation (904)
- Add a monitor feature to the shell touch screen (touch-monitor) (905)
- Ensure no huge sleep times in touch screen playback (touch-play) (906)
- Add ability to activate SAM and related tasks in the boot loader
- Shell command is "datastart" (900)
- Prevent new channels from being tracked after starting STS data (892)
- Modify new patient dialog setting to 30 minutes (899)
- Selecting the same item on a list box initiates no change (894)
- STS On/Off button: Remove image jitter (907)
- Remove grey "STS data" from top of main screen when disabled (908)
- Changed "Cannot save current case" to "USB file error" (911)
- Increase size of text boxes at top of MainScreen (912)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.2G**

Release Notes: SCB Gemini 0.5.2G Build & SCB Gemini Package 0.3.2G Build

- Engineering dialog in Boot screen shall be password protected (873)
- Update Patient Data Flow operation (852, 889)
- Display "Faulty Serial Port" if VueLink/Intellibridge communication lost (862, 864)
- Add title to Events dialogs. OR Events, ICU, Vascular, NICU (866)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

- Change "FS Data" in title bar to "STS Data" (846)
- Title Bar Launch Dialogs for ID, View & Time (867)
- Display of channels w/unused body locations in STS View (833)
- Update events as per marketing changes (870)
- Make number in numeric field launch Patient Setup Dialog (834)
- Display state of the batter (on AC or various levels of discharge) (868, 858, 874, 877, 879, 884)
- Update Factory Default dialog Title & Text (848)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.1G**

Release Notes: SCB Gemini 0.5.1G Build & SCB Gemini Package 0.3.1G Build

- Bug Fix - Remove next button on button bar for manufacturing. (821)
- New VueLink/IntelliBridge condition messages to handle (831)
- Bug Fix - Selection of body location from numeric field causes error. (828)
- Bug Fix - Add "investigation use only" message at exit of Engineering screen if any alarm is disabled. (840)
- Fix spacing and size of Alpha keypad (826)
- On alpha keypad the remaining characters is not initialized (829)
- Change dialog text when asking for new patient after body location change (832)
- Change USB to File icon in Setup->Files menu. (838)
- Change order of Events button bar to “OR ICU Vascular” (839)
- Round corners of Silence and Home icons (842)
- Reduce size of backspace key in Alpha keypad (843)
- When using keyboard for password, hide char entry (830)
- Use white image background on body location icons when rendered on white (837)
- When Ref button touched, draw all corresponding dashed reference lines
- Mainscreen New patient dialog Title is: “New Patient” text is “Start a new patient?” (863)
- Change title of Engineer setting from “Demo” to “Engineer Settings” (863)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0G**

Release Notes: SCB Gemini 0.5.0G Build & SCB Gemini Package 0.3.0G Build

- Bug Fix - New patient and default confirmations "OK" now work correctly (766)
- Bug Fix - Numeric field font is too big in 4 channel mode (771)
- Bug Fix - Display view time was not updating on the main screen. (775)
- Bug Fix - Minor cosmetic fix - move Patient ID down a few pixels in Main screen. (785)
- Bug Fix - Intellibridge was not working, baud rate selections were not taking effect. (794)
- Bug Fix - Setting year in date/time dialog sets the date to 4 digits. (807)
- Bug Fix - Transition from 2 channel CSV to off causes system crash. (809)
- Bug Fix - UNDO of a selected event leaves dashed lines on multi-graphs. (789)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

- Bug Fix - Occasional RTC loss of time and date (473)
- Bug Fix - NSAM Bootloader & Main Software download without NSAM Module (449)
- Ability to use touch screen test scripts (805)
- ATE is now available as a port selection (782)
- New patient is not started if the user presses OK but the date has not changed (795)
- 4 event categories are now available - ICU, OR, Vascular, (NICU - disabled) (769)
- Added high/low limit violations to the exported file data (773)
- Added new/continue patient timers & prompting (772)
- Disable greying out and dynamic area under curve feature. (776)
- Alarm delay now available (777, 778, 779)
- Minimal functionally ATE is available - sends out a continuous stream in ATE format (738)
- Patient setup dialog - replace bitmap numbers with text and add column titles (781)
- Re-order time date dialog to Day-Month-Year and add warning text (787)
- Remove unused USB icons and FS icon (790)
- Add 4 blank help screens as place holders (796)
- Engineering configuration allowing disable of audio and visual alarms (800)
- New backspace icon (810)
- Event marks are placed onto the trace after a power cycle (808)
- Crisper and nicer looking icons (767)
- Remove power down button hysteresis / fixed power down lockup problems (803)
- Core dump file no longer being saved at power down (803)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0F**

Release Notes: SCB Gemini 0.5.0F Build & SCB Gemini Package 0.3.0F Build

- Bug Fix - Date & time improperly changed during software updates (570)
- Extended core dump - now saves audit and error logs (748)
- Extended shell command for testing "dm -tdssize" to create faster use of patient storage (739)
- Shell command "usbdir" indicates if there is a stick present in the front/back (549)
- Core on shutdown to USB stick is in the format core-date-time.txt
- (e.g. core-06042013-085037.txt) (759)
- Default IP address will now be 192.168.10.90 to accommodate manufacturing (763)
- Bug Fix - Existing patient setup cancel improperly allowed changes to stick in memory (740)
- Bug Fix - Sto2 data is now being saved to the USB memory stick (741)
- Bug Fix - TCP activation can only be pressed once (751)
- Bug Fix - Gap in data records no longer occurs (572)
- Core dump button under password now dumps the core to any USB stick (748)
- New body location prompts the user if they want to start a new patient (752)
- New patient button prompts with an "Are you sure?" dialog (755)
- Reference value resets on new patient (756)

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

- Display "Investigational unit" based on NVRAM settings - audio/led disabled, body locations (760)
- Display saving to USB percentage progress with more detail (758)

(NOTE: New patient is broken in this version and will be fixed in the next version that will be available shortly. However, this version can still be used for button testing, package update testing, and testing the newly available features.)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App Ver: 0.5.0E

Release Notes: SCB Gemini 0.5.0E Build & SCB Gemini Package 0.3.0E Build

- Core dump function to snap shot the state of the system (708, 711)
- If a memory stick is present a "core.txt" file is saved on system power down (takes approx 4-5 seconds) (733)
- Bug Fix - Grid lines are no longer displayed (710)
- Manufacturing default can now be activated from the setup menu (694, 698)
- Network no longer automatically starts in the main application - turned ON in password/setup button bar (714)
- Fore-Sight 2 Channel CSV (700, 712)
- Restructure of GUI components / password is now alpha keyboard (722)
- Add investigational use text when in entering special system modes - currently in password/setup button bar entry (729)
- Add "Silence" to alarm button, some icons updated to be much nicer (719)
- Expanded data storage to include space for alarm events (674)
- When no StO2 data is being acquired data is not being saved to memory (735)
- Shell command available "sam -sto2on <N>" when N is the seconds of preamp disconnect cycle simulation - useful for testing (735)

Known Issues in this release

- Pressing cancel on the patient setup still takes values that were changed
- Saving patient data to the USB stick does not save the data

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App Ver: 0.5.0D

Release Notes: SCB Gemini 0.5.0D Build & SCB Gemini Package 0.3.0D Build

- Likely cause of many network related crashes has been fixed (629)
- Bug Fix - Audio Volume set to zero without apparent reason / loss of sync with led/sound alarms (527, 569)
- Bug Fix - Change in the ports dialog will eventually crash the system (695)
- Bug Fix - Intermittent GUI hangs and does not recognize button up for several seconds. (705)
- Added more audit trail information on the main application starting up and shutting down (703)
- Bug Fix - Default parameters in the shell were being set to zero (676)
- Bug Fix - Battery temperature sensor was not appearing in the system temperature table

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(207)
- New shell command to dump OS health manager information (702)
- Remove quick event from events button bar. (679)
- Touching limits launches patient setup dialog & remove outline of limits when selected. (680)
- Add in color coordination of events with circles on graph (681, 683)
- Add single event UNDO to events button bar (685)
- For events use background color instead of text color (686)
- Add information to the about dialog box. (682)
- Update the alpha numeric keyboard - added space bar, cleaned up look (699)
- First cut of case management storage/delete to USB stick (684)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0C**

Release Notes: SCB Gemini 0.5.0C Build & SCB Gemini Package 0.3.0C Build
- Likely cause of many network related crashes has been fixed (629)
- Adjustment to system task priorities to reduce system hang problems (644)
- The logs now display the task name along with the task ID (648)
- System temperature monitoring is now distributed across time instead of a single block (649)
- Modified code to handle system shutdown more gracefully (657)
- Additional MQX debug information added to the shell (669)
- Display the correct percentage ranges on the STS dialog (626)
- Disallow selection by use to ALL channels to unused - one must remain a valid body location (630)
- Display software package version and installation date in the about box under help (645)
- Numeric keypad now auto-completes when a valid value is entered (e.g. alarm limit) (659)
- Patient ID input (651)
- Serial port configuration baud rates are now restricted (655)
- Modified setup button bar order, minor mods to STS dialog (662)
- Bug Fix - Color was not set back to black after a system error resolved (660)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0B**

Release Notes: SCB Gemini 0.5.0B Build & SCB Gemini Package 0.3.0B Build
- Random crash with scientific serial steam enabled frequency reduced (632)
- Kernel logging debug tool - engineering use (634, 639)
- Fully implement validity test of SAM data on the SCB. (633, 637)
- Data management to accommodate Numonyx flash (606)
- Add handling for new NSAM messages related to Sensor Off and Sensor Lifting (635)
- Display of about box that shows package number (636)
- Add password-protected button bar for service/developer actions (625)

SPR	Description (Refer to QSP1026 for Risk Assessment)

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

N/A	

Associated Release(s): Gemini Main US App **Ver: 0.5.0A**

Release Notes: SCB Gemini 0.5.0A Build & SCB Gemini Package 0.3.0A Build

- Port to Numonyx / 512K NVRAM (608, 620, 621)
- First cut implementation of SAM values system test - needs update with more parameters (561)
- Bug fix - Eratic silence alarm count down - sometimes 1, 2, or 3 seconds between updates (584)
- Bug fix - VueLink reset problem (571)
- Language selection and graph layout now saved in NVRAM (615)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.4.0A**

Release Notes: SCB Gemini 0.4.0A Build & SCB Gemini Package 0.2.0A Build

- Bug fix - Problems with alarm limits dialog (609)
- Numerous user interface changes (610, 613)
- Start/Stop text now appears on the STS start/stop toggle button (612)
- Major architectural change - running fully out of RAM instead of partially out of FLASH (605)
- Package update system (601)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6E**

Release Notes: SCB Gemini 0.3.6E Build & SCB Gemini Package 0.1.0C Build

- Bug Fix - sometimes systems took too much time to shutdown (589)
- Bug Fix - Selecting port with port menu crash (588)
- Bug Fix - exit of patient setup can cause system crash (585)
- Bug Fix - exit of empty numeric dialog box causes a crash (594)
- Bug Fix - backspace works properly in password dialog (520)
- Improved performance of the screen drawing (579, 599)
- Event items are now shown in color on the list box (591, 598)
- Items that are the current value in list boxes (e.g. brightness) are now highlighted in green (603)
- STS Toggle button now works - FSData shows up on "status" bar (602)

SPR	Description (Refer to QSP1026 for Risk Assessment)
717	Exit of patient setup can cause system crash.

Associated Release(s): Gemini Main US App **Ver: 0.3.6D**

Release Notes: SCB Gemini 0.3.6D Build & SCB Gemini Package 0.1.0B Build

- Button bar now displays icons with language independent text at the bottom (545, 578, 583)
- VGA and alarm LEDs should be turned off at shutdown - VGA turned on at power up (566)
- Bug fix - lost REF values switching from 4 to 2 channels (567)

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- Various GUI updates (573)
- Bug fix - alarm messages lost when screen is reconfigured 2 <-> 4 channels (567)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6C**

Release Notes: SCB Gemini 0.3.6C Build & SCB Gemini Package 0.1.0A Build

- Graphs on the screen can be combined/split using the touchscreen (480)
- Channel errors and warnings used with VueLink (498)
- Bug fix - drop of a blank event when the cancel button is used on the dialog (509)
- StO_2 data is now stored in NVRAM - graph is maintained through power cycles (513)
- Dialog boxes are automatically centered (526)
- Normalize the look of all list dialog boxes (529)
- Modify power down to be more user responsive - adjust down hysteresis, blank screen after push in power button (535)
- Add in basic Gemini statistics & STS dialog (532, 533, 540, 546)
- Possible improvement in the "crash" issue - possible decreased incidence (557)
- Tie in of numeric regions to display reference, limits, AUT
- Tie in of STS start/stop into gathering statistics (521, 542. 562)
- Change various GUI screens for consistency (558)
- Increased font for Numeric Field
- Standardized key size on NumericKeyPad to match (future) alpha numeric
- Changed OK/Cancel button to same size on NumericKeyPad, PatientSetup, DateTimeDlg, and SerialPortDlg.
- Corrected title color to white on STSviewDlg and centered text and spreadsheets.
- Bug Fix - Boot would crash after a long while (501)
- Bug Fix - Fix rounding errors in SctO2 (454)
- Transfer of data and management of flash extending recording to approximately 24 days. (538)
- (This version of software is a short transition to multiple patients)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6B**

Release Notes: SCB Gemini 0.3.6B Build

- Numerous bug fixes, interim release

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6A**

Release Notes: SCB Gemini 0.3.6A Build

- Corrected VueLink file to allow display of graphs on the Philips monitor (487)
- Bug fix to the serial stream user interface (488)
- Display of screen occurs earlier in the power up cycle (489)
- Display of event marks including touch of event mark on graph to show the text of the

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event mark (483)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.6**

Release Notes: SCB Gemini 0.3.6 Build

- Log files are synced to the file system in a background task (439)
- Increased monitoring of system performance that is records to the error log (467)
- Preliminary GUI configuration of serial ports for VueLink/scientific outputs (447, 470)
  Note: That the baud rates are currently unrestricted
- First cut of the Philips VueLink - numbers and sensor connect/disconnect are displayed (395)
  Note: Other SAM and system errors are currently not sent to the Philips
- Event list now display the correct OR list (468)
- Graphing has been refactored (466)
- New graph displays "pen" at the current value on the right side of the screen
- Graph allows through touch screen to reconfigure graph windows on the fly (472)
- SAM allows for case simulation data - only available through the shell (471)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.5E**

Release Notes: SCB Gemini 0.3.5E Build

- RTC battery fault - SPR 711 (365)
- Task analysis and control from shell (448)
- Display of "..." with spaces in boot loader to indicate detected errors (446)
- Searchable help in shell (456)
- NVRAM setting to prevent OS health manager from resetting system (459)
- Allow reset of NVRAM sections (460)
- Change boot loader to indicate "Fore-Sight Elite" not "Gemini" (461)
- Increased OS health manager error logging (462)

SPR	Description (Refer to QSP1026 for Risk Assessment)
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing.

Associated Release(s): Gemini Main US App **Ver: 0.3.5D**

Release Notes: SCB Gemini 0.3.5D Build

- Temporarily increase timeout of PEG from 10 to 30 seconds (451)
- Correct display of dashes instead of numeric on the main screen (450)
- Minor corrections to the GUI (441)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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Associated Release(s): Gemini Main US App	Ver: 0.3.5C

Release Notes: SCB Gemini 0.3.5C Build

- Shows 2 graphs (403)
- Graph colors match numeric values (404)
- Graph spike starting/ending at zero has been fixed (406)
- Added the ability to allow login as engineering for Paul to be able to see all body locations (399)
- Added acknowledge of disconnected sensor/preamps using the alarm button (369)
- Graphs did not start until a patient was modified (409)
- New button bar icons - white on black (410)
- Date/time now select text month - use of new ok/cancel icons (413)
- Boot allows flash of successive elements from the USB stick (416)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App	Ver: 0.3.5B

Release Notes: SCB Gemini 0.3.5B Build

- Shows 2 graphs (403)
- Graph colors match numeric values (404)
- Graph spike starting/ending at zero has been fixed (406)
- Added the ability to allow login as engineering for Paul to be able to see all body locations (399)
- Added acknowledge of disconnected sensor/preamps using the alarm button (369)
- Graphs did not start until a patient was modified (409)
- New button bar icons - white on black (410)
- Date/time now select text month - use of new ok/cancel icons (413)
- Boot allows flash of successive elements from the USB stick (416)

SPR	Description (Refer to QSP1026 for Risk Assessment)
710	**Not all Audio and Visual Alarms removed after Condition cleared**: It was noted that at certain occasions the Yellow or Red Alarm LED, the Yellow or Red Background on the system or channel message area and the High or Medium Priority Alarm Audio are not always removed after the condition (e.g. Low or Depleted Battery) has been cleared. Only the Alarm text message was removed. Same was observed with certain channel alarm conditions such as "External Interference". Issue is only cleared if the Unit is power cycled or if a new alarm is initiated.

Associated Release(s): Gemini Main US App	Ver: 0.3.5A

Release Notes: SCB Gemini 0.3.5A Build

- Corrected problem with the interpretation of incorrect locations for the touch screen (305 / SPR 708)
- A number of corrections to the patient configuration dialog including making it modal (396)
- This version has all body locations available (401)

SPR	Description (Refer to QSP1026 for Risk Assessment)
708	**Incorrect Interpretation of Geographical Location of Entries on the Touch**

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	Screen: User touches one location of the touchscreen in order to activate or select a specific Menu or Submenu. It was noted in certain occasions that either a different location become activated or a different action is performed (e.g. the Views selections will open up if the silence key is pressed while the View menu is open)

Associated Release(s): Gemini Main US App **Ver: 0.3.5**

Release Notes: SCB 0.3.5 Build

- TPI value no longer starts at full bars - now zero bars (352)
- NVRAM now supports cross version changes (366, 367)
- New button bar with next page capability (371)
- Refactored list boxes for brightness, volume etc. (370, 389)
- Events are now sent out to the scientific data stream (386)
- View time is now saved and restored from NVRAM (392)
- Ability to flash SCB boot loader (378)
- Refactor of boot loader to have look of main application (374)
- Use of new patient/alarm limits configuration dialog (382)

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.4**

Release Notes: SCB 0.3.4 Build

- Unified build of NSAM and SCB code
- A variety of NSAM algorithm changes
- Addition of a PC utility to verify scientific output
- Resolution of SPRs 709, 711
- Addition of error, audit, and service log accessible via telnet
- Brightness and volume displayed via a list box
- Added cleanscreen command to the telnet shell
- Login to the telnet shell with "machine9" changes to machine friendly mode

SPR	Description (Refer to QSP1026 for Risk Assessment)
709	**Set Audio Volume not automatically implemented:** The newly selected Audio volume is not always automatically implemented. It is sometimes necessary to enable or disable the Audio Silence for the new volume settings to be implemented.
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing. **Note/Mitigation**: Last Date & Time are also saved into the system Flash that will keep them unless the System Battery and AC are disconnected from the Unit. The User is instructed to/how set the Time and Date if the last setting was lost.

Associated Release(s): Gemini Main US App **Ver: 0.3.3**

Release Notes: SCB 0.3.3 Build

- Audio is now played for plugging in the preamp and sensor

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- Provide for scientific output only when $St0_2$ is valid
- $St0_2$ values are now rounded - NOT truncate
- Dialog boxes are now modal
- Use of a new generic "button bar" - should be transparent to the user
- (b)(4) [redacted]

SPR	Description (Refer to QSP1026 for Risk Assessment)	
708	**Incorrect Interpretation of Geographical Location of Entries on the Touch Screen**: User touches one location of the touchscreen in order to activate or select a specific Menu or Submenu. It was noted in certain occasions that either a different location become activated or a different action is performed (e.g. the Views selections will open up if the silence key is pressed while the View menu is open)	
	Probability	Occasional
	Severity	Minor
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
709	**Set Audio Volume not automatically implemented**: The newly selected Audio volume is not always automatically implemented. It is sometimes necessary to enable or disable the Audio Silence for the new volume settings to be implemented.	
	Probability	Frequent
	Severity	Negligible
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
710	**Not all Audio and Visual Alarms removed after Condition cleared**: It was noted that at certain occasions the Yellow or Red Alarm LED, the Yellow or Red Background on the system or channel message area and the High or Medium Priority Alarm Audio are not always removed after the condition (e.g. Low or Depleted Battery) has been cleared. Only the Alarm text message was removed. Same was observed with certain channel alarm conditions such as "External Interference". Issue is only cleared if the Unit is power cycled or if a new alarm is initiated.	
	Probability	Occasional
	Severity	Minor
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released
711	**RTC Battery Backup missing not detected:** The RTC Battery (Part BH1 on SCB 03-59-0402) is removed from the system, that thereafter loses the then set time and date once the system is completely de-energized. The system does not report the RTC battery as missing or defect	
	Probability	Frequent
	Severity	Negligible
	Risk	Investigate Further Risk Reduction (IFRR)
	Disposition	The SPR will be fixed prior to the commercial released

Associated Release(s): Gemini Main US App **Ver: 0.3.2**

Release Notes: SCB 0.3.2 Build

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- Double beep is once again playing at boot up time
- The UI is more resilient to fast keyboard touches - crashes have been prevented
- Access to the boot loader screen is now working
- Audio "click" is available when pressing buttons in the boot loader
- Audio is now played for plugging in the pre-amp and sensor

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

Associated Release(s): Gemini Main US App **Ver: 0.3.1**

Release Notes: SCB 0.3.1 Build

- Boot loader "bios" screen now displays the boot loader and main application version
- Bug fix: Audio "buzz" on start of the main application has been removed
- Shell touch screen playback now can be looped N times with a specified delay between loops
- Implemented loop back for DUARTs
- Clean screen feature partially implemented as a potential product feature
- New function in the shell to get and set parameters - prelude for manufacturing
- Dialog boxes in the main application now work without memory leaks or major problems
- Traces now display data. Limitation for now is that it is restricted to about 18 hours of data and does not persist through power cycles
- Scientific binary output is now provided through the DUART ports based on configuration in NVRAM. (Currently no GUI for this configuration.)
- Changes to the numeric key pad. Now includes a cancel button.
- A preliminary key “click” has been implemented only in the boot GUI. This plays key click in between any alarm being played. This is very preliminary and does not always sound correct.

SPR	Description (Refer to QSP1026 for Risk Assessment)
N/A	

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3.7 Spectrum SCM Change Request (CR) for Gemini Builds (Newest to Oldest):

SCM Build: Package 1.1.1	
CR Number	**Description** (newest to oldest, except release CR)
Gemini001164	Package 1.1.1
Gemini001163	Add klog tools to Engineering Dialog
Gemini001160	OUS Configuration & Body Location (SPR 765)
Gemini001159	GUI Strings Translation (SPR 763)
Gemini001158	Dutch under STS & other string fixes(SPR 762-1)
Gemini001156	Reference Value: Horizontal dotted line not toggling (SPR 757)
Gemini001155	STS Data Calculation (SPR 756)
Gemini001154	NSAM Auto Event Mark on USB (SPR 755)
Gemini001153	Event Mark vertical dotted line (SPR 754)
Gemini001151	Clicking the Ref value does not toggle the Ref line on graph
Gemini001150	(b)(4) [redacted]
Gemini001149	Change STS statistics to match CSV
Gemini001148	Remove active case from USB save list (SPR 758 & 760)
Gemini001147	Numeric Field "Current Value" sometimes blank after fast boot (SPR 764)
Gemini001146	Remove unused Arial 14 point Narrow font (not used)
Gemini001145	In 4 CH CAS protocol, crash when baud rate is selected. (SPR 761)
Gemini001142	Add toggling bitmap Checkbox to Engineering settings dialog
Gemini001140	NSAM - Ignore Low brain 690nm values & do not include in spectral window calculation of "Sensor Off"
Gemini001136	In Italian "View" 24 Hour selection is 1Ore, should be 24 Ore (SPR 762-2)
Gemini001129	Caution - Investigational Device not displayed when engineering body locations are enabled

SCM Build: Package 1.1.0	
CR Number	**Description** (newest to oldest, except release CR)
Gemini001122	Package 1.1.0
Gemini001135	In Dutch "Pre induction base line ..." 1st char not Capitalized
Gemini001134	Help About Dialog: Serial number spacing is wrong.
Gemini001132	Add lookup string by language to PEG
Gemini001131	Russian events appear as "junk" in CSV file
Gemini001130	Russian keyboard problems.
Gemini001128	Text cosmetic changes
Gemini001127	Invalid login does not display dialog box.
Gemini001126	Minor format change of event output in the shell.
Gemini001125	Save Patient data to USB broke in Russian
Gemini001124	Do not display NSAM specific events.
Gemini001123	Silence not centered in Dutch
Gemini001121	Bug fix to event list display
Gemini001120	SensorLocation: Spacing missing between “Ch 2” and “Emplacement”.
Gemini001119	Saving...Done on save to usb missing ... if not English
Gemini001118	CAS/ATE - Add Model Number for OUS
Gemini001117	Help about dialog not correct. Overlap and gaps.
Gemini001116	Undefined users do not always give "Bad password" message

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Gemini001115	Engineering mode does not show all body icons when in Non US mode
Gemini001114	Correct Formatting in STS Data in USB file
Gemini001112	Correct Almost black to black in body location icons
Gemini001111	STS state does not persist when changing button bars
Gemini001110	Translation dead string removal, updates and corrections
Gemini001108	Setting Password in Russian displays ASCII keypad
Gemini001107	Message "Caution - Investigational Device" does not work correctly.
Gemini001105	German translations: Seconds and Minutes not consistent
Gemini001104	Reset body icons to L/R brain when changing between US/OUS
Gemini001103	Change "Service" button to "Biomed"
Gemini001101	Update Spanish translations using Eng-Spa GUI_Rev1MA file
Gemini001100	When logging in as "Service", all body locations are displayed
Gemini001099	Ports streams mismatch in NVRAM
Gemini001098	Create Mfg serial memory test for all 1st blocks
Gemini001097	Fix PN in Help -> "Sensor Selection" screen
Gemini001096	ICU Event list "Reposition Patient" should be Green Event after "Prostaglandin
Gemini001095	Add languages to USB patient file
Gemini001094	USB File - need to add a decimal digit precision to STS data
Gemini001093	(b)(4) [redacted]
Gemini001092	Update German, Russian & Dutch strings
Gemini001091	Correct formatting for ThresholdSaturationCell
Gemini001090	Update Spanish translations
Gemini001089	Center Right/Left above pics in body location dialog
Gemini001088	Update French translations
Gemini001087	Adjust sensor location dialog size and location
Gemini001086	Unit Test CheckSystemStatus Battery Low fails
Gemini001084	Body location dialog not centered
Gemini001083	Restore the CheckNSAMStatus Unit Test Functionality
Gemini001082	Cosmetic & stability fix. Ports dialog border & Baud text overwriting
Gemini001081	Add translation for Ports -> scientific.
Gemini001080	Modify temperature/fan algorithm slightly
Gemini001079	NSAM - Add Adult Somatic IFU, adjust Adult Cerebral TPI Levels
Gemini001078	Modify one wire CRC logic for old/new
Gemini001077	Add body location icons when In OUS mode
Gemini001076	Minor cleanup CurrentSystemUser and MainScreen
Gemini001075	Add scientific mode to all users.
Gemini001074	Change isOUS flag to isOS for Outside US logic
Gemini001073	Add Patient Id to USB File Name
Gemini001072	Add streaming capability to time and date objects.
Gemini001071	CAS/ATE Remap Unstable Signal status
Gemini001070	NSAM - Do not invalidate 1 wire type when getting 1 wire S/N (MFG build)
Gemini001068	Add string utility functions.
Gemini001067	STS - Add one decimal digit to Cumulative Sat Below Thresh & Reg O2 % Ranges

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Gemini001066	STS Button loses state on screen switch.
Gemini001065	Add White Background body location images
Gemini001064	Change Brightness settings scale
Gemini001063	Update Dutch strings
Gemini001062	Adjust priorities and error messages
Gemini001061	Add automatically generated events based on special NSAM conditions.
Gemini001060	diag -ext in shell does not work in manufacturing boot loader
Gemini001059	Change shell name from Gemini to Fore-Sight Elite
Gemini001058	Add confirm dialog to Stop STS data
Gemini001057	Correct underlying alarm led and audio problems.
Gemini001056	(b)(4) [redacted]
Gemini001055	
Gemini001054	Entering Biomed password will display Button bar with Language and defaults
Gemini001053	Create Unit test of one wire Serial memory
Gemini001052	Create secondary level of reporting NSAM issues to the user.
Gemini001051	Refactor binary file code.
Gemini001050	NSAM - MFG build doesn't build
Gemini001049	NSAM - Enhance the Bovie Filter
Gemini001048	NSAM - Adjust high Ambient Light Threshold
Gemini001047	Special file on the USB stick automatically starts the network.
Gemini001046	Code clean up.
Gemini001045	Create serial memory tests
Gemini001044	NSAM - Enable the Enhanced AGC, allow higher dynamic range for the gains
Gemini001043	NSAM - Account for the 1 wire temperature NSAM offsets & Code Cleanup
Gemini001042	(b)(4) [redacted]
Gemini001041	External Interference causes the Numeric field to go blank instead of dashes
Gemini001040	Change action when time exceeds high limit
Gemini001039	Change checkout type in SharedGui
Gemini001038	Rapid changes in Settings-View causes crash
Gemini001037	Change level of memory warning reporting level.
Gemini001035	Clean up Peg wbx file
Gemini001034	Add Dutch string updates
Gemini001033	NSAM - Add for MFG ability to get the 1 wire device S/N
Gemini001032	Minor code cleanup.
Gemini001030	Adjust Ambient light upper threshold for NSAM test
Gemini001029	Add Cyrillic keypad. Update strings in some languages
Gemini001028	Modify PEG to group Do Not Translate strings
Gemini001027	Create new SIDs for events to Group them
Gemini001026	Touch screen calibration range check.
Gemini001024	Minor code cleaning.
Gemini001023	Add integer to hex string functions.
Gemini001022	Add new Italian strings to PEG and correct help screen punctuation

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini001021	Implement adaptive fan speed based on internal temperatures.
Gemini001020	STS Data field too small
Gemini001019	Add Russian Language, Update Russian keypad
Gemini001013	Fix problems noted in CR 990
Gemini001008	Add commands specific to 4 channel ATE/CAS protocol
Gemini001003	Monitor reset if Factory Defaults activated
Gemini001000	Possibility to delete more than the last Event entered
Gemini000965	Rapid switching between Event button and Undo button causes crash
Gemini000949	Event Menu Freeze
Gemini000928	Sensor Off Tissue and StO2 Value
Gemini000827	Serial Stream Crash when configuring a second port
Gemini000746	Correct redraw speed of numeric fields
Gemini000667	Modify TaskClassBase management of pool and queue

SCM Build: Package 1.0.2

CR Number	**Description** (newest to oldest, except release CR)
Gemini001018	Package 1.0.2
Gemini001017	Spelling incorrect for "Venous Return Down"

SCM Build: Package 1.0.1

CR Number	**Description** (newest to oldest, except release CR)
Gemini001014	Package 1.0.1
Gemini000978	Increase the size of Help About for French and make month text
Gemini000979	Add Russian key pad
Gemini000983	Correct image palettes
Gemini000987	Correct underlying code for snapshot functionality
Gemini000988	Sto2 seems to be truncated and not rounded
Gemini000989	Add 4 Channel CSV serial stream output
Gemini000990	Add 4 Channel ATE/CAS serial stream output
Gemini000991	Minor shell typos
Gemini000992	Fix STS output problems
Gemini000993	NSAM - Spikes above "High Ambient Light" will reset ""Ambient Light" de-bouncing / warning
Gemini001001	New update to Events: Reposition head/heart etc.
Gemini001004	ECLs off event is attached to ECL's On and saves to USB wrong
Gemini001006	NSAM - LPF Ambient light
Gemini001007	Correct mapping of Faulty Clock Battery SPR744
Gemini001010	diag -ext response has changed
Gemini001015	Add audit trail events for channel and system errors
Gemini001016	Correct package version update in the boot loader

SCM Build: Package 1.0.0

CR Number	**Description** (newest to oldest, except release CR)
Gemini000986	Package 1.0.0

SCM Build: Package 0.4.0.D

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CR Number	Description (newest to oldest, except release CR)
Gemini000976	Package 0.4.0D
Gemini000977	Recover lost code
Gemini000975	Force restart after port config change
Gemini000973	(b)(4) [redacted]
Gemini000971	Change Help Dialogs, Fix Strings & Events
Gemini000948	CAS ATE Protocol and 2-Minute Audio Disabled State
Gemini000824	Power up with active VueLink connection

SCM Build: Package 0.4.0.C

CR Number	Description (newest to oldest, except release CR)
Gemini000945	Package 0.4.0C
Gemini000970	NSAM - Disable AGC Enhancements, Default MFG build setting
Gemini000969	Increase stack size for USB and Flasher task.
Gemini000967	Crash when pressing OK twice to cancel a case save USB
Gemini000966	Translation String length tweaks
Gemini000963	New Sensor Off remapping of warnings
Gemini000962	NSAM - Sensor off enhancement
Gemini000961	Baud Rate Selection on CAS ATE and CSV Output
Gemini000960	The “g” in the “Saving… %” & “Saving…Done” overwritten by line below
Gemini000959	Add Boot exception handling
Gemini000958	Use simple printf to clean up some USB output code.
Gemini000957	Add improved performance sprintf.
Gemini000956	Alarm strings Translation Switch
Gemini000955	ATE/CSV Alarm State update
Gemini000954	StO2 Values Differences between Values on Display and on ATE/IntelliBridge Devices
Gemini000953	System crash during second Patient File saving
Gemini000952	STS Stop Key update
Gemini000951	STS Warning at end of STS Data Collection
Gemini000950	Fix plain text Ch, Hrs, L/R icon, and other strings
Gemini000947	Add German, Italian, Russian, Spanish, Dutch Translation
Gemini000946	Add "Do not remove USB" to case save dialog
Gemini000943	Previous Reference Value on Numerics Display right after Channel Activation
Gemini000923	Defaults Menu only Partially Implemented
Gemini000915	Red LED Alarm Flashing Rate
Gemini000881	NSAM - Enhance AGC
Gemini000701	LED & Audio remains after condition clears

SCM Build: Package 0.4.0.B

CR Number	Description (newest to oldest, except release CR)
Gemini000945	Package 0.4.0B
Gemini000944	Add the ability to wipe the system clean in the manufacturing boot loader.
Gemini000942	Improve USB save performance.
Gemini000940	Data Collection prevented until 1 valid channel
Gemini000935	Incorrect IntelliBridge/VueLink Communication Error Message

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000934	Language is lost at reboot
Gemini000933	Increase size of Patient Setup Hi/Low limit buttons for 5 French
Gemini000929	Patient File deletion - Confirmation Screen/Menu Missing
Gemini000927	Add French Translation to PEG
Gemini000925	USB Data Saving Progress Status
Gemini000921	STS allowed to start without Patient Data
Gemini000920	Event Mark Line not removed after New Patient
Gemini000918	Patient File not saved after switching to a new Patient
Gemini000917	STS Feature only working for current cases
Gemini000916	Patient Files deleted/lost after Time & Date change
Gemini000914	Display IP address when TCP/IP button is pressed.
Gemini000913	Move Scientific output to engineering mode ONLY.
Gemini000825	Hitting exit during Save Case to USB causes crash.

SCM Build: Package 0.4.0.A

CR Number	**Description** (newest to oldest, except release CR)
Gemini000903	Package 0.4.0A
Gemini000882	NSAM - Add Authentication code to sensor 1 Wire
Gemini000891	Amend battery shutdown
Gemini000892	Prevent new channels from being tracked after starting STS data
Gemini000894	Modify Gemini button list selection
Gemini000895	Remove display of IP address from boot loader
Gemini000896	Modify NVRAM configuration
Gemini000897	NSAM - Low THB Warning on super outlier
Gemini000898	Clear shutdown error detected
Gemini000899	Modify new patient dialog setting to 30 minutes
Gemini000900	Add ability to activate SAM and related tasks in the boot loader
Gemini000901	Set first time started time in NVRAM
Gemini000902	Force package information update in NVRAM even when no update is necessary
Gemini000904	Add touch screen play back with random variation
Gemini000905	Add a monitor feature to the shell touch screen
Gemini000906	Add cap in sleep time in touch screen playback
Gemini000907	STS On/Off button: Remove image jitter
Gemini000908	Remove grey "STS data" from top of main screen when disabled
Gemini000909	Ensure negative number does not occur in touch screen playback
Gemini000910	Occasional crash with initial new patient dialog at boot-up time
Gemini000911	Change "Cannot save current case" to USB file error
Gemini000912	Increase size of text boxes at top of MainScreen

SCM Build: Package 0.3.2G

CR Number	**Description** (newest to oldest, except release CR)
Gemini000885	Package 0.3.2G
Gemini000337	Unit test involving RTC failed in the Windows environment
Gemini000476	NSAM - Support Preamp Offsets
Gemini000724	Remove unused stings in PEG
Gemini000833	Display of channels w/unused body locations in STS View

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000834	Make number in numeric field launch Patient Setup Dialog
Gemini000844	Update USB output
Gemini000846	Change "FS Data" in title bar to "STS Data"
Gemini000848	Update Factory Default dialog Title & Text
Gemini000852	Update Patient Data Flow operation
Gemini000858	Add Battery state icons
Gemini000862	Add flag to indicate connection status
Gemini000864	Add display of any external port communication errors
Gemini000865	Remove unused GUI colors. Fix R brain color
Gemini000866	Add title to Events dialogs. OR Events, ICU, Vascular, NICU
Gemini000867	Title Bar Launch Dialogs for ID, View & Time
Gemini000868	Add processing of battery state
Gemini000869	USB Case Management: Update dialog boxes
Gemini000870	Update events as per marketing changes
Gemini000871	Change STs/FS icon to STS
Gemini000872	Ports dialog shall not update configuration if no user changes made
Gemini000873	Engineering dialog in Boot screen shall be password protected
Gemini000874	Update battery thresholds
Gemini000875	Restart Accumulations with New Patient plus other display enhancements
Gemini000876	Minor changes to Event Lists
Gemini000877	Add new battery icons
Gemini000878	Change language from Swedish to Dutch
Gemini000879	Update battery behavior
Gemini000880	Remove factory default button
Gemini000883	Fix Alarm Suppress color
Gemini000884	Change battery level logic
Gemini000886	Home button appears gray. Change back to green
Gemini000887	Normalize colors, fix greens
Gemini000888	Add "Factory Defaults" button
Gemini000889	Improve startup of system with new patient dialog
Gemini000890	Modify saved patient information to USB

SCM Build: Package 0.3.1G

CR Number	**Description** (newest to oldest, except release CR)
Gemini000841	Package 0.3.1G
Gemini000821	Remove next button on button bar for manufacturing
Gemini000826	Fix spacing and size of Alpha keypad. Add missing image files
Gemini000828	Selection of body location from numeric field causes error
Gemini000829	On alpha keypad the remaining characters is not initialized
Gemini000830	When using keyboard for password, hide char entry
Gemini000831	New VueLink/IntelliBridge condition messages to handle
Gemini000832	Change dialog text when asking for new patient after body location change
Gemini000836	Minor code cleanup
Gemini000837	Use white image background on body location icons when rendered on white
Gemini000838	Change USB to File icon in Setup->Files menu

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Gemini000839	Change order of Events button bar to “OR ICU Vascular”
Gemini000840	Add "investigation use only" message at exit of Engineering screen if any alarm is disabled
Gemini000842	Round corners of Silence and Home icons
Gemini000843	Reduce size of backspace key in Alpha keypad
Gemini000845	Change Splash Screen to TM (trade mark)
Gemini000849	When Ref button touched, draw all corresponding dashed reference lines
Gemini000863	Update various GUI text strings

SCM Build: Package 0.3.0G

CR Number	**Description** (newest to oldest, except release CR)
Gemini000797	Package 0.3.0G
Gemini000449	NSAM Bootloader & Main Software download without NSAM Module
Gemini000473	Occasional RTC loss of time and date
Gemini000490	Not Responsive Power switch Button
Gemini000595	No Event Marks on trace after Power cycle
Gemini000727	Transition from 2 channel CSV to off causes system crash
Gemini000737	Peg wbx updates for clean XLIF translation file
Gemini000738	Continue with ATE Implementation
Gemini000753	Have new patient confirmation dialog ask "New Patient?"
Gemini000754	Replace the TCP/IP message box with a Gemini dialog based message box
Gemini000766	Correct new patient action
Gemini000767	Add crisper button bar images
Gemini000768	Slight refactor of the network dialog
Gemini000769	Add more events
Gemini000770	SCB BootLoader about won't display NSAM BootLoader version when NSAM main is not available
Gemini000771	Font too Big in Numeric Field 4 ch mode
Gemini000772	Add new/continue patient timers & prompting
Gemini000773	Add fields to data file export
Gemini000774	Data file export cleanup
Gemini000775	Display view time was not updating on the main screen
Gemini000776	Disable greying out and dynamic area under curve feature
Gemini000777	Add alarm delay to NVRAM
Gemini000778	Add alarm limits to the business layer
Gemini000779	Add alarm delay to the user interface
Gemini000780	Allow Util message box to use string ID's
Gemini000781	Remove bitmap numbers in patient setup. Add header
Gemini000782	Add ATE Commands
Gemini000783	Move events strings and dialog to shared GUI
Gemini000785	Move Patient ID down in Main screen
Gemini000786	Add code to allow external modules access event string and color information
Gemini000787	Re-order time date dialog to Day-Month-Year
Gemini000788	Allow clearing/setting of package in NVRAM from the shell
Gemini000789	UNDO of a selected event leaves dashed lines on multi-graphs
Gemini000790	Remove unused USB icons and FS icon

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000791	Hitting SAM reset switch during SAM boot update leaves SAM inoperable
Gemini000793	Detect presence of SAM Mfg build on SAM
Gemini000794	Correct problems with VueLink/IntelliBridge
Gemini000795	Do not cancel current patient if time not changed
Gemini000796	Launch help dialogs when help buttons pressed. Phase 1: No content
Gemini000798	Fix code refactoring problems
Gemini000799	Correct touch play back feature in shell
Gemini000800	Add button to Eng Mode to turn off alarms
Gemini000801	NSAM - Main version bump
Gemini000802	Modify vascular event list
Gemini000803	Remove power button hysteresis
Gemini000804	Temporarily remove NICU event button
Gemini000805	Add touch screen scripts
Gemini000806	Package Updater display items
Gemini000807	Setting year in date/time dialog sets the date to 4 digits
Gemini000808	Add events to output data file
Gemini000809	Transition from 2 channel CSV to off causes system crash
Gemini000810	New battery and backspace icons. Icons updated true black background
Gemini000811	NSAM - Invalidate Sto2 for "Signal Out of range"
Gemini000812	Change Help-About Foresight logo
Gemini000813	Broke Win32 build when fixing flash update issues
Gemini000814	Add content to help dialogs
Gemini000816	Remove unique ID from Case Mgmt dialog
Gemini000817	Remove Russian from Language dialog. Change view dialog to one column
Gemini000818	Change cancel icon to wide on baud dialog. Fix L icon to black
Gemini000820	Fix BL unit test

SCM Build: Package 0.3.0F

CR Number	Description (newest to oldest, except release CR)
Gemini000764	Package 0.3.0F
Gemini000765	NSAM - Bump Bootloader version
Gemini000763	Default IP address change
Gemini000762	NSAM - Increase High Temperature Threshold, Lower Brain Low signal Thresholds, Lower high Ambient Light Threshold
Gemini000761	Stop in boot loader if trigger file is detected on USB stick
Gemini000760	Display investigational unit based on NVRAM settings
Gemini000759	Have core file dump at shut down save with date/time format
Gemini000758	Increase usability of Save to File progress reporting
Gemini000757	Decrease CPU utilization of the OS health manager
Gemini000756	Reset reference on a new patient
Gemini000755	Add "Are you sure?" to the new patient button
Gemini000752	Ask if new patient if different body location
Gemini000751	Allow network to only be started once. Provide better user feedback
Gemini000750	Minor text change
Gemini000749	DataManager cleanup and refactoring
Gemini000748	Extend core dump to include audit and error logs

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000747	Create a start-up thread
Gemini000745	Activate special investigation mode text
Gemini000744	Add TCP-IP address dialog
Gemini000743	Fix redraw speed of numeric fields
Gemini000741	Fix saving of case to file to save data
Gemini000740	Exiting patient setup with cancel still allows changes to stick
Gemini000739	Add ability to modify TimeDataStore size for testing
Gemini000736	Move FlashUpdateDialog from Mfg and Boot to Shared Dir
Gemini000691	NSAM - Main & boot NSAM Flash update failure
Gemini000673	Package updater starts before SAM is booted and does arbitrary update of SAM
Gemini000596	Reference values on Numerics area right after Channel Reactivation
Gemini000572	Gap in Data Records
Gemini000570	Time & Date changed during Software upgrade
Gemini000549	Add USB detect stick to the shell

SCM Build: Package 0.3.0E

CR Number	Description (newest to oldest, except release CR)
Gemini000725	Package 0.3.0E
Gemini000735	Prevent invalid data entries from being saved in data stores
Gemini000734	Fix TimeDataStoreCollection unit test
Gemini000733	Save core file to any present USB memory stick instead of NVRAM
Gemini000731	Make flash update dialog a shared GUI entity
Gemini000729	Add investigational use text when in entering special system modes
Gemini000728	Do not start SAM in the manufacturing build
Gemini000726	Center alpha dialog box
Gemini000723	NSAM - Flash Update failure
Gemini000722	Modify various UI components to return values
Gemini000721	NSAM - Overriding Monitor PD values
Gemini000719	Various GUI related changes
Gemini000718	Cannot update boot loader from manufacturing build
Gemini000717	Add ATE Serial Protocol & UI
Gemini000715	Create a Shared PEG GUI wbx project to share dialogs between projects
Gemini000714	Add button to turn TCP-IP on. Set it off by default
Gemini000713	USB. MQX error on usb drive removal
Gemini000712	Add Events to CSV Serial Stream
Gemini000711	Add information to core dump
Gemini000710	Grid lines appear when graph layout changes
Gemini000709	Case Table related cleanup
Gemini000708	Core dump diagnostic feature
Gemini000707	Do not start SAM and data tasks in boot
Gemini000700	Add Simple CSV Serial Output Stream
Gemini000698	Add "Are you sure" dialog
Gemini000694	Add manufacturing default
Gemini000674	Increase size of data elements to store alarms
Gemini000624	Improve graph update timing

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SCM Build: Package 0.3.0D	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000706	Package 0.3.0D
Gemini000705	GUI hangs and does not register button up for several seconds. Intermittent
Gemini000704	Modify stack sizes to accommodate log and debug
Gemini000703	Add audit trail information to the main application
Gemini000702	Add OS Health manager dump from shell
Gemini000699	GUI updates, Alpha keypad
Gemini000697	NSAM - TOP Lock / outlier decision after a certain period of time in the case
Gemini000696	Change manufacturing splash screen
Gemini000695	Memory crash problem - Change in serial stream
Gemini000693	Add Asserts to fopen in serial stream based entities
Gemini000692	NSAM - MFG features enhance sensor calibration and support diagnostics info for the NSAM test
Gemini000689	NSAM - 1.Sto2 out of range will sometimes not report an error. 2. Add NSAM ADC offsets
Gemini000688	Modify set date/time
Gemini000687	NSAM - Turn off LEDs of an invalid sensor
Gemini000686	Set event list background color instead of text color
Gemini000685	Add UNDO to event list
Gemini000684	Add case management dialog
Gemini000683	Make event mark circles match the event code color
Gemini000682	Add information to the about dialog box
Gemini000681	Draw in filled circle on graph
Gemini000680	Modify touch of numeric area
Gemini000679	Remove quick event
Gemini000678	Auto detection of USB with SW package
Gemini000677	Problems updating SCB boot in the package updater
Gemini000676	Default parameters in shell are being set to zero
Gemini000672	Remove set task error if fopen fails and fix any fopen that fails to check null
Gemini000666	Improve efficiency of PegString
Gemini000646	Add Case Table
Gemini000569	Alarm Audio not always on during System Alarm state
Gemini000550	Closing the command window with a shell session causes the system to crash
Gemini000527	Audio Volume set to zero without apparent reason
Gemini000207	Add battery one wire back into the one wire table

SCM Build: Package 0.3.0C	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000671	Package 0.3.0C
Gemini000670	Modify task stack sizes
Gemini000669	Add additional debug information to the MQX kernel
Gemini000668	PEG ICON fix body locations
Gemini000665	Increase PegString buffers to prevent memory errors
Gemini000664	Fix GeminiTextButton constructor
Gemini000663	Fix Peg colors. Remove transparent icon from button bar

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Gemini000662	GUI updates: STS dialog, etc.
Gemini000661	NSAM - Adjust Sensor Off parameters and behavior
Gemini000660	System Message background color remains non-black when error clears
Gemini000659	Numeric Key pad -Auto close on valid data
Gemini000658	Shell error
Gemini000657	Address various system shutdown issues
Gemini000656	Add in 1-wire power test in POST
Gemini000655	Modify Serial dialog to add new stream protocol
Gemini000653	NSAM - Enable a retry in reading the sensor 1 -wire 2nd page
Gemini000652	NSAM - Lower thresholds for Monitor PD levels with Phantoms
Gemini000651	Add Keypad for patient ID input
Gemini000650	Move Update Package from Eng Mode bar to first Boot bar, first item
Gemini000649	Modify temperature monitoring to be more distributed in time
Gemini000648	Display task name along with ID when logging
Gemini000647	Add Transparent Icons to button bar
Gemini000645	Fix Boot update: Add Software Version Package to Help button
Gemini000644	Adjust system stack, poll rate, etc. to avoid system problems
Gemini000641	Add basic output of patient data to file
Gemini000638	Copy NSAM *.txt files to the Binaries Directory after build
Gemini000630	System crash if all channels are set to "Unused"
Gemini000629	Occasional system crashes related to network traffic
Gemini000626	Incorrect STS Percentiles Range Distribution

SCM Build: Package 0.3.0B

CR Number	**Description** (newest to oldest, except release CR)
Gemini000640	Package 0.3.0B
Gemini000643	Change image displayed on manufacturing build
Gemini000642	NSAM - Fix debouncing in Sensor Off for recalculating TOP
Gemini000639	Enhance kernel logging in the shell
Gemini000637	Change Data limits of the NSAM test
Gemini000636	Add Software Version Package to Help button
Gemini000635	Add handling for new NSAM messages related to Sensor Off and Sensor Lifting
Gemini000634	Add kernel logging function to shell
Gemini000633	Fully implement validity test of SAM data on the SCB
Gemini000632	Random Crash with scientific serial steam enabled
Gemini000627	Modify task stack sizes
Gemini000625	Add password-protected button bar for service/developer actions
Gemini000623	NSAM - Add sensor S/N to scientific data
Gemini000606	Modify data management for Numonyx
Gemini000477	NSAM - Sensor on / off detection

SCM Build: NSAM 0.7.4d

CR Number	**Description** (newest to oldest, except release CR)
Gemini000662	NSAM - Lower thresholds for Monitor PD levels with Phantoms
Gemini000661	NSAM - Adjust Sensor Off parameters and behavior
Gemini000653	NSAM - Enable a retry in reading the sensor 1 -wire 2nd page

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SCM Build: NSAM 0.7.4b	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000642	NSAM - Fix debouncing in Sensor Off for recalculating TOP
Gemini000623	NSAM - Add sensor S/N to scientific data
Gemini000477	NSAM - Sensor on / off detection

SCM Build: Package 0.3.0A	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000619	Ensure NVRAM elements are valid
Gemini000618	Document NVRAM debug facility
Gemini000617	Fix Boot to build with PackageUpdate dialog
Gemini000615	Save graph layout and Language to NVRAM on user change. Restore at start.
Gemini000608	Add Numonyx M29W128GL flash device driver
Gemini000607	Fix Boot and Manufacturing builds for RAM release
Gemini000584	Alarm silence countdown
Gemini000571	System Resets due to VueLink Connection
Gemini000561	Create a validity test of SAM data on the SCB.

SCM Build: Package 0.2.0A	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000616	Package 0.2.0A
Gemini000614	Add graph channel layout and grids to NVRAM.
Gemini000613	GUI: Ch 2 and 4 text, swap Body icons, etc
Gemini000612	Add State aware Start and Stop to STS button on button bar
Gemini000610	Correct colors in PEG builder.
Gemini000609	A second dialog for alarm limit numerics sometimes appears.
Gemini000605	Move all code to run from RAM
Gemini000601	Implement package update system

SCM Build: Package 0.1.0C	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000604	Package 0.1.0C
Gemini000603	Allow highlight of list box items.
Gemini000602	Add toggle state persistence to button bar buttons. Second phase
Gemini000599	Event dialog box does not redraw numeric fields.
Gemini000598	Add set of individual colors to button list dialog.
Gemini000594	NumericKeyPad does not handle empty entry properly
Gemini000593	Add support to srecordchecksum for new SAM app part numbers
Gemini000592	NSAM - Don't allow the HOST task to start before the channels have been initialized
Gemini000591	Rework Gemini button base class.
Gemini000590	Add lightweight debug info system
Gemini000589	Investigate long shutdown time on some systems
Gemini000588	Selecting the port selection within Port menu causing a system crash (SPR 716)
Gemini000587	NSAM - Sensor test fixture option - use default temperature offset

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

SCM Build: Package 0.1.0B	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000580	Package 0.1.0B
Gemini000583	Change button bar bitmaps to allow text at bottom
Gemini000582	Change FlexBus Chip Selects to be inputs
Gemini000578	Add text strings for button bar
Gemini000577	Fix graph crash when big gap in data at startup
Gemini000575	Fix data delivery and display with multiple TimeDataStores
Gemini000574	Alarm message is lost when screen is reconfigured 2 <-> 4 channel
Gemini000573	GUI updates
Gemini000568	Numeric key pad does not work.
Gemini000567	Ref values lost after switching from 4 to 2 channels
Gemini000566	System Alarm LED & VGA left on during shutdown sequence
Gemini000564	Add toggle state persistence to button bar buttons
Gemini000545	Modify the button bar to display text on the bottom of the icons.

SCM Build: Package 0.1.0A	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000563	Package 0.1.0A
Gemini000565	Temporary patch to handle power off gaps in graphs
Gemini000562	Add touch zone to NumericField to launch patient setup dialog
Gemini000560	Add package number to NVRAM
Gemini000559	Clean up namespace dependencies
Gemini000558	Change various GUI screens for consistency
Gemini000557	Increase task priority of spawn manager to improve performance
Gemini000556	NSAM - TOP 690/730 outlier transition / detection
Gemini000555	Modify STS dialog spreadsheets to be more narrow
Gemini000554	Set STS threshold to 75% of the starting value
Gemini000553	Create calls to manage patient data in flash memory
Gemini000551	NSAM - Averaging of StO_2 Values
Gemini000548	Large dialog box was being improperly displayed centered on the screen
Gemini000547	Increase log delta time from 4 to 6 digits
Gemini000546	Add more information to Gemini statistics
Gemini000544	NSAM - Remap channels to accommodate Mt. Sinai IRB channel ordering
Gemini000543	Modify PEG spread sheet object to disable display of scroll bars
Gemini000542	Ref / AUT wiring through UI
Gemini000540	Add fields to STS Dialog
Gemini000539	Combine logic in PegUtil for setNumericValue with comma
Gemini000538	Add transfer of data from NVRAM to flash
Gemini000537	Modify PEG to support screen snapshot
Gemini000535	Modify power down process to be more user responsive
Gemini000534	Improve main application start up
Gemini000533	Add STS dialog
Gemini000532	Add in collection of case statistics
Gemini000531	Jump to main from boot quickly in the event of a power down incorrectly.
Gemini000530	Clean up main screen code

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Gemini000529	Normalize how list dialogs are displayed
Gemini000528	Modify system files to support PEG languages
Gemini000526	Auto center dialogs.
Gemini000525	fix a few drawing issues in graph
Gemini000524	Create shell macros facility
Gemini000523	Add cleanup for each task when system is powering down
Gemini000521	Clean up patient info to UI wiring
Gemini000518	Change task priorities to accommodate serial input
Gemini000517	Save improper power down into the error log
Gemini000514	Fix log merging changes to compile under Windows build
Gemini000513	Move data store from RAM to NVRAM
Gemini000512	Add error logging to serial loopback
Gemini000511	Allow pollute blocks to be turned on/off dynamically via the shell.
Gemini000510	Add machine to human mode command in shell.
Gemini000509	Cancel on event drop menu still drops an event.
Gemini000508	Adjust new priority scheme (see description)
Gemini000507	Change warning levels for memory health.
Gemini000506	PEG startup sync code broke manufacturing build
Gemini000503	Ports Configuration Setting
Gemini000501	Fix Boot to not run out of memory
Gemini000499	Provide mechanism for intermingled ErrorLog and AuditLog data
Gemini000498	Add Channel Errors and Warnings for VueLink
Gemini000480	Implement 4-channel overlay and controls
Gemini000478	Add language support
Gemini000454	StO_2 on graph is being truncated and not rounded

SCM Build: Gemini 0.3.6C	
CR Number	**Description** (newest to oldest, except release CR)
Gemini000548	Large dialog box was being improperly displayed centered on the screen.
Gemini000546	Add more information to Gemini statistics
Gemini000543	Modify PEG spread sheet object to disable display of scroll bars.
Gemini000540	Add fields to STS Dialog
Gemini000539	Combine logic in PegUtil for setNumericValue with comma
Gemini000537	Modify PEG to support screen snapshot
Gemini000535	Modify power down process to be more user responsive
Gemini000534	Improve main application start up
Gemini000533	Add STS dialog
Gemini000532	Add in collection of case statistics
Gemini000531	Jump to main from boot quickly in the event of a power down incorrectly
Gemini000530	Clean up main screen code
Gemini000529	Normalize how list dialogs are displayed
Gemini000528	Modify system files to support PEG languages
Gemini000526	Auto center dialogs
Gemini000525	fix a few drawing issues in graph
Gemini000524	Create shell macros facility

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000523	Add cleanup for each task when system is powering down
Gemini000521	Clean up patient info to UI wiring
Gemini000518	Change task priorities to accommodate serial input
Gemini000517	Save improper power down into the error log
Gemini000514	Fix log merging changes to compile under Windows build
Gemini000513	Move data store from RAM to NVRAM
Gemini000512	Add error logging to serial loopback
Gemini000511	Allow pollute blocks to be turned on/off dynamically via the shell
Gemini000510	Add machine to human mode command in shell
Gemini000509	Cancel on event drop menu still drops an event
Gemini000508	Adjust new priority scheme (see description)
Gemini000506	PEG startup sync code broke manufacturing build
Gemini000499	Provide mechanism for intermingled ErrorLog and AuditLog data
Gemini000498	Add Channel Errors and Warnings for VueLink

SCM Build: Gemini 0.3.6B

CR Number	**Description** (newest to oldest, except release CR)
Gemini000504	0.3.6B Release notes
Gemini000505	run checkmessage in samman in debug build
Gemini000493	Reorder task priorities
Gemini000500	Block peg task until RTC is read
Gemini000481	Make sure logging classes clean up varargs in all return paths

SCM Build: Gemini 0.3.6A

CR Number	**Description** (newest to oldest, except release CR)
Gemini000492	0.3.6A Release notes
Gemini000496	Test graph startup
Gemini000488	Serial Stream baud/protocol not saving correctly
Gemini000483	Make the event markers work
Gemini000489	Have the screen display earlier in the boot sequence
Gemini000491	For debugging, make graph optional (conditional compile)
Gemini000495	Fix Windows app build errors relating to SerialSpawnManager
Gemini000497	Fix the array of Win32 compiler warnings in pegStringArray
Gemini000475	Create message distribution mechanism
Gemini000487	Change the VueLink Specification File
Gemini000486	Add new strings and remove obsolete strings in PEG

SCM Build: Gemini 0.3.6

CR Number	**Description** (newest to oldest, except release CR)
Gemini000482	0.3.6 Release notes
Gemini000485	Make shell access to NVRAM numbered sections sync'd
Gemini000484	Add 15 second power button hold of reset into the manufacturing build
Gemini000479	fix warnings in GeminiButtonListDialog in windows build
Gemini000474	Power button press and hold in boot loader to reset NVRAM
Gemini000472	Implement on-the-fly graph layout changes

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

Gemini000471	Add in case simulation data
Gemini000470	Protocol and Baud dialog: Add Correct Header and show selected values
Gemini000469	Modify Build to Fix Problem
Gemini000468	First Event list shall display OR events
Gemini000467	Update error logging
Gemini000466	Clean up graph object
Gemini000447	Add GUI serial port configuration
Gemini000439	Create flash file access task
Gemini000426	High Pitch Tones while On Battery
Gemini000408	Slow plug in of preamp causes 2nd preamp to show disconnect
Gemini000395	Add Philips VueLink DataStream handler
Gemini000387	Add VueLinkConverter to Tools
Gemini000265	Graph data does not start at right hand side of graph

SCM Build: Gemini 0.3.5E

CR Number	**Description** (newest to oldest, except release CR)
Gemini000465	0.3.5E Release notes
Gemini000462	Add OS health manager problems to the error log
Gemini000461	Change boot loader text of "Gemini" to "Fore-Sight Elite"
Gemini000460	Allow of reset of sections of NVRAM from the shell
Gemini000459	Create system setting that will prevent the OS health manger from rebooting
Gemini000458	Add RTC-SRAM Battery Health Monitor - SPR # 711
Gemini000456	Allow for display of help by search in the shell
Gemini000448	Add task class analysis and control from the shell
Gemini000446	Add system error detection code to be displayed in the boot loader
Gemini000365	RTC battery fault not displayed - SPR # 711

SCM Build: Gemini 0.3.5D

CR Number	**Description** (newest to oldest, except release CR)
Gemini000452	0.3.5D Release notes
Gemini000455	Events size too big
Gemini000453	Bug fixes, Added boot delay, Fix GUI artifacts
Gemini000451	Temporarily increase peg task timeout
Gemini000450	Numeric Field does not always work
Gemini000445	Correct shell help
Gemini000441	GUI updates

SCM Build: Gemini 0.3.5C

CR Number	**Description** (newest to oldest, except release CR)
Gemini000442	0.3.5C Release notes
Gemini000444	Minor fix to Windows build
Gemini000443	Remove obsolete MainConfigWindow.cpp from the windows project
Gemini000440	Button bar blank when no bitmap is used (as in boot mode)
Gemini000438	Make greater use of error log and audit trail

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Gemini000437	Clean-up before create file access task
Gemini000435	Audio Volume not matching set Volume level - SPR #710
Gemini000432	Date Auto Correct without warning
Gemini000431	Create a shell tool to detect threads
Gemini000430	Add display of error messages in the shell
Gemini000429	Out of Range Issue with Preamp or Sensor disconnected
Gemini000428	(b)(4) [redacted]
Gemini000427	Clear alarms / signal warnings when a channel has been invalidated
Gemini000425	Color themes: Unify Gemini code with PEG
Gemini000424	Fix (so far inconsequential) typo in duart init structure
Gemini000423	Allow SAM communications to lag more before triggering restart strategy
Gemini000422	Add header to numeric keypad, Clean up old Limits logic
Gemini000421	Support updated 1-Wire information for sensors
Gemini000420	Create a manufacturing build application
Gemini000418	Remove 5% selection from Brightness and Volume dialogs
Gemini000397	Add file support to CircularBuffer
Gemini000325	Not all Audio and Visual Alarms removed after Condition cleared - SPR # 710
Gemini000319	(b)(4) [redacted]
Gemini000303	Investigate spontaneously created task

SCM Build: Gemini 0.3.5B

CR Number	**Description** (newest to oldest, except release CR)
Gemini000417	0.3.5B Release notes
Gemini000416	Fix boot to allow entry to multiple update dialogs
Gemini000415	Add diagnostic audit logs to (maybe) help track down crash
Gemini000414	Code change to set graph colors crashes win win32 build
Gemini000413	Add month to time date, Add header to keypad, Clean up
Gemini000412	GuiUnitTest will not build, Remove include ForeSightTextButton.h
Gemini000411	Support new 1-wire parameters for the preamp
Gemini000410	Change button bar bitmaps: Black background
Gemini000409	Graphs don't start until patient setup is modified
Gemini000407	Untangle header files, Remove global from SensorLocation
Gemini000406	Graph traces start with a spike from bottom of graph to initial value
Gemini000404	main screen graph colors should match sensor location color
Gemini000403	Main graph only shows 1 graph (2 channels)
Gemini000402	Create class to maintain the current system user
Gemini000400	Flashing SCB boot via shell interface does not work
Gemini000399	Add Warning/Info Dialog
Gemini000369	Dismissing Sensor or Preamp Disconnected Errors

SCM Build: Gemini 0.3.5A

CR Number	**Description** (newest to oldest, except release CR)
Gemini000401	0.3.5A Release notes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Gemini000396	Make Body Location dialog modal
Gemini000394	Add user configuration to NVRAM
Gemini000311	Add in facility for touch screen press and hold
Gemini000305	Touch screen touch event is sometimes incorrect - SPR # 708

SCM Build: 0.3.5

CR Number	Description (newest to oldest, except release CR)
Gemini000393	0.3.5 Release notes
Gemini000392	Have the view time persist over power cycles
Gemini000390	fix windows build
Gemini000389	Save GUI information into NVRAM
Gemini000388	Automate registration of class foundation classes
Gemini000386	Tie events into the serial stream
Gemini000384	Add the ability to use icons and set selected items in a button list dialog box
Gemini000383	firmware download to SAM from HyperTerminal doesn't work
Gemini000382	Add new Patient Setup dialog
Gemini000381	Fixes to SCB Main after refactoring
Gemini000380	Modify Main project files to build release mode correctly
Gemini000379	Add multi-line capability to GeminiButton
Gemini000378	Implement ability to field-update SCB boot
Gemini000377	update srecordchecksum
Gemini000376	Minor code clean up
Gemini000375	Boot's win32 build is broken
Gemini000374	Modify Boot module to use ButtonBar
Gemini000372	Minor code clean up
Gemini000371	Modify ButtonBar to provide 'Next' button
Gemini000370	Modify Button List Dialog
Gemini000367	Modify NVRAM saves to provide cross-version compatibility
Gemini000366	Modify NVRAM layout to support cross-module variables
Gemini000363	Document serial output setup procedure
Gemini000362	Fix bugs in SCB boot SAM updater code
Gemini000358	check in srecordchecksum executable
Gemini000352	TPI value at startup when sensor is not connected is at max
Gemini000350	Consolidate custom controls and buttons

SCM Build: 0.3.4

CR Number	Description (newest to oldest, except release CR)
Gemini000359	0.3.4 Release notes
Gemini000364	Delay communication to NSAM to fix auto start bug
Gemini000361	Temporarily remove RTC Oscillator check
Gemini000360	Fix SystemErrorCodes to properly activate alarms
Gemini000357	Add NVRAM disable of LED alarm
Gemini000356	Allow non-cerebral sensor locations
Gemini000355	Refactor GeminiButtonListDialog

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Gemini000348	Plug in of sensor and preamps produces no audio
Gemini000345	Add "Change Brightness" Dialog
Gemini000343	Add requested fields to scientific binary output
Gemini000342	NSAM comm recovery gets in the way of NSAM flashing
Gemini000340	Add full screen touch analysis for use by diagnostics
Gemini000339	Make SCB and NSAM image checksums stored in same relative location
Gemini000336	Unit test for FixedSizeQueue and CircularBuffer failed
Gemini000332	Add functionality to Read/Write 1 wire memory chips
Gemini000331	Test Xon Xoff for serial output stream over DUART
Gemini000330	Modify ButtonBar to meet new UI requirements
Gemini000328	Change Alarm Pulse durations to match 60601-1-8
Gemini000327	Create generic button list window
Gemini000326	Set Audio Volume not automatically implemented - SPR # 709
Gemini000324	Write a C++ utility to verify Scientific output sequence numbers and checksums
Gemini000322	Fix last check-in for RTC alarm
Gemini000321	Delay slightly between channels in scientific output to allow LV to keep up
Gemini000320	Enable Flash Filesystem
Gemini000317	Add RTC-SRAM Battery Health Monitor - SPR # 711
Gemini000315	Add diagnostic data collection to SamManager communication errors
Gemini000314	Update NSAM boot task
Gemini000301	Add Error, Audit, and Service Logging
Gemini000290	Clarify changes made for CR 233
Gemini000284	Adding binary file language support to PEG
Gemini000249	Create a single build for the NSAM and SCB
Gemini000247	Rework building of the NSAM boot loader and main application to match the SCB
Gemini000070	Develop a machine readable version of the shell

SCM Build: 0.3.3

CR Number	**Description** (newest to oldest, except release CR)
Gemini000299	0.3.3 Release notes
Gemini000318	Modify audio play based on ITS 0.2.1
Gemini000313	Add compile switch to create a boot loader that is in serial pass-through mode
Gemini000309	Add Messages for new NSAM error conditions
Gemini000308	Add in new NSAM mappings
Gemini000307	Modify MQX serial I/O to allow a blocking read or write to be abandoned
Gemini000306	SAM task stopped working
Gemini000302	Modify Button-Bar to highlight buttons along selection path
Gemini000298	Correct ITS Issues with version 0.2.0
Gemini000297	Breaking out PEG modules for Unit Testing and Using Custom Widgets
Gemini000296	Round the $St0_2$ value
Gemini000294	Speed up start of data acquisition at startup

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Gemini000293	Scientific output data becomes static when $St0_2$ is not valid
Gemini000292	Add version number to unit tests
Gemini000291	Touch screen events appear to be sometimes incorrect
Gemini000289	Refactor button bar design
Gemini000288	Clean up Sound-Manager
Gemini000287	Migrate dialogs to being modal

SCM Build: 0.3.2

CR Number	Description (newest to oldest, except release CR)
Gemini000281	0.3.2 Release notes
Gemini000286	Allow registered buttons to receive presses while in modal dialog
Gemini000285	Clean up Data-Manager code
Gemini000283	Change audio tones for system sounds to play at their own volume
Gemini000279	Startup beep does not play
Gemini000278	don't emit serial stream data for invalid channels
Gemini000275	Fast tap on the main menu does not work
Gemini000266	Access to boot loader screen no longer works
Gemini000258	Improve SAM communication
Gemini000256	Add in a fixed queue template

SCM Build: 0.3.1

CR Number	Description (newest to oldest, except release CR)
Gemini000215	0.3.1 Release notes
Gemini000277	Fix crash on start of Main App
Gemini000276	Get Release Build to complete building
Gemini000274	Scientific output debug data was left on
Gemini000273	Prevent invalid SAM readings from being displayed as 0
Gemini000272	Display of "RETRY" on patient window
Gemini000270	NSAM is losing power between boot loader and main application
Gemini000269	NumericKeyPad does not handle a 1 keystroke entry appropriately
Gemini000267	Adjust Patient Setup dialog to fix issues
Gemini000264	Change default baud of external ports to 115200
Gemini000263	Start $St0_2$ graph automatically at startup
Gemini000262	Start Serial-Stream-Manager tasks automatically at startup
Gemini000261	Improvements to external loopback DUART test
Gemini000260	Scientific Output Build
Gemini000259	Ensure build steps happen in proper order
Gemini000257	Migrate graph x-axis from using Date-Time to Abs-Date-Time
Gemini000255	Create single port DUART loop back test
Gemini000254	Minor Windows build changes
Gemini000253	Adjust Scientific output format
Gemini000252	Make cosmetic changes to Peg-Date & Time-Bar
Gemini000251	Correct timer for alarm suppression
Gemini000250	Implement scientific serial output

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Gemini000248	Create a higher level build for the SCB
Gemini000246	Sensor calibration, Top Active flag
Gemini000245	Track down excessive CPU spikes
Gemini000244	Implement binary serial stream output test code
Gemini000243	initialize Duart ports (baud rate from NVRAM)
Gemini000242	Add new larger images
Gemini000240	DUART driver documentation
Gemini000239	Add ability to play sounds with alarms
Gemini000238	Create software documentation area for the SCB
Gemini000236	Remove obsolete Duart support files
Gemini000235	Create standalone Windows unit test facility
Gemini000234	Update diagnostic shell commands to new shell structure
Gemini000233	Improve Usability of Numeric Key Pad
Gemini000232	Eliminate old I^2C interface
Gemini000231	Duart performance is slow
Gemini000230	Add functions to set and get system configuration parameters via the shell
Gemini000229	Remove Status-Bar and Graph-Scroll-Bar from Data-Time-Graph
Gemini000228	Adjust code to match the latest NSAM code
Gemini000227	Additional changes for new Algorithm
Gemini000226	Minor name changes in the shell & suspend OS health manager during m-test command
Gemini000225	New Algorithm (V1.09)
Gemini000224	Touch screen play back loop
Gemini000223	Implement Data-Store objects
Gemini000222	Clean up date/time object and scroll bar
Gemini000220	Set images in main to RLE
Gemini000216	Enable ability from shell to stop/start the SAM manager and SAM feeder
Gemini000214	Exit the clean screen when it has been mostly cleaned
Gemini000213	Remove Timer for Graph Updates
Gemini000212	Modify New Patient dialog to meet new UI requirements
Gemini000211	Add clean screen facility
Gemini000210	Remove quick cases from the system
Gemini000209	Download of code from TFTP server reset in the middle
Gemini000208	Features in the shell cause a system reset
Gemini000206	Audio buzz on application start
Gemini000205	Update how the SAM timing and graph updates function
Gemini000203	Use of a modal dialog box causes the health manager to kill the PEG
Gemini000202	Simplify Multi-Button implementation and usage by clients
Gemini000201	Add display of version information to the boot loader
Gemini000195	Update Duart driver
Gemini000190	Add unit tests for graph

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

CASMED®	What's In This Release		
P/N 15-06-0285	**Description** FS-ELITE Main Application	**Ver** 1.1.1	**Date** 16-Dec-13

1.0 Programming Notes:

Value of Unused bytes:	0xFFFF
File Name:	15-06-0285_SCBMain_1.1.1_0d73ab5c.S19
16-bit Checksum:	0x0d73ab5c

2.0 New/Changed Features:

The following are New/Changes Features associated with this release:

- Addition of languages including Russian (CR multiple CRs)
- 4 Channel ATE and CSV (CR 1008)
- Different body locations available in OUS (CR 1077)
- Implement adaptive fan speed based on internal temperatures (CR 1021, 1080)
- Entering Biomed password will display Button bar with Language and defaults (CR 1054)
- Add confirm dialog to Stop STS data (CR 1058)
- Change Brightness settings scale (CR 1064)
- Adjust priorities and error messages (CR 1062)
- Ports no longer require a system reset (CR 827)
- Add languages to USB patient file (CR 1095)

3.0 Improvements:

The following are Improvements associated with this release:

- Add toggling bitmap Checkbox to Engineering settings dialog (CR 1142)
- Add klog tools to Engineering Dialog (CR 1163)
- Caution - Investigational Device not displayed when engineering body locations are enabled (CR 1129)
- In 4 C4 CAS protocol crash when baud rate is selected. (SPR 761) (CR 1145)
- Change STS statistics to match CSV (CR 1149)
- (b)(4) [redacted]
- Clicking the Ref value does not toggle the Ref line on graph (1151)
- Sensor Off Tissue and StO_2 Value (CR 928)
- Russian Cyrillic keyboard (CR 1029)
- Special file on the USB stick "eng1984.cas" automatically starts the network (CR 1047)
- Shell - 1-wire serial memory tests (CR command "serm") (CR 1045)
- Create secondary level of reporting NSAM issues to the user (CR 1052, 1053)
- CAS/ATE Remap Unstable Signal status (CR 1071)
- Add Patient ID to USB File Name (CR 1073)
- Add one decimal digit to Cumulative Sat Below Thresh & Reg O2 % Ranges (CR 1067)
- Add scientific mode to all users (CR 1075)
- Add translation for Ports -> scientific (CR 1081)
- Add automatically generated events based on special NSAM conditions (CR 1061)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CASMED®	What's In This Release		
P/N 15-06-0285	**Description** FS-ELITE Main Application	**Ver** 1.1.1	**Date** 16-Dec-13

- Correct redraw speed of numeric fields after display of events - Still may occur but is vastly improved (CR 746)
- Rapid changes in Settings, e.g., View causes crash (CR 1038)
- External Interference causes the Numeric field to go blank instead of dashes (CR 1041)
- Monitor reset if Factory Defaults activated (CR 1003, 827)
- Correct underlying alarm led and audio problems (CR 1057)
- Pressed Events, then OR then screen froze showing just bottom 3 options (CR 949)
- Rapid switching between Event button and Undo button causes crash (CR 965)
- Possibility to delete more than the last Event entered (CR 1000)
- USB File - need to add a decimal digit precision to STS data (CR 1094)
- ICU Event list "Reposition Patient" should be Green Event after "Prostaglandin" (CR 1096)

4.0 Software Fixes:

The following are Software Fixes associated with this release:

- SPR 762-2 - In Italian "View" 24 Hour selection is 1Ore, should be 24 Ore (CR 1136)
- SPR 761 - In 4 C4 CAS protocol crash when baud rate is selected (CR 1145)
- SPR 764 - Numeric Field "Current Value" sometimes blank after fast boot (CR 1147)
- SPR 758 & 760 - Remove active case from USB save list (CR 1148)
- SPR 754 - Event Mark vertical dotted line (CR 1153)
- SPR 762-1 - Dutch under STS & other string fixes (CR 1158)

5.0 Hardware Changes:

There are no Hardware Changes associated with this release known at this time.

6.0 Incompatibilities:

There are no Incompatibilities associated with this release known at this time.

7.0 Dependencies:

The following are SW Dependencies of Main Application, 15-06-0285 V1.1.1 associated with this release:

- Main Bootloader, 15-06-0284 V1.1.0

8.0 Idiosyncrasies:

The following is a list of known Idiosyncrasies associated with this release:

None

Each has been examined and determined to have the following risk assessment:

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

CASMED®	What's In This Release		
P/N 15-06-0283	**Description** FS-ELITE NSAM Application	**Ver** 2.0.0	**Date** 16-Dec-13

1.0 Programming Notes:

Value of Unused bytes:	0xFFFF
File Name:	15-06-0283_SamMain_2.0.0_033cf6dc.S19
16-bit Checksum:	0x033cf6dc

2.0 New/Changed Features:

The following are New/Changes Features associated with this release:

- Enhance the Bovie Filter (1049)
- Add Adult Somatic IFU, adjust Adult Cerebral TPI Levels (1079)
- Enable the Enhanced AGC, allow higher dynamic range for the gains (1044)

3.0 Improvements:

The following are Improvements associated with this release:

- Add for MFG ability to get the 1 wire device S/N (1033)
- (b)(4) [redacted]
- Account for the 1 wire temperature NSAM offsets & Code Cleanup (1043)
- Adjust high Ambient Light Threshold (1048)
- (b)(4) [redacted]
- (b)(4) [redacted]
- (b)(4) [redacted], Adjust Low Thb levels, High Ambient Light (1093)
- Ignore Low brain 690nm values & do not include in spectral window calculation of "Sensor Off" (1140)

4.0 Software Fixes:

There are no Software Fixes associated with this release known at this time.

5.0 Hardware Changes:

There are no Hardware Changes associated with this release known at this time.

6.0 Incompatibilities:

There are no Incompatibilities associated with this release known at this time.

7.0 Dependencies:

The following are SW Dependencies of NSAM Application, 15-06-0283 V 2.0.0 associated with this release:

- NSAM Bootloader, 15-06-0282 V1.0.0
- Main Application, 15-06-0285 V1.1.1

8.0 Idiosyncrasies:

The following is a list of known Idiosyncrasies associated with this release:

None

Each has been examined and determined to have the following risk assessment:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

K133879/S003

March 28, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAR 31 2014
Received

Regarding: K133879 March 19, 2014 Request for Additional Information

To whom it may concern:

This letter and the accompanying eCopy should answer the points raise in the March 19th Additional Information Request Letter. The eCopy is an exact duplicate of the paper copy.

Q1. You have provided a description of the proposed system and its 3 main components. In the description you provided figures of the monitor and the sensor (SuppO1, Vol2 section 12. Device Description figures 1&2), but you didn't elaborate on their parts, dimensions and materials. The device description section should include the engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. Please provide detailed engineering drawings of the system's components, including all their parts dimension, labeling and materials.

A1. To address the 3 main components, CAS submits the following:
Monitor – CAS has enclosed a 7-page exploded view drawing (08-04-3000) with the detail requested. The actual labels are found in VOL 003. The monitor dimensions and weight are found in the User Manual;
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Q2a. In the user manual you have provided a figure of the patient environment (figure 1 p.18/53), and parts that are included in this environment (The oximeter, accessories, AC power cord). You wrote in the device description section (SuppO1, Vol2 section 12- Device Description p.3/3) that "The monitor is transportable for use in various hospital locations", however you didn't indicate what is the intended environment in the labeling. Please revise your user manual to include the intended environment (operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments), and indicate if the device is likely to be misused in another environment.

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1. The statement - "The FORESIGHT ELITE sensor is contraindicated for use on patients with physical site area too limited for proper sensor placement" has been modified to become – "The FORESIGHT ELITE sensor is contraindicated for use on patients with insufficient area for complete sensor attachment". We believe this better defines the intention of the contraindication.
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A3a. There is no difference between the large sensor in this submission and that which was submitted for the cleared predicate device in K123700. They are identical in every way.

Q3b. FDA has reviewed the above mentioned biocompatibility data, we were unable to verify whether the parts are in direct/indirect contact with the surface, and the material compositions of all patient contacting materials. Biocompatibility testing is not necessary only if the materials are identical to the final sterilized materials of a technologically comparable predicate device in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.). Biocompatibility testing is necessary in order to ensure the patient contact materials do not react adversely with the patient's skin. Please refer to standard ISO 10993-1 for more information.

Please provide a justification as to why a biocompatibility testing is not necessary for each part of the sensor, or provide detailed tests reports that will include the exact composition of the patient contacting materials, Direct/indirect contact, test methods, and Pass/fail criteria.

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2. What's In This Release No. 15-06-0283 ver. 2.0.0 for the FS-ELITE NSAM Application.

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2. 21-07-0369 FORE-SIGHT ELITE Interface Requirements, and
3. 21-07-0370 FORE-SIGHT ELITE Software Performance and Functional Requirements.

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A6. We do not intend to incorporate wireless capability, components or labeling at this time. The referenced document has been updated. Enclosed please find revision 03 of 21-07-0325.

Q7. You have indicate USB stick as means to transfer data in requirements 3.1.12.2 (p.12/16 main application - SW SRS) and 3.2.2. (p.15/16 main-SW SRS). We didn't identify any hazards related to these requirements. Please revise your submission to include the relevant hazards, or provide a reference to them in the submission.

A7. This originally intended functionality (wireless as well) is not yet incorporated into the system. CAS has removed the Transfer of USB data from the SRS document, fully removing section 3.2.2, the location where transferring data was found. Section 3.1.12.2 has not changed as this refers to a "copy" function. Enclosed please find revision 03 of 21-07-0325. Certain USB related risk mitigation information can be found in our Risk Analysis document in VOL 008 sections 4.6.4.1 and 4.7.1.2.

Q8a. You provided a list of 15 conditions that exclude a subject from participating in the study. Please provide a justification as to why the results of the study are applicable to the general population, or change the target population to include the exclusions.

A8a. <u>The protocol exclusion criteria are not target population exclusions</u> but rather exclusions for potential enrollable adult subjects in which the validation protocol may present an elevated risk to the subject. Because enrolled subjects undergo controlled stepped hypoxia to induce a range of oxygen saturation values, there may be elevated risk to the subjects with one of the 15 characteristics listed in the protocol's exclusion criteria. There are no elevated risks in attaching a non-invasive FORE-SIGHT II Elite or other model tissue oximeter sensor to these subjects with one of the 15 characteristics in clinical environments nor are there issues in obtaining a valid measurement on these subjects. Validation of cerebral, tissue, and likely pulse oximeters with similar controlled induced hypoxia protocols will have similar exclusion criteria for safety reasons. Predicate tissue oximeter (FORE-SIGHT & Equanox) 510(K)'s with similar validation protocol exclusion criteria include K123700, K051257, K102715, and K090807 (the validation protocols for all these 510(K)s were done in the same laboratory at Duke University Medical Center). These monitors do not have population exclusions of subjects with one of the 15 characteristics in the clinical environment.

Q8b. In your report, you referenced 16 publications. Please determine which of the 16 publications are most relevant to the study and provide a legible copy. Please also provide a legible copy of: Bland JM, Altman DG. "Statistical methods for assessing agreement between two methods of clinical measurement". Lancet 1986; 1 (8476):307-10.

A8b 13 publications, including the Bland Altman document, are included in this response. They are identified as attachments at the bottom of this letter.

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Q8c. The provided test measuring Bias ± Precision (1 standard deviation) from Bland-Altman: 0.24 ± 5.17%. It appears that it is almost 2 times worse than the predicate with a ± 5% from the "gold standard", and it appears that you have studied fewer subjects. Please justify why this Bias is not clinically significant, and why the number of subjects is sufficient to support your findings.

A8c. NIRS tissue oximeters report oxygen saturation (StO2) values as integers, for example 70%, 71%, 72%, 73%, etc. The bias of 0.24% is substantially less than the display resolution of 1% and is not clinically significant. Furthermore, the bias changes the root mean square (ARMS) accuracy by only 0.01% (from 5.17% to 5.18%). There are also different expectation of precisions depending on sensor location and population type. For adult subjects, cerebral StO2 measurements have the best precision 3-5%, (one standard deviation), which can be seen in the FORE-SIGHT predicate devices K123700 and K051257. For adult somatic or body measurements other than the brain, the precision decreases to 4-6% (1 sd), likely reported in the Equanox tissue oximeter 510(k) K102715. Also in the INVOS tissue oximeter adult somatic validation data reported in 510(k) K051274 (page 580, document provided), the bias was 1% and the precision was 6.9% (1sd). The lower reported precision of StO2 in somatic tissues is likely due to increased heterogeneity of somatic tissue oxygen saturation StO2 values likely due to the larger tissue volumes relative to brain when compared to the invasive blood reference measurements. In general the FDA has accepted a tissue oximeter precision < 6% (1 sd) from personal verbal communication on previous 510(k)s and an documented accepted precision of 5.9% for the predicate Equanox tissue oximeter reported in a recent 510(k) (K113215).

Sample Size: The **Table** below shows recent NIRS cerebral / tissue oximetry 510(k) adult validation subject enrollment and total number of data points. In this application for FORE-SIGHT II Elite, there were 24 subject enrolled with a total of 432 data points collected from two sensors placed on different parts of the body for *somatic* StO2 measurements. For the FORE-SIGHT II Elite first 510(k) K123700 for brain StO2 measurements, there were 25 subject enrolled with a total of 225 data points collected from one sensor placed on the forehead. The purpose of this 510(k) application under review to expand FORE-SIGHT II Elite to measure StO2 for non-brain (i.e. somatic) locations of the body. So by comparison there was one less subject enrolled but 207 more data points (432-225) for this 510(k). The higher number of data points justifies enrollment of one less subject.
When compared to the predicate Equanox 510(k)s K090807 and K102715, the number of subjects and data points obtained for that monitor's adult cerebral StO2 validation was 18 subjects with 218 data points and 23 subjects with 219 data points, respectively (see **Table**). So by comparison to this FORE-SIGHT II Elite 510(k) application, FORE-SIGHT II Elite enrolled more subjects and had a higher total of data points than the predicate Equanox validations.

Table: Comparison of subject enrollment and sample size FORE-SIGHT II Elite and Equanox 510(k)s.

Model & Sensor	**Number of Subjects**	**Number of FiO2 Plateaus (co-oximetry measurements)**	**Number of data points**	**510(K)**
FORE-SIGHT II Elite *Somatic*	24	216	432 (2 sensors)	**This application**
FORE-SIGHT II Elite Cerebral	25	225	225 (1 sensor)	K123700
Equanox 8000CA Cerebral	18	218	218 (1 sensor)*	K090807
Equanox 8004CA Cerebral	23	219	219 (1 sensor)*	K102715
	***Reference:** MacLeod et al. 2012 (provided)			

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Q9 If your response to the above deficiencies will affect the Indication For Use, the FDA Standards Forms or the information included in the 510(k) Summary, please provide the following:

Q9a. A new Indications for Use Statement with Rx and/or a TC designation
Q9b. A revised 510(k) Summary
Q9c. If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.

A9a-c. The stated Indications for Use is not affected.

This concludes our reply.

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs

Attachments / Related question

1. 08-04-3000 drawing / Q1
2. 01-06-3100 drawing / Q1
3. 03-05-0511 drawing / Q1
4. Replacement Device Description section / Q2a
5. 21-22-3000 Rev 01-Xb User Manual / Q2a & 2b
6. 15-06-0285 ver. 1.1.1 document for the FS-ELITE Main Application / Q4
7. 15-06-0283 ver. 2.0.0 document for the FS-ELITE NSAM Application / Q4
8. 21-07-0368 FORE-SIGHT ELITE Hardware Requirements / Q5
9. 21-07-0369 FORE-SIGHT ELITE Interface Requirements / Q5
10. 21-07-0370 FORE-SIGHT ELITE Software Performance and Functional Requirements / Q5
11. 21-07-0325 SRS document / Q6 & Q7
12. Bland Altman publication / Q8b
13. Carrasco 2003 publication / Q8b
14. Ito PET Arterial Fraction publication / Q8b
15. K051274 Somanetics Adult Somatic reference / Q8b
16. K102715 Nonin reference / Q8b
17. Laird Meta-Analysis publication / Q8b
18. Linnet 1990 publication / Q8b
19. Linnet 1993 publication / Q8b
20. Linnet 1998 publication / Q8b
21. Nonin K113215 reference / Q8b
22. Nonin Equanox reference / Q8b
23. Pang publication / Q8b
24. Strangman publication / Q8b

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March 28, 2014

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A7. This originally intended functionality (wireless as well) is not yet incorporated into the system. CAS has removed the Transfer of USB data from the SRS document, fully removing section 3.2.2, the location where transferring data was found. Section 3.1.12.2 has not changed as this refers to a "copy" function. Enclosed please find revision 03 of 21-07-0325. Certain USB related risk mitigation information can be found in our Risk Analysis document in VOL 008 sections 4.6.4.1 and 4.7.1.2.

Q8a. You provided a list of 15 conditions that exclude a subject from participating in the study. Please provide a justification as to why the results of the study are applicable to the general population, or change the target population to include the exclusions.

A8a. <u>The protocol exclusion criteria are not target population exclusions</u> but rather exclusions for potential enrollable adult subjects in which the validation protocol may present an elevated risk to the subject. Because enrolled subjects undergo controlled stepped hypoxia to induce a range of oxygen saturation values, there may be elevated risk to the subjects with one of the 15 characteristics listed in the protocol's exclusion criteria. There are no elevated risks in attaching a non-invasive FORE-SIGHT II Elite or other model tissue oximeter sensor to these subjects with one of the 15 characteristics in clinical environments nor are there issues in obtaining a valid measurement on these subjects. Validation of cerebral, tissue, and likely pulse oximeters with similar controlled induced hypoxia protocols will have similar exclusion criteria for safety reasons. Predicate tissue oximeter (FORE-SIGHT & Equanox) 510(K)'s with similar validation protocol exclusion criteria include K123700, K051257, K102715, and K090807 (the validation protocols for all these 510(K)s were done in the same laboratory at Duke University Medical Center). These monitors do not have population exclusions of subjects with one of the 15 characteristics in the clinical environment.

Q8b. In your report, you referenced 16 publications. Please determine which of the 16 publications are most relevant to the study and provide a legible copy. Please also provide a legible copy of: Bland JM, Altman DG. "Statistical methods for assessing agreement between two methods of clinical measurement". Lancet 1986; 1 (8476):307-10.

A8b 13 publications, including the Bland Altman document, are included in this response. They are identified as attachments at the bottom of this letter.

CAS Medical Systems, Inc.
44 East Industrial Road, Branford CT 06405, USA
Tel: (203) 488 6056 • Toll Free: (800) 227 4414 • Fax: (203) 488 9438
www.casmed.com

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Q8c. The provided test measuring Bias ± Precision (l standard deviation) from Bland-Altman: 0.24 ± 5.17%. It appears that it is almost 2 times worse than the predicate with a ± 5% from the "gold standard", and it appears that you have studied fewer subjects. Please justify why this Bias is not clinically significant, and why the number of subjects is sufficient to support your findings.

A8c. NIRS tissue oximeters report oxygen saturation (StO2) values as integers, for example 70%, 71%, 72%, 73%, etc. The bias of 0.24% is substantially less than the display resolution of 1% and is not clinically significant. Furthermore, the bias changes the root mean square (ARMS) accuracy by only 0.01% (from 5.17% to 5.18%). There are also different expectation of precisions depending on sensor location and population type. For adult subjects, cerebral StO2 measurements have the best precision 3-5%, (one standard deviation), which can be seen in the FORE-SIGHT predicate devices K123700 and K051257. For adult somatic or body measurements other than the brain, the precision decreases to 4-6% (1 sd), likely reported in the Equanox tissue oximeter 510(k) K102715. Also in the INVOS tissue oximeter adult somatic validation data reported in 510(k) K051274 (page 580, document provided), the bias was 1% and the precision was 6.9% (1sd). The lower reported precision of StO2 in somatic tissues is likely due to increased heterogeneity of somatic tissue oxygen saturation StO2 values likely due to the larger tissue volumes relative to brain when compared to the invasive blood reference measurements. In general the FDA has accepted a tissue oximeter precision < 6% (1 sd) from personal verbal communication on previous 510(k)s and an documented accepted precision of 5.9% for the predicate Equanox tissue oximeter reported in a recent 510(k) (K113215).

Sample Size: The **Table** below shows recent NIRS cerebral / tissue oximetry 510(k) adult validation subject enrollment and total number of data points. In this application for FORE-SIGHT II Elite, there were 24 subject enrolled with a total of 432 data points collected from two sensors placed on different parts of the body for *somatic* StO2 measurements. For the FORE-SIGHT II Elite first 510(k) K123700 for brain StO2 measurements, there were 25 subject enrolled with a total of 225 data points collected from one sensor placed on the forehead. The purpose of this 510(k) application under review to expand FORE-SIGHT II Elite to measure StO2 for non-brain (i.e. somatic) locations of the body. So by comparison there was one less subject enrolled but 207 more data points (432-225) for this 510(k). The higher number of data points justifies enrollment of one less subject.
When compared to the predicate Equanox 510(k)s K090807 and K102715, the number of subjects and data points obtained for that monitor's adult cerebral StO2 validation was 18 subjects with 218 data points and 23 subjects with 219 data points, respectively (see **Table**). So by comparison to this FORE-SIGHT II Elite 510(k) application, FORE-SIGHT II Elite enrolled more subjects and had a higher total of data points than the predicate Equanox validations.

Table: Comparison of subject enrollment and sample size FORE-SIGHT II Elite and Equanox 510(k)s.

Model & Sensor	**Number of Subjects**	**Number of FiO2 Plateaus (co-oximetry measurements)**	**Number of data points**	**510(K)**
FORE-SIGHT II Elite *Somatic*	24	216	432 (2 sensors)	**This application**
FORE-SIGHT II Elite Cerebral	25	225	225 (1 sensor)	K123700
Equanox 8000CA Cerebral	18	218	218 (1 sensor)*	K090807
Equanox 8004CA Cerebral	23	219	219 (1 sensor)*	K102715
	***Reference:** MacLeod et al. 2012 (provided)			

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Q9 If your response to the above deficiencies will affect the Indication For Use, the FDA Standards Forms or the information included in the 510(k) Summary, please provide the following:

Q9a. A new Indications for Use Statement with Rx and/or a TC designation
Q9b. A revised 510(k) Summary
Q9c. If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.

A9a-c. The stated Indications for Use is not affected.

This concludes our reply.

Sincerely,

Ron Jeffrey
Director, Regulatory Affairs

Attachments / Related question

1. 08-04-3000 drawing / Q1
2. 01-06-3100 drawing / Q1
3. 03-05-0511 drawing / Q1
4. Replacement Device Description section / Q2a
5. 21-22-3000 Rev 01-Xb User Manual / Q2a & 2b
6. 15-06-0285 ver. 1.1.1 document for the FS-ELITE Main Application / Q4
7. 15-06-0283 ver. 2.0.0 document for the FS-ELITE NSAM Application / Q4
8. 21-07-0368 FORE-SIGHT ELITE Hardware Requirements / Q5
9. 21-07-0369 FORE-SIGHT ELITE Interface Requirements / Q5
10. 21-07-0370 FORE-SIGHT ELITE Software Performance and Functional Requirements / Q5
11. 21-07-0325 SRS document / Q6 & Q7
12. Bland Altman publication / Q8b
13. Carrasco 2003 publication / Q8b
14. Ito PET Arterial Fraction publication / Q8b
15. K051274 Somanetics Adult Somatic reference / Q8b
16. K102715 Nonin reference / Q8b
17. Laird Meta-Analysis publication / Q8b
18. Linnet 1990 publication / Q8b
19. Linnet 1993 publication / Q8b
20. Linnet 1998 publication / Q8b
21. Nonin K113215 reference / Q8b
22. Nonin Equanox reference / Q8b
23. Pang publication / Q8b
24. Strangman publication / Q8b

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(b)(4) Drawing

(b)(4) Drawing

(b)(4) Drawing

(b)(4) Drawing

(b)(4) Drawing

(b)(4) Drawing

(b)(4) Drawing

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CAS MEDICAL SYSTEMS, INC.
TECHNOLOGY APPLIED TO MEDICINE

Material Specification

Item Number: 01-06-3100
Item Description: FS-Elite Oximeter Dual Preamp
Revision Level: 05
Engineering Approval: _____
Date Approved: 8/21/13

Notes:
This unit is supplied to us from (b)(4) [redacted] complete. See attached dwg.

See WP3449 if change to material or fit may affect mechanical properties

Approved Manufacturer:

Manufacturer	Mfg Item Number	Mfg Item Description
(b)(4) [redacted]	DWG NO C728 REV E	

Engineering Change Documents:

EC Number	Date Entered	Short Description	Status	Revision Level
010598	08/14/2013	product improve: replace loctite with locwasher.	Done	
010579	07/15/2013	VARIANCE-accept 12 Preamp Assy's to diff. V-limit	Done	
010557	06/17/2013	Improvement: S/N label on polybag; move bed clip	Done	
010530	05/06/2013	FS-Elite Sensor product improvement, 01-06-3100	Done	

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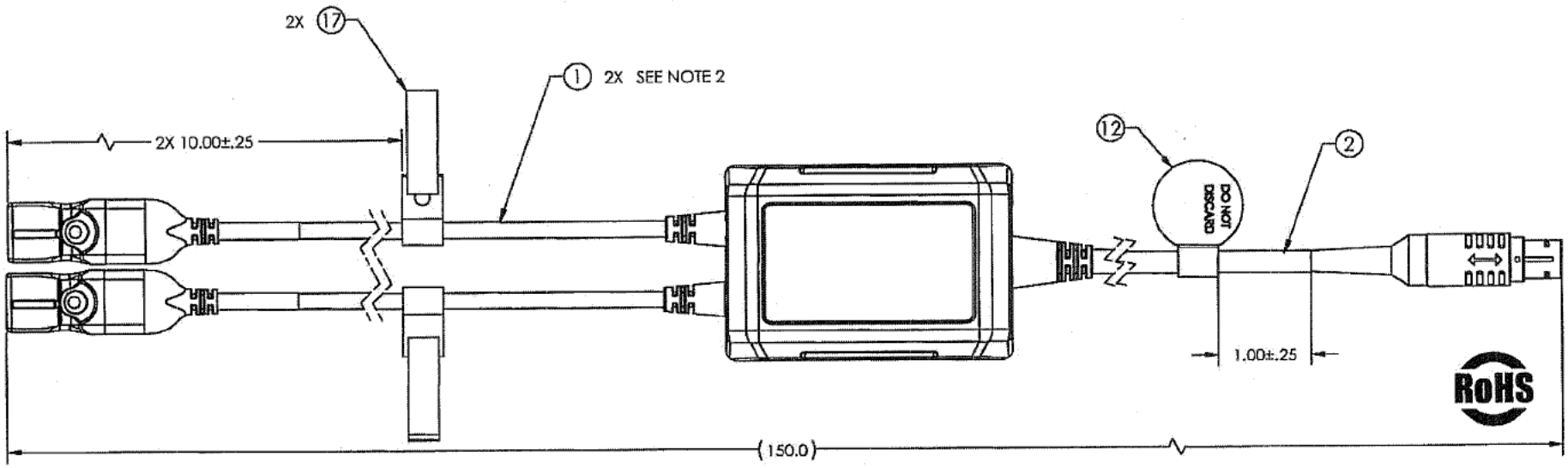
REVISIONS			
REV	DATE	INITIALS	DESCRIPTION
A	11/28/12	SS	RELEASED
B	2/7/13	BW/SS	SEE ECN #2419
C	5/1/13	BW/SS	SEE ECN #2711
D	6/7/13	BW/SS	SEE ECN #2837
E	8/8/13	HS/SJ	SEE ECN #2975



SEE EXPLODED VIEW

NOTES

1) ASSEMBLE PER IPC/WHMA -A- 620, CLASS 2

2) REF: C714 SH2 FOR WIRING DIAGRAMS

3) CAREFULLY COIL CABLES AS TO AVOID DAMAGE. SECURE WITH TIE-WRAP. ILLUSTRATION SHOW IS REFERENCE ONLY. (SEE SHEET 3)

4) AFTER FILLING BAG WITH CONTENTS, FOLD BAG AND APPLY LABEL LB1076 TO SEAL BAG. (SEE SHEET 3)

5) NO COMPONENT,CONTRUCTION, OR PROCESS CHANGE TO BE MADE WITHOUT CUSTOMER APPROVAL.

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.X ONE PLACE DECIMAL: ±0.1 INCH
.XX TWO PLACE DECIMAL: ±.02 INCH
.XXX THREE PLACE DECIMAL: ±.005 INCH

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO: 01-06-3100

DRAWN BY: B.WHELAN	DATE: 11/28/12	
APPROVED BY: S. STOUT	DATE: 11/28/12	
MANUFACTURING: M. BENEDICT	DATE: 11/28/12	
QUALITY: S. APPIAH	DATE: 11/28/12	

[redacted] (b)(4)

TITLE: 145" (2) SENSOR - MONITOR ASSEMBLY

SCALE: N/A
REV: E

NAME/CO: CASMED
SHEET: 1 OF 3
DWG NO: C728

01-06-3100

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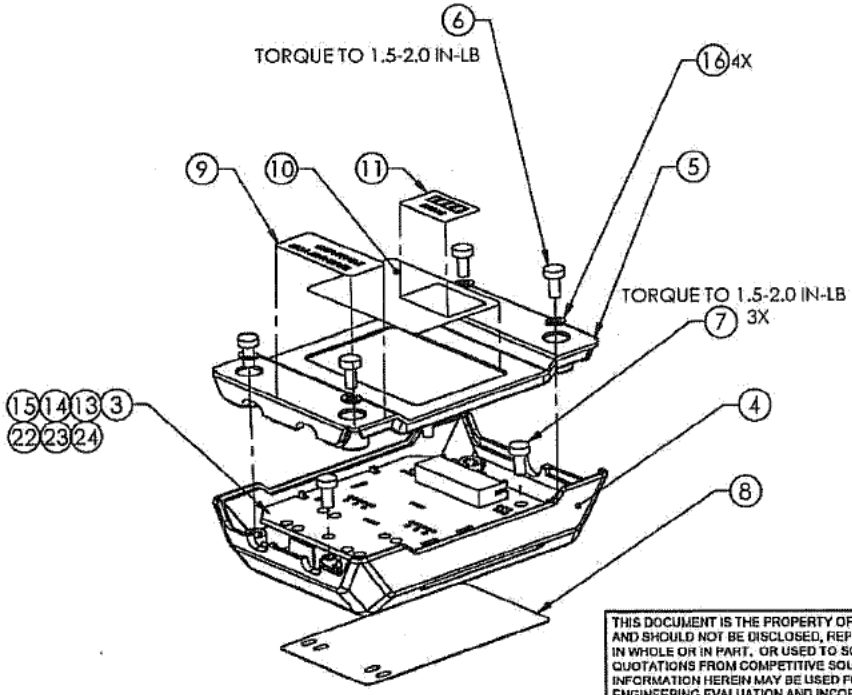

PARTS LIST

ITEM	QTY	DESCRIPTION	SERIES	PART NO	COLOR	MATERIAL
1	2	SENSOR SUBASSEMBLY		C714		
2	1	MONITOR SUBASSEMBLY		C713		
3	1	PCBA		IC0046		
4	1	PREAMP HOUSING BASE		CM1138		
5	1	PREAMP HOUSING COVER		CM1139		
6	4	#4-40 X .25 PHS		MI9039		
7	3	#4-40 X .25 PHS THREAD CUTTING		MI9040		
8	1	LABEL MAIN		LB1078		
9	1	LABEL VOID		LB1080		
10	1	LABEL BOTTOM		LB1059		
11	1	LABEL SN/BARCODE		LB1060		
12	1	LABEL DO NOT DISCARD		LB1079		
13	AR	COPPER TAPE .5" WIDE		WR0047		
14	AR	KAPTON TAPE		WR0060		
15	4	CABLE TIE		TW0010		
16	4	WASHER, #4, SPLIT LOCK		MI0821		
17	2	SPRING CLIP		MI0794		
18	1	LABEL, SENSOR LABEL		LB1072		
19	1	LABEL		LB1076		
20	1	BAG, 4X4 2MIL ZIPLOCK		MI0079		
21	1	BAG, 13X18 2MIL ZIPLOCK		MI0800		
22	.083'	3/32 ID HEATSHRINK, BLK		HS3320A	BLK	
23	.083'	1/16 ID HEATSHRINK, BLK		HS1169	BLK	
24	.0004 LB	26 7/34 TC Ø .019		TC2607		
25	1	LABEL BAG, SN		LB1105		

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.XXX THREE PLACE DECIMAL ±.005 INCH

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO 01-06-3100

DRAWN BY B.WHELAN	DATE 11/28/12	[redacted] (b)(4)	
APPROVED BY S. STOUT	DATE 11/28/12	145" (2) SENSOR - MONITOR ASSEMBLY	N/A
MANUFACTURING M. BENEDICT	DATE 11/28/12		REV E
QUALITY S. APPIAH	DATE 11/28/12	NAME/CO CASMED	SHEET 2 OF 3 / DWG NO C728

01-06-3100

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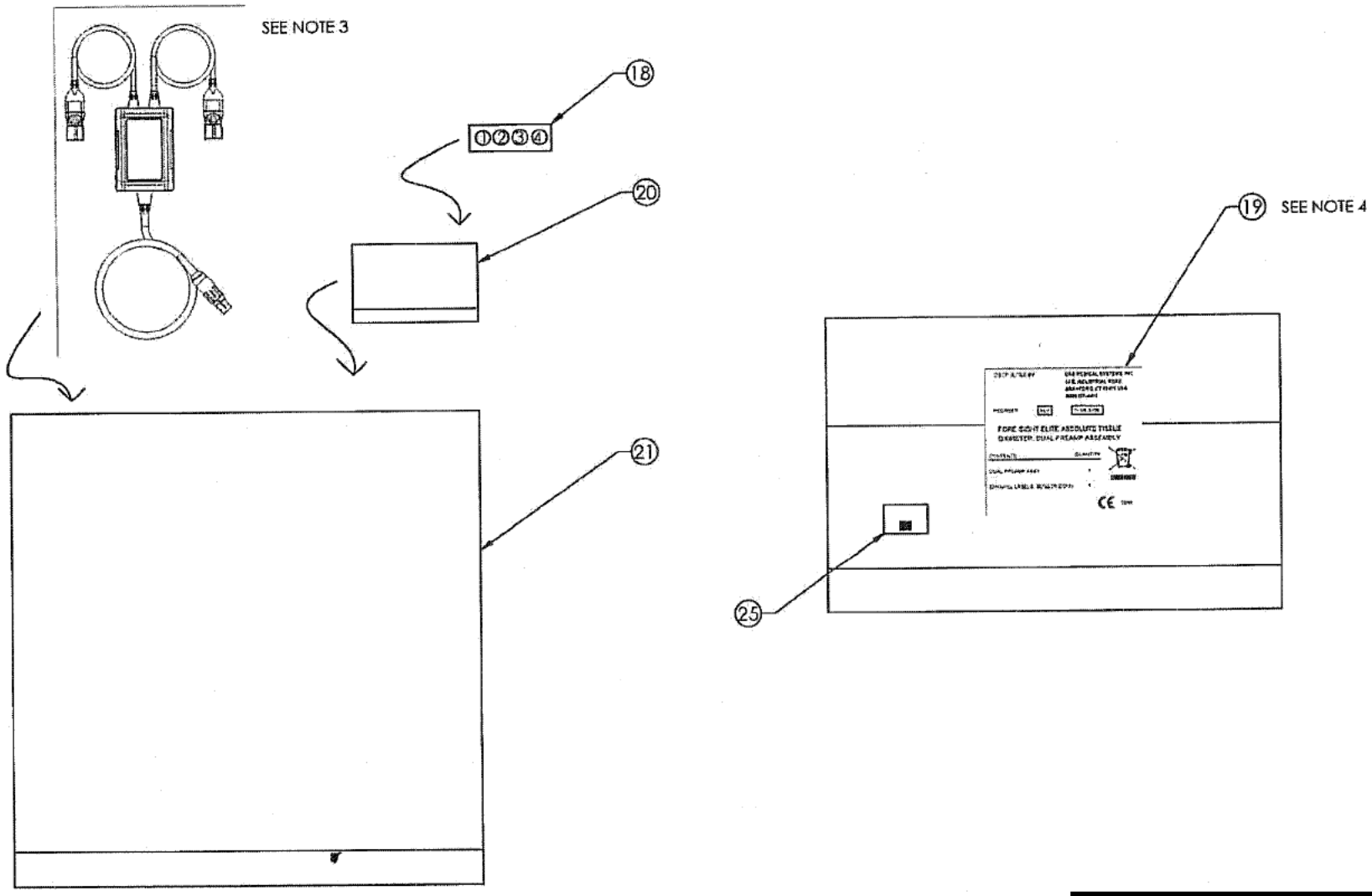

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.XX TWO PLACE DECIMAL: ±.02 INCH
.XXX THREE PLACE DECIMAL ±.005 INCH

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO 01-06-3100

DRAWN BY B.WHELAN	DATE 11/28/12	[redacted]
APPROVED BY S. STOUT	DATE 11/28/12	(b)(4)
MANUFACTURING M. BENEDICT	DATE 11/28/12	TITLE 145" (2) SENSOR - MONITOR ASSEMBLY
QUALITY S. APPIAH	DATE 11/28/12	REV N/A E
NAME/CO CASMED	SHEET 3 OF 3	DWG NO. C728

01-06-3100

ns? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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01-06-3100 PREAMP ASSY, ELITE

COMPONENT DRAWINGS

C7M → SEE CASMED # 03-58-0010
C7B → SEE CASMED # 03-58-0011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISIONS			
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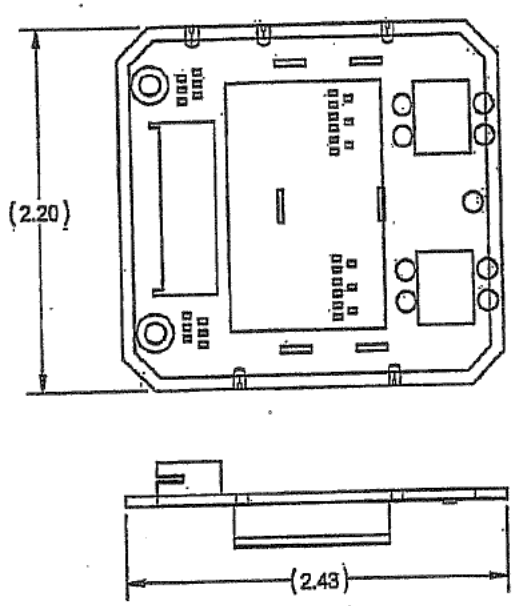

8 of 25

[redacted] (b)(4)

MW P/N: ICO046

PART NAME: PCB REV: B

DATE INITIATED: 11/26/12 BY: B.WHELAN CHK BY: BILL WHELAN

DESCRIPTION: DUAL PRE-AMP BOARD

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
CASMED	S	03-59-0452 REV 7

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REVISIONS			
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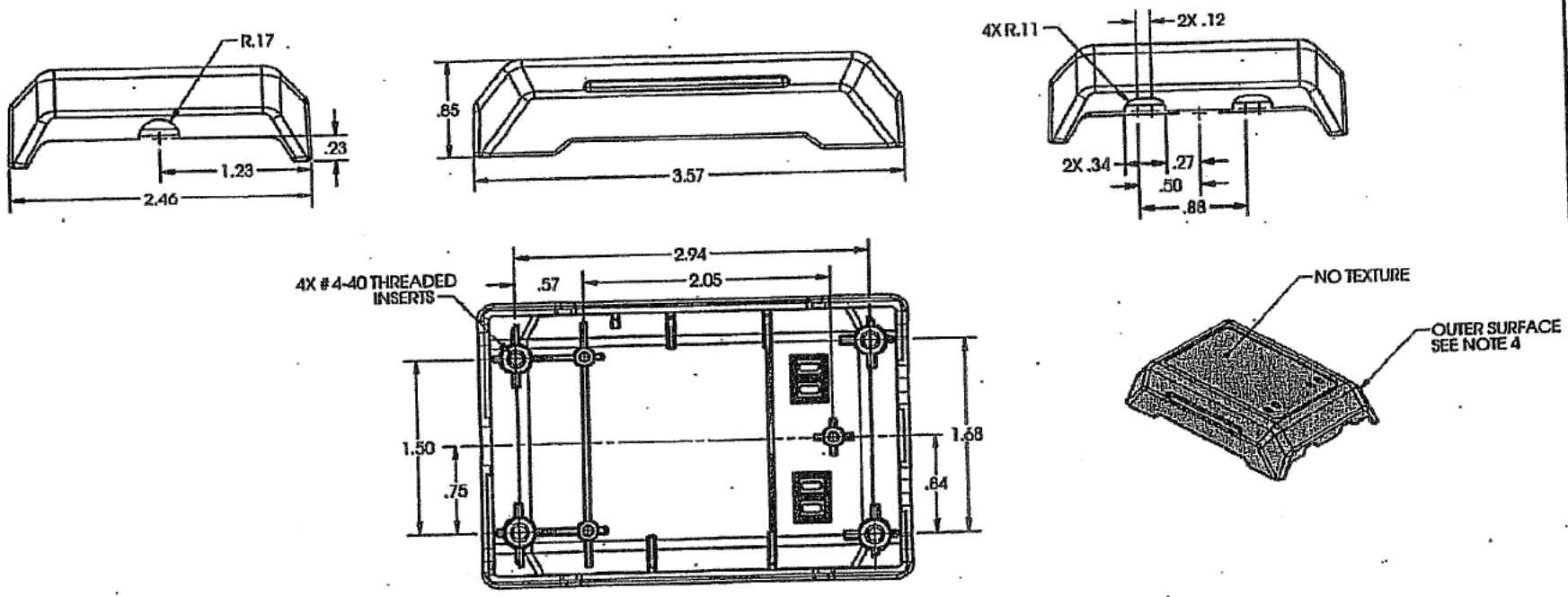

NOTES:
1) MATL: ABS LUSTRAN 348-012002
2) GEOMETERY NOT DIMENSIONED IS CONTAINED IN CAD DATA FILE.
3) DIMENSIONS ARE REFERENCE.
4) LIGHT TEXTURE OUTER SURFACE EXCEPT NOTED

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.XXX THREE PLACE DECIMAL: ±0.005 INCH

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO

DRAWN BY B.WHELAN	DATE 11/7/12	[redacted] (b)(4)
APPROVED BY S. STOUT	DATE 11/7/12	
MANUFACTURING	DATE 11/7/12	
QUALITY	DATE 11/7/12	

TITLE PREAMP HOUSING TOP		REV A
NAME/CO CASMED	SHEET 1 OF 1	DWG NO CM1138

3 of 25

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REVISIONS			
REV	DATE	INITIALS	DESCRIPTION
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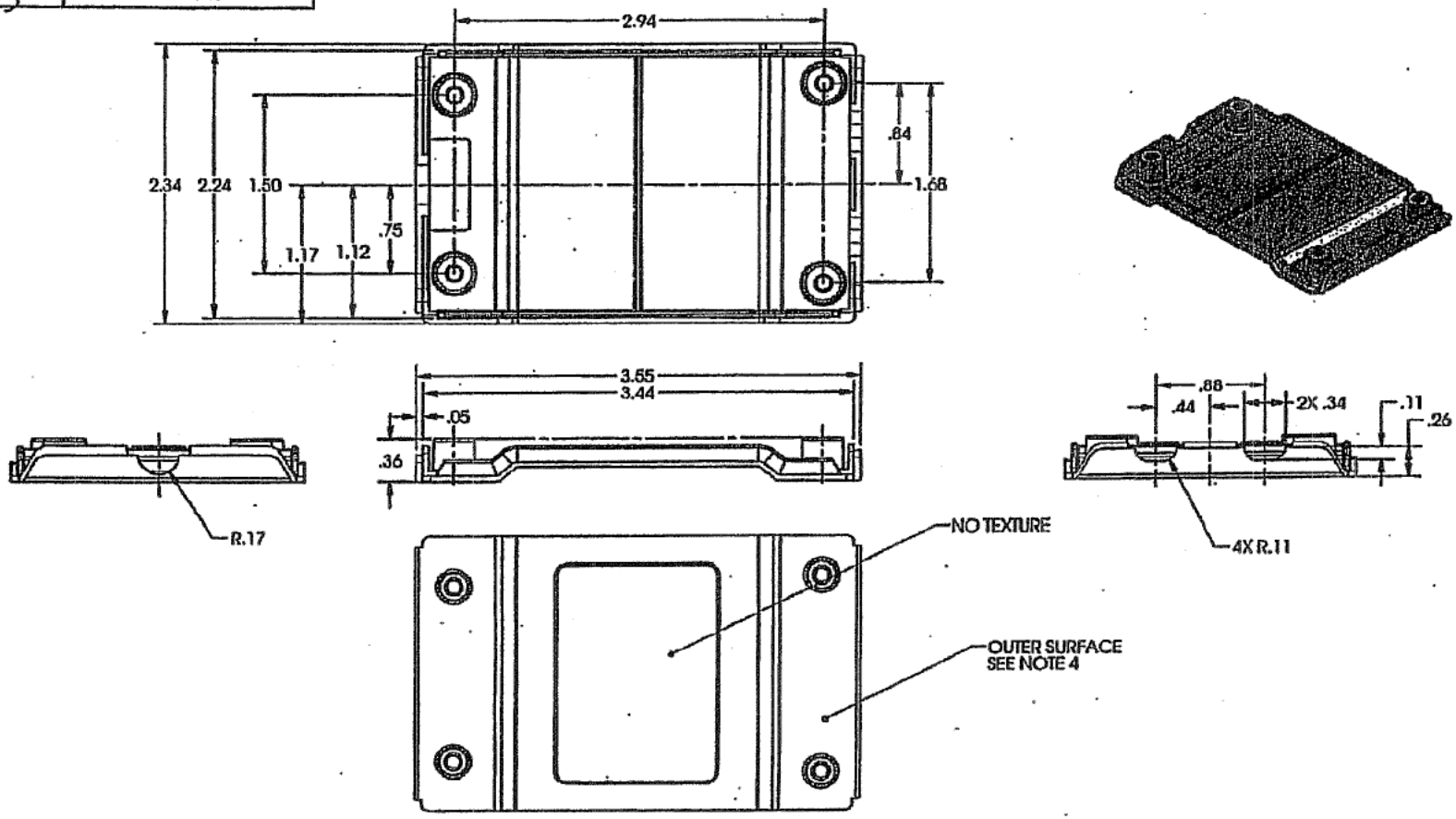

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.XX TWO PLACE DECIMAL ±.02 INCH
.XXX THREE PLACE DECIMAL ±.005 INCH

PROJECTION

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO

DRAWN BY	B.WHELAN	DATE	11/7/12
APPROVED BY	S. Stout	DATE	11/7/12
MANUFACTURING	M. Berghoff	DATE	11/7/12
QUALITY	M. Thevenet	DATE	11/7/12

[redacted] (b)(4)

TITLE	PREAMP HOUSING BOTTOM		SCALE N/A, REV A
NAME/CO	CASMED	SHEET 1 OF 1	DWG NO CM1139

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(b)(4) [redacted]

IW P/N: MI9039

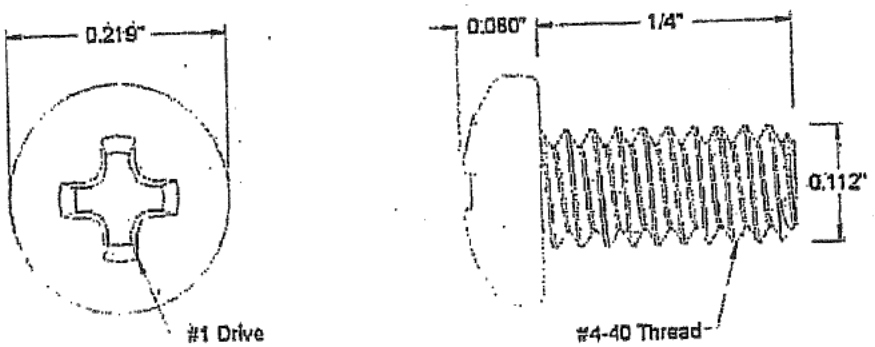
PART NAME: SCREW REV: B

DATE INITIATED: 7/13/12 BY: H. SCHNOBRICH CHK BY: BILL WHELAN

DESCRIPTION: PAN HEAD SCREW, #4-40 X 1/4" LG, STAINLESS STEEL

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
MCMASTER-CARR	S	91735A102 316SS



REV	DATE	INITIALS	DESCRIPTION
B	3/5/13	HS/SS	SEE ECN #2578
A	7/14/12	BW	RELEASED

REVISIONS

1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

MW P/N: MI9040

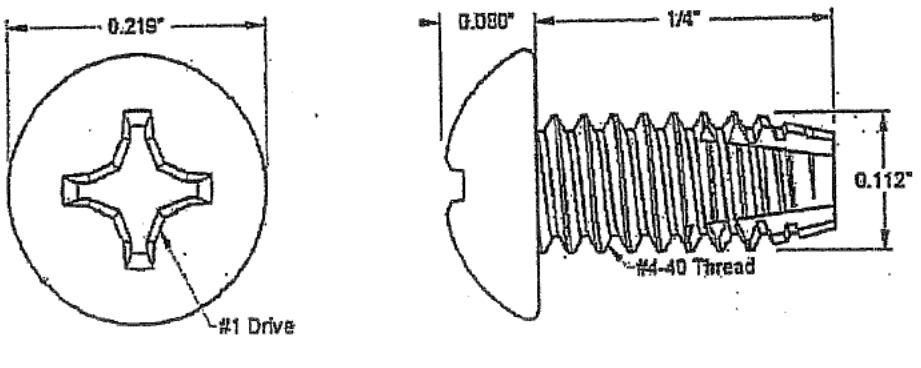
PART NAME: SCREW REV: A

DATE INITIATED: 7/16/12 BY: H. SCHNOBRICH CHK BY: Bill Wh

DESCRIPTION: #4-40 STAINLESS STEEL PHILLIPS PAN HEAD THREAD CUTTING SCREW

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
MCMASTER-CARR	S	90410A106



6 of 9

REV	DATE	INITIALS	DESCRIPTION
A	7/16/12	BW	RELEASED

REVISIONS

1 OF 1

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(b)(4) [redacted] Released by CDRH on 12-8-2015

MW P/N: LB1078

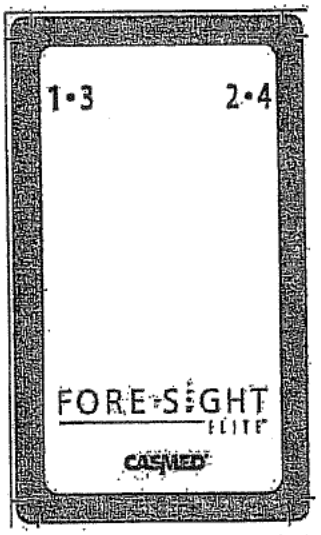
PART NAME: LABEL REV: C

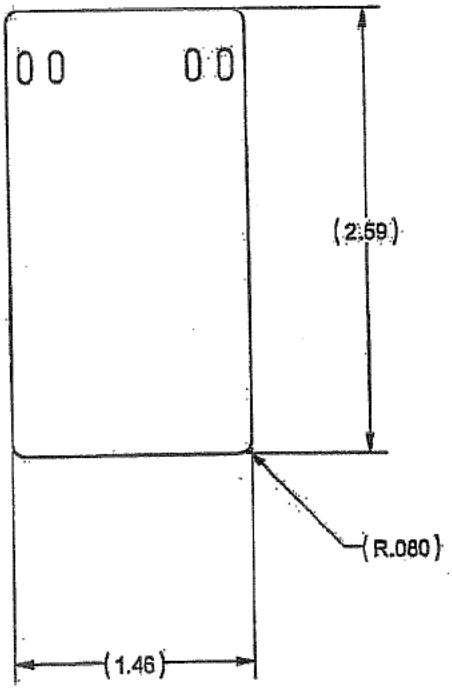
DATE INITIATED: 11/14/12 BY: B.WHELAN CHK BY: S. STOUT

DESCRIPTION: LABEL MAIN

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
SCREENPRINT/DOW	M	21-01-2008 REV-02





THE CURRENT ARTWORK FILE TO BE 05-02-0186-R02.EPS
THIS DATA WILL BE MAITAINED B[redacted] (b)(4)
(b)(4) [redacted] AND CANNOT BE CHANGED WITHOUT CASMED APPROVAL.

7 of 25

REV	DATE	INITIALS	DESCRIPTION
C	4/29/13	BW/SS	SEE ECN #2706
B	2/26/13	BW/SS	SEE ECN #2524
A	11/15/12	SS	RELEASED

REVISIONS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

MW P/N: LB1080

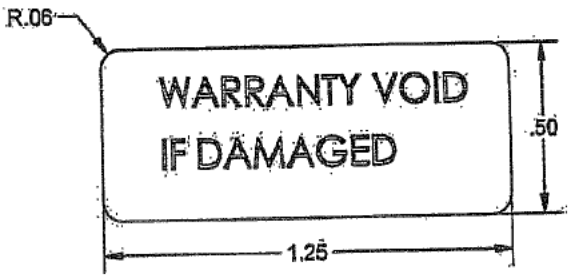
PART NAME: LABEL REV: C

DATE INITIATED: 11/26/12 BY: B.WHELAN CHK BY: BILL WHELAN

DESCRIPTION: LABEL WARRANTY VOID

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
CASMED	S	21-01-1009 REV 03



NOTES:

1. MATERIAL: FASSON 2 MIL WHITE TAMPERFAS VINYL/S730/50# SCK WITH 1205 CLEAR POLYPROPYLENE OVER LAMINATE BY SEKISUI TA IND.

2. COLORS: BANKGROUND - PMS 406
LETTERING - BLACK

3. ARTWORK SHOWN IS FOR REFERENCE ONLY. ARTWORK PROVIDED BY VENDOR

REV	DATE	INITIALS	DESCRIPTION
C	4/29/13	BW/SS	SEE ECN #2707
B	3/1/13	BW/SS	SEE ECN #2560
A	11/26/12	BW	RELEASED

REVISIONS

8 of 25

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

MW P/N: LB1059

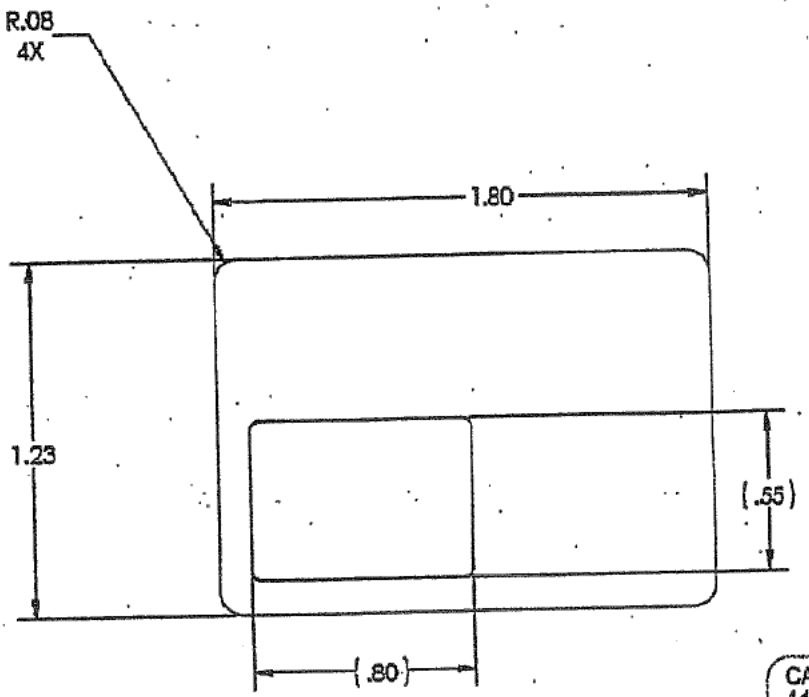
PART NAME: LABEL REV: B

DATE INITIATED: 7/3/12 BY: H. SCHNOBRICH CHK BY: BILL WHELAN

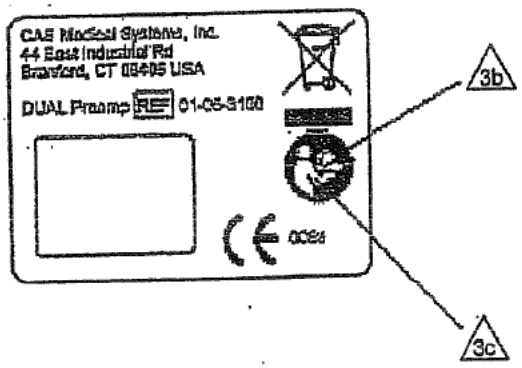
DESCRIPTION: DUAL PREAMP BTM LABEL

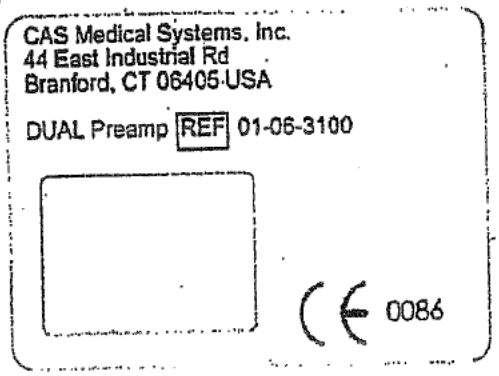
M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
ST.PAUL STAMP WORKS	M	MINNE065-33047-2



9 of 25





NOTES:

1. MATERIAL: .002" MATTE SILVER MYLAR
2. ADHESIVE: .001" ACRYLIC FLEXCON V-23
3. COLOR:
   a. TEXT BLACK
   b. BACKGROUND, "INST. FOR USE" SYMBOL (ISO-7010-M002): BLUE, PMS 287
   c. ICON, "INST. FOR USE" SYMBOL: WHITE

REV	DATE	INITIALS	DESCRIPTION
B	10/17/12	BW/SS	SEE ECN #2135
A	7/27/12	BN	RELEASED

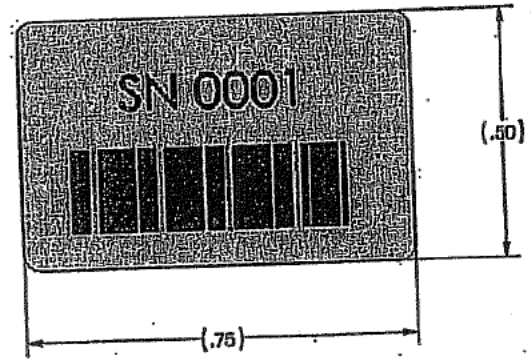
REVISIONS

1 OF 1

Questions? Contact FOIA Staff, OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REVISIONS			
REV	DATE	INITIALS	DESCRIPTION
A	1/11/13	SS	RELEASED



5) BAR CODE REQUIREMENTS
4) 4 DIGIT SERIAL NUMBER USED IN FORMAT: WHERE "0001" IS A SEQUENTIAL NUMBER
3) LABEL IS PRINTED ON A LASER PRINTER ON MATERIAL SPECIFIED IN NOTE 1
2) PRINT COLOR: BLACK

NOTES: 1) MATERIAL: 1/2" X 3/4" METALIZED POLYESTER LASER LABEL CILS INTERNATIONAL # AL4-9200-5

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PROJECTION

ALL DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED
TOLERANCE UNLESS INDICATED OTHERWISE
WHOLE NUMBER DECIMAL PRECISION ±1 PLACE
X.XX PLACE DECIMAL ±0.1 INCH
X.XX TWO PLACE DECIMAL ±0.03 INCH
X.XXX THREE PLACE DECIMAL ±0.005 INCH

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO

DRAWN BY	B.WHELAN	DATE	7/3/12
APPROVED BY	S. STOWE	DATE	1/11/13
MANUFACTURING	[illegible]	DATE	1/11/13
QUALITY	M. Thurston	DATE	1/11/13

(b)(4) [redacted]

TITLE	PREAMP BOX SERIAL NUMBER		SIZE N/A REV A
NAME/CO MINNESOTA WIRE	SHEET 1 OF 1	DWG NO LB1060	

10 of 25

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

MW P/N: LB1079

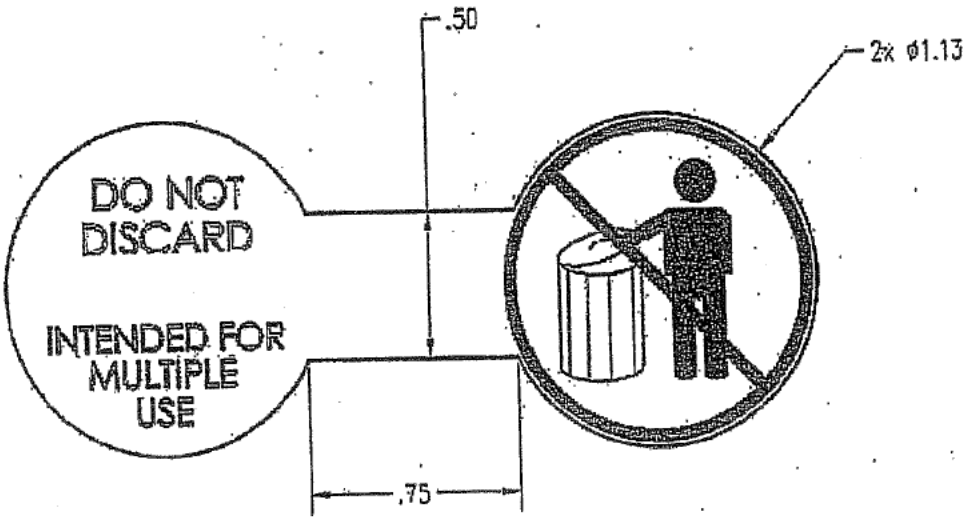
PART NAME: LABEL "DO NOT DISCARD" REV: C

DATE INITIATED: 11/14/12 BY: B.WHELAN CHK BY: S. STOUT

DESCRIPTION: LABEL

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
CASMED	S	21-01-1966 REV 0



11 of 85

REV	DATE	INITIALS	DESCRIPTION
C	3/11/13	BW/SS	SEE ECN #2587
B	3/1/13	BW/SS	SEE ECN #2559
A	11/14/12	SS	RELEASED

REVISIONS

1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

(b)(4) [redacted] P/N: WR0047

PART NAME: COPPER TAPE REV: C

DATE INITIATED: 6/2/06 BY: H. SCHNOBRICH CHK BY: S FITZHARRIS

DESCRIPTION: EMI/RFI COPPER SHIELDING TAPE, 1/2" WIDE, ADHESIVE BACKED

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
3M	M	1181-1/2
ALL APPROVED VENDORS	S	1181-1/2
ALPHA	M	CST-5

SEE ATTACHED

REV	DATE	INITIALS	DESCRIPTION
C	4/22/08	MB/HS	SEE ECO #08-034
B	10/22/07	HS/MB	SEE ECO #07-307
A	6/5/06	SS	RELEASED

REVISIONS

Questions? Contact FDA/CDRH/OCE/DID at CDRH_FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

3M

WR00147

1181 Tape

Copper Foil with Conductive Adhesive

Data Sheet

Product Description

3M™ 1181 Tape consists of a 1-ounce deadsoft copper foil backing and a unique electrically conductive pressure-sensitive acrylic adhesive.

- Deadsoft 1-ounce copper foil backing
- Conductive acrylic adhesive
- Supplied on a removable liner for easy handling and dieculting

Like all 3M shielding tapes, 3M 1181 is available in standard and custom widths and lengths. Standard length is 18 yards.

- Widths from 1/4" to 23"
- Longer lengths up to several times normal length, dependent upon width. Check with Customer Service.

Applications

3M 1181 Tape is typically used for applications requiring excellent electrical conductivity from the application substrate through the adhesive to the foil backing. Common uses include grounding and EMI shielding in equipment, components, shielded rooms, etc. The copper foil backing is solderable and resists oxidation and discoloration.

Shielding Effectiveness

Many factors determine the true shielding effectiveness of a shielding tape, including type and thickness of foil, adhesive type, intimacy of contact, smoothness of application surface, strength and frequency of the EMI signal, etc. However, using standard tests and fixtures, it is possible to determine a value for the attenuation.

For 3M 1181 Tape, typical shielding effectiveness (far field) is in the range of 60dB to 80dB (30 MHz to 1 GHz).

Properties / Typical Values

Properties	Typical Values
Backing thickness	1/4 mil (0.04mm)
Total thickness (backing plus adhesive)	2.6mil (.066mm)
Breaking strength	25 lb/in (43 N/10mm)
Adhesion to steel	35 oz/in (3.8 N/10mm)
Electrical resistance through adhesive	0.005 ohm
Flame retardancy	Pass

*Footnote: 1. Tested and 3M MP 1000 2. MIL-STD-202 Method 307 mounted to 5 psi (34 N/m) measured over the surface area conductive pressure sensitive adhesive and the foil backing. 3. Tested per 3M Test Method 1 using 1 oz/yd² copper foil backing. 4. Tested per 3M Test Method 2 using 1 oz/yd² foil backing. 5. Tested per 3M Test Method 3 using 1 oz/yd² foil backing. 6. Tested per 3M Test Method 4 using 1 oz/yd² foil backing. 7. Tested per 3M Test Method 5 using 1 oz/yd² foil backing. 8. Tested per UL 510 and UL 94 Flammability Class 94V-0 (Underwriters Laboratories).

13 of 25

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

MW P/N: wr0060

PART NAME: TAPE REV: A

DATE INITIATED: 10/21/11 BY: T. TURNER CHK BY: T. TURNER

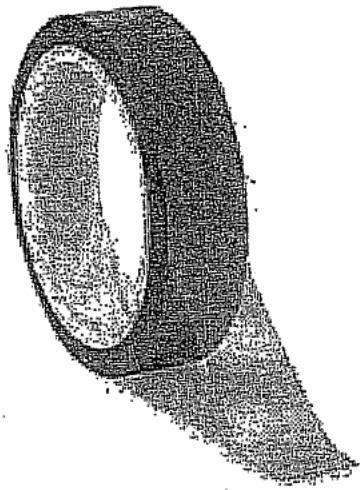
DESCRIPTION: KAPTON TAPE, 1" X .002"

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
U-LINE	S	S-17214

Home > Tape > High Temperature Tapes > Kapton® Tape

1" x 36 yards 2 Mil Kapton Tape



Maximum resistance to high temperatures.

- Recommended for masking circuit boards and splicing wires.
- Polyimide film with silicone adhesive for easy release.
- Flame retardant.

Enlarge

MODEL NO.	SIZE	FILM THICKNESS	TOTAL THICKNESS	PRICE PER ROLL			ADD TO CART
				1	4	8+	
S-17214	1" x 36 yds.	2 mil	3.5 mil	$54	$51	$47	1 ADD

14 of 85

REV	DATE	INITIALS	DESCRIPTION
A	10/21/11	TJT	RELEASED

REVISIONS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

MW P/N: TW0010

PART NAME: CABLE TIE REV: B

DATE INITIATED: 11/19/08 BY: H. SCHNOBRICH CHK BY: M. BALLA

DESCRIPTION: CABLE TIE, 6/6, NATURAL

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
ALL APPROVED VENDORS	S	L-4-18-9-C
GENTEX	S	N630015-00

SUGGESTED SOURCES OF SUPPLY

SUPPLIER DATA

FSCM	PART NUMBER	NAME AND ADDRESS
05383	PLT1M9	PANDUIT CORPORATION 17303 SOUTH RIDELAND AVENUE TINLEY PARK, IL 60477 (312) 532-1500
	L-4-18-9-C	THOMAS & BETTS CORPORATION 1555 LYNNFIELD ROAD MEMPHIS, TN 38119 (800) 344-4744
	41-809	IDEAL INDUSTRIES, INC. 1018 BECKER PLACE SYCAMORE, IL 60178 (815) 895-5181 & (800) 435-07015
	08429	DENNISION MANUFACTURING CO. 305 HOWARD STREET FRAMINGHAM, MA 01701 (508) 879-0511

DESCRIPTION: AN ELECTRICAL COMPONENT TIE-DOWN STRAP, ADJUSTABLE, SELF-CLINCHING, PLASTIC, TYPE 1, CLASS 1

SPECIFICATIONS:

CONTROLLING DOCUMENT(S): MS 3367

MATERIAL: NYLON 6/6

COLOR: NATURAL (WHITE)

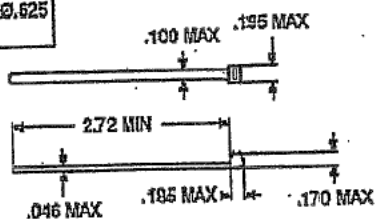
TENSILE STRENGTH: 18 LB MINIMUM

GRIP RANGE: Ø.062 TO Ø.625

CORRESPONDING MIL STD PART NO.: MS3367-4-9

DWG NO. 630 015 SH 1 REV D

REV	DESCRIPTION	DATE	APPROVAL
D	[illegible]	[illegible]	RJF
D	[illegible]	[illegible]	[illegible]



SPECIFICATION CONTROL DRAWING

NOTES:

1. IDENTIFICATION OF THE "SUGGESTED SOURCE(S) OF SUPPLY" HEREON IS NOT TO BE CONSTRUED AS A GUARANTEE OF PRESENT OR CONTINUED AVAILABILITY AS A SOURCE OF SUPPLY FOR THE ITEM(S).

N630015-00 CABLE TIE, 6/6 NAT .10"X4" 7L772 1

QTY PART NUMBER DESCRIPTION DWG NO. REV NO.

UNLESS OTHERWISE SPECIFIED DIMENSIONS IN INCHES

TOLERANCES: XX± XXX± ANGLES±

THIS DRAWING IS THE EXCLUSIVE PROPERTY OF GENTEX CORPORATION AND IS TRANSMITTED NOW FOR REVIEW. IT IS NOT TO BE USED FOR MANUFACTURING PURPOSES OR REPRODUCED IN PART OR IN ENTIRETY WITHOUT EXPRESS WRITTEN AUTHORIZATION.

DFTG AF DATE 991123
CHK
ENG R. Tuculis 997710
MFG CJ Connell 997703
QA GR Richards 997703
MKT ME Smith 997710
CONTRACT NO.

GENTEX CORPORATION ELECTRO-ACOUSTICS GROUP DEPT. 14 [illegible]

CABLE TIE, 6/6 NAT .10"X4"

SIZE B CAGE CODE 7L772 DWG NO. 630 015 REV D

SCALE 1/1 SHEET 1 OF 1

REV	DATE	INITIALS	DESCRIPTION
B	5/24/11	HS/SS	SEE ECO #09-316
A	11/26/08	MB	RELEASED

REVISIONS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4)

[redacted]

MW P/N: MI0794

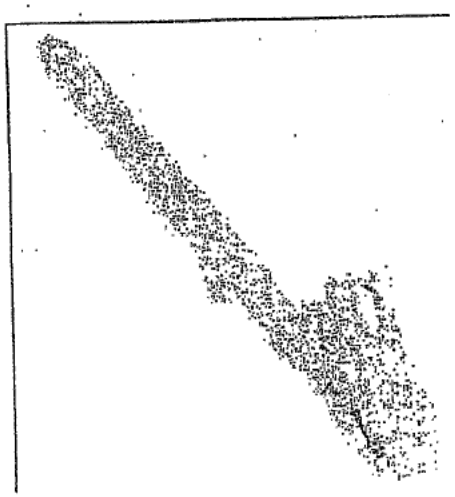
PART NAME: SPRING CLIP REV: A

DATE INITIATED: 9/5/12 BY: H. SCHNOBRICH CHK BY: Bill Whelan

DESCRIPTION: PLASTIC 1-HOLE FACE STEEL SPRING CLIP W/2-1/4". STRAP

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
ID CARD GROUP	S	2115-4008



PLASTIC 1-Hole Face Steel Spring Clip with 2 1/4" Frosted White Molded Plastic Strap.

Part #: 2115-4008

16 of 25

REV	DATE	INITIALS	DESCRIPTION
A	9/7/12	BW	RELEASED

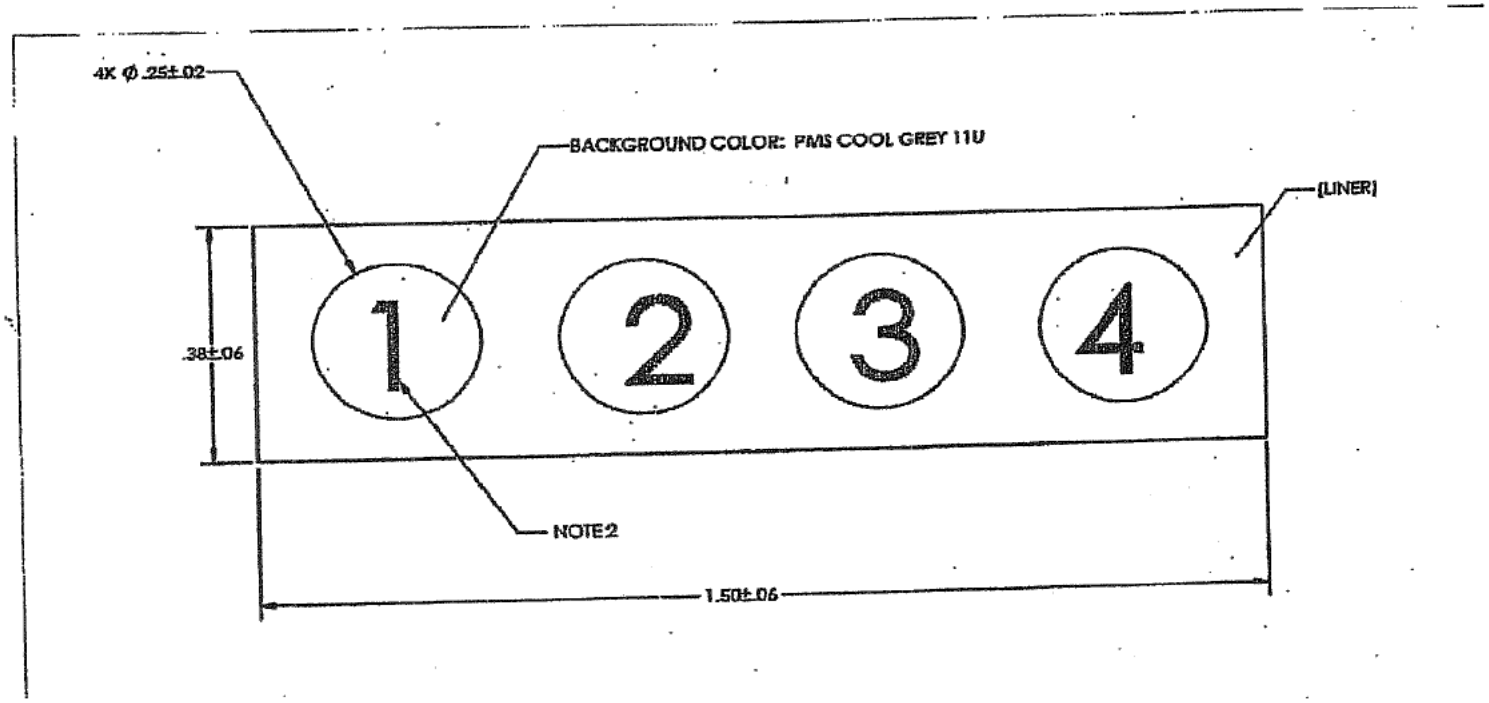
REVISIONS

1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on

REVISIONS			
REV	DATE	INITIALS	DESCRIPTION
A	11/1/12	SS	RELEASED



NOTES:

1. MATERIAL: GE 5 MIL VELVET, LEXAN # 8835, ADHESIVE BACK: 3M 467 MP
2. TEXT COLOR: WHITE, CENTER ON LABEL

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PROJECTION

ALL DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED
TOLERANCE UNLESS INDICATED OTHERWISE:
WHOLE NUMBER INCH DIMENSIONS: ±1 INCH
.X ONE PLACE DECIMAL: ±0.1 INCH
.XX TWO PLACE DECIMAL: ±0.02 INCH
.XXX THREE PLACE DECIMAL: ±0.005 INCH

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO:

DRAWN BY B.WHELAN	DATE 11/1/12	[redacted]	
APPROVED BY S. STOUT	DATE 11/1/12	TITLE LABEL, SENSOR NUMBER	N/A
MANUFACTURING	DATE 11/1/12		REV A
QUALITY M. Thurmond	DATE 11/1/12	NAME/CO	SHEET / DWG NO LB1072

(b)(4)

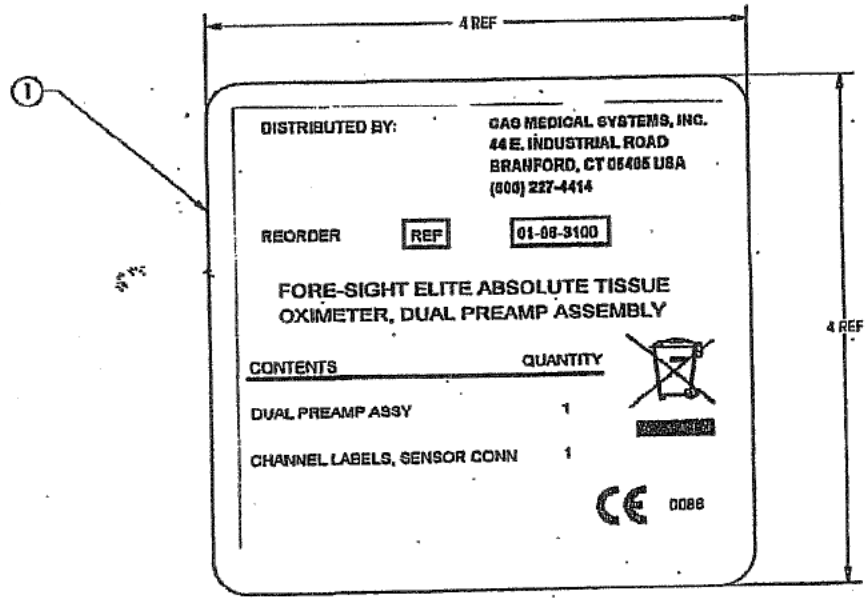
17 of 25

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REVISIONS			
REV	DATE	INITIALS	DESCRIPTION
A	10/9/12	SS	RELEASED FOR PRODUCTION

PARTS LIST						
ITEM	QTY	DESCRIPTION	SERIES	PART NO	COLOR	MATERIAL
1	1	BLANK LABEL		LB471	WHITE	



NOTES:

1) BLACK TEXT ON WHITE BACKGROUND

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PROJECTION

ALL DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED
TOLERANCE UNLESS INDICATED OTHERWISE
WHOLE NUMBER ±1 INCH DISTANCE ±1 INCH
X ONE PLACE DECIMAL ±0.1 INCH
XX TWO PLACE DECIMAL ±0.03 INCH
XXX THREE PLACE DECIMAL ±0.005 INCH

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO

DRAWN BY B.WHELAN	DATE 10/1/12	[redacted] (b)(4)	
APPROVED BY S. SOUTE	DATE 10/9/12	TITLE LABEL, BAG FOR C728	REV N/A
MANUFACTURING	DATE 10/9/12		REV A
QUALITY	DATE 10/9/12	NAME/CO CASMED	SHEET 1 OF 1 / DWG NO LB1076

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted] (b)(4) [redacted] P/N: MI0079

PART NAME: 4X4X.002 ZIPLOCK POLY BAG REV: B

DATE INITIATED: 4/11/94 BY: GS CHK BY: R.B.CASS

DESCRIPTION: 4X4X.002 ZIPLOCK POLY BAG

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
LITTON	M	P2Z44

P/N MI0079

2 MIL

Inside Dimensions W x L (in.)	Bags in Carton	Price Per Carton
2 x 2	1000	$ 27.85
2 x 3	1000	28.80
3 x 3	1000	29.85
3 x 4	1000	32.70
3 x 5	1000	34.45
4 x 4	1000	36.90
4 x 6	1000	38.90
4 x 7	1000	43.30
4 x 8	1000	43.60
5 x 7	1000	47.40
5 x 8	1000	50.80
6 x 6	1000	53.60
6 x 8	1000	57.80
6 x 9	1000	60.40
6 x 12	1000	71.60
8 x 8	1000	68.80
8 x 10	1000	76.90
9 x 12	1000	87.85
10 x 12	1000	89.85
12 x 12	1000	108.85
12 x 15	1000	129.70

10 of 25

REV	DATE	INITIALS	DESCRIPTION
B	5/28/99	AL/MG	SEE ECO #99-116
A	4/11/94	RBC	RELEASED.

REVISIONS

1224

Questions? Contact FDA@CDRH@CDRH@CDRH@CDRH.gov or 301-796-8110

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

MW P/N: MI0800

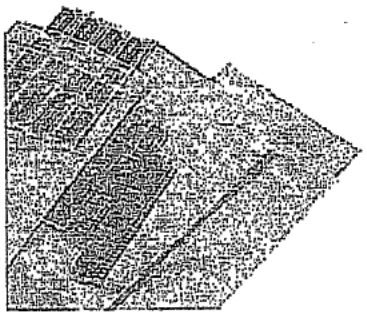
PART NAME: ANTI STATIC BAGS REV: A

DATE INITIATED: 12/4/12 BY: H. SCHNOBRICH CHK BY: Bill Whelan

DESCRIPTION: ANTI STATIC RECLOSABLE BAGS, 4 MIL THICK, 13" X 18"

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
U-LINE	S	S-1460



Uline 4 Mil Anti-Static Reclosable Bags

MODEL NO.	INSIDE W x L	LBS./ CTN.	QTY./ CTN.
S-3700	2 x 3"	3	1,000
S-1322	2 1/2 x 3"	4	1,000
S-3701	3 x 4"	5	1,000
S-1323	3 x 5"	6	1,000
S-1324	4 x 6"	9	1,000
S-1457	4 x 8"	11	1,000
S-8316	5 x 8"	14	1,000
S-3702	6 x 6"	13	1,000
S-1325	6 x 8"	16	1,000
S-3703	6 x 9"	18	1,000
S-3704	8 x 8"	21	1,000
S-1458	8 x 10"	27	1,000
S-1326	9 x 12"	35	1,000
S-7625	10 x 12"	40	1,000
S-1327	12 x 12"	24	500
S-12580	12 x 15"	29	500
S-8317	12 x 18"	36	500
S-1459	12 x 24"	20	250
S-1460	13 x 18"	36	500

20 of 25

REV	DATE	INITIALS	DESCRIPTION
A	12/4/12	BW	RELEASED

REVISIONS

1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted]

MW P/N: HS3320A

PART NAME: HEATSHRINK REV: A

DATE INITIATED: 8/23/11 BY: H. SCHNOBRICH CHK BY: S. FITZHARRIS

DESCRIPTION: 3M HEATSHRINK TUBING, FP-301, 3/32" ID, 2:1

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
ALL APPROVED VENDORS	S	FP301 3/32 BLK

3M™ Heat Shrink Tubing FP-301

Flexible, Polyolefin

Data Sheet July 2010

Description

3M™ Heat Shrink Tubing FP-301 offers an outstanding balance of electrical, physical and chemical properties for a wide variety of industrial and military applications. Rated for 135°C continuous operation, all FP-301 tubing is split resistant, mechanically tough, easily marked and resists cold flow.

FP-301 tubing is rated for continuous operation at -55°C (-67°F) to 135°C (275°F), and is designed to withstand elevated temperatures to 300°C (572°F) for short periods. Minimum shrink temperature for all FP-301 tubing is 100°C (212°F).

Agency Approvals & Self Certifications

Meets requirements of:

- SAE-AMS-DTL-23053/5, Class 1, Class 2 (Clear)*
- AMS-3636, AMS-3637
- UL Recognized, File E-39100, at 600 volts maximum @ 125°C
- CSA Certified, CSA LR38227, at 600 volts maximum @ 125°C
- ABS

*Formerly MIL-I-23053/5 and MIL-DTL-23053/5

Applications

FP-301 tubing is typically used as a shrink-fit electrical insulation over cable splices and terminations. It is also used for lightweight wire harness covering, wire marking, wire bundling, component packaging and fire-resistant covering.

Shrink Ratio

FP-301 tubing has a 2:1 shrink ratio. When freely recovered, the tubing will shrink to 50% of its as-supplied internal diameter. The recovered wall thickness is proportional to the degree of recovery.

Standard Sizes and Dimensions

Ordering Size (Nominal)	Expanded I.D. (Minimum) in.	(mm)	Recovered I.D. (Maximum) in.	(mm)	Recovered Wall Thickness (Nominal) in.	(mm)
3/64	.046	(1,17)	.023	(0,58)	.016	(0,41)
1/16	.063	(1,60)	.031	(0,79)	.017	(0,43)
3/32	.093	2,36)	.046	(1,17)	.020	(0,51)

21 of 25

REV	DATE	INITIALS	DESCRIPTION
A	8/23/11	SF	RELEASED

REVISIONS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4)

[redacted]

MW P/N: HS3320A

3M™ Heat Shrink Tubing FP-301

Typical Properties

Not for specifications. Values are typical, not to be considered minimum or maximum. Properties measured at room temperature 73°F (23°C) unless otherwise stated.

Physical Property	Typical Value US units (metric)
Tensile Strength	2400 psi
Ultimate Elongation	400%
Longitudinal Change	±5%
Secant Modulus (2%)	13,000 psi
Specific Gravity	1.3 (Opaque) .93 (Clear)
Operating Temperature	-67° to 275°F (-55° to +135°C)
Shrink Temperature (minimum)	212°F (100°C)
Heat Aging (336 hrs. @ 175° C)	Elongation 175%
Heat shock (4 hrs. @ 250° C).	No dripping, flowing, cracking, passes mandrel wrap test
Low Temperature Flexibility (4 hrs @ -55° C)	No cracking
Scant Modules (2%)	13,000 psi
Flammability Self-extinguish, Meets UL 224 All Tubing Flame Test (Except Clear)	Pass

Electrical Property (Test Method)	Typical Value
Dielectric Strength	600 V/mil
Volume Resistivity	10^{15} ohm/cm

Chemical Property (Test Method)	Typical Value
Corrosion Resistance (Copper mirror)	Non-corrosive
Fungus Resistance	Non-nutrient
Water Absorption	0.2%
Solvent Resistance	Excellent

22 of 25

Standard Colors

Black, Clear

Also available in Blue, Green, Red, White and Yellow. Price, MOQ and Lead Time will vary for these colors. Please contact Local Sales Representative or Customer Service Representative for more information.

NOTE: The clear tubing is not flame retardant or UL listed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

(b)(4) [redacted] (b)(4) [redacted] P/N: HS1169

PART NAME: 1/16 HEATSHRINK TUBING REV: B

DATE INITIATED: 4/12/94 BY: GS CHK BY: R.B. CASS

DESCRIPTION: 1/16 HEATSHRINK TUBING

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
RAYCHEM	M	RAYVER 1/16-0 VERSAFIT

P/N HS 1169

RAYCHEM

Polyolefin Tubing

Thermofit® - Versafit®

Electrically insulates and protects in-line components, disconnect terminals, and splices. Bundles wires for very flexible light-duty harnesses. Strain-relieves electrical wire connections for long-term reliability. Identifies wires, cables, terminals, and components. UL VW-1 and CSA OFT flame-retardancy ratings. 90°C shrink temperature reduces installation time and risk of damage to temperature-sensitive components. Higher temperature rating, better thermal stability, and higher resistance to physical abuse than nonrosslinked materials. Operating temperature, −30°C to 125°C.

Ordering Information

Standard Colors: Black (all sizes) and white (all sizes except 1¼").

Special Order Colors: White (1¼" size only); red, yellow, blue, green, brown, orange, violet, and gray (all sizes).

Standard Marking: Marked with UL/CSA legends.

Standard Packaging: On spools.

Size Selection: Always order the largest size that will shrink snugly over the component to be covered.

Ordering Description: Specify product name, size, and color (for example, Versafit 1/4-black).

Special Order Sizes: Special sizes may be made available on request.

Tannehill No.	Size In.	Inner Dia., In. Expanded As Supplied Min.	Inner Dia., In. Recovered After Heating Max.	Wall Thick. Recovered After Heating In.*
VER-3/64	3/64	.016	.023	.016±.003
VER-1/16	1/16	.023	.031	.017±.003
VER-3/32	3/32	.033	.046	.020±.003
VER-1/8	1/8	.125	.062	.020±.003
VER-3/16	3/16	.187	.093	.020±.003
VER-1/4	1/4	.250	.125	.025±.003
VER-3/8	3/8	.375	.187	.025±.003
VER-1/2	1/2	.500	.250	.025±.003
VER-3/4	3/4	.750	.375	.030±.003
VER-1	1	1.000	.500	.035±.005
VER-1 1/4	1 1/4	1.250	.625	.040±.006
VER-1 1/2	1 1/2	1.500	.750	.040±.006
VER-2	2	2.000	1.000	.045±.007

*Wall thickness will be less if tubing recovery is restricted during shrinkage.

Note: UL Recognized, CSA Certified.

23 of 25

REV	DATE	INITIALS	DESCRIPTION
B	9/7/99	AL/AP	SEE ECO #99-254
A	4/12/94	RBC	RELEASED.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@[illegible]

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TC2607

(b)(4) [redacted] (b)(4) [redacted] P/N: TC2607

PART NAME: 26 AWG TC CONDUCTOR REV: B

DATE INITIATED: 4/22/94 BY: GS CHK BY: R.B. CASS

DESCRIPTION: 26 7/34 TINNED COPPER CONDUCTOR ø.019

M = MANUFACTURER S = SUPPLIER

VENDOR NAME	M/S	VENDOR PART NUMBER
OMEGA	M	26 7/34 TINNED COPPER .019
NUTMEG	S	26 7/34 TINNED COPPER .019
A.E.B.	S	26 7/34 TINNED COPPER .019

TOPCOAT STRANDED COPPER CONDUCTORS (1)

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

REV	DATE	INITIALS	DESCRIPTION
B	4/3/06	MB/[illegible]	SEE ECO #06-054
A	4/22/94	RBC	RELEASED.

REVISIONS

Questions or comments regarding this document should be directed to CDRH FOIA Staff: DSC@fda.hhs.gov or 301-796-9115

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

REVISIONS			
REV	DATE	INITIALS	DESCRIPTION
A	6/10/13	SS	RELEASED FOR PRODUCTION

PARTS LIST						
ITEM	QTY	DESCRIPTION	SERIES	PART NO	COLOR	MATERIAL
1	1	2" X 3" BLANK LABEL		LB445	WHITE	

P/N: 01-06-3100

SN00001

25 of 25

THIS DOCUMENT IS THE PROPERTY OF MN WIRE AND SHOULD NOT BE DISCLOSED, REPRODUCED IN WHOLE OR IN PART, OR USED TO SOLICIT QUOTATIONS FROM COMPETITIVE SOURCES. INFORMATION HEREIN MAY BE USED FOR ENGINEERING EVALUATION AND INCORPORATION INTO TECHNICAL SPECIFICATIONS AND OTHER DOCUMENTS WHICH SPECIFY PROCUREMENT FROM MN WIRE.

PROJECTION

ALL DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED
TOLERANCE UNLESS INDICATED OTHERWISE:
WHOLE NUMBER INCH DIMENSIONS: ±1 INCH
X ONE PLACE DECIMAL: ±0.1 INCH
XX TWO PLACE DECIMAL: ±0.02 INCH
XXX THREE PLACE DECIMAL: ±.005 INCH

INTERPRET PER ASME Y14.5-2009

CUSTOMER PART NO

DRAWN BY B.WHELAN	DATE 6/10/13	[redacted]
APPROVED BY S. STOUT	DATE 6/10/13	
MANUFACTURING	DATE 6/10/13	LABEL BAG, C728 — REV N/A
QUALITY S. Appiah	DATE 6/10/13	NAME/CO — SHEET 1 OF 1 — DWG NO LB1105 — REV A

2) MUST ADHERE TO BULK PACKAGING BAG

NOTES: 1) WHITE LABEL WITH BLACK 12 POINT LETTERS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Drawing

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(b)(4) Drawing

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

12. Device Description

FORE-SIGHT Elite™ Absolute Tissue Oximeter - Purpose:

The FORE-SIGHT Elite Oximeter measures a single parameter of oxygenated hemoglobin under the Sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation in the tissue.

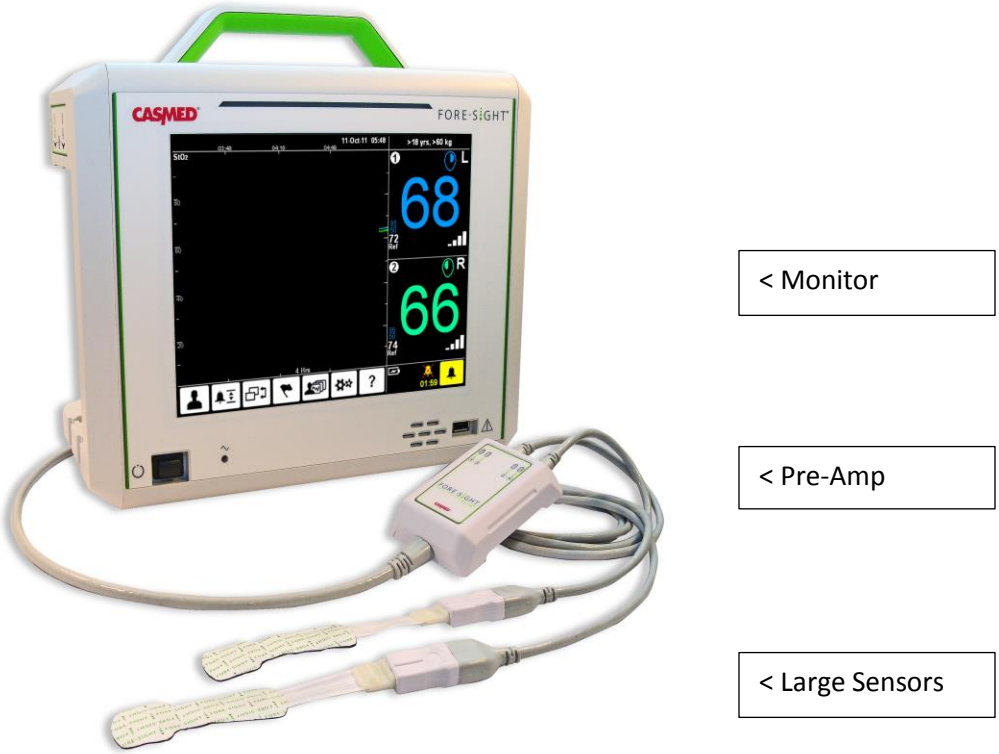

Figure 1

The FORE-SIGHT Elite System:

The FORE-SIGHT Elite System (Figure 1) consists of three distinct components. None can be used independently of the others in this system.

The **Monitor** (01-06-3000/01-05-3005) contains the systems software, power supply, display, user interface, communication ports, and other electronics. The Monitor is responsible for all configuration, display, surveillance, and alarm management functions. The Monitor electronics also coordinate all measurement activities including light generation, processing of detected signals, and computation of the tissue oxygenation. See drawing 08-04-3000 for additional information.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The **Dual Preamp Monitor Cable** (01-06-3100) is a reusable assembly consisting of electrical cabling, connectors, and a preamplifier circuit to pre-process the signals received from the sensors. Each preamp assembly connects to the monitor with a single connector, but provides the capability to monitor tissue oxygen saturation levels for two sensors. The monitor has connection ports for two preamps enabling simultaneous monitoring on up to 4 sensors. See drawing 01-06-3100 for additional information.

The **Sensors** (01-07-2103) are the single use patient applied part. They connect to the Preamp Monitor Cable delivering modulated light of predetermined wavelengths into the tissue and converting the detected light into electrical signals for subsequent processing. See drawing 03-05-0511 for additional information.

Figure 2 depicts a representative illustration of a Large Sensors components and some assembly details.

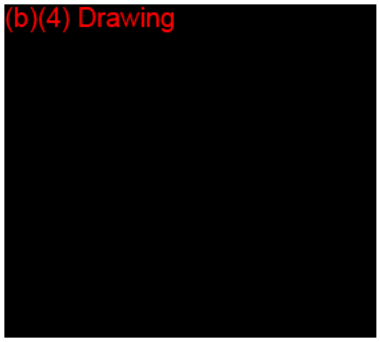

Figure 2

Performance Specifications:

The method of %StO2 measurement is derived from a modified Beer-Lambert equation using the Near Infrared Spectroscopy (NIRS) wavelengths of 690, 735, 810 & 870 nm. The information outputted is as absolute tissue oxygen saturation (%StO2) in a measurement range of 0 to 99%. The display resolution is 1% and the data acquisition rate is approximately10Hz. The measurement refresh rate is every 2 seconds. System diagnostics are performed during a power-on self-test.

Bias ± Precision has been determined for the range 45% to 95% as follows:

Large Sensors (Somatic): 0.24 ± 5.17% to 1 SD (this submission)
Large Sensors (Cerebral): -0.14 ± 3.05% to 1 SD (cleared under K123700)

The FORE-SIGHT Monitor generates alarms for (user-selectable) high or low limit violations. Equipment and system status messages are displayed independently for each sensor and augmented with audible enunciation when appropriate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Power is provided by input voltages of 100-240 VAC, 50-60 Hz with a field-replaceable battery module.

The operating environment is rated for 10°C to 40°c at 30% - 75% RH non-condensing. Storage conditions are rated for -20 C to 60°C with 90% RH @ 50°C to 15% RH @ 0°C

General Design Features:

- The monitor is used in various hospital locations;
- The monitor uses a LED light source;
- The monitor uses one size sensor to monitor adults and transitional adolescent's;
- The monitor's measurement accuracy is not affected by melanin, temperature, or perfusion;
- The monitor displays an StO_2 numeric value in the range of 01-99%;
- The monitor displays an indicator of optimal sensor placement called a Tissue Perfusion Index (TPI);
- The monitor contains an easy to read 10.4" color LCD VGA touch-screen display;
- The monitor provides a 24 hour review of historical data during or after a case;
- The monitor has modes for demonstration, servicing, programming and operating;
- The monitor provides patient data storage via USB memory sticks;
- The monitor provides a serial data output for compatibility with several third-party data review, charting, and acquisition systems;
- The monitor documentation and software, is available in multiple languages.

FORE-SIGHT Elite Models:

There are two models of the FORE-SIGHT Elite Absolute Tissue Oximeter. They are designated as part number(s) 01-06-3000 and 01-06-3005. They are identical. See figure 1.

FORE-SIGHT Accessories:

Part Number	Name	Function
01-06-3100 01-06-3005	FORE-SIGHT Elite Absolute Tissue Oximeter Dual Pre-Amp	Necessary part of the operating system. Included with monitor.
01-06-3014	FORE-SIGHT Elite Oximeter Battery Pack	For short term operation while not on mains power.
01-06-3036	User Manual on CD (English)	Included with each monitor
01-02-0395	Replacement Power Cord	Included with each monitor
01-07-2103	FORE-SIGHT Elite Large Sensor. Carton of 20.	Necessary part of the operating system. Patient contact part. Purchased separately.
01-06-0238	FS Roll Stand	A hospital grade roll stand, making the FS portable.

Full descriptive information may be found in the Project Gemini Product Specification 21-07-0302 Rev. 02. See Attachment A

Note: "Gemini" is the project name used during development. That name will appear on some documents that actually refer to FORE-SIGHT Elite Absolute Tissue Oximeter.

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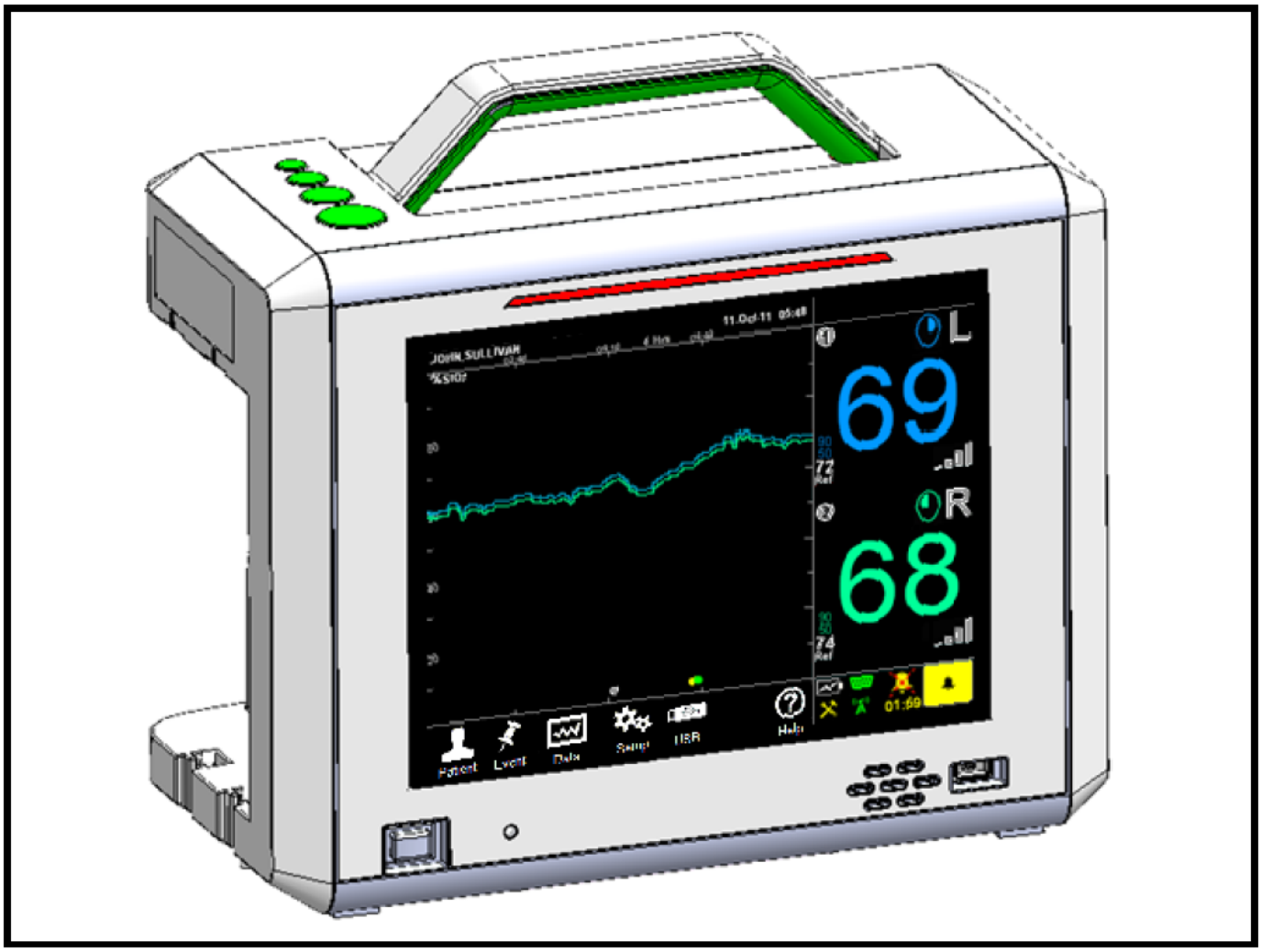
FORE-SIGHT ELITE™
Absolute Tissue Oximetry



User Manual

CE 0086

CASMED®
FOR WHAT'S VITAL

This User Manual describes the features and operations of FORE-SIGHT ELITE Oximeter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Overview

Trademarks

Trademarked names appear throughout this document. Instead of inserting a trademark symbol with each mention of the trademarked name, the publisher states that it is using the names only for editorial purposes and to the benefit of the trademark owner with no intention of improperly using that trademark.

CASMED® is a registered trademark of CAS Medical Systems, Inc.

FORE-SIGHT ELITE™ is a trademark of CAS Medical Systems, Inc.

Contact Addresses

CAS Medical Systems, Inc. 44 East Industrial Road Branford, CT 06405 U.S.A. Phone: in the US: (800) 227-4414 +1 (203) 488-6056 Fax: +1 (203) 488-9438 E-Mail: custsrv@casmed.com sales@casmed.com techsrv@casmed.com Web: www.casmed.com	**EC REP** MediMark® Europe 11 rue E. Zola 38100 Grenoble. France

Please contact the distributor in the country of purchase if product information or service should be required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Manufacturer's Declaration of Conformity

Manufacturers Declaration of Conformity
Electronic Emissions and Immunity

The FORE-SIGHT ELITE Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Oximeter should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment
RF emissions – CISPR 11	Group 1	The Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions – CISPR 11	Class A	The Oximeter is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions	Complies	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Level 3	Level 3	The Oximeter is designed for use in controlled environments only. Per OSHA guidelines for operating rooms, the area must employ adequate static electricity controls. The relative humidity should be maintained at about 50%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	The Oximeter is designed for use in controlled environments only. Per OSHA guidelines for operating rooms, the Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) mode ±2 kV line(s) to earth mode	±0.5 kV line(s) to line(s) mode ±2 kV line(s) to earth mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If user of the Oximeter requires continued operation during power mains interruptions, it is recommended that the Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the A.C. mains voltage prior to application of the test level.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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FORE-SIGHT Elite Oximeter

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The FORE-SIGHT ELITE Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Oximeter should insure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. ***Recommended separation distance:*** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and *d* is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1 At 80 MHz and 800MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is effected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Oximeter is used exceeds the applicable RF compliance level above, the Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Oximeter.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Oximeter

The Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	Separation distance according to frequency of transmitter (Meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters operating at a maximum output power not listed above, the recommended separation distance *d* in meters can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.
Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

CE Marking Information

Compliance The FORE-SIGHT ELITE Oximeter bears the CE mark CE-0086 indicating conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive.

Exceptions None

Conventions Used in this Manual

Warning: Directions that warn of conditions that put the patient or the caregiver at risk.

Caution: Directions that help to avoid damaging the Oximeter or losing data.

Note: Directions that make it easier to use the Oximeter, something not readily apparent.

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General Information

This manual is an integral part of the product and describes its intended use. Compliance with the manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety. Refer to Symbols starting on page 44 for additional information.

The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers.

CAS Medical Systems, Inc., (CASMED) is responsible for the effects on safety, reliability, and performance of the product only if:

- Assembly, operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by CASMED.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The device is used in accordance with the instructions for use.
- All publications conform to the product specifications and applicable IEC publications on safety and essential performance of electro-medical equipment as well as with applicable UL requirements and AHA recommendations valid at the time of printing.

For complete warranty information, refer to the Warranty Policy located on page 49.

The CASMED quality management system complies with the international standards ISO 13485 and the Council Directive on Medical Devices 93/42/EEC.

The parts of the Oximeter include the Oximeter, Preamp cable(s), Battery Pack, AC power Cord and Sensor(s). Refer to Oximeter on page 53.

The accessories for the Oximeter include, but are not limited to: USB Flash Drive, $St0_2$ Simulator and mounting hardware. Refer to Accessories on page 53

Note: Due to continuing product innovation, specifications in this manual are subject to change without notice.

Warning: Before using the Sensors and Oximeter for the first time, please read the information given in Safety section, starting on page 12 and the directions for use provided with the Sensors.

In the U.S. the following **Caution** applies: Rx only

Caution: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

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About This Manual

This User Manual describes the features and operation of the FORE-SIGHT ELITE Oximeter.

Manual Purpose

This manual contains the instructions necessary to operate the Oximeter safely and in accordance with its functions and intended use.

Note: All illustrations in this manual are provided as examples only. They may not necessarily reflect your monitoring setup or data displayed on your Oximeter.

Intended Audience

This manual is written for clinical professionals. Clinical professionals are expected to have working knowledge of medical procedures, practices, and terminology as required for monitoring of critically ill patients.

Warning: For continued safe use of this equipment, it is necessary that the listed instructions be followed. Nothing in this user guide is intended to override procedures and regulations imposed at the institutional level or above. Hospital's quality system, privacy rules, or other legal or policy requirements may govern whether and how to implement any specific procedure in this manual.

Training

Training on this Oximeter for the safe and effective use of the primary operating functions can be provided through CAS Medical Systems. Refer to Contact Addresses on page 2 for e-mail and phone number information.

CAS Medical Systems recommends in-service training on the Oximeter after the initial installation or whenever a new User intends to operate the device. No periodic retraining should be required. Training can also be provided when updates to the system are provided or whenever a User may be unfamiliar with the device.

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Revision History

This manual has a revision number located at the bottom of each page. It changes whenever the manual is updated.

Rev-00	Oct, 2013
Rev 01-Xb	Mar, 2014

Read this manual carefully before patient use of the Oximeter

CASMED reserves the right to make changes to this manual and improvements to the product it describes at any time without notice or obligation.

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Contents

Overview **2**
Trademarks 2
Contact Addresses 2

Manufacturer's Declaration of Conformity **3**
CE Marking Information 5
Conventions Used in this Manual 5
General Information 6
About This Manual 7
Manual Purpose 7
Intended Audience 7
Training 7
Revision History 8

Safety **12**
Indications for Use 12
Contraindications 12
Installation and Setup 13
Device Handling 15
Safety Checks 15
Monitoring 16
Initial Inspection 17
Oximeter Checklist 17
Patient Environment 18
Oximeter Classifications of Electrical Insulation 19

Basic Operations **20**
Introduction 20
Getting Started 20
Physical Configuration 21
Front View 21
Rear View 22
Side View 23
Oximeter Controls 24
On / Off Button 24
Touchscreen 24
Oximeter Display 25
Parts of the Display Screen 25
Starting the Oximeter 26
Turning the Oximeter On 26
Touchscreen Navigation 26
Patient/Case Menu 26
Alarm Limit Menu 26
Start Patient Monitoring 27
Connecting Preamp Cable 27
Connecting Sensor to Preamp Cable 28
Preparing Patient 29
Applying Sensor 29
Sensor Selection Guide 30
TPI Indicator 30
Stop Patient Monitoring 31
Removing Sensor 31
Disconnecting Sensor from Preamp Cable 31
Disconnecting Preamp Cable (Optional) 31

DRAFT COPY

Monitoring the Patient 32
Controlling Alarm Volume & Limits 32
Adjusting Alarm Volume & Limits 32
Alarm Volume 32
High & Low Limits 32
Saving Alarm Volume and Limits 33
Responding to Alarms 34
Alarm LEDs 34
System Messages 34
Channel Messages 36
Philips IntelliVue Messages 38

Cleaning 39
Cleaning the Oximeter 39
Cleaning Preamp Cables 39
Cleaning Sensors 39

Maintenance 40
Maintenance Intervals 40
Waste Electrical and Electronics Equipment (WEEE) 40
Fuse Replacement 41
AC Fuse Replacement 41
PC Board Fuse Replacement 42
Battery Maintenance 43
Installing/Removing the Battery Pack 43

Appendix 44
Symbols 44
Symbols on Front of Oximeter 44
Symbols on Left Side of Oximeter 44
Symbols on Rear of Oximeter 44
Symbols on Display of Oximeter 45
Symbols on Battery Pack 47
Symbols on Oximeter Packaging 47
Symbols on Preamp 47
Symbols on Preamp Packaging 47
Symbols on Sensor Packaging 48
Warranty Policy 49
Oximeter Configuration Record 50
Specifications 50
Parts 53
Oximeter 53
Accessories, Detachable Parts and Materials 53
Philips IntelliVue/VueLink Accessories and Options 54

DRAFT COPY

Figures

Figure 1: Patient Environment 18
Figure 2: Front View 21
Figure 3: Rear View 22
Figure 4: Side View 23
Figure 5: Major Areas of Display 25
Figure 6: 1st Level buttons 26
Figure 7: Connecting Preamp Cable 27
Figure 8: Preamp top label, Ch1 & Ch2 Preamp connected 28
Figure 9: Preamp top label, Sensor connected to Ch1 28
Figure 10: Sensor Selection Guide 30
Figure 11: AC Fuse Placement 41
Figure 12: System Control Board Fuse Locations & Ratings 42
Figure 13: NSAM Board Fuse Placement 42

Tables

Table 1: System Messages 35
Table 2: Channel Messages 37
Table 3: Oximeter Messages on Philips IntelliVue 38

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Safety

The operator must comply with the following **Warnings**, **Cautions**, and **Notes** to guarantee safe operation of the Oximeter.

Additional **Warnings**, **Cautions**, and **Notes**, which apply to specific parameters, are listed in the sections that pertain to each parameter.

Indications for Use

The noninvasive FORE-SIGHT ELITE Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced-flow or no-flow ischemic states and is indicated for use as follows:

When used with Large Sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescent's ≥40 Kg.

Contraindications

The FORE-SIGHT ELITE sensor is contraindicated for use on patients:

- With insufficient area for complete sensor attachment.
- With allergic reactions to sensor adhesive.
- Undergoing an MRI scan.

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Installation and Setup

Warning: The Oximeter is to be operated by qualified personnel only. Failure to read this manual, accessory direction for use, all precautionary information, and specifications could result in injury.

Warning: The Oximeter needs special precautions if it is placed close to a strong EMC transmitter such as X-ray, ESU or MRI devices. There is a risk that these signals could interfere with the Oximeter resulting in disruption of performance of this device. For continued protection against this risk, replace the AC power cord only with one provide by CASMED. Authorized CASMED or biomedical engineering personnel should replace the AC power cord.

Warning: To reduce the risk of injury, do not move or place the Oximeter in any position that might cause it to fall on patient, bystander or operator.

Warning: As with all medical equipment, carefully route and secure all cables to reduce the risk of patient entanglement or strangulation.

Warning: Do not lift or pull the Oximeter by any cable, or place the Oximeter or accessories in any position that might present a risk that the Oximeter may fall on the patient, bystander or operator.

Warning: The proper assembly of the various mounting solutions cannot be assured for structural integrity. There is risk that a damaged or improperly assembled Oximeter mounting solution may fall on patient, bystander or operator.

Warning: Do not come into contact with patients during defibrillation otherwise serious injury or death could result.

Warning: To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

Warning: The Oximeter is defibrillator-proof. It may remain attached to the patient during defibrillation, but the readings may be inaccurate during use and up to twenty (20) seconds thereafter. For proper protection against the effects of a cardiac defibrillator only CASMED supplied Preamp cables and Sensors shall be used.

Warning: Do not come into contact with patients during defibrillation. Otherwise serious injury or death could result.

Warning: Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

Warning: Avoid placing anything in front of the Oximeter that will cause the speaker output to be muffled.

Warning: Avoid placing the Oximeter where the controls can be changed by the patient.

Warning: Do not use the Oximeter for any purpose other than specified in this manual. Doing so will invalidate the Oximeter's warranty.

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Warning: Do not connect more than one patient to an Oximeter.

Warning: *Leakage Current Test* - When interfacing with other equipment, qualified biomedical engineering personnel must perform a test for leakage current before using it with patients. Serious injury or death could result if the leakage current exceeds applicable standards.

Warning: Patient Safety – If a Sensor is damaged in any way, discontinue use immediately.

Warning: The Oximeter is not "Category AP or APG Equipment."

Warning: Isolation of product from mains can only be achieved by removal of external AC power cord. If the integrity of the protective earth conductor is in doubt, the Oximeter may be operated from the internal batteries by disconnecting the AC power cord completely from the Oximeter. Do not position the Oximeter in a position that makes it difficult to remove the external AC power cord.

Warning: Do not place Sensor over poorly perfused tissues. Avoid uneven skin surfaces for best adhesion. Do not place sensor over sites with ascites, cellulitis or edema.

Warning: Do not position Sensor under the weight of the patient. Prolonged periods of pressure (such as taping over the Sensor or the patient lying on a Sensor) transfers weight from the Sensor to the skin, which can injure skin and reduce Sensor performance.

Warning: Measurements may be affected in the presence of strong electromagnetic sources such as electro-surgery equipment and measurements may be inaccurate during use of such equipment.

Caution: The USB connector accommodates a CASMED USB Flash Drive; do not connect any other USB type device or cable.

Caution: Qualified biomedical engineering personnel only must interface monitoring equipment with other types of medical equipment. Be certain to consult manufacturers' specifications to maintain safe operation.

Caution: Avoid placing either side of the Oximeter against objects that would restrict air flow through the air intakes and exhausts (other side).

Note: In the event that the location of the selected tissues cannot be palpated or visualized, confirmation by ultrasound or x-ray is recommended.

Note: The Oximeter is designed for continuous operation.

Note: The Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

The Oximeter can remain connected to the patient during cardiac defibrillation. All applied parts are "Type BF Defibrillation Proof."

The Oximeter has been designed to promote patient safety. All equipment parts are protected against the effects of the discharge of a defibrillator. No separate actions are required when using this equipment with a defibrillator.

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Device Handling

Warning: Do not, under any circumstances, perform any liquid cleaning while the Oximeter or AC power cord while the Oximeter is being used to monitor a patient. The Oximeter must be turned off, Sensors removed from the patient and the AC power cord disconnected before servicing or cleaning the Oximeter. There is a risk of serious injury or death if this procedure is not followed.

Warning: If the Preamp Cable should become grossly contaminated with blood or other bodily fluids, it should be discarded to reduce the risk of contamination and cross infection.

Caution: Pressing the front display touchscreen with a sharp or pointed instrument may permanently damage the membrane. Press the touchscreen using only your finger.

Caution: Do not attempt to sterilize, gas sterilize or autoclave the Oximeter or accessories.

Note: There are no known risks with common disposal of equipment or accessories; however, the disposing of accessories should follow in accordance with local hospital policies. The user should ensure these policies do not conflict with any local, state, or federal guidelines.

Safety Checks

Warning: There is a risk of an explosion hazard if a damaged Oximeter or accessory is used in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

Warning: Inspect the cables and Sensors for damage prior to operation. If any damage is noted, the cables or Sensor should not be used until it has been serviced or replaced. There is a risk that these damaged parts could reduce the performance of the Oximeter or present a safety hazard.

Warning: Liquids must not be allowed to enter the device. There is a risk of electric shock or device malfunction if liquids enter a device. If the Oximeter or Preamp is accidentally wetted, take it out of operation. It should be thoroughly dried (minimum 1 hour) and have it checked by a service technician before it is used again.

Warning: The operator should not perform any servicing except as specifically stated in this manual.

Warning: If the accuracy of any value displayed on the Oximeter is questionable, determine the patient's vital signs by alternative means. The functions of the Alarm system for monitoring of the patient must be verified at regular intervals and whenever the integrity of the product is in doubt, periodically test all functions.

Warning: Only use CASMED-supplied accessories with this Oximeter. CASMED-supplied accessories ensure patient safety and preserve the integrity, accuracy, and electromagnetic compatibility of the Oximeter.

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Caution: If the Oximeter fails to respond, do not use it until the situation has been corrected by authorized CASMED personnel.

Caution: Inspect the Oximeter and accessories for damage prior to operation. If any damage is noted, the Oximeter or accessory should not be used until it has been serviced. Only personnel authorized to do so by CASMED should repair the Oximeter. Refer to Contact Addresses on page 2 for e-mail and phone number information.

Monitoring

Warning: If the accuracy of any value displayed on the Oximeter is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly. Failure to comply may lead to injury.

Warning: The Sensor site must be inspected at least every eight hours; to reduce the risk of inadequate adhesion, circulation, and skin integrity. If the circulatory condition or skin integrity has deteriorated, the Sensor should be applied to a different site.

Warning: The Sensor is designed for single patient use, and is not to be reprocessed. There is risk of contamination and cross infection from used sensors. The disposing of accessories should follow in accordance with local hospital and institution policies.

Warning: *Conductive Connections* - Extreme care must be exercised when applying Sensors. Sensor circuits are conductive and it is very important that the Sensor does not come into contact with other grounded, conductive parts. Such contact would bridge the patient's isolation and cancel the protection provided by the Sensor.

Warning: Interfering substances: Elevated levels of Carboxyhemoglobin (COHb) or methemoglobin (MetHb) may lead to inaccurate measurements. Intravascular dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings. Other factors that may affect the accuracy of measurement include: myoglobin, hemoglobinopathies, anemia, pooled blood under the skin, interference from foreign objects in Sensor path, Bilirubinemia, externally applied coloring (tattoos) or birthmarks.

Warning: Sensors are not sterile and therefore should not be applied to sites with compromised skin integrity. Exercise caution when applying Sensors to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.

Warning: Failure to apply Sensors properly may cause incorrect measurements. Misapplied Sensors or Sensors that become partially dislodged may cause either over- or under-reading of oxygen saturation.

Warning: Do not modify or alter the Oximeter or Sensor in any way. Alterations or modification may affect performance and/or accuracy.

Warning: *Electrocautery* – To prevent unwanted skin burns; apply electrocautery electrodes as far as possible from all other Sensors, a distance of at least 15 cm (6 in.) is recommended.

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Note: For patients experiencing complete bilateral ECA occlusion, measurements may be lower than expected.

Note: Body location does not change any settings for output of the Oximeter, but is used to improve measurement accuracy.

Initial Inspection

Before unpacking the Oximeter, inspect the packaging for damage. If there are any signs of damage to the package, a claim should be filed immediately with the shipping agent. It is the receiver's responsibility to notify the carrier's local office to arrange for the pickup of the damaged items. Save the damaged shipping carton as evidence.

Contact your distributor, CASMED sales representative, or CASMED to report external damage and to arrange for repair or replacement of damaged equipment.

The shipping carton should contain the items listed below. Unpack the Oximeter and account for each item. Inspect each item for signs of external damage, dents, cracks, scratches, etc. If an item is missing or damaged, contact your distributor, CASMED sales representative, or CASMED.

Refer to Contact Addresses on page 2 for e-mail and phone number information.

Record the serial number and date of purchase at the back of this manual.

Oximeter Checklist

- 1 FORE-SIGHT ELITE Oximeter
- 1 FORE-SIGHT ELITE Preamp Cable
- 1 FORE-SIGHT ELITE User Manual
- 1 Hospital Grade AC power cord

Warning: Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Grade".

Note: The Oximeter is shipped with the appropriate line cord for the country and voltage being used.

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Patient Environment

System The Oximeter has been tested with specific parts of the system used within the patient environment (see Figure 1 below).

These parts are:

- The Oximeter
- Appropriate accessories as listed under Parts, on page 53, at the back of this manual.
- AC power cord

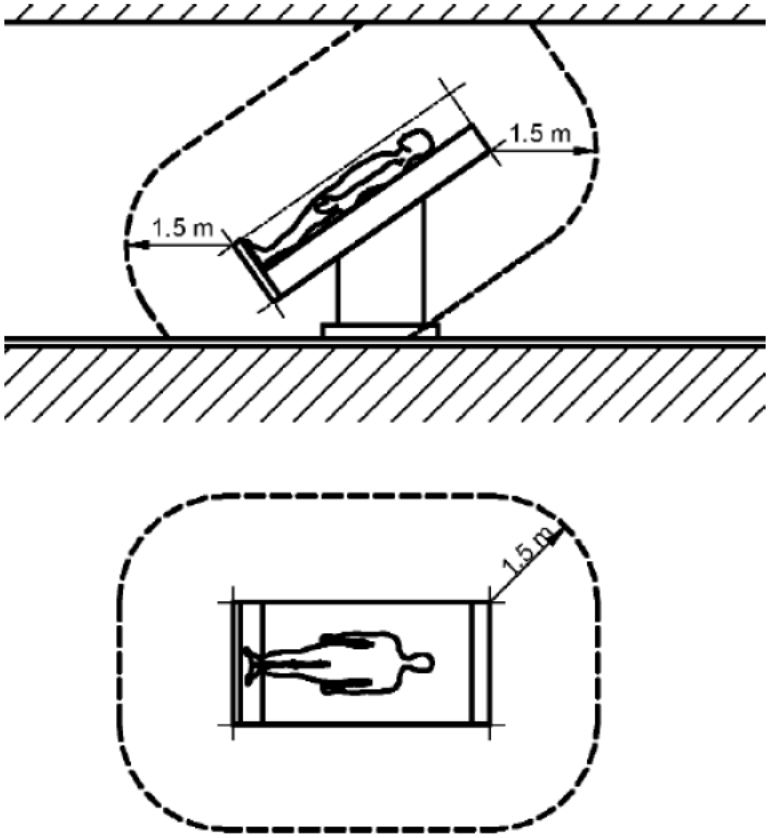

Figure 1: Patient Environment

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Intended Environment

The Oximeter is intend to be used in the following environments: operating, exam/procedure rooms, surgical recovery, critical care, emergency room, and long-term care.

Likely Misuse

The Oximeter may be misused if used in the following environments:

- Transport vehicles
- Areas with flammable anesthetic gases
- In or near MRI equipment
- Outside the recommended temperature range
- Outdoors or in high humidity environments

Note: The Oximeter is intended to be stationary, but may be moved intra-hospital via a cart or roll stand. It may also be carried by its handle when in non-operational mode (Off).

Oximeter Classifications of Electrical Insulation

The Oximeter (with integrated AC power supply) is a Class I device.

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Basic Operations

Introduction

The Oximeter is pre-configured to measure absolute tissue oxygen saturation.

The Oximeter detects oxygenation changes in biological tissue mainly at the microcirculation level (capillary, arteriole, and venula) based on different absorption characteristics of the chromophores oxyhemoglobin (HbO_2) and deoxyhemoglobin (Hb) in the near-infrared spectrum. A biological spectroscopic window exists at the wavelength range 660–940 nm in which Hb and HbO_2 can be differentiated and measured. Tissue oxygen saturation (StO_2) is determined from the ratio

$$((HbO_2)/(HbO_2 + Hb)) \times 100\%$$

The Oximeter uses LED Technology to project light into tissue to measure oxygen saturation.

The Oximeter is equipped with a rechargeable backup battery pack that allows the Oximeter to be used independently from an external power source.

Refer to the Battery Maintenance section on page 43.

Getting Started

Before operating the Oximeter, the user should be thoroughly familiar with the following:

- **Warnings** and **Cautions** in the Safety section starting on page 12.
- Physical configuration of the Oximeter, page 21.
- Content and use of the Oximeter display, page 25.
- Procedures described in this guide, pages 27 and following,
- Use the Oximeter, starting on page 24.
  1. Set up the Oximeter for the patient (optional). See page 27.
  2. Connect the Preamp Cable(s) to the Oximeter. See page 27.
  3. Connect the Sensors(s) to the Preamp Cable(s). See page 27.
  4. Affix the Sensor(s) to the patient. See page 28.
  5. Begin monitoring. See page 27.

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Physical Configuration

Front View

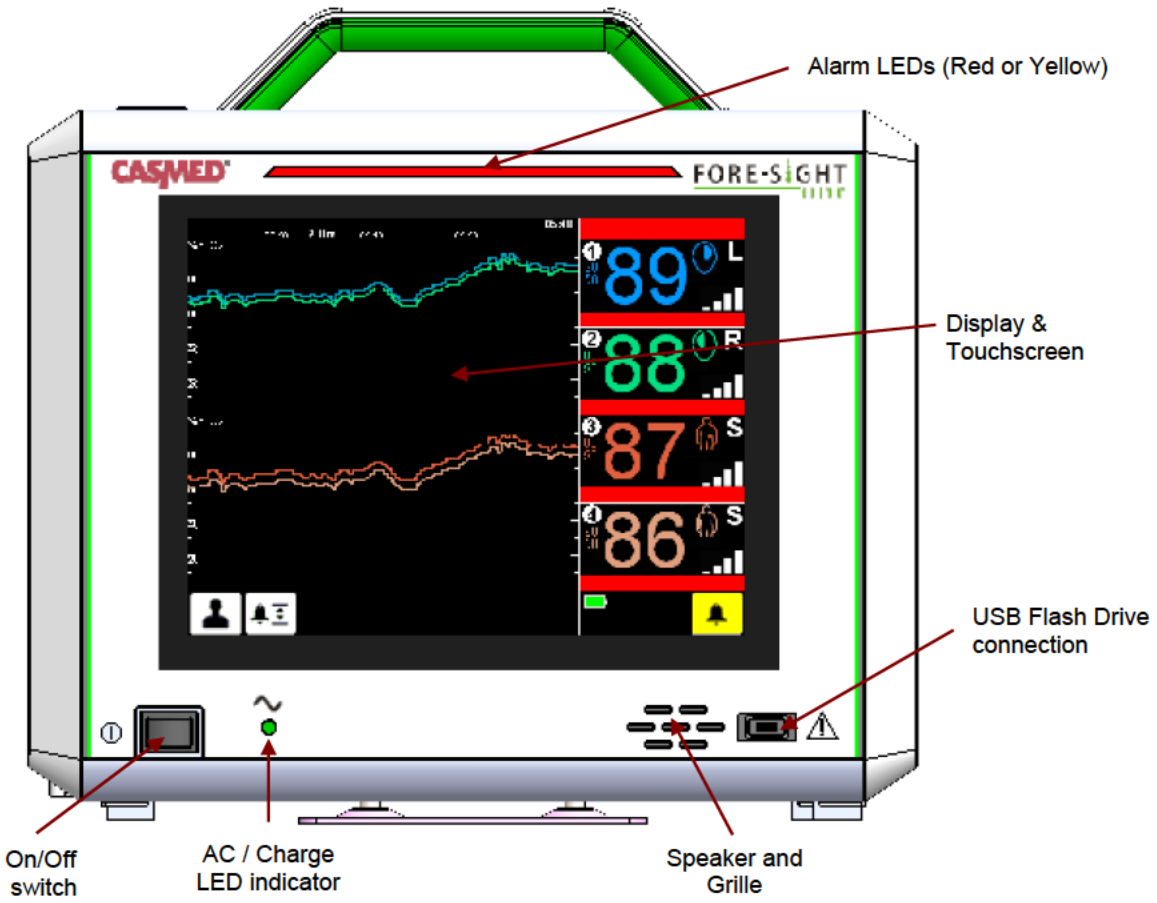

Figure 2: Front View

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Rear View

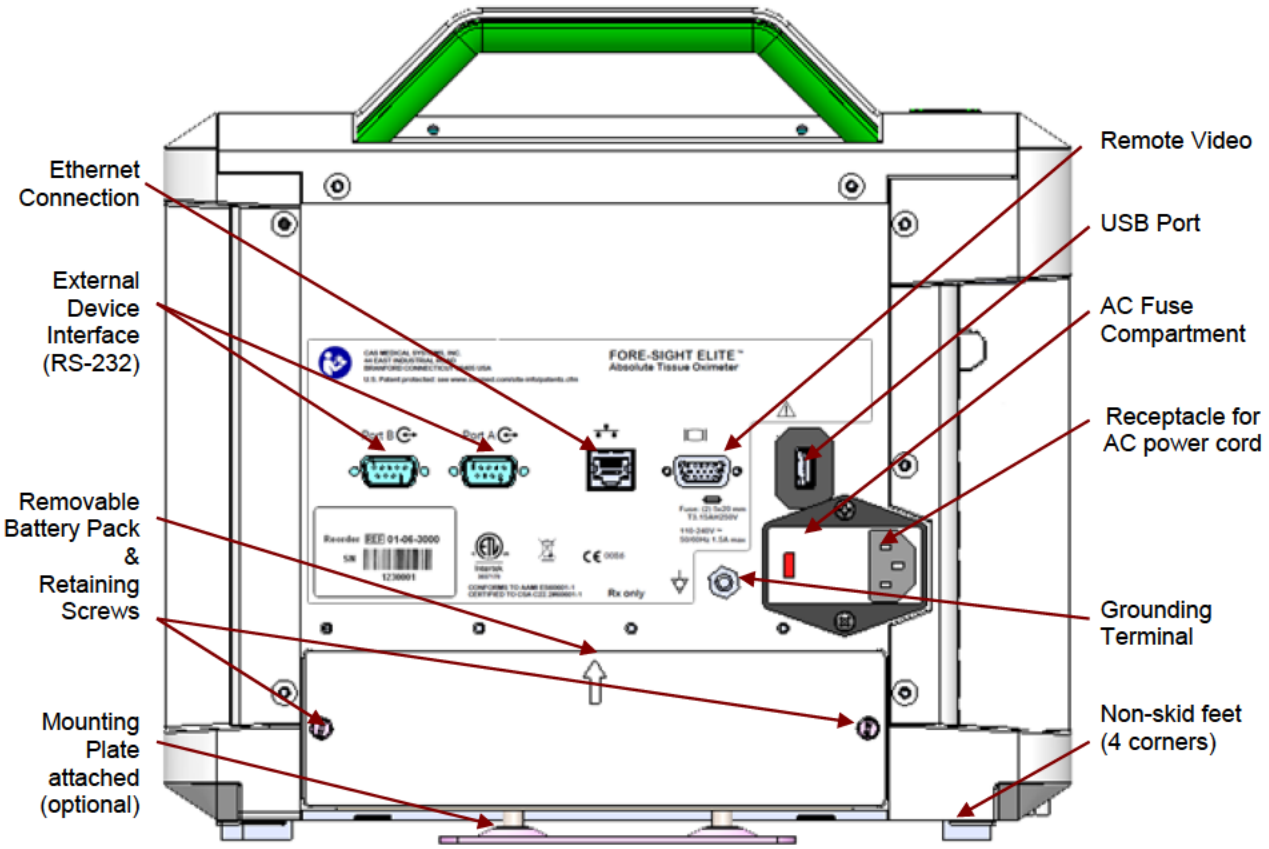

Figure 3: Rear View

Note: The Ethernet connection is for the use of CASMED service personnel only.

Note: The 4 non-skip feet may be removed (feet are attached with sticky tape) to make installation with the various mounting solutions easier.

Note: The Grounding Terminal can provide a connection between the Oximeter and the potential equalization bus-bar of the electrical installation.

When using the Grounding Terminal, the line cord shall not incorporate a potential equalization conductor.

Refer to IEC 60601-1 for additional information.

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Side View

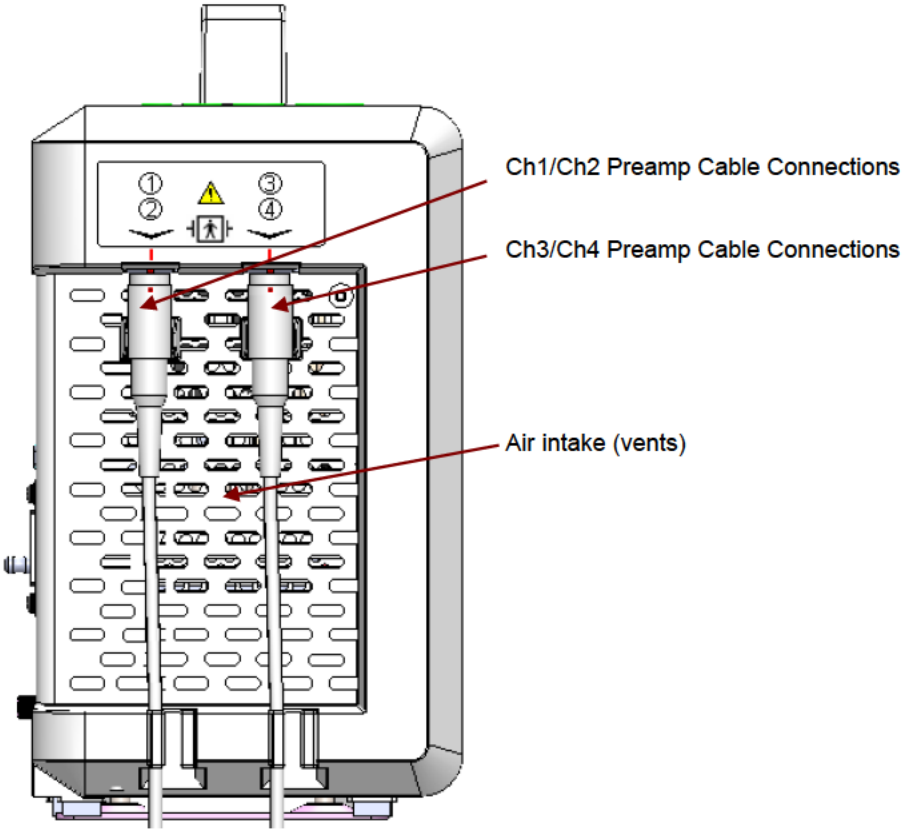

Figure 4: Side View

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Oximeter Controls

On / Off Button

Press the On / Off button to switch from Off to On.

Press the On / Off button to switch from On to Off.

The Oximeter will remain Off when connected to AC power and the On / Off button is not pressed

Touchscreen

The touchscreen gives the user access to on-screen Oximeter functions.

The user can:

- Silence Audio Alarms
- Navigate through all menu selections
- Choose optional settings
- Enter data

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Oximeter Display

Parts of the Display Screen

The major indicators on the Oximeter display are shown in Figure 5 below.

Note: The Major Areas of the Oximeter display illustrate all the areas of the display and certain settings presented may not represent actual display configurations.

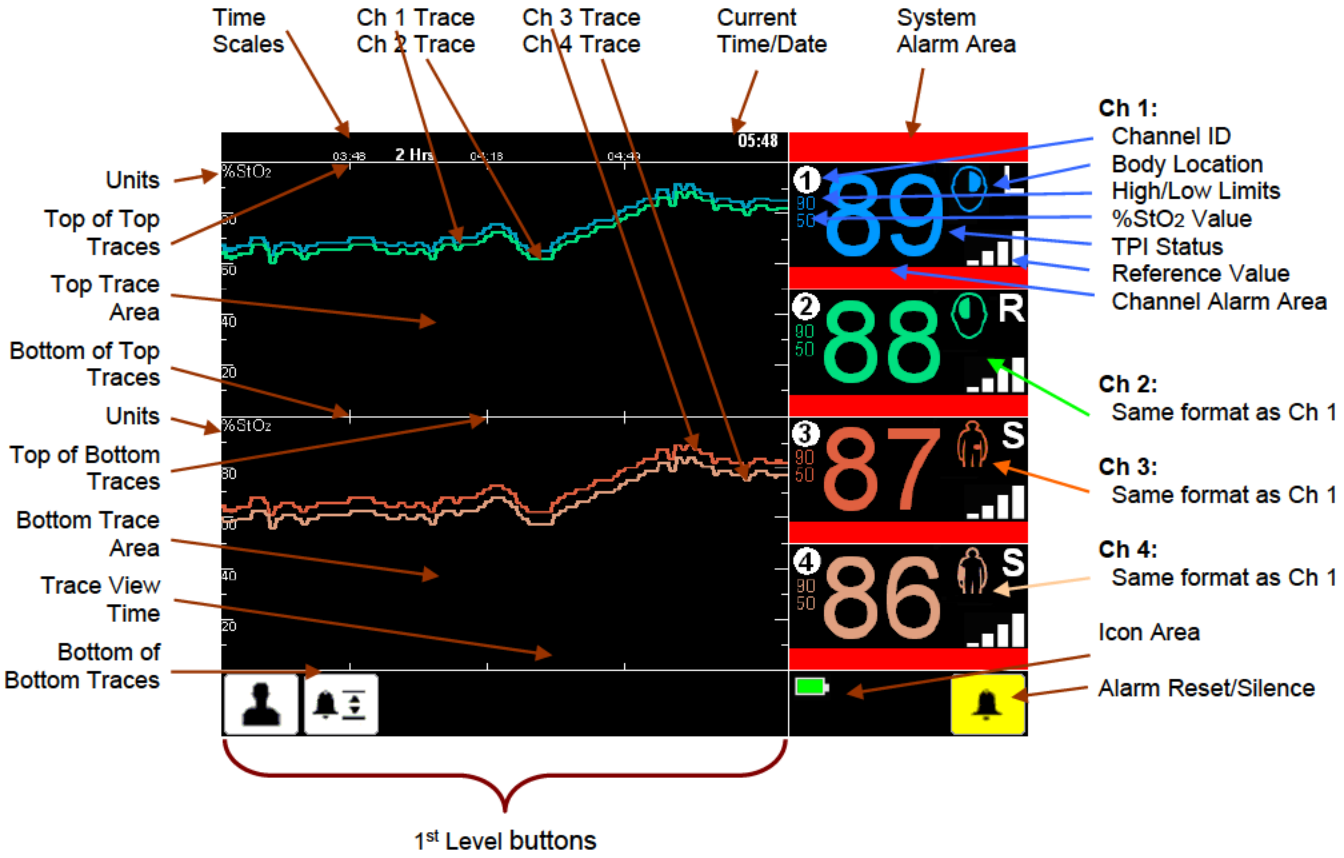

Figure 5: Major Areas of Display

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Starting the Oximeter

Turning the Oximeter On

Note: The Oximeter may be turned on before or after connecting cables and Sensors.

To turn the Oximeter on:

1. Plug the AC power cord into a power outlet.

Note: The Oximeter is equipped with a removal battery pack that allows the user to turn the Oximeter on without plugging it into an outlet. The battery status indicator shows the state of charge in the form of a colored battery icon on the display. Refer to the Battery Maintenance section on page 43.

2. Push the On / Off switch on the front of the Oximeter. The Oximeter will power on within a few seconds.

While the software initializes, a splash screen and a set of diagnostic tests are displayed. When the diagnostic tests are done the Oximeter will switch to the main screen, and is ready to begin normal operation.

Touchscreen Navigation

The user can control the operations of the Oximeter through the touchscreen system (see Figure 6 below). The procedures in this manual make frequent reference to the touchscreen system. This section explains how to navigate through it.

Figure 6: 1st Level buttons

The following paragraphs briefly describe what can be done from the various menus.

This section serves as an orientation to the touchscreen system.

Specific procedures making use of the touchscreen system are found in later sections of this manual.

Patient/Case Menu

The Patient/Case menu lets the user select the body locations of the sensors on the Patient.

Alarm Limit Menu

Touching the Alarm Limit icon allows user change each Channel's High & Low Alarm Limit.

Note: Powering the Oximeter off and on (for any period of time) will retain the last saved High & Low Limits.

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Start Patient Monitoring

Connecting Preamp Cable

Preamp Cables (see Figure 7, below) connect the Oximeter to the Sensors. Preamp Cables are reusable.

Note: Preamp Cables can remain connected to the Oximeter between uses.

Note: Preamp Cables should be replaced when they no longer properly functioning. Keep track of cable installation date and usage. See Parts on page 53 for reorder information.

To connect the Preamp Cables to the Oximeter:

1. Remove the Preamp Cable from the packaging.
2. Position the Preamp connector under the desired Oximeter Preamp connector (1&2 or 3&4). The Preamp connector housing may rest on the Guides under each Oximeter connection.
3. Line-up the alignment marks (red dots) on the Preamp Cable and Oximeter Preamp Receptacle. The Preamp Connector may be placed in the Oximeter Receptacle and rotated until the Preamp connectors inserts further.
4. Gently push the Preamp Cable Connector straight up into the Oximeter Preamp Receptacle, the Preamp Connector should snap into place.
5. Pull down gently on the Preamp cable to make sure the Preamp Connector has fully snapped into place.

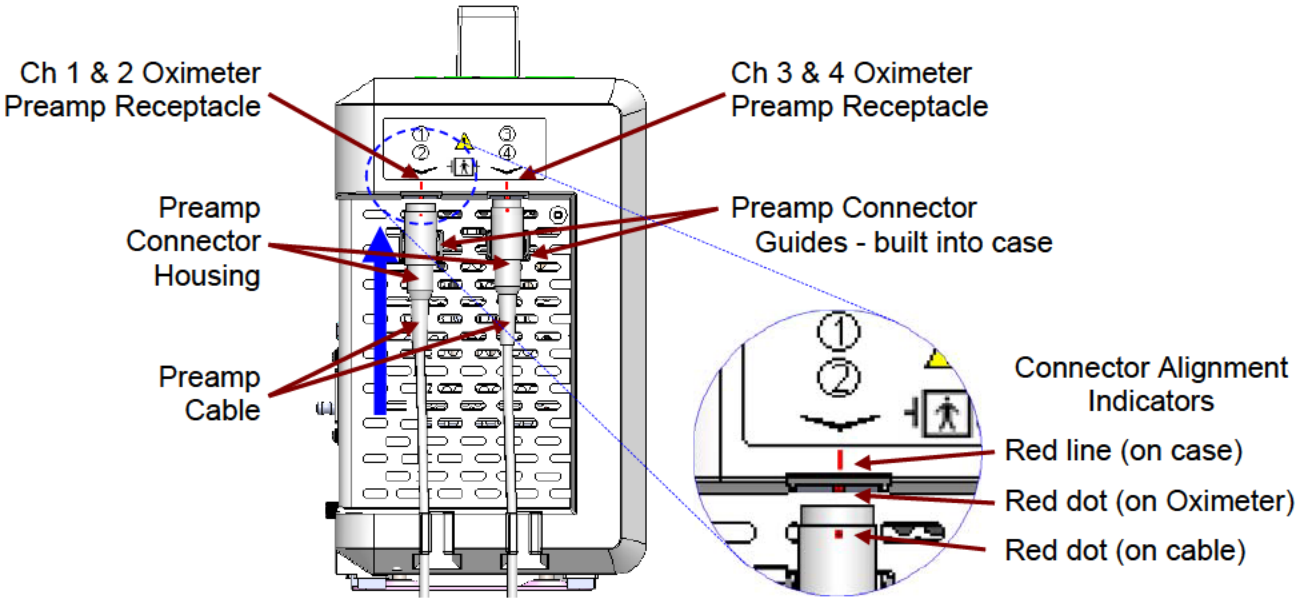

Figure 7: Connecting Preamp Cable

6. The small box at the far end of the Preamp cable contains indicators that will illuminate when the Preamp and Sensors are connected. The indicators will denote Preamp channel assignment 1, 2, 3 or 4.

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The Preamp plastic housing has a top label (refer to Figure 8) to indicate Channel Identification as well as Sensor connection status. Each Channel identification contains 2 LEDS; 1 green, 1 white

When a Preamp cable is connected to the Oximeter, the appropriate pair of white Channel ID LEDs (① ② or ③ ④) will be lit.

Preamp Cable connected to Ch1 & Ch2 Patient input

Ch1 & Ch2 White LEDs lit (No Sensors connected)

Ch3 & Ch4 LEDs off

Figure 8: Preamp top label, Ch1 & Ch2 Preamp connected

Connecting Sensor to Preamp Cable

Sensors connect the Preamp Cables to the patient.

Caution: The Sensor is designed for single patient use, and is not to be reprocessed. Use a new Sensor for every patient and discard after use.

To connect a Sensor to the Preamp Cable:

1. Remove Sensor from its packaging.
2. Position the Sensor connector in front of the Preamp Sensor connector.
3. Line-up the alignment marks on the Sensor and Preamp Sensor connector.
4. Gently push the Sensor connector straight into the Preamp Sensor connector, the connector should snap into place.

The Channel ID LED on the preamp housing will change to green when a Sensor is connected (refer to Figure 9).

Sensor connected to Ch1

Ch1 Green LEDs lit (Sensor connected)

Ch2 White LED lit (No Sensor)

Figure 9: Preamp top label, Sensor connected to Ch1

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Preparing Patient

To prepare the patient's skin for placement of the Sensor:

1. Make sure the skin area where the Sensor is to be placed is clean, dry, intact and free of powder, oil or lotion.
2. If necessary, shave hair from skin at chosen site.
3. Use an appropriate cleanser to gently clean the intended Sensor site. Allow the skin to dry completely before applying the Sensors.

Applying Sensor

Caution: Sensors should not to be placed on high density hair areas.

Caution: The Sensor must be flush with clean, dry skin. Any debris, lotion, oil, powder, perspiration, or hair that prevents good contact between the Sensor and the skin will affect the validity of the data collected and may result in an alarm message.

Note: Skin pigmentation does not affect the validity of collected data. The Oximeter compensates automatically for skin pigmentation.

Note: For cerebral applications, If possible, locate the Sensor away from the midline of the forehead or over a sinus cavity.

Note: Refer to Figure 10: Sensor Selection Guide below to help select the proper Sensor for the patient.

Apply Sensor using the instructions provided in the Sensor kit package.

1. Be sure that all cables are fully connected and Sensors are placed correctly on the patient's skin.
2. Use the clip/hook near the Preamp to secure the cable to prevent the cable from being pulled away from the patient.

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Sensor Selection Guide

Cerebral & Skeletal Muscle Applications

kg	40-60	>60
10-18 yrs		L
> 18 yrs	L	L
lbs	88-132	>132

Figure 10: Sensor Selection Guide

L – Large Sensor

TPI Indicator

A 4-bar indicator of the Tissue Perfusion Index (TPI) represents the amount of hemoglobin in the tissue under a Sensor and is displayed near the $St0_2$ value (see Symbols on Display of Oximeter on page 45).

The TPI level is useful for the initial placement of a Sensor or for assessing an existing Sensor site:

Initial Placement:

- Without removing the white protective paper, hold the Sensor on the selected monitoring site.
- Slide the Sensor over the target sensing area until the highest TPI level is achieved.
- Visually note the Sensor position and remove & discard the protective paper prior to affixing the Sensor.

Routine Assessment:

- In normal operation, the TPI level should be 3 to 4 bars.
- If the TPI level changes to 2 bars, the user should verify proper Sensor contact and assess the site for reliability (e.g., edema is more present).
- For subjects that become hemodiluted during monitoring, a decrease in the TPI level is likely (e.g., during initiation of cardiopulmonary bypass).
- If 1 bar is present, the Sensor must be moved to a location with a higher TPI level. After 10 seconds this condition may trigger a warning message and $St0_2$ values will become dashes.

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Stop Patient Monitoring

Removing Sensor

Carefully peel the Sensor from the patient to avoid damaging the skin.

Discard the adhesive Sensors.

Disconnecting Sensor from Preamp Cable

To remove a Sensor from the Preamp Cable:

1. Grasp the Sensor connector of desired Preamp Cable to be disconnected.
2. Gently pull the Sensor connector straight out until the Sensor connector disengages from the Preamp Sensor connector.

When the Sensor is disconnected from the Preamp, the associated Channel ID LED on the Preamp housing will change back to white (refer to Figure 8).

3. Discard the Sensor.

Disconnecting Preamp Cable (Optional)

To remove a Preamp Cable from the Oximeter (see Figure 7 on page 18):

1. Grasp the housing of the connector (near The Oximeter Preamp Receptacle) of desired Preamp Cable to be disconnected.
2. Gently pull straight down on the Preamp Cable connector housing until the Preamp Cable connector disengages from the Oximeter Preamp Receptacle.

When the Preamp cable is disconnected from the Oximeter, all Channel ID LEDs on the Preamp housing will turn off.

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Monitoring the Patient

This section assumes that you are familiar with the front panel controls (see Figure 2: Front View on page 21) and the parts of the display screen (see Figure 5: Major Areas of Display on page 25).

Controlling Alarm Volume & Limits

The user can disable audible alarms by pressing the Alarm Silence / Reset button on the Oximeter front panel. Pressing the button disables the audio associated with all alarms for two (2) minutes. This does not affect the visual alarms. See Responding to on page 34 for a list of alarm conditions.

One the two minute audio disable time reaches zero, the audio will be re-enabled, assuming an alarm condition is still present.

The user can re-enable the audible alarms by pressing the Alarm Silence / Reset button on the Oximeter front panel when the audio is currently being disabled.

The user can set the High and Low Alarm limits of acceptable percentages on each channel independently.

The Oximeter shall annunciate an alarm when the Numeric value is below the Low limit or above the High limit. The Oximeter shall generate an alarm sound at the selected volume, indicate an alarm limit violation (text) in the Numeric field as well as flashed the Alarm LEDs at the top of the front display.

Adjusting Alarm Volume & Limits

To view or change the Alarm Volume or Alarm Limits:

1. Touch the Alarm Limit icon on the Main menu (see Figure 6 on page 26).
2. Touch the High/Low Limit icon and the High/Low Limit screen should appear

Alarm Volume

To adjust the Alarm Volume perform the following:

1. Touch the target area entitled “Volume”.
2. A selection of available Alarm Volumes will appear.
3. Touch the desired Alarm Volume, the selection shall be outlined for as long as the selection is touched.
4. Release the selection. The selected Volume shall be updated in the Volume target area.

High & Low Limits

To adjust the Alarm Limits perform the following:

1. Touch the target area entitled “High Limit” to adjust the High limit or “Low Limit” to adjust the Low limit

Note: Each High & Low limit selections shall be adjacent (to the left) of the corresponding channel Numeric

2. Numeric buttons (0-9, accept & backspace) will appear.
3. Enter a 2-digit limit

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The Backspace button may be used to delete the last entered digit

4. After the 2nd digit is entered, the Accept icon should be available, touch to accept.

   If the value entered is valid, the value shall be updated as the appropriate High or Low Alarm Limit (depending on which selection was made) and the numeric buttons shall disappear.

   OR

   If the value entered is invalid, the value shall be displayed as red and the numeric buttons shall remain. The value must be deleted and re-entered as a valid value before proceeding.

Caution: Setting the High Alarm limit to an extreme high value can render the High Limit detection ineffective.

Caution: Setting the Low Alarm limit to an extreme low value can render the Low Limit detection ineffective.

Note: The alarm delay for High and Low limits remains constant during any alarm condition. The alarm delay High and Low limits are factory set to 0 and cannot be altered.

Note: The High Limit cannot be set less than the Low Limit (for the same channel). The Low Limit cannot be set greater than the High Limit (for the same channel). There is always 5% difference between the Low and High limits (same channel).

Saving Alarm Volume and Limits

Once the Alarm Volume and High/Low limits have been entered, perform the following to save them:

Touch Accept icon to accept this Alarm Limit changes.

OR

Touch Cancel icon to discard this channel's Alarm Limit changes.

Note: For proper identification of the Alarm signals generated by the Oximeter, the operator should be positioned directly in the front of the Oximeter, facing the front panel.

Note: To test the Alarm operation, connect a $St0_2$ simulator (available through CASMED) to the patient connection of the Oximeter. Set the High Alarm limits to at least 1% less than the current displayed value and verify the activation of the High limit detection. Reset the High Alarm limits to the desired level. Set the Low Alarm limits to at least 1% more than the current displayed value and verify the activation of the Low limit detection. Reset the Low Alarm limits to the desired level. Testing of the Alarm operation should be done at least once every 6 months.

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Responding to Alarms

Alarm LEDs

High Priority Alarms will flash the Red Alarm LEDs, refer to Figure 2.

High Priority Alarms will be generated over any Medium Priority alarms.

Medium Priority Alarms will flash the Yellow Alarm LEDs.

Medium Priority Alarms will be generated over any Low Priority alarms.

Low Priority Alarms will also turn on the Yellow Alarm LEDs.

Low Priority Alarms will be generated over any Informational alarms.

All Alarm Messages are displayed in the following order:

- High Priority messages will be displayed before any Medium Priority message.
- Medium Priority messages will be displayed before any Low Priority message.
- Low Priority messages will be displayed before any Informational message.

System Messages

Table 1 lists the System Messages in order of priority, the conditions they signify, and the recommended action you should take.

System condition message appear in the System Alarm area, refer to Figure 5 for additional information.

Message	*Condition*	*Recommended Actions*
Medium Priority Alarms (Black on Yellow) - listed highest to lowest		
System Error E##	Internal component failure E##, ## indicates type of Error	If condition persists, contact CASMED customer service
Depleted Battery	Battery needs to be recharged	Plug Oximeter into AC outlet
Internal Temp	Unit is above upper operating temperature	If condition persists, contact CASMED customer service
Low Priority Alarms (Yellow on Black) - listed highest to lowest		
Low Battery	Battery needs to be recharged	Plug Oximeter into AC outlet
Port *X* Comm Lost	Communications problem with bi-directional wired device *X* indicates Port A or B	Inspect the Serial cable connections Make sure the Serial cable connectors are properly engaged Verify the Serial settings are correct Verify target device is turned on and actively displaying information
Informational Alarms (White on Black) - listed highest to lowest		
Connect to AC	AC power loss, Oximeter operating on Battery power	Plug Oximeter into AC outlet Make sure outlet is powered

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Message	Condition	Recommended Actions
Faulty System Fan	Operation of fan faulty	Check for free flow of temperate air around Oximeter Move Oximeter away from wall or other obstruction Move it to a cooler area If condition persists, contact CASMED customer service
Faulty Battery	Battery Pack is incapable of operating unit w/o AC	If condition persists, contact CASMED customer service to replace Battery Pack
Unknown Battery	Problem with Battery Pack Memory or Temp device	If condition persists, contact CASMED customer service to replace Battery Pack
Set Time/Date	Time & Date not set Clock Battery not capable of retaining Time & Date values	Enter Setup screen and set correct Time & Date If condition persists, contact CASMED customer service to replace Clock Battery
Faulty USB/VGA	Problem with VGA and USB Ports	If condition persists, contact CASMED customer service
Faulty Serial Port	Problem with RS-232 ports	If condition persists, contact CASMED customer service
Faulty Front USB	Problem with Front USB Port	If condition persists, contact CASMED customer service
Faulty Rear USB	Problem with Rear USB Port	
Faulty Clock Battery	RTC Battery not capable of storing Time & Date values	If condition persists, contact CASMED customer service

Table 1: System Messages

Note: Priorities of these Alarm Conditions are Factory configured and cannot be altered by the user.

A High Priority auditory signal is characterized by 10 audio pulses repeated every 10 seconds at a frequency of 970 Hz.

A Medium Priority auditory signal is characterized by 3 audio pulses, repeated every 20 seconds at a frequency of 575 Hz.

The Low Priority auditory signal is characterized by 1 pulse at a frequency of 575 Hz.

There is no auditory signal associated with Informational messages, only visual.

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Channel Messages

The message area at the bottom of each Numeric field and are associated with that Channel. Table 2 lists the Channel Messages in order of priority, the conditions they signify, and the recommended action you should take.

Channel condition message appear in the Channel Alarm area(s), refer to Figure 5 for additional information.

Message	*Condition*	*Recommended Actions*
High Priority Alarms (White on Red)		
High StO^2	Reading exceeds user-selected High alarm limit	Assess the patient and physiologic Oximeter to verify the condition and then respond accordingly
Low StO^2	Reading is below user-selected Low alarm limit	Assess the patient and physiologic Oximeter to verify the condition and then respond accordingly
Medium Priority Alarm (Black on Yellow) - listed highest to lowest		
Faulty Preamp	Preamp Cable is defective	If condition persists, contact CASMED customer service to replace Preamp Cable
Preamp Disconnected	Preamp cable has become disconnected	Connect Preamp cable to Oximeter
Faulty Sensor	Sensor is defective	Replace disposable Sensor if necessary
Sensor Disconnected	Sensor has become disconnected	Connect Sensor to Preamp
Sensor Over Temp	Temperature under Sensor is > 41°C	Cooling of patient or environment may be required
Signal out of Range	Sensor on inappropriate object	Remove Sensor from inappropriate object and place on patient
Check under Sensor	Tissue under Sensor may have fluid accumulation/edema	Check patient for edema under Sensor When tissue condition returns to normal range (e.g. patient is no longer edematous)
High Ambient Light	Sensor is not in correct contact with patient	Check that Sensor is in direct contact with skin
Low Priority Alarm (Yellow on Black) - listed highest to lowest		
Incorrect Sensor Size	Sensor is not compatible with the specified Body Location	Use the Sensor recommended for the specified Body Location
External Interference	Interference from outside source	Move Sensor away from interfering source
Sensor Under Temp	Temperature under Sensor < 8 °C	Warming of patient or environment may be required
Informational Alarms (White on Black) - listed highest to lowest		
Ambient Light	Ambient light approaching maximum value	Check that the Sensor is in direct contact with skin
Set Body Location	Sensor connected with no body location assigned	Set Body location for channel

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Message	Condition	Recommended Actions
Connect Preamp	Connect Preamp to start monitoring channels	Connect Preamp to Oximeter
Connect Sensor	Connect Sensor to start monitoring channel	Connect Sensor to Preamp
Acquiring Data	Channel is acquiring data	Normal operation Wait for message to clear

Table 2: Channel Messages

Note: Priorities of these Alarm Conditions are Factory configured and cannot be altered by the user.

A High Priority auditory signal is characterized by 10 audio pulses repeated every 10 seconds at a frequency of 970 Hz.

A Medium Priority auditory signal is characterized by 3 audio pulses, repeated every 20 seconds at a frequency of 575 Hz.

The Low Priority auditory signal is characterized by 1 pulse at a frequency of 575 Hz.

There is no auditory signal associated with Informational messages only visual.

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Philips IntelliVue Messages

Table 3 below lists the conversion of High, Medium and Low Priority System and Channel Alarm Messages displayed on the Oximeter to the Alarm Message displayed on the Philips IntelliVue:

Oximeter Message	Philips IntelliVue Message
High StO_2	High rSO_2-# [1]
Low StO_2	Low rSO_2-# [1]
System Error Exx Internal Temp Depleted Battery Low Battery	FS Sys Warning
Diff Ch *x* & Ch *y* [2]	Diff StO_2
Faulty Preamp [3] Faulty Sensor	FS-# [1] Error
Preamp Disconnected [3] Sensor Disconnected Sensor Over Temp Signal out of Range Check under Sensor High Ambient Light	FS-# [1] Warning
Incorrect Sensor Size External Interference Sensor Under Temp	FS-# [1] Chk Sensor

Table 3: Oximeter Messages displayed on Philips IntelliVue

Note: Only High, Medium and Low Priority System and Channel Alarm Messages are displayed on the Philips IntelliVue.

Note: Alarm messages displayed the Oximeter may appear different on the Philips IntelliVue due to text length limitations.

[1] # Represents the corresponding Patient Data Channel 1, 2, 3 or 4

[2] Differential Alarm message Ch *x* & Ch *y*, where *x* & *y* represent Patient Data Channel 1, 2, 3 or 4, e.g., ***Diff Ch1 & Ch 2***

[3] Preamp messages will present 2 VueLink messages, 1 for each Preamp channel: 1 & 2 or 3 & 4

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Cleaning

Warning: The Oximeter is designed to be cleaned with soft cloths dampened with cleaning solutions. If the Oximeter or Preamp is accidentally wetted, take it out of operation. It should be thoroughly dried (minimum 1 hour) and have it checked by a service technician before it is used again.

Caution: Do not open the Oximeter to clean it.

Caution: Do not use abrasive cleaners, isopropyl alcohol or organic solvent for cleaning. Use of these cleaners can cause damage, stiffness and brittleness to the Oximeter's surface and to cables and wires.

Cleaning the Oximeter

Examine the Oximeter's case for damage and check the AC power cord for bent or broken prongs, cracks or fraying. Neither the Oximeter nor the AC power cord should be used if damaged. If any damage is noted, contact the appropriate service personnel. Refer to Contact Addresses on page 2 for e-mail and phone number information.

- **Housing:** The Oximeter surfaces may be disinfected using a soft cloth dampened with a 10% (1:10) solution of chlorine bleach in tap water. When all of the surfaces have been disinfected, wipe the entire surface of the Oximeter using a soft cloth dampened with fresh water to remove any trace amounts of residue and/or fumes.
- **Display:** Clean the display window using a soft, lint-free cloth sprayed with an alcohol free glass cleaner. The use of paper towels is not recommended as it may scratch the surface.

Thoroughly wipe off any excess cleaning solutions

Cleaning Preamp Cables

Clean the Preamp Cable using a soft cloth dampened with a 10% (1:10) solution of chlorine bleach in tap water. Do not use alcohol.

Cleaning Sensors

Sensors are not design to be cleaned and/or re-used.

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Maintenance

Warning: No modification of this equipment is allowed.

Caution: Service performed by unauthorized personnel could be damaging to the Oximeter and may void the warranty. For service, contact your CASMED Representative. Refer to Contact Addresses on page 2 for e-mail and phone number information.

The only Oximeter parts requiring preventive inspection and maintenance are the AC Fuse Replacement on page 41 and the Battery Maintenance on page 43.

CASMED will make available on request circuit diagrams, component parts lists, to assist CAS Authorized Service personnel.

Maintenance Intervals

Preventive maintenance of the Oximeter is an important function that should be performed routinely to ensure safe and efficient Oximeter operation. The following maintenance intervals are recommended:

- **Oximeter:** No user calibration is required
- **Battery Pack:** Should be replaced every 2 years

Caution: To maintain proper battery charge, plug the Oximeter into mains power when not in use. Failure to do so may diminish the service life and function of the battery.

Waste Electrical and Electronics Equipment (WEEE)

To facilitate the sound treatment of WEEE, information will be made available for current CASMED products upon request. EU distributors and treatment facility personnel may contact techsrv@casmed.com to obtain relevant information.

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Fuse Replacement

Warning: Before changing any fuse, turn power off, remove battery pack and unplug the AC power cord.

Warning: For continued protection against fire hazard, replace only with identically rated fuses.

Warning: The Oximeter has multiple fuses located inside the Oximeter and Battery Pack. These fuses are not user replaceable. These fuses should only be replaced by CAS Authorized Service personnel.

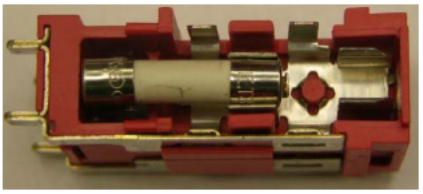
AC Fuse Replacement

The Oximeter has a dual fuse AC power input receptacle. Both AC lines are fused.

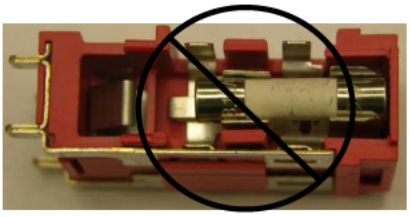
A fuse may need to be replaced if the Oximeter is plugged into an electrical outlet but the AC Power indicator is not illuminated.

To replace the AC power fuses, proceed as follows:

- Turn the Oximeter off and disconnect the AC power cord.
- Using a small screw driver, open the fuse cover on the AC Fuse Compartment (see Figure 3 on page 22).
- Using a small screw driver, pull out the red fuse holder from the AC Fuse compartment.
- Remove the suspect fuse.
- Place the new fuse into the fuse holder as indicated by the orientation (see Figure 11 below).
- Repeat this process for the fuse on the other side of holder.
- Insert the fuse holder back into the power input receptacle (the fuse holder can be inserted in either orientation).
- Close the fuse cover on the AC Fuse Compartment.
- There should be an audible click when it is secured.
- Reconnect the AC power cord back to the Oximeter.



Correct Placement



Incorrect Placement

Figure 11: AC Fuse Placement

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PC Board Fuse Replacement

The Oximeter has fuses located inside the Oximeter.

Below are the locations and ratings for the fuses on the System Control Printed Circuit Board Assembly, CAS PN 03-59-0402:

Ref Des	Rating
F3	F5.00A/125V
F2	F5.00A/125V
F1	F5.00A/125V
F4	F2.00A/125V
F5	F250mA/125V

Figure 12: System Control Board Fuse Locations & Ratings

Below are the locations and ratings for the fuses on the NSAM Printed Circuit Board Assembly, CAS PN 03-50-0450:

Ref Des	Rating
F2	F250mA/125V
F4	F250mA/125V
F1	F2.00A/125V
F3	F125mA/125V
F5	F125mA/125V

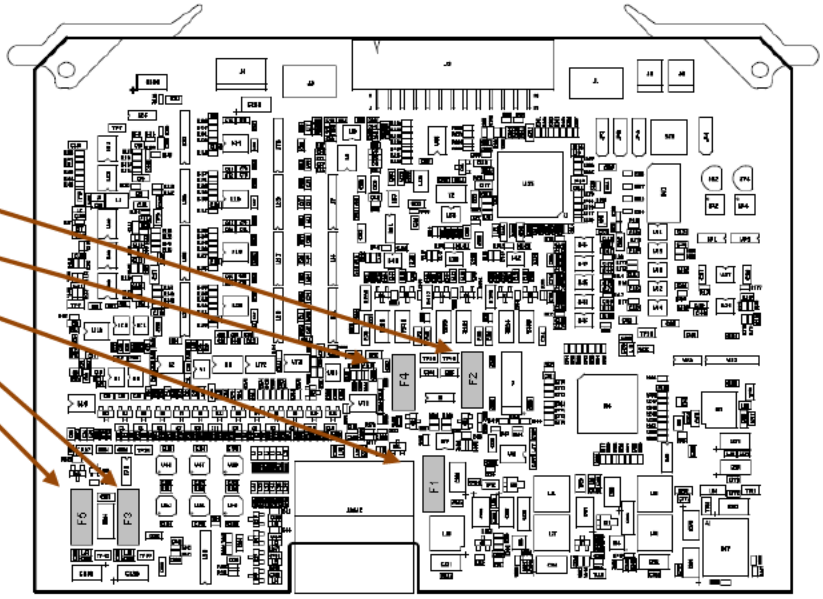

Figure 13: NSAM Board Fuse Placement

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Battery Maintenance

The Battery Pack provides power to operate the Oximeter for up to a half hour (on a new, fully charged battery).

To properly maintain the battery charge level and prolong battery life, the Oximeter should be connected to AC power at all times.

As with all batteries, the capacity will diminish over time. It is recommended that properly maintained batteries be replaced by CASMED service every 2 years.

If Oximeter will not operate for more than 10 minutes on battery power prior to the 2 year replacement interval, then the Oximeter should be returned to CASMED for service and battery replacement.

Installing/Removing the Battery Pack

Warning: Use only the battery pack that is listed in the Accessories, Detachable Parts and Materials section on page 53.

The Battery Pack in the Oximeter is designed to be easily replaced. Turn the Oximeter Off and remove the AC power cord whenever removing or installing a battery pack.

To remove a Battery Pack:

1. Locate the Battery Pack – bottom area of rear of Oximeter (see Figure 3).
2. Loosen the retaining screws on either side of the Battery Pack.
3. Grasp the retaining screws of the battery pack and pull the Battery Pack slightly out of the Oximeter - this will disconnect the Battery pack electrically from the Oximeter.
4. Gently slide the Battery pack out of the remainder of the Battery compartment of the Oximeter.

To reinstall a Battery Pack:

1. Position the Battery Pack with the arrow on outside cover facing up and the two side tabs towards the top of the pack.
2. Gently slide the Battery pack in to the Battery compartment of the Oximeter until a slight resistance if encountered.
3. With equal force on both sides of the Battery Pack, push the Battery Pack into the Battery compartment until the outside of the Battery Pack is flush with the rear of the Oximeter.

Caution: If significant resistance in encountered, do not force the Battery Pack into the Battery compartment. Ensure the arrow on outside cover facing up and the two side tabs towards the top of the pack.

4. Tighten the retaining screws on either side of the Battery Pack. Do not over tighten the screws.
5. With the AC power cord disconnected, press the front panel power button and verify the Oximeter will power on with the Battery Pack installed
6. Reconnect the AC power cord back to the Oximeter.

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Appendix

Symbols

The following is a summary of all symbols used on the Oximeter and accessories. Symbols may occur on the product or on its packaging. Symbols shall be black unless otherwise indicated.

Symbols on Front of Oximeter

AC power indicator / Charge mode enabled (Green circle)

On / Off

Caution

Symbols on Left Side of Oximeter

(Near the Oximeter Patient Connections)

Patient connections are Type BF

Warning (Yellow background)

Symbols on Rear of Oximeter

Caution

Potential Equalization Post (Grounding Terminal)

This symbol appears here instead of on the Oximeter. The first two digits of the Oximeter's serial number indicate the year of manufacture in the 21st century.

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Indicates this Oximeter is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

Alternating current

Communication port, RS-232 Connector

Video port, VGA Connector

Follow instructions for use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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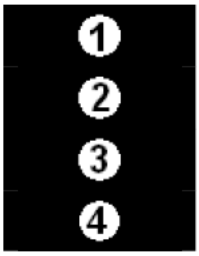
Symbols on Display of Oximeter

Audio Disable State

Temporary Audio Disabled (Yellow bell w/red dotted X) - Indication the Alarm Audio is temporarily disabled

Channel Indicators



Channel 1 (Black number on White circle background)

Channel 2 (Black number on White circle background)

Channel 3 (Black number on White circle background)

Channel 4 (Black number on White circle background)

Body Locations

Left Brain - Frontal lobe (Blue). Position over the left eyebrow, but below the hairline (higher up is best to avoid air sinus).

Left Arm Muscle - (Tan). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

Left Flank Muscle - (Tan). Position over the lateral abdominal wall below the rib cage (rib margins should be palpable or too much adipose or edema maybe present).

Left Leg Muscle - (Tan). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

Right Brain - Frontal lobe (Green). Position over the right eyebrow, but below the hairline (higher up is best to avoid air sinus).

Right Arm Muscle - (Orange). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

Right Flank Muscle - (Orange). Position over the lateral abdominal wall below the rib cage (rib margins should be palpable or too much adipose or edema maybe present).

Right Leg Muscle - (Orange). Position over muscle (if cannot palpate the muscle, too much adipose or edema maybe present).

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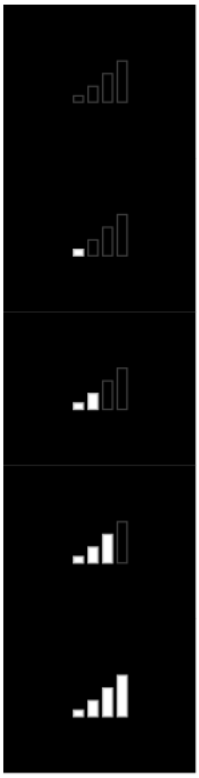
TPI Indicators



NONE (four empty Gray bars) No Sensor or Preamp connected or Sensor and Preamps connected, but Sensor off patient.

POOR (one White-filled bar & three empty Gray bars) Indicates that the Sensor should be moved as monitoring will soon stop. After 10 seconds, this condition triggers the "Check tissue under Sensor" message and $St0_2$ values become two dashes, "--".

FAIR (two White-filled bars & two empty Gray bars) If seen when first placing the Sensor, reposition to achieve a GOOD or EXCELLENT level. If TPI reduces to FAIR during monitoring, verify that the Sensor is well adhered and assess the site for reliability, e.g., edema.

GOOD (three White-filled bars & one empty Gray bar) For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site.

EXCELLENT (four White-filled bars) Ideal monitoring state. For subjects that become hemodiluted (e.g., initiation of CPB), the TPI may decrease; this change in level is understandable without need to assess the Sensor site.

Actions

Accept (Green) - Accepts changes and return to previous menu.

Cancel (Red) - Discards changes and return to previous menu.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Symbols on Battery Pack

Caution

Recycling suggested

Indicates this Battery pack contains lead (Pb) and is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

Symbols on Oximeter Packaging

Symbol used to indicate the minimum and maximum storage and transport Temperatures.

Refer to Storage/Transport Environment on page 51.

Symbol used to indicate the minimum and maximum relative humidity for storage and transport.

Refer to Storage/Transport Environment on page 51.

Symbol used to indicate the minimum and maximum atmospheric pressure for storage and transport.

Refer to Storage/Transport Environment on page 51.

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Fragile, handle with care

This end up

Symbols on Preamp

Follow instructions for use

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Indicates this Preamp is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

Do not Discard
Intended for Multiple use

Found on the Preamp cable
(Black text & symbol on Green background)

Symbols on Preamp Packaging

CE 0086 The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Indicates this Preamp is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.

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Symbols on Sensor Packaging

Rx only	In the U.S. the following **Caution** applies
NON STERILE	Non-Sterile
	Storage and transport temperatures
	Use only once
PVC	PVC Free
	Follow instructions for use
Latex	Latex free
	Do not cut or trim Sensor
	Do not apply prolonged pressure to the Sensor
	Manufacturer
LOT	Lot number
CE 0086	The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Warranty Policy

All products are sold by CASMED, under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this product directly from CASMED or CASMED's Authorized Distributors as new merchandise and are extended to the first buyer thereof, other than for resale.

The CASMED FORE-SIGHT ELITE Oximeter is warranted for a period of twelve (12) months. All products, if applicable, are warranted to be free from functional defects in materials and workmanship and to conform to the description of the product contained in the User Guide, published specifications, and accompanying labels and/or inserts, provided that the same is properly operated under conditions of normal use in accordance with applicable safety and regulatory requirements, and that replacements and repairs are made in accordance with the instructions provided by CASMED.

The same warranty conditions are made for a period of twelve (12) months with respect to the battery. A ninety (90) days warranty is provided for non-disposable accessories such as reusable Preamp Cables and other accessories provided by CASMED as part of the original purchase. CASMED warrants disposable or single-patient-use products, including Sensors for out-of-box failure only. Where the accessory is not a CASMED manufactured product, the manufacturer's own warranty applies. Warranty of accessories purchased separately from listed suppliers will be the responsibility of such listed suppliers. Damage to any part through misuse, neglect, or accident, or by affixing any accessories or attachments other than CASMED manufactured accessories or attachments, is not covered by this warranty.

The foregoing warranties shall not apply if the product has been configured, modified, adjusted or repaired other than by CASMED or by persons expressly authorized by CASMED, or not in accordance with written instructions provided by CASMED, or if the product has been subjected to misuse, negligence, or accident.

CASMED reserves the right to perform warranty service operations in its own factory, at an authorized repair facility, or at the customers' site. The sole and exclusive obligation of CASMED and Buyer's sole and exclusive remedy under the above warranties, is limited to repairing or replacing, free of charge, a product which is reported in writing or via telephone to CASMED has a Return Material Authorization (RMA) number assigned and which is returned during normal business hours, transporting charges prepaid to:

CAS Medical Systems, Inc.
44 East Industrial Road
Branford, CT 06405 USA

Telephone:	+1 203 488 6056
Fax:	+1 203 488 9438
E-mail:	custsrv@casmed.com

CASMED SHALL NOT BE OTHERWISE LIABLE FOR ANY DAMAGES INCLUDING, BUT NOT LIMITED TO, INCIDENTAL DAMAGES, CONSEQUENTIAL DAMAGES OR SPECIAL DAMAGES.

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Oximeter Configuration Record

Serial Number: _____

Date of Purchase: _____

Specifications

Physical Dimensions and Weight

H × W × D: (without feet)	10 in (25.4 cm) × 12 in (30.5 cm) × 9 in (22.9 cm)
Weight:	13.2 lbs (5.9 kg)

Operating Environment

Operating temperature:	10°C (50°F) to 40°C (104°F)
Humidity:	30 to 90% RH, non-condensing
Altitude:	-1,000 ft (106 kPa) to 10,000 ft (68 kPa)

Oximeters may not meet performance specifications if stored or used outside temperature and humidity ranges. When moving an Oximeter from a storage location, wait at least one hour prior to use to allow it to adjust to room temperature.

Measurement

Method:		Modified Beer-Lambert Law Near Infrared Spectroscopy (NIRS)
Information output:		Absolute saturation of tissue oxygenation (StO_2)
Measurement range:		0 to 100%
Display resolution:		1%
Data rates:		Acquisition ≤ 100 Hz, numeric display = .5 Hz
Accuracy:	**Cerebral**	Accuracy not determined < 45%. Oximeter may not be accurate at saturations below 45%.
	Large Sensors	45% to 95%: ±3.05% to 1 standard deviation
	Skeletal Muscle	Accuracy not determined < 45%. Oximeter may not be accurate at saturations below 45%.
	Large Sensors	45% to 95%: ±5.17% to 1 standard deviation

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Patient Alarms

Adjustable alarms:	High, Low limits for Ch1, Ch2, Ch3 & Ch4
Alarm indicators:	• Visual • Audible • Text in Channel alarm message window
Audible sound pressure @ 100% Volume	High Priority Alarms: >56db (Fast A) @ 1m in front of Oximeter Medium Priority Alarms: <56db (Fast A) @ 1m in front of Oximeter

Patient Parameter	**Low (Default 40%)**	**High (Default 90%)**
Range: Ch1, Ch2, Ch3, Ch 4	5 to 90%	10 to 95%

Low limits cannot be set above the associated high limit.
High limits cannot be set lower than the associated low limit.
There is a min of 5% difference between the Low and High limit values at any time.

Display

Display:	LCD display of measurement results, instructions, troubleshooting messages, waveforms, and signal strength bar.
Numerics:	1 corresponding to each channel

Storage/Transport Environment

Storage Temperature:	-20°C (-4°F) to 60°C (149°F)
Transport Temperature:	-20°C (-4°F) to 60°C (149°F)
Humidity:	15 to 90% RH, non-condensing
Altitude:	-1,000 ft (106 kPa) to 10,000 ft (68 kPa)

Power

External AC power:	100 to 240 VAC, 50/60 Hz, 1.5A Max (1.5A to 0.75A) Fuse rating: T3.15AH250V (two provided)
Chassis leakage current:	100 µA (maximum)
Heat dissipation:	60 watts (205 BTU/hr)
Battery:	Sealed lead-acid battery
Charge Time:	6 hours
Operating Time:	0.5 hour (minimum with new and properly maintained battery)

Note: The life of batteries is influenced by actual use, temperature, charging & discharging cycles, and mechanical abuse.

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Serial Interface

Interface type:	Bi-directional serial communication
Speed:	User-programmable
Signal level:	RS-232C
Data length:	8 bits
Start bit:	1 bit
Stop bit:	1 bit
Parity:	None
Flow control:	None

Standards

Oximeter comply with the following requirements:

CE marking according to Directive 93/42/EEC
IEC 60601-1:2005
IEC 60601-1-2:2007
IEC 60601-1-6:2010
IEC 60601-1-8:2006
ANSI/AAMI ES 60601:2005
ANSI/AAMI IEC 62366:2007
CAN/CSA C22.2 #60601-1

U.S. Patent protected: see www.casmed.com/site-info/patents.cfm

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Parts

Contact our Customer Service department or see our website for the latest product information. Refer to Contact Addresses on page 2 for e-mail and phone number information.

Oximeter

Catalog No.	Description
01-06-3000	(1) FORE-SIGHT ELITE Oximeter
Provided With:	(1) FORE-SIGHT ELITE Dual Preamp (1) FORE-SIGHT ELITE Battery Pack (1) FORE-SIGHT ELITE User Manual (on CD) (1) Hospital Grade AC power cord (country specific) (1) Service Card & Sleeve

Accessories, Detachable Parts and Materials

Catalog No.	Description
01-02-0395	Replacement power cord, North America
01-02-0384	Replacement power cord, U.K.
01-02-0385	Replacement power cord, Australian
01-02-0386	Replacement power cord, European
01-06-3100	FORE-SIGHT ELITE Dual Preamp
01-06-3011	FORE-SIGHT ELITE USB Flash Drive
01-06-3014	FORE-SIGHT ELITE Battery Pack
01-06-3036	FORE-SIGHT ELITE User Manual on CD
01-07-1110	FORE-SIGHT ELITE $St0_2$ Simulator
01-07-2103	FORE-SIGHT ELITE Large Sensor Carton (20 sensors)
01-06-0231	Giraffe®[4] Dovetail Attachment
01-06-0232	FORE-SIGHT 3 inch Utility Basket for 01-06-0234, 01-06-0235 or 01-06-0236 Arms
01-06-0233	FORE-SIGHT 6 inch Utility Basket for 01-06-0234, 01-06-0235 or 01-06-0236 Arms
01-06-0234	FORE-SIGHT 16 inch Arm Wall Mount
01-06-0236	FORE-SIGHT 16 inch Arm Pole Mount
01-06-0238	FORE-SIGHT Roll Stand, with basket & Handle
01-06-0239	FORE-SIGHT ELITE GCX Mounting Plate Kit
The following part require the 01-06-0231 Giraffe Dovetail Attachment:	
01-06-0235	8 inch Arm Giraffe Bed Mount

[4] Giraffe® is a registered trademark of GE Healthcare

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Philips IntelliVue/VueLink Accessories and Options

Description - Purchased directly from Philips:

Philips VueLink Module AUXPLUS PN: M1032A #A05

Philips Interface Cable PN: M1032A #K6C, M1032-61699

Philips contact information:

www.medicalphilips.com Web
medical@philips.com E-Mail

Catalog No.	Description
01-06-2133	**FORE-SIGHT** VueLink Extension Cable

Warning: Connection of the Oximeter to a Philips Patient Monitor could result in previously unidentified risks to Patients, or Operators and the User should identify, analyze, and control such risks.

Warning: Changes in the Oximeter to a Philips Patient Monitor connection including changes to configuration, additional or deletion of items and updating or upgrading of equipment could introduce new risks that may require new analysis.

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CASMED®	What's In This Release		
P/N 15-06-0285	**Description** FS-ELITE Main Application	**Ver** 1.1.1	**Date** 16-Dec-13

1.0 Programming Notes:

Value of Unused bytes:	0xFFFF
File Name:	15-06-0285_SCBMain_1.1.1_0d73ab5c.S19
16-bit Checksum:	0x0d73ab5c

2.0 New/Changed Features:

The following are New/Changes Features associated with this release:

- Addition of languages including Russian (CR multiple CRs)
- 4 Channel ATE and CSV (CR 1008)
- Different body locations available in OUS (CR 1077)
- Implement adaptive fan speed based on internal temperatures (CR 1021, 1080)
- Entering Biomed password will display Button bar with Language and defaults (CR 1054)
- Add confirm dialog to Stop STS data (CR 1058)
- Change Brightness settings scale (CR 1064)
- Adjust priorities and error messages (CR 1062)
- Ports no longer require a system reset (CR 827)
- Add languages to USB patient file (CR 1095)

3.0 Improvements:

The following are Improvements associated with this release:

- Add toggling bitmap Checkbox to Engineering settings dialog (CR 1142)
- Add klog tools to Engineering Dialog (CR 1163)
- Caution - Investigational Device not displayed when engineering body locations are enabled (CR 1129)
- In 4 C4 CAS protocol crash when baud rate is selected. (SPR 761) (CR 1145)
- Change STS statistics to match CSV (CR 1149)
- (b)(4) [redacted]
- Clicking the Ref value does not toggle the Ref line on graph (1151)
- Sensor Off Tissue and StO_2 Value (CR 928)
- Russian Cyrillic keyboard (CR 1029)
- Special file on the USB stick "eng1984.cas" automatically starts the network (CR 1047)
- Shell - 1-wire serial memory tests (CR command "serm") (CR 1045)
- Create secondary level of reporting NSAM issues to the user (CR 1052, 1053)
- CAS/ATE Remap Unstable Signal status (CR 1071)
- Add Patient ID to USB File Name (CR 1073)
- Add one decimal digit to Cumulative Sat Below Thresh & Reg O2 % Ranges (CR 1067)
- Add scientific mode to all users (CR 1075)
- Add translation for Ports -> scientific (CR 1081)
- Add automatically generated events based on special NSAM conditions (CR 1061)

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CASMED®	What's In This Release		
P/N 15-06-0285	**Description** FS-ELITE Main Application	**Ver** 1.1.1	**Date** 16-Dec-13

- Correct redraw speed of numeric fields after display of events - Still may occur but is vastly improved (CR 746)
- Rapid changes in Settings, e.g., View causes crash (CR 1038)
- External Interference causes the Numeric field to go blank instead of dashes (CR 1041)
- Monitor reset if Factory Defaults activated (CR 1003, 827)
- Correct underlying alarm led and audio problems (CR 1057)
- Pressed Events, then OR then screen froze showing just bottom 3 options (CR 949)
- Rapid switching between Event button and Undo button causes crash (CR 965)
- Possibility to delete more than the last Event entered (CR 1000)
- USB File - need to add a decimal digit precision to STS data (CR 1094)
- ICU Event list "Reposition Patient" should be Green Event after "Prostaglandin" (CR 1096)

4.0 Software Fixes:

The following are Software Fixes associated with this release:

- SPR 762-2 - In Italian "View" 24 Hour selection is 1Ore, should be 24 Ore (CR 1136)
- SPR 761 - In 4 C4 CAS protocol crash when baud rate is selected (CR 1145)
- SPR 764 - Numeric Field "Current Value" sometimes blank after fast boot (CR 1147)
- SPR 758 & 760 - Remove active case from USB save list (CR 1148)
- SPR 754 - Event Mark vertical dotted line (CR 1153)
- SPR 762-1 - Dutch under STS & other string fixes (CR 1158)

5.0 Hardware Changes:

There are no Hardware Changes associated with this release known at this time.

6.0 Incompatibilities:

There are no Incompatibilities associated with this release known at this time.

7.0 Dependencies:

The following are SW Dependencies of Main Application, 15-06-0285 V1.1.1 associated with this release:

- Main Bootloader, 15-06-0284 V1.1.0

8.0 Unresolved Anomalies:

The following is a list of known Unresolved Anomalies associated with this release:

None

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CASMED®	What's In This Release		
P/N 15-06-0283	**Description** FS-ELITE NSAM Application	**Ver** 2.0.0	**Date** 16-Dec-13

1.0 Programming Notes:

Value of Unused bytes:	0xFFFF
File Name:	15-06-0283_SamMain_2.0.0_033cf6dc.S19
16-bit Checksum:	0x033cf6dc

2.0 New/Changed Features:

The following are New/Changes Features associated with this release:

- Enhance the Bovie Filter (1049)
- Add Adult Somatic IFU, adjust Adult Cerebral TPI Levels (1079)
- Enable the Enhanced AGC, allow higher dynamic range for the gains (1044)

3.0 Improvements:

The following are Improvements associated with this release:

- Add for MFG ability to get the 1 wire device S/N (1033)
- Average sensor temperature reading (1042)
- Account for the 1 wire temperature NSAM offsets & Code Cleanup (1043)
- (b)(4) [redacted]
- (b)(4) [redacted]
- (b)(4) [redacted]
- (b)(4) [redacted], Adjust Low Thb levels, High Ambient Light (1093)
- Ignore Low brain 690nm values & do not include in spectral window calculation of "Sensor Off" (1140)

4.0 Software Fixes:

There are no Software Fixes associated with this release known at this time.

5.0 Hardware Changes:

There are no Hardware Changes associated with this release known at this time.

6.0 Incompatibilities:

There are no Incompatibilities associated with this release known at this time.

7.0 Dependencies:

The following are SW Dependencies of NSAM Application, 15-06-0283 V 2.0.0 associated with this release:

- NSAM Bootloader, 15-06-0282 V1.0.0
- Main Application, 15-06-0285 V1.1.1

8.0 Unresolved Anomalies:

The following is a list of known Unresolved Anomalies associated with this release:

None

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CASMED®	Document Number	Rev
	21-07-0368	00

Title: FORE-SIGHT ELITE Hardware Requirements

Author: H. Triebel 20-Feb-14

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals: Engineer 24-Feb-14 Date

Engineering Manager 2/24/14 Date

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REVISION HISTORY

Rev	Date	Editor(s)	Reason for Change
00	20-Feb-14	HT	Original release

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TABLE OF CONTENTS

1. Introduction 4
   1.0 Purpose of Document 4
   1.1 Scope of Document 4
2. Reference Documents 4
3. Specifications 5
   3.1 Microprocessors 5
      3.1.1. SCB – System Control Board 5
      3.1.2. NSAM – NIRS Signal Acquisition Module 5
   3.2 Memory devices 6
      3.2.1 Internal – SCB 6
      3.2.2 Internal – NSAM 6
   3.3 Power Supply 6
      3.3.1 110-240 VAC to DC 6
      3.3.2 SCB Power Supplies 7
      3.3.3 NSAM Power Supplies 7
      3.3.4 NSAM Timing 7
   3.4 Battery 7
      3.4.1 Charger (from SCB) 7
      3.4.2 System DC (from SCB) 8
   3.5 Communications 8
      3.5.1 Internal – SCB to NSAM 8
      3.5.2 External – RS232 8
      3.5.3 External – Ethernet 8
      3.5.4 External – USB 8
   3.6 Safety Features 8
      3.6.1 Temperature Sensors 8
      3.6.2 LED current limits 9
      3.6.3 Isolation 9
      3.6.4 Low Battery Voltage cutoff 9
      3.6.5 Sensor Size and Indications for Use 9
      3.6.6 Sensors and Preamps 9
      3.6.7 System LEDs (front panel LED bar) 9
   3.7 Support Assemblies 10
      3.7.1 Front Panel 10
      3.7.2 Backplane 10
      3.7.3 Battery 10

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1. Introduction

1.0 Purpose of Document

This document exists for the purposes of listing the Hardware Requirements for the FORE-SIGHT ELITE (FS-ELITE) Tissue Oximeter;

- Microprocessors;
- Memory devices;
- Power Supply;
- Battery;
- Communications;
- Safety Features; and
- Support Assemblies.

1.1 Scope of Document

This document covers the major Hardware Requirements of the FS-ELITE Tissue Oximeter including the System Control Board (SCB) and NIRS Signal Acquisition Module (NSAM).

2. Reference Documents

- 21-07-0302, FORE-SIGHT ELITE Product Specification
- 21-07-0309, FORE-SIGHT ELITE System Controller Board Programmer Reference
- 21-07-0313, FORE-SIGHT ELITE NIRS Signal Acquisition Module (NSAM) Reference Guide

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3. Specifications

3.1 Microprocessors

3.1.1. SCB – System Control Board

Refer to 21-07-0309, FS-ELITE System Controller Board Programmer Reference for additional details regarding the hardware design of the System Control Board (SCB).

The SCB is controlled by a Freescale MCF5329CVM240 (SCB MCF5329) microprocessor. The SCB MCF5329 provides the following functions necessary to monitor and control the system infrastructure:

- Monitor the System Power Supply output that provides the 15VDC first stage System DC Power;
- Monitor and control the battery and battery charging circuits;
- Monitor and control the secondary power distribution circuits (backplane power, display & audio power, fan power;
- Control the cooling fan power and speed (PWM), and monitor the fan locked rotor sense indication;
- Monitor the system temperature Sensors; and
- System self-configuration – subassembly identification and management through 1-wire SEEPROMS on all major subassemblies.

The SCB MCF5329 controls and provides the following primary user interfaces:

- Graphical User Interface (GUI) implemented through LCD display, Touch screen input, LED & Audio alarms;
- LCD Display via on-chip LCD controller and PWM backlight control;
- Touch screen input via SPI interface to touch screen controller IC;
- Visual Alarms through LED Indicators; and
- Audible Alarms through a system speaker.

3.1.2. NSAM – NIRS Signal Acquisition Module

Refer to 21-07-0313, FS-ELITE NIRS Signal Acquisition Module (NSAM) Reference Guide for additional details regarding the hardware design of the NIRS Signal Acquisition Module.

The NSAM is controlled by a Freescale MCF52258 (NSAM MCF52258) microprocessor. The NSAM MCF52258 provides the following functions necessary to monitor and control the NIRS Signal Acquisition Module subsystem:

- Channel multiplexing/de-multiplexing;
- Analog signal processing and signal detection;
- Signal sample and holds;
- A/D multiplexers and A/D;
- Microcontroller;
- LED current drivers;

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- CPLD logic controller; and
- Power supplies.

(b)(4)

[redacted]

3.2 Memory devices

3.2.1 Internal – SCB

The SCB MCF5329 shall provide 16 MByte Bottom-Boot Block Flash memory, organized as 8 MB x 16-bit. This is where the actual Main Application shall reside.

The SCB MCF5329 shall provide 4 MByte of Static Random Access Memory (SRAM), organized as 1 MB x 32-bit. This memory shall be used by the SCB MCF5329 code for program variables. This memory is volatile, and when power is removed the contents are destroyed.

The SCB MCF5329 shall provide 512 KByte or 1 Mbyte of NVSRAM, organized as 512K or 1M x 8-bit. This memory shall be used by the SCB MCF5329 for monitor setup and configuration variables as well as patient data. This memory is nonvolatile, and when power is removed the contents are retained.

3.2.2 Internal – NSAM

The NSAM MCF52258 shall have all internal memory, no external memory is accessible.

The NSAM MCF52258 shall provide 512 Kbytes of internal Flash. This is where the actual Main Application reside.

The NSAM MCF52258 shall provide 64 Kbytes of SRAM memory. This memory shall be used by the NSAM code for program variables. This memory is volatile, and when power is removed, the contents are destroyed.

The NSAM MCF52258 shall contain no non-volatile memory. All information the NSAM MCF52258 needs to operate properly is obtained from the SCB MCF5329 via a dedicated interprocessor UART channel routed through the Backplane. Information is supplied by the SCB to the NSAM after power cycle and periodically during operations.

3.3 Power Supply

3.3.1 110-240 VAC to DC

The FS-ELITE Tissue Oximeter shall utilize a medical grade Power Supply capable of inputting 100-240 VAC, 50-60 Hz and generating an isolated 15VDC.

The 15VDC shall be routed first to the SCB MCF5329. It is then distributed to the NSAM MCF52258 and Support Assemblies. The distribution to the NSAM MCF52258 is referred to as System DC - The DC voltage may be derived from the AC-DC power supply or from the internal battery.

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3.3.2 SCB Power Supplies

The SCB MCF5329 shall generate the following DC voltages for use on itself:

- 5.0 and 3.3 VDC.

The VGA converter shall generate VGA signals to the rear panel VGA connector. The VGA controller is powered through an isolated power DC converter on the SCB MCF5329.

The SCB MCF5329 shall generate a pulse width modulated (PWM) signal to the LCD LED Backlight controller. The duty cycle of the PWM shall determine the brightness of the LEDs. The minimum duty cycle shall be set so that the bright of the LCD allows the user to still read the values on the screen.

3.3.3 NSAM Power Supplies

The NSAM MCF52258 shall have its power supplied by the SCB MCF5329. The power from the SCB MCF5329 is fused on the NSAM assembly. It also passes through a low pass filter to reduce the noise on this signal.

The NSAM MCF52258 shall generate +3.3 VDC with a maximum current of 2A. This provides the supplies for the microcontroller and the CPLD and well as the input for a +5V switching boost converter used to power the external preamplifiers.

The NSAM MCF52258 shall generate +5.0 VDC with a maximum current of 0.5A.

The NSAM MCF52258 shall generate +12V and -12V each is capable of providing 0.6A. The ±12V is used by the LED driver stage and are controlled by the NSAM MCF52258.

The NSAM MCF52258 shall generate -5V from the -12V by a linear regulator. The ±5V are used to power the external preamplifiers. Both the +5V and -5V supplies are fused prior to exiting the NSAM board.

3.3.4 NSAM Timing

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3.4 Battery

3.4.1 Charger (from SCB)

A Linear Technologies (LTC4008) battery charger shall provide a linear voltage signal proportional to the percentage of full charge current.

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3.4.2 System DC (from SCB)

When no external AC is available, the FS-ELITE shall obtain power from the internal Battery. The battery voltage shall be routed to the SCB MCF5329 via the backplane and is distributed in a similar manner of the 15VDC obtained from the isolated power supply. If the battery voltage drops too low the system shall automatically shut down. Refer to 3.6.4, Low Battery Voltage cutoff for additional details.

3.5 Communications

3.5.1 Internal – SCB to NSAM

The SCB MCF5329 shall provide the following NSAM MCF52258 management:

- Controls and monitors the NSAM MCF52258 through power control & serial communication with the NSAM MCF52258 processor via a dedicated interprocessor UART channel routed through the Backplane.
- The SCB also has a dedicated interprocessor UART channel to and from the NSAM MCF52258 routed through the Backplane.

3.5.2 External – RS232

The SCB MCF5329 shall provide the following external RS-232 interface:

- Two RS232 DTE channels (via I^2C dual UART).

3.5.3 External – Ethernet

The SCB MCF5329 shall provide the following external Ethernet interface:

- One Ethernet 10/100 BASE-T channel (On-chip Ethernet Controller, external PHY).

3.5.4 External – USB

The SCB MCF5329 microprocessor shall provide support for the following external peripherals:

- Two USB 2.0 LS/FS Host channels (on-chip USB Host Controllers).

3.6 Safety Features

3.6.1 Temperature Sensors

The SCB MCF5329, NSAM MCF52258 & Support Assemblies shall contain digital temperature sensing devices.

Note: The NSAM MCF52258 digital thermometer temperatures shall not be directly accessible to the SCB MCF5329, but rather shall be reported by the NSAM MCF52258 through the inter-processor UART0 communication channel.

The SCB MCF5329 monitors the temperature from all Sensors and controls the speed of the fan to attempt to control the internal temperature. If the internal temperature rises above a temperature warning threshold, the SCB MCF5329 shall alert the user. If the If the internal temperature rises above a temperature alarm threshold, the SCB MCF5329 shall alert the user and perform an automatic shutdown of the system.

Note: When the power is first applied, the system fan shall operate at full speed until the SCB MCF5329 programs the speed to its initial value. Once programmed, the speed of the fan is set by all the temp Sensors in the system.

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3.6.2 LED current limits

The NSAM MCF52258 shall control digital potentiometers that are used to adjust the individual LED currents in the Sensor. The individual output LED currents are scaled and captured by analog to digital (A/D) converter that the SCB MCF5329 uses to verify the output is proportional to the actual current. If the expected LED output current read by the A/D values does not match the digital potentiometer output, the all the LEDs are turned off and an appropriate message is reported to the SCB MCF5329 for front panel user notification.

3.6.3 Isolation

Along with the medical grade power supply, additional system isolation shall be provided for each Serial RS-232 output as well as the Ethernet port. Refer to section 3.3.2 SCB Power Supplies for additional information

3.6.4 Low Battery Voltage cutoff

When the system is operating from battery power, and the battery voltage falls below the battery drain limiter "ON" threshold, hardware circuits shall enable software controlled power-down. The battery drain limiter circuit shall unconditionally power down the system when the battery voltage falls below the power down threshold value.

3.6.5 Sensor Size and Indications for Use

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3.6.6 Sensors and Preamps

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3.6.7 System LEDs (front panel LED bar)

All of the front panel LEDs shall be controlled by the SCB MCF5329. The SCB MCF5329 can turn on all the red, all the yellow or all the red & yellow (orange). 4 dedicate red LEDs are controlled directly by the SCB MCF5329 microprocessor (all other LEDS are control by General Purpose Input / Output (GPIO) signals) and are located in the center of the bar. Upon power on, these 4 red LEDs automatically turn on and then the SCB MCF5329, through its normal operation, shall turn them off. If a problem in the Main Application exists, these 4 LEDS shall remain on, providing a visual indication of a fault to the user.

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3.7 Support Assemblies

3.7.1 Front Panel

The Front Panel assembly shall provide the following functionality with the SCB MCF5329:

- Interface to the display - 640x480 VGA LCD;
- Interface to the LED backlight for the LCD - brightness;
- Interface to the 4-wire resistive touchscreen;
- Interface to the front panel USB port;
- Interface to the system LEDs - array of red & yellow LEDs behind a diffused lens;
- Interface to the power switch; and
- Interface to the audio speaker - mounted on front panel w/grill to outside.

Note: The Front Panel Assembly also provide the 6th side of the internal cage structure of the monitor.

3.7.2 Backplane

The Backplane assembly shall provide the following functionality with the SCB MCF5329:

- Interface between SCB and Front Panel Assembly;
- Interface between SCB and internal battery power;
- Interface between SCB and AC-DC power supply;
- Interface between SCB and System Fan;
- Interface between SCB and NSAM - power and communications;
- Interface to the one rear panel USB port connection;
- Interface to the one rear panel Ethernet connection;
- Interface to the two rear panel RS-232 communications ports;
- Interface to the one rear panel VGA output connection; and
- Monitoring of various temperature locations on the Backplane (numerous dedicated Temp Sensors).

3.7.3 Battery

The Battery assembly shall provide the following functionality with the SCB MCF5329:

- Power connection to/from the Battery; and
- Monitoring of Battery temperature (dedicated Temp Sensor).

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Author: H. Triebel 20-Feb-14

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

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Engineering Manager 25-Feb-14 Date

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TABLE OF CONTENTS

1. Introduction 3
   1.1 Purpose of Document 3
   1.2 Scope of Document 3
2 Reference Documents 3
3 Specifications 4
   3.1 RS-232 Interface 4
      3.1.1 Hardware 4
      3.1.2 Selecting a Serial Port 4
      3.1.3 Protocols 4
         3.1.3.1 Philips VueLink 4
         3.1.3.2 CSV Serial Output 5
         3.1.3.3 CAS ATE Serial Output 5
   3.2 Ethernet Interface 6
   3.3 USB Interface 6
   3.4 Video Interface 6

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1. Introduction

1.1 Purpose of Document

The 21-07-0302, FORE-SIGHT ELITE (FS-ELITE) Product Specification specifies the External Interfaces of the FS-ELITE design. This document exists for the purposes of listing the External Interfaces for the FS-ELITE Tissue Oximeter:

- RS-232 Interface;
- Ethernet Interface;
- USB Interface; and
- Video Interface.

1.2 Scope of Document

This document covers all the external interfaces supported by the FS-ELITE.

2 Reference Documents

- 21-07-0302, FS-ELITE Product Specification
- 21-07-0304, FS-ELITE Hazard Identification
- 21-07-0306, FS-ELITE Risk Analysis
- 21-07-0322, FS-ELITE Philips VueLink Translation Document
- 21-07-0346, FS-ELITE 4-Ch Comma Separated Value Serial Output Format
- 21-07-0363, FS-ELITE CAS Serial Command Protocol Specifications
- 21-07-0325, FS-ELITE Main Application Software Requirement Specifications (SRS)
- 21-07-0327, FS-ELITE NSAM Application Software Requirement Specifications (SRS)
- 21-07-0329, FS-ELITE Main Application Software Design Specifications (SDS)
- 21-07-0331, FS-ELITE NSAM Application Software Design Specifications (SDS)
- 21-22-3000, FS-ELITE User Manual

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3 Specifications

3.1 RS-232 Interface

3.1.1 Hardware

Serial Communications Port for the RS-232 Interface shall use a 9-pin D (DB9 connector). The RS-232 uses the standard interface format and pin assignment

The RS-232 Interface shall use the following format to transmit and receive data to and from the FS-ELITE:

- 1 Start Bit;
- 8 Data bits;
- No Parity bit;
- 1 Stop bit; and
- No Flow control.

Note: The baud rate for each protocol shall be user selectable.

Refer to the individual protocols in Section 3.1.3 Protocols as well as the 21-22-3000, FORE-SIGHT ELITE User Manual for additional information.

3.1.2 Selecting a Serial Port

The user shall be able configure either serial RS-232 port (A or B), located on the rear of the monitor, to transmit and receive information using various types of communications protocols.

Refer to the 21-22-3000, FORE-SIGHT ELITE User Manual for additional information.

3.1.3 Protocols

3.1.3.1 Philips VueLink

The FS-ELITE shall support the serial RS-232 interface to the Philips (Medical) VueLink device. Refer to the 21-22-3000, FORE-SIGHT ELITE User Manual for additional information regarding Philips Accessories and Options.

The FS-ELITE shall allow for communications to the Philips VueLink at 4800, 9600 or 19200 baud. Selecting any of these baud rates shall automatically be detected and sync'd to the Philips VueLink device.

The VueLink interface shall allow each channel value and associated patient and equipment alarms to be displayed on a Philips' Vital Signs Monitor. Channel alarms (High or Low limit violations) are displayed adjacent to the channel value. Equipment alarm messages shall be displayed on the Philips' device as ***FS Sys Warning***. Channel alarm messages shall be displayed on the Philips' device as ***FS-# Error***, ***FS-# Warning*** or ***FS-# Chk Sensor***, where # indicate the channel number (1, 2, 3 or 4). The text displayed on the Philips' device shall be generated by the FS-ELITE per instructions provide by Philips. The text exchange is part of the initial setup between the FS-ELITE and Philips device.

For additional details regarding the mapping of equipment and channel alarm messages, refer to 21-07-0322, FORE-SIGHT ELITE Philips VueLink Translation Document.

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3.1.3.2 CSV Serial Output

The FS-ELITE shall support the serial RS-232 interface to the external devices using a Comma Separated Values (CSV) protocol. Data shall be outputted using CSV format contains only 8-bit ASCII digits ('0' through '9') and ASCII commas (","). Output strings shall have each data value separated by an ASCII comma (0x2C), therefore, commas are not allowed in the data fields. All strings shall be terminated by an ASCII Carriage Return (0x0D) and an ASCII Line Feed (0x0A).

The FS-ELITE shall allow for communications to external devices using CSV Serial Output protocol, at 19200, 38400, 57600 & 115200 baud. Selecting the CSV Serial Output protocol shall cause the FS-ELITE to continuously output CSV information once every two (2) seconds.

The information outputted shall represent the channel numeric values and alarm status as well as line termination (carriage return & line feed).

For additional details regarding the CSV Serial Output, refer to the FORE-SIGHT ELITE 4-Ch Comma Separated Value Serial Output Format Document.

For additional details regarding the use of a CSV Serial output and the FS-ELITE, refer to 21-22-3000, FORE-SIGHT ELITE User Manual.

3.1.3.3 CAS ATE Serial Output

The FS-ELITE shall support the serial RS-232 interface to the external devices using a CAS Automated Test Equipment (ATE) Serial protocol. The ATE Serial protocol shall use a Request-Reply paradigm. The FS-ELITE shall not transmit unsolicited replies, unless enabled via a specific Streaming Data Request. All Requests shall be "answered" by the FS-ELITE with some Reply. Invalid Requests shall be Replied with a "don't know" Reply. The following is the list of valid Requests:

- Request & Reply with Model Number;
- Request & Reply with Device Serial Number;
- Request & Reply with Software Versions;
- Request & Reply with Communication Version;
- Request & Reply with Channel Capacity of Device;
- Request & Reply with Time/Date;
- Request & Reply with Patient Identification (ID);
- Request & Reply with Channel Numeric/Trace values;
- Request & Reply with Channel Low Alarm Limit values;
- Request & Reply with Channel High Alarm Limit values;
- Request & Reply with Channel Body Location values;
- Request & Reply with Channel Sensor Sizes;
- Request & Reply with Channel TPI Calculations;
- Request & Reply with Patient Alarms;
- Request & Reply with Equipment Alarms;
- Request & Reply with Specific Channel STS Data Calculations Values;
- Enable/Disable Streaming Measurement Values; and

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- Enable/Disable FS ELITE Response Checksum.

For additional details regarding the CAS ATE Serial Output, refer to FORE-SIGHT ELITE CAS Serial Command Protocol Specifications the Document.

For additional details regarding the use of a CSV Serial output and the FS-ELITE, refer to 21-22-3000, FORE-SIGHT ELITE User Manual.

3.2 Ethernet Interface

The FS-ELITE shall provide a 10Base-T / 100Base-T Ethernet connection for the purpose of testing the device.

The FS-ELITE may be connected to an IBM compatible PC at the factory or service center for the sole purpose of executing commands to test its functionality.

The FS-ELITE should not be connected via the Ethernet to any device by the user, appropriate warnings have been placed in 21-22-3000, FORE-SIGHT ELITE User Manual.

3.3 USB Interface

The FS-ELITE shall provide storage of patient data file(s) via a standard USB V2.0 interface.

There shall be two (2) USB ports located on the FS-ELITE; one on the front panel and one on the rear panel. Access to these uses ports shall appear as unique drives (similar to that on an IBM compatible PC). Only one USB port shall be acknowledged at a time, on a first come first serve basis. Plugging a USB Memory stick into the front port shall ignore the USB rear panel port until the front panel USB stick is removed. Acknowledgement of another USB stick when another USB has been acknowledge, shall require the remaining USB memory stick to be removed and re-inserted.

Non-powered USB memory devices (e.g., USB flash drives, USB memory sticks, etc.) are the only permissible devices that may be attached to the FS-ELITE, appropriate warnings have been placed in 21-22-3000, FORE-SIGHT ELITE User Manual.

The patient data files stored on the USB memory devices are ASCII text format compatible with IBM type Personal Computers (PC).

The FS-ELITE shall allow for the upgrading of software code within the FS-ELITE via these same USB memory devices. SW Code shall only be provide by CAS Medical.

3.4 Video Interface

The FS-ELITE shall provide a video output of the front panel screen (LCD). Whatever is currently being displayed on the LCD, is outputted via the video output.

The video output connector shall be a DE15 style connector using the standard VGA pin out. The video output shall be standard VGA (640 x 480) resolution, supporting 256 colors.

The FS-ELITE video output should only be connected to a Medical Grade display screen, appropriate warnings have been placed in 21-22-3000, FORE-SIGHT ELITE User Manual.

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Title: FORE-SIGHT ELITE SW Performance and Functional Requirements

Author: H. Triebel 20-Feb-14

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

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Engineering Manager 20-Feb-14 Date

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TABLE OF CONTENTS

1. Introduction 4
   1.0 Purpose of Document 4
   1.1 Scope of Document 4
2. Reference Documents 4
3. Specifications 5
   3.1 Algorithm Characteristics for Monitoring 5
   3.2 Control characteristics of Alarm/Conditions 7
   3.3 Device limitations due to software 8
   3.4 Internal Software tests and checks 10
      3.4.1 Main Application 10
      3.4.2 NSAM Application 10
   3.5 Error and Interrupt handling 11
      3.5.1 Main Application 11
      3.5.2 NSAM Application 11
   3.6 Fault detection, tolerance, and recovery characteristics 12
      3.6.1 Main Application 12
      3.6.2 NSAM Application 13
   3.7 Safety requirements 13
      3.7.1 Main Application 13
      3.7.2 NSAM Application 14
   3.8 Timing and memory requirements 15
      3.8.1 Main Application 15
      3.8.2 NSAM Application 15

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1. Introduction

1.0 Purpose of Document

This document exists for the purposes of listing the Software Performance and Functional Requirements of the FORE-SIGHT ELITE (FS-ELITE), including the followings

- Algorithms characteristics for monitoring;
- Control characteristics of alarms;
- Device limitations due to software;
- Internal software tests and checks;
- Error and interrupt handling;
- Fault detection, tolerance, and recovery characteristics;
- Safety requirements; and
- Timing and memory requirements.

1.1 Scope of Document

This document covers the Software Performance and Functional Requirements of the FS-ELITE System Control Board (SCB) and NIRS Signal Acquisition Module (NSAM).

2. Reference Documents

- 21-07-0304, FS-ELITE Hazard Identification document
- 21-07-0306, FS-ELITE Risk Analysis document
- 21-07-0325, FS-ELITE Main Application Software Requirement Specifications (SRS)
- 21-07-0327, FS-ELITE NSAM Application Software Requirement Specifications (SRS)
- 21-07-0329, FS-ELITE Main Application Software Design Specifications (SDS)
- 21-07-0331, FS-ELITE NSAM Application Software Design Specifications (SDS)
- 21-07-0334, FS-ELITE Main Application Software Life Cycle
- 21-07-0336, FS-ELITE NSAM Application Software Life Cycle
- 21-07-0365, FS-ELITE Main Application Software Architecture Design Chart
- 21-07-0367, FS-ELITE NSAM Application Software Architecture Design Chart
- 21-07-0343, FS-ELITE Displayed Message Priority Assignment Document

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3. Specifications

3.1 Algorithm Characteristics for Monitoring

The Main Application shall use the paradigm of programmable concurrent running threads and interrupt handling to perform the following task:

- Communications with NSAM Application – Send commands & receive patient data;
- Interface the front panel Liquid Crystal Display (LCD) – Microprocessor has built in LCD VGA interface w/multi-plane images;
- Interface with front panel touchscreen – User input for navigation and selection;
- Interface with front panel Alarm LEDs – Red and Yellow Alarm bar;
- Interface with Audio attenuator – Provide frequency and attenuator controls amplitude;
- Communication with external devices – Serial communications & Ethernet; and
- Interface with USB memory devices – Patient Data (files) transfer;

Also refer to 21-07-0325, FS-ELITE Main Application Software Requirement Specifications (SRS) and 21-07-0329, FS-ELITE Main Application Software Design Specifications (SDS) for additional details regarding the Main SW.

The NIRS algorithm needs to have prior knowledge of some usage scenarios, patient parameters and specific calibration parameters that are stored in the Sensor EEPROM prior to executing the NIRS algorithm. Diagram 1 represents the major parameters that are needed:

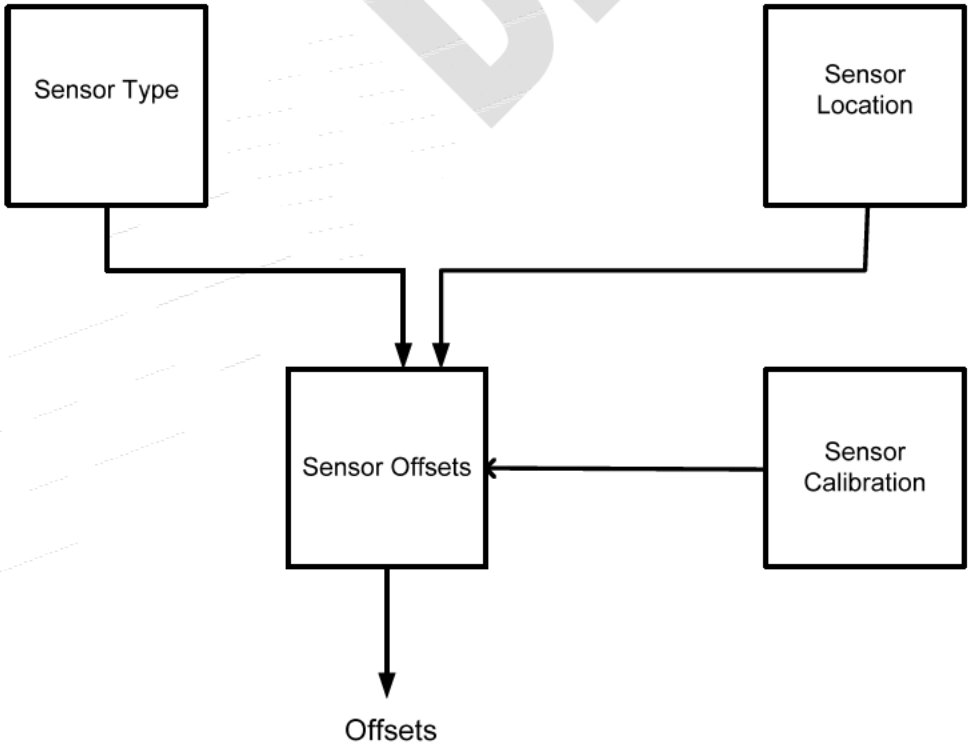

Diagram 1: Sensor Calibration

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- The NIRS algorithm shall calculate the TPI, alerting of an inappropriate use of the device / Sensors - Refer to 4.4.4.1, 4.5.1.1, 4.5.3.1, 4.5.3.2 of 21-07-0304 FS-ELITE Hazard ID & 21-07-0306 FS-ELITE Risk Analysis.
- The NIRS algorithm shall check for correct Sensor type and shall alert if inappropriate, only when Sensor type and all patient and physical parameters are correct the NIRS algorithm shall actually start running on the specific channel - Refer to 4.4.5.2, 4.4.6.2, 4.4.6.4, 4.5.1.2 of 21-07-0304 FS-ELITE Hazard ID & 21-07-0306 FS-ELITE Risk Analysis.
- The NIRS algorithm shall check for correct signal levels and shall alert in case they are outside the appropriate - Refer to 4.4.6.3 of 21-07-0304 FS-ELITE Hazard ID & 21-07-0306 FS-ELITE Risk Analysis.

3.2 Control characteristics of Alarm/Conditions

The System Control Board Main Application shall be responsible for the annunciations of all conditions. Conditions include the following types:

- System Messages:
  - Equipment Alarms.
- Channel Messages:
  - High or Low Limit Violation Alarms; and
  - Preamp and Sensor condition Alarms.

The Main Application shall use the front panel red/yellow LEDs to indicate when a condition is present. The Main Application shall use the following assignment of conditions to determine which Alarm condition to annunciate, the order represents the order in which Alarms are annunciated:

1. **High Priority Alarms** - Flashing Red LEDs, with white text on a red background displayed in the corresponding message area (System or Channel).
2. **Medium Priority Alarms** - Flashing Yellow LEDs with black text on yellow background displayed in the corresponding Message area (System or Channel).
3. **Low Priority Alarms** - Steady Yellow LEDs with yellow text on black background displayed in the corresponding Message area (System or Channel).
4. **Information Signals** - No LEDs with white text on black background displayed in the corresponding Message area (System or Channel).

High, Medium and Low Priority Alarms shall generate an appropriate audio tone that shall be compliant with IEC 60601-1-8:2006 Medical electrical equipment - Part 1-8: General requirements test and guidance for alarm systems in medical electrical equipment and medical electrical systems. High and Medium Audio tones shall have the capability to be silenced for a maximum of 2 minutes.

If multiple messages with different priority are active at the same time for a given message area, the message with the highest priority shall be displayed.

Refer to 21-07-0343, FS-ELITE Displayed Message Priority Assignment Document for additional details regarding all displayed alarms.

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3.3 Device limitations due to software

The following are known software limitations of the device and do not impact the overall performance or functionality of the FS-ELITE:

- **Single Point Touchscreen**

  The touchscreen shall be a single point vs. multiple point touch. Multi-touch functionality would allow for zoom in & out with two (2) fingers.

  Multiple point touchscreen is not a current or future Marketing requirement.

- **Memory Limitations**

  The Flash & RAM memory for the System Control board and NIRS Signal Acquisition Module architecture shall use microprocessors that have a finite amount of addressable memory space.

  The design shall attempt to maximize the full address memory space of each microprocessor.

  The ability to continue to add features (Main and NSAM applications) that require large amounts of code (Flash) and variable space (RAM) may need to be prioritized at some future time.

- **Patient Data Storage**

  The Flash memory of the SCB architecture shall limit the amount of Patient Data that may be stored. The Flash memory space is shared with both executable code and Patient Data memory.

  The Flash memory shall be partitioned to give the largest possible amount of space to the Patient Data storage, while also attempting to provide sufficient allocation of code space for all current features as well as future features.

  The Patient Data storage shall be approximately 20 days of continuous storage of 4 channels of information. The 20 days may be broken up into 20 1-day Patient Data files, 40 12-hr files or any combination that results in 20 days of storage. There shall be a minimum allowable size for a Patient Data file of 1 minute.

  The repartitioning of the Flash Memory space by taking space from Patent Data file storage and adding to code space may need to be prioritized at some future time.

- **Event Storage**

  The user shall be allowed to associate an Event (for a pre-determined list) with the current Patient Data. The amount of storage for these Events is limited, and shall be allocated to provide the maximum estimated usage obtained through CAS Marketing with the use of CAS FORE-SIGHT Oximeter.

  Since the amount of storage of Events is limited, a user that exceeds the estimated number of events per case may risk losing the oldest Events stored in this memory.

- **Colors**

  The FS-ELITE shall use an LCD with limited color palette, 8-bits or 256 distinct colors and shades of gray. The LCD shall not be displayed hi-resolution images, only icons that may have some limited sharing.

  Colors shall be assigned to Body locations (Left & Right Brain and Somatic areas) using a similar scheme similar to that of FORE-SIGHT.

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Exact color matching may not be possible from FORE-SIGHT to FS-ELITE due to updates & changes in purchased graphic development tools.

- **USB**

  The FS-ELITE shall be capable of reading and writing to USB memory sticks (flash drives, USB drives, etc.).

  Large capacity USB Memory sticks (>32 GB) may respond slower than smaller capacity sticks due to the larger sector size. The larger sector size requires addition time to search and store information in the File Allocation Tables (FAT).

  Drivers for additional USB devices (printers, scanners, etc.) may not be readily available with the development tools and may need to be developed.

  The USB driver provided with the development tools was not necessarily developed for this microprocessor, but more for the family and certain adjustments to the driver may need to done to optimize performance.

  The FS-ELITE shall have 2 USB ports, one in front and one in the rear. The ability to access both USB ports at the same time shall not be possible. Access to the USB ports shall be on a first-come, first-serve basis.

- **VGA**

  The FS-ELITE shall use a programmable VGA controller to provide a video output. The video output displays is what is currently being displayed on the main screen. The ability to display something different than what is on the Main screen shall not be possible.

- **Audio**

  The volume of the speaker for alarms tones is limited in hardware as well as the acoustics of the grill adjacent to the speaker.

  The timing of tones generated to the speaker shall be limited due the priority scheme with the Main application. The timing shall allow for the un-interrupted alarm tones, but not necessarily the playing of songs.

  The resolution of the frequencies generated shall be limited by the frequency generated by the Main Application microprocessor. The frequencies generated for the various alarm priorities shall comply the IEC 6060-1-8 Standard.

- **Thermal Management**

  The Main and NSAM application shall have the ability to monitor the internal temperature.

  The Main Application shall control the System Fan to assist in the removal of heat within the enclosure. The System Fan can only remove so much heat. Operating the System Fan at increased speeds does not necessary increase thermal exchange, but shall increase audible noise.

  The Main Application shall have the ability to perform an orderly shutdown in the event of elevated temperatures above set thresholds.

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3.4 Internal Software tests and checks

3.4.1 Main Application

The Main Application shall perform the following Power On Self-Test (POSTs) functions:

- System Control Board (SCB) generated Power supplies:
  - 3.3 Volt power supply;
  - System DC power supply;
  - 3.0 Volt power supply;
  - LCD power supply; and
  - One-wire power supply;
- Configure all on-board peripherals (RS-232, Ethernet, USB, etc.);
- Match received 1-wire information with system configuration requirements;
- Determine/rebuild patient data status from non-volatile static memory;
- Establish communications with NSAM;
- System (SCB, Front panel, Backplane & Battery) Temperature Sensor; and
- Main Application checksum.

Once the Main Application has completed the POSTs & system initialization have been completed, and all POSTs pass, the Main Application shall enter monitoring mode. The duration to display the splash screen shall be kept to a minimum, but shall be no shorter than 2 sec to view system version information.

If any of the Main Application POSTs fail, the Main Application shall not enter monitoring mode and shall present an appropriate Alarm conditions.

Refer to 21-07-0309, FS-ELITE System Controller Board Programmer Reference for additional details regarding the POSTs of the System Control Board (SCB).

3.4.2 NSAM Application

The NSAM Application shall perform the following POSTs functions:

- NSAM generated power supply;
- Analog to Digital converter (ADC) offsets;
- NSAM board Temperature Sensors;
- NSAM Application checksum; and
- Match received 1-wire information with system configuration requirements.

Once the NSAM Application has completed the POSTs & NSAM initialization have been completed, and all POSTs pass, the NSAM Application shall enter monitoring mode.

If any of the NSAM Application POSTs fail, the NSAM Application shall not enter monitoring mode and shall present an appropriate Alarm condition to the Main Application via dedicated serial communications with System Control Board.

Refer to 21-07-0313, FS-ELITE NIRS Signal Acquisition Module (NSAM) Reference Guide for additional details regarding POSTs of the NIRS Signal Acquisition Module.

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3.5 Error and Interrupt handling

3.5.1 Main Application

The Main Application shall respond to the following Interrupts:

- Watchdog – System health manager;
- General Purpose Input / Output – Various system inputs;
- Nonvolatile Static RAM – Busy flag for coping RAM to Flash;
- Touchscreen – When screen touched;
- UART rear panel Port A & B – Transmit & Receive, when enabled;
- Microprocessor UART Port– Transmit & Receive to NSAM;
- Ethernet PHY – Transmit & receive data, when enabled;
- Dynamic memory Controller (DMA) – Transfer of blocks of memory;
- USB controller – Memory Stick insertion, extraction and busy / done; and
- Real Time Clock (RTC) – System programmable.

Each indicated Interrupt shall have a corresponding Interrupt Service Routine (ISR). The priority of the IRS handling shall be determined for optimum system performance taking into account length (execution time) and importance of task (tasks related to safety related shall have the highest priorities (e.g., Flashing LEDs, Audio).

All un-used HW Interrupts provide to the System Control Board microprocessor and not used or implemented shall also have an ISR. These IRS shall include the handling of the interrupt, an attempt to recover (if necessary) and report the interrupt occurrence in the System Error Log.

Any other error condition that generate SW Interrupts (e.g., divide by zero, invalid memory access) shall all be handled by specific ISR. These IRS shall include the handling of the interrupt, an attempt to recover (if necessary) and report the interrupt occurrence in the System Error Log.

Refer to 21-07-0309, FS-ELITE System Controller Board Programmer Reference for additional details regarding the interrupt handling of the System Control Board (SCB).

3.5.2 NSAM Application

The NSAM Application shall respond to the following Interrupts:

- UART Port – Transmit & Receive to SCB; and
- CPLD Complex Programmable Logic Device) – Main timing to Sensor interface.

The NSAM Application shall transmit and receive data to and from the Main Application via dedicated ISR. The ISR shall take into account data verification to and from the NSAM Application – computed a data checksum.

The CPLD shall be configured as a state machine to generate all the timing signals associated with the operation and control of the hardware used in the NSAMs data acquisition.

The CPLD shall generate an interrupt for the microcontroller to signal the completion of one channel cycle and the start of the next. At this interrupt, the NSAM microprocessor

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shall acquire all the analog data held in the sample and hold circuits from the just completed channel cycle, program all the digital potentiometers for the start of the next cycle.

The microprocessor shall also check for any changes in the Sensors / preamplifiers status (connection or disconnection).

Refer to 21-07-0313, FS-ELITE NIRS Signal Acquisition Module (NSAM) Reference Guide for additional details regarding the interrupt handling of the NIRS Signal Acquisition Module.

3.6 Fault detection, tolerance, and recovery characteristics

3.6.1 Main Application

The Main Application shall implement the following fault detection and associated recovery:

- Watchdog – System health manager; and
- NSAM Serial Communications – information contains a calculated checksum.

The Watchdog shall be part of the Main Application's Heath Manager. At a pre-determined rate, the Main Application shall access the Watchdog. Accessing the watchdog periodically prevents the Watchdog from resetting the system. If the Watchdog is not accessed within a preset period of time, the Watchdog shall automatically reset the system. The Main Application as well as the NSAM Application shall be restarted.

The System Manager shall also keep track of all running threads (routines). Threads that are launched and have a deterministic repetition rate requiring they "check in" with the Health Manager. If a thread does not "check in" within the allotted time, the Health Manager shall assume that the thread is not operating properly; e.g. lost, hung in an infinite loop. The Health Manager shall attempt to restart the thread once. If the thread does not restart, the Health Manger discontinues access to the Watchdog, forcing the Watchdog to restart the system. Missing threads (not "check in") shall be recorded in the System Error log. The System Error log shall record the offending task, the date and time of the offense as well as any other relevant information.

Information passed from SCB to NSAM shall contain an embedded checksum value. Based on the values of the information, a unique checksum shall be computed for the information passed. If the embedded checksum does not match the checksum computed by the SCB microprocessor, all the information contained it that packet shall be ignored. The Main Application shall record the receipt of a "bad" packet in the System Error log. The Main Application shall annunciate a System Error to the user if the number of "missed" packets reaches the minimum threshold.

If an expected packet of information is request by the SCB microprocessor and the corresponding response is not received within the expected period, the Main Application shall record the lack of an expected packet in the System Error log. The Main Application shall annunciate a System Error to the user if the number of "bad" packets reaches the minimum threshold.

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3.6.2 NSAM Application

The NSAM Application shall implement the following fault detection and associated recovery:

- NSAM Serial Communications – information contains an calculated checksum; and
- Preamp & Sensor – Faulty circuit detected.

Information received by the NSAM from the Main Application with incorrect checksum shall be ignored. The NSAM shall respond to the "bad" command response to the Main Application. The Main Application shall record these condition in the System Error. The Main Application shall annunciate a System Error to the user if the number of "bad" commands reaches the minimum threshold.

Command sent to the NSAM, that set conditions within the NSAM (body Location, modes, etc.), shall be echoed back by the NSAM to the Main Application. The echo shall be periodic to insure all Main Application commands are properly received by the NSAM. In the event the Main Application receives a response from the NSAM that is incorrect (e.g., not the same body location as expected) the Main Application shall attempt a retry of that command. If this condition continues, the Main Application shall record the lack of a command acceptance in the System Error log. The Main Application shall annunciate a System Error to the user if the number of "missed" commands reaches the minimum threshold.

The NSAM monitors the signals from each Preamp and each channel continuously. If any of the signals associated with Preamp sensing circuitry are determined to be out of range, the NSAM reports and error condition to the Main Application and the Main Application shall annunciate a Faulty Preamp condition and invalidate the numeric associated with the Preamp channels. If any of the signals associated with Sensor circuitry are determined to be out of range, the NSAM reports an error condition to the Main Application and the Main Application shall annunciate a Faulty Sensor condition and invalidate the numeric for that channel.

3.7 Safety requirements

3.7.1 Main Application

The Main Application shall implement the following features associated with safe operating requirements:

- Not display information received from the NSAM when the checksum associated with that data packet has been determined to incorrect. The Main Application shall dash the numerics. Sustained periods of "bad" packets shall cause the Main Application to annunciate a System Error.
- Automatically shut down of the system, if the internal temperature exceeds a pre-determined alarm threshold. A warning shall be provide when the internal temperature reaches the warning threshold.
- Shall provide fault conditions of internal components to the user via audible and/or visual indications (LED alarm bar and speaker).
- Non-operation of monitor due to defective code (Application software checksum has been computed to incorrect).

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- Automatic restart of system for system crash. SW crash response is recorded in the Error log and upon return to power on state, the SW shall restore the previous state as quickly as possible (e.g., < 5 sec).
- The LCD backlight control shall not allow the user to set the brightness so low that the user cannot read the display.
- The Volume control of the audio tones shall not be allowed to be so low that the user cannot hear the alarm tones. Alarms shall be allowed to be temporarily silenced (max 2 minutes), but not turned off.
- High and Low limits shall not be allowed to overlap (High < Low or Low > High) and the High and Low Limits shall not be allowed to be set to OFF.
- Automatically shut down of the system, if the battery voltage reaches a pre-determined depleted battery alarm threshold. A warning shall be provide when the battery voltage reaches the low battery warning threshold.

3.7.2 NSAM Application

The NSAM Application shall implement the following features associated with safe operating requirements:

- The NSAM shall not starting monitoring until a valid body location setting has been received from the Main Application. Monitoring includes turning on the Sensor LEDs and computing a StO2 value based on the signals received from the Sensor.
- The NSAM shall invalidate the channel values when the signals received from the Preamp are out of range. The channel values associated with the Preamp shall be invalidated for the following conditions:
  - Faulty Preamp - Detection of fault in Preamp circuitry; and
  - Preamp disconnected - Preamp no longer connected.
- The NSAM shall invalidate the channel value when the signals received from the Sensor are out of range. The channel values shall be invalidated for the following conditions:
  - Faulty Sensor - Detection of fault in Sensor circuitry;
  - Sensor disconnected - Sensor no longer connected;
  - (b)(4) [redacted]
  - High Ambient light - Sensor not adhered to tissue, Light levels too high;
  - Signal out of range - 1 or more signals out of range;
  - Sensor off patient - Sensor not adhered to tissue;
  - Incorrect Sensor size - Sensor connected is not appropriate for IFU; and
  - Unstable Signal - Usually associated when uses with Electrosurgical Units (ESU).

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3.8 Timing and memory requirements

3.8.1 Main Application

The Main Application shall implement the following timing for SCB memory:

- **External Flash** – Timing to properly access external microprocessor Flash shall be adjusted by programming the correct number of wait states. The number of wait states shall be determined for optimum speed to access the Flash based on the recommended crystal that does not exceed the maximum SCB Microprocessor clock. The selection of the chip select (CS) associated with the Flash memory shall cause the SCB microprocessor to automatically insert the programmed number of wait states.
- **External Static RAM** – Timing to properly access external microprocessor Static RAM shall be adjusted by programming the correct number of wait states. The number of wait states shall be determined for optimum speed to access the Static Ram based on the recommended crystal that does not exceed the maximum SCB Microprocessor clock. The selection of the chip select (CS) associated with the Static RAM memory shall cause the SCB microprocessor to automatically insert the programmed number of wait states.
- **External NVSRAM (RTC)** – Timing to properly access external microprocessor Non-Volatile Static RAM shall be adjusted by programming the correct number of wait states. The number of wait states shall be determined for optimum speed to access the Non-Volatile Static Ram based on the recommended crystal that does not exceed the maximum SCB Microprocessor clock. The selection of the chip select (CS) associated with the NVSRAM memory range shall cause the SCB microprocessor to automatically insert the programmed number of wait states.

Refer to 21-07-0309, FS-ELITE System Controller Board Programmer Reference for additional details regarding the memory and system timing of the SCB.

3.8.2 NSAM Application

The NSAM Application shall implement the following timing for NSAM memory:

- **Internal Flash** – Timing is fixed by a maximum external clock (crystal). The NSAM design shall use a recommended crystal that does not exceed the microprocessor's maximum clock.
- **Internal RAM** – Timing is fixed by a maximum external clock (crystal). The NSAM design shall use a recommended crystal that does not exceed the microprocessor's maximum clock.
- **CPLD** – Timing is limited by a maximum rated clock speed via a fixed crystal. The NSAM design shall use a recommended crystal that does not exceed the CPLD's maximum rated clock speed.

Refer to 21-07-0313, FS-ELITE NIRS Signal Acquisition Module (NSAM) Reference Guide for additional details regarding the memory & CPLD timing of the NIRS Signal Acquisition Module.

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Author: R. Bystrianyk 20-Feb-14

By signing this document you are giving approval to the comments, actions and outcomes documented here and on any appended pages.

Approvals:

Software Eng — Date 3/20/14

Engineering — Date 3/20/14

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01	18-Nov-13	RB, HT	Update to include requirements for latest DFU (Adult Skeletal Muscle), new Section 3.2.1
02	24-Jan-14	RB, HT	Update title to SRS
03	20-Feb-14	RB, HT	Remove reference to the future Wireless Feature and all >Phase 1.5 features

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TABLE OF CONTENTS

1. Introduction 4
   1.0 Purpose of Document 4
   1.1 Scope of Document 4
2. Reference Documents 4
3. Specifications 5
   3.1 Main Application Software Requirements 5
      3.1.1 Screen layout 5
      3.1.2 Main screen 5
      3.1.3 POSTs & Initialization 6
      3.1.4 Title line 6
      3.1.5 System Message Area 7
      3.1.6 System LEDs 7
         3.1.6.1 Off 7
         3.1.6.2 High Priority 7
         3.1.6.3 Medium Priority 7
         3.1.6.4 Low Priority 7
      3.1.7 Trace Area 8
      3.1.8 Numeric Field 8
      3.1.9 Status Icons 9
      3.1.10 Alarm Silence touch key 10
      3.1.11 1st Level touch keys 10
      3.1.12 Data Collection 11
         3.1.12.1 STS Data 11
         3.1.12.2 Copy Patient Data to USB Memory Stick 11
      3.1.13 Events 11
      3.1.14 Audio Generation 12
         3.1.14.1 High Priority 12
         3.1.14.2 Medium Priority 12
         3.1.14.3 Low Priority 13
         3.1.14.4 Audio Volume 13
         3.1.14.5 Audio Priority 13
      3.1.15 Languages 14

LIST OF FIGURES

Figure 1 – Main Screen Targets 5
Figure 2 – Title line (not to scale) 6
Figure 3 – Status Icons (not to scale) 9
Figure 4 – Battery Icons 10
Figure 8 – High Priority Audio Timing (not to scale) 12
Figure 9 – Medium Priority Audio Timing (not to scale) 12
Figure 10 – Low Priority Audio Timing (not to scale) 13

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1. Introduction

1.0 Purpose of Document

This Document exists for the purposes of:

a) Defining the requirements of the design of Project Gemini's Main Application Software;

1.1 Scope of Document

This document covers the Software Architecture and Specifications of the Project Gemini's Main Application software.

2. Reference Documents

- 21-07-0301, Gemini Design Plan
- 21-07-0302, Gemini Product Specification
- 21-07-0312, Gemini GUI Specifications
- 21-07-0319, Gemini NSAM Serial Protocol Specifications
- 21-07-0323, Gemini Software Icons Specifications
- 21-07-0329, Gemini Main Application Software Design Specifications (SDS)
- 21-07-0334, Gemini Main Application Software Life Cycle Worksheet
- 21-07-0337, Gemini Software Level of Concern Document
- 21-07-0338, Gemini Software V&V History
- 21-07-0339, Gemini Software Revision History
- 21-07-0344, Gemini Displayed Message Priority Assignment Document
- 21-07-0365, Gemini Main Application Software Architecture Design Chart

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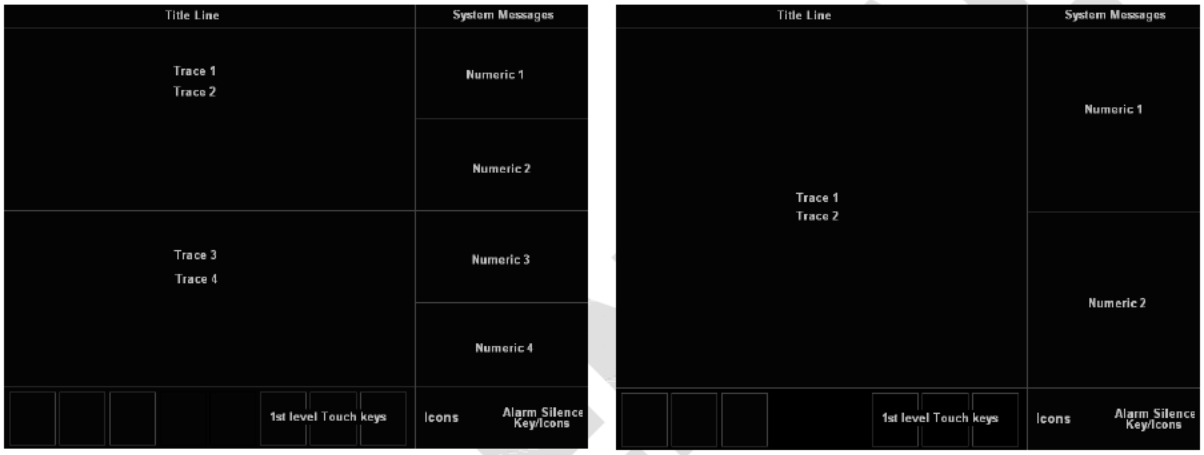
3. Specifications

3.1 Main Application Software Requirements

3.1.1 Screen layout

Figure 1 illustrates the screen layout of the Main Screen for 2 and 4 channel modes. Not all areas of the screen are possible touchscreen targets. The possible touch targets are listed within this document as well 21-07-0312, Gemini GUI Specifications and 21-07-0323, Gemini Software Icons Specifications.



4-Ch Main Screen – 1st Level Touch keys enabled 2-Ch Main Screen – 1st level Touch keys enabled

Figure 1 – Main Screen Targets

Note: Some lines illustrated on screens may only define the areas of features or touch keys and may not be visible in the final application.

3.1.2 Main screen

The Main screen shall be comprised of the following elements:

- **Title line** – Displays Patient ID (If entered), Current Time/Date & Preset name. Refer to Section 3.1.4
- **System Message Area** – Displays System messages associated with internal operation of the Monitor. Refer to Section 3.1.5
- **Trace Area** – Display the graphic indication of computed %StO_2 value using a fixed scaling. Refer to Section 3.1.7
- **Numeric Fields** – Displays all the information associated with each channels input. Refer to Section 3.1.8
- **Alarm Silence touch key** – When pressed, disables the audio portion of certain alarms or acknowledges others. Refer to Section 3.1.10
- **1st Level touch keys** – Enables the User configure the Oximeter to monitor the patient for optimum performance refer to Section 3.1.11

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3.1.3 POSTs & Initialization

The Main application shall perform the following power on functions:

- Configure all on-board peripherals (RS-232, Ethernet, USB, etc.)
- Match received 1-wire information with system configuration requirements
- Determine/rebuild patient data status from non-volatile static memory
- Establish communications with NSAM

Once the POSTs & Initialization have been completed the Main Application shall enter the Main screen. The duration to display the splash screen shall be kept to a minimum, but should be no shorter than 2 sec.

3.1.4 Title line

Figure 2 illustrates an example of Title line information:

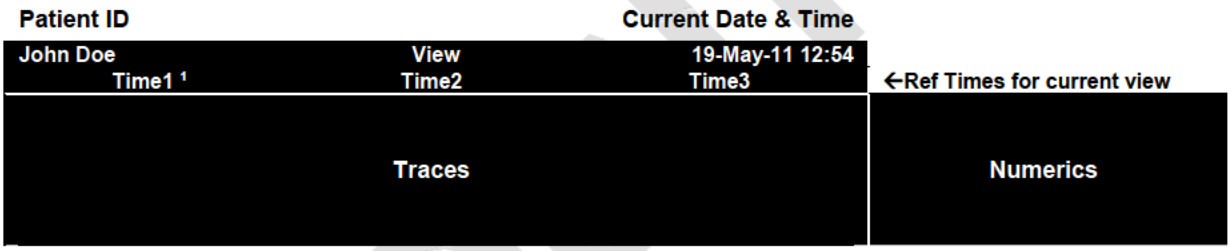

Figure 2 – Title line (not to scale)

The Title line shall display and update the information as often as required. The Title line shall occupy the top line of the display. All text on the Title line shall be white on a black background. The font size shall be adjusted to maximum visibility and clarity from a fixed distance..

- **Patient ID** – The patient ID may be entered via the Patient menu group. The Patient ID may also be left blank. The Patient ID shall be located to the extreme left of the Title line (Left justified form left side). The max length of the Patient ID character string shall be limited to 22 characters.
- **Current Date & Time** – The Current Data & Time shall be displayed using **dd-mmm-yy hh:mm** format, where **dd** is a 2-char day of the month (01-31), **mmm** is a 3-char abbreviation for the month of the year (Jan-Dec) and **yy** is a 2-char year (e.g. 13 for 2013), where **hh** is a 2-char hour of the day (00-23 always 24-hoiur format), where **mm** is a 2-char minute of the hour (00-59).

[1] Time1, Time 2 & Time3 represent the time marks for the 3 vertical marks for the current view based on the current date/time.

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3.1.5 System Message Area

The System Message area shall be adjacent to the Title line, directly above the Numeric fields. The System Message area shall display System Alarms. Refer to 21-07-0344, Gemini Displayed Message Priority Assignment Document for additional details.

The max number of chars capable of being displayed in the System Message area shall be determined by the width of the Numeric field. The font size shall be determined to maximum visibility and clarity for a distance.

3.1.6 System LEDs

An area along the top of the front panel bezel shall incorporate a set of System LEDs for the purpose of indicating various Alarm states. The System LEDs shall be capable of displaying three (3) system states:

- Off
- High Priority
- Medium Priority
- Low Priority

3.1.6.1 Off

The System LEDs shall be turned off when no Alarms (High, Medium or Low priority) are present.

3.1.6.2 High Priority

The System LEDs shall flash Red when a High Priority Alarm is present.

The flashing frequency for High Priority Alarm LEDs shall be 2.0 Hz w/50% duty cycle (250 mSec on & 250 mSec off)[2]. A High Priority Alarm condition may be caused by a System or Channel Alarm.

3.1.6.3 Medium Priority

When a Medium or High Priority Alarms is present, w/o any High Priority Alarm present, the System LEDs shall flash Yellow.

The flashing frequency for Medium Priority System Alarm LEDs shall be 0.5 Hz w/50% duty cycle (1.0 sec on & 1.0 sec off)[3]. A Medium Priority Alarm condition may be caused by a System or Channel Alarm.

If a High Priority Alarm becomes active while a Medium Priority Alarm is present, the System LEDs shall change to flashing red. If the High Priority Alarm is resolved, the System LEDs shall change back to flashing yellow (assuming the Medium Priority Alarm still present).

3.1.6.4 Low Priority

When a Low Priority Alarms is present, w/o any High or Medium Priority Alarm present, the System LEDs shall indicate Yellow (no flashing). [4]

[2] IEC 60601-1-8 defines the flashing frequency for High Priority indicator lights to be 1.4 to 2.8 Hz, 20 to 60% On time.
[3] IEC 60601-1-8 defines the flashing frequency for Medium Priority indicator lights to be 0.4 to 0.8 Hz, 20 to 60% On time.

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If a High or Medium Priority Alarm becomes active while a Low Priority Alarm is present, the System LEDs shall change to flashing red or yellow. If the High or Medium Priority Alarm is resolved, the System LEDs shall change back to indicating yellow (assuming the Low Priority Alarm still present).

3.1.7 Trace Area

There shall be an area to display the graphic trend (Traces) for each computed $\%StO_2$ channel. The Trace area shall be bordered on the top by the Title line, on the right side by the Numeric fields, and on the bottom by the 1st Level touch keys. The left side of the Trace area shall be the left side of the display area. The Trace area shall be replaced with a menu screen when activated. Upon returning to the Main screen, the Trace area shall reflect the current graphic trend of collected data e.g., the trace information shall be updated and reflect the most recent inputs.

The Trace area areas shall have the following characteristics:

- Newest data shall appear on the right side, oldest data will appear on the left, with the oldest data moving off the screen to the left, the method of display is known as moving-waveform (at a very slow rate).
- The Vertical scale for each trace may be fixed at left at 0-100%.
- All trace areas will have same time scale and view scale (see below). Time reference marks shall appear at the top of the Trace area that shall be applicable to all traces, and there shall be 3 vertical time references marks that move with the traces.
- 2-Channel Mode: The Trace area shall be divided into 1 large trace area with the height of the trace area shall be the height of the 2 Numeric fields.
- 4-Channel Mode: The Trace area shall be divided into 2 horizontal trace areas with the height of each trace area being the same (2 numerics tall). Channel 1 & 2 shall appear in top trace area, and Channel 3 & 4 shall appear in bottom trace area.
- The color of the trace shall correspond to the Numeric color (based on body location) on a black background.

3.1.8 Numeric Field

There shall be an area to display the Numeric values for each computed $\%StO_2$ channel. Channel 1 Numeric Field area shall be bordered on the top by the System Alarm area, and on the left side by the Trace area. Channel 2 or 4 Numeric Field shall be bordered on the bottom by the Alarm Silence key & Icon area. The right side of the Numeric Field area shall be the right side of the display. The Numeric Field area shall be displayed at all times. The default background for the Numeric fields shall be black. Numeric Fields shall include the following information:

- **Channel Number** – Indication of channel number
- **Numeric Value** – Largest possible font to occupies as much as the full height of the Numeric field, range 00 to 99 (valid), "- -" when numeric is invalid, Numerics will be color coded based on sensor body location.

[4] IEC 60601-1-8 defines the Low Priority indicator lights to be on.

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- **Alarm Limits** – There shall be an area to display the High and Low limit value. The Alarm limits will be color coded based on the sensor body location.
- **TPI** – Tissue Perfusion Index (TPI) bar graph consisting of 4 boxes to indicate 5 distinct levels (0, 1, 2, 3 or 4)
- **Body Location Icon** – Graphic indication of where the sensor is located on the body, if channel is unused a blank icon will be displayed. Body location icons shall be color coded. The 1st letter of the type of body location (Left, Right or Somatic) shall appear to the right of the icon. These 1st letters shall be translated accordingly.
- **Channel Message Area** – Area within the Numeric field the bottom most area shall be used to display messages associated with channel activity, The Channel Message area shall be the width of the Numeric field and be located at the bottom of each Numeric field. When no message is available for display the area will be blank. 21-07-0344, Gemini Displayed Message Priority Assignment Document for additional details

3.1.9 Status Icons[5]

The system Status icons will appear below the bottom Numeric Field (Ch 4 in 4-ch Mode or Ch 4 in 2-Ch Mode), and to the left of the Alarm Silence key area:

Numeric Field	
Icon a	Alarm Silence key area

Figure 3 – Status Icons (not to scale)

- Icon a – Battery

The icons should be approximately the same height, but could be different in length.

[5] The size of icons/keys within this document shall be determined based on available space. The final image and color of all icons/keys shall be approved by Mktg (icon pixel size shall be conveyed to Mktg). Refer to Appendix A of the 21-07-0323, Gemini Software Icons Specifications for actual icon images.

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- **Battery Status Icon** (e.g., image of Battery-D Cell) shall display the Battery back state. Through the use of color, the icon shall indicate the status/activity of the Battery.

Color	Description
None	No Battery currently installed
White	Unit connected to AC, Battery charging
Green	Battery capable of operating Monitor
Yellow	Low Battery condition, limited run time remaining
Red	Depleted Battery condition, Monitor will power off soon

Figure 4 – Battery Icons

3.1.10 Alarm Silence touch key

There shall be an area on the display that shall act as the Alarm Silence key. The Alarm Silence key shall be available at all times. The Alarm Silence key shall be used to silence the alarm audio for 2-minutes. The Alarm silence state is not saved during a power cycle - the power On default state shall be Audio enabled.

The Alarm Silence key shall be bordered on the top by the bottom most Numeric field, on the left side by status icon area. The bottom of the Alarm Silence key shall be the bottom of the display. The right side of the Alarm Silence key shall be the right side of the display (refer to Figure 3).

The Alarm Silence key shall use the following rule:

- 1st touch – Audio silenced for 2 minutes
- Touched while audio is silenced – Audio is re-enabled
- 2 minute silence time expires – Audio is re-enabled

3.1.11 1st Level touch keys

There shall be an area on the display that shall contain up to seven (7) 1st Level touch keys. The 1st Level touch keys shall be available on the Main Screen.

The 1st Level touch keys shall be bordered on the top by the Trace area and on the left side by the left side of the display. The bottom of the 1st Level touch keys shall be the bottom of the display. The right side of the 1st Level touch keys shall be the Status icon area.

The 1st Level touch keys shall contain icons to represent the associated feature. Refer to 21-07-0312, Gemini GUI Specifications & 21-07-0323, Gemini Software Icons Specifications for additional functionality and images of the touch keys.

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3.1.12 Data Collection

There shall be one (1) Start and Stop time for data collection for all channels. The Start & Stop times shall be determined using the following paradigm:

- **Start Time** – Data starts to be collected when the User selects the appropriate touch target. A channel/sensor could become active after the start of TUT/AUT, any sensor not currently connected will not be included in the TUT/AUT calculations.
- **Stop Time** – Data stops being collected when the User selects the appropriate touch target. Data stops being collected regardless of the status of the channels (assuming data collection was started for that channel).

3.1.12.1 STS Data

Each channel shall have the ability to set its' own STS threshold based on 75% of initial $\%StO_2$ at the Time data is Started to be collected. Accumulated STS values & Threshold values for each channel shall be saved during power cycle.

There shall be a STS review screen to review the computed STS data. Data for each channel shall be available on each review screen.

3.1.12.2 Copy Patient Data to USB Memory Stick

Information regarding a previous stored Patient case (Patient ID, FS, STS and collected Data and Events) may be copied to a USB Memory stick. The process to copy Patient Data file to a USB Memory stick shall be as follows:

- Install a USB Memory stick into Monitor
- Navigate and select "***Copy Patient Data to USB memory stick"***
- Select the file to be copied to the USB Memory stick
- Select copy – File will be copied to USB memory stick
- Copied file may be erased from the Monitor at any time

3.1.13 Events

The User may select to place an Event from pre-entered/configured lists. There shall be a maximum of 5 lists. Each list may have up to 41 events. Event text shall be limited to 22 characters each.

Events are associated with a timestamp and not with a specific channel, therefore, placed events shall be located at the bottom of the Trace area. Events will be placed along the right side of the Trace Area (current Time) when selected. A separate list of the most recent placed events shall be available for review (>Phase 1). Events are recorded along with the Patient data information (time when selected). Only the last placed real-time Event can be removed.

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3.1.14 Audio Generation

The Monitor shall be capable of producing the following audio tones to comply with IEC 60601-1-8:

- **High Priority** Signal indicating that immediate operator response is required; associated with a High Priority conditions [6]
- **Medium Priority** Signal indicating that prompt operator response is required; associated with Medium Priority conditions [7]
- **Low Priority** Indicating that Operator awareness is required [8]
- **Informational** No audio is associated with informational conditions

3.1.14.1 High Priority

Figure 5 illustrates the timing for a High Priority Tones that shall be 10 Beeps every 10 seconds, with each Beep being 970 ± 5 Hz:

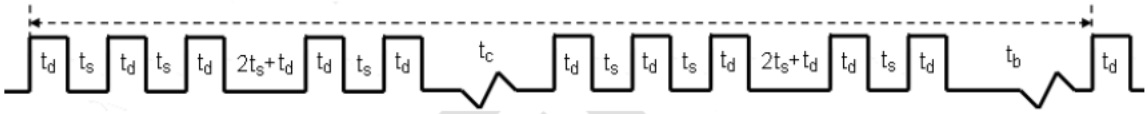

Figure 5 – High Priority Audio Timing (not to scale)

Where: t_d = 75 to 200 mSec ± 1%[9] (150 mSec)
t_s = 50 to 125 mSec ± 1% (100 mSec)
t_c = 350 to 1300 mSec ± 1% (800 mSec)
t_b = 2.5 to 15.0 Sec ± 1%

3.1.14.2 Medium Priority

Figure 6 illustrates the timing for a Medium Priority Tones that shall be 3 Beeps every 20 seconds, with each Beep being 575 ± 3 Hz:

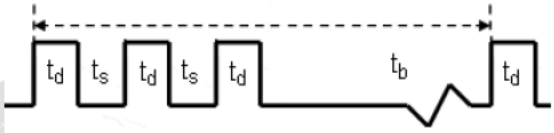

Figure 6 – Medium Priority Audio Timing (not to scale)

Where: t_d = 125 to 250 mSec ± 1%
t_s = 125 to 250 mSec ± 1%
t_b = 2.5 to 30.0 Sec ± 1%

[6] High Priority conditions include High Priority Systems Alarms and High/Low Limit violations
[7] Medium Priority conditions include Medium Priority Systems Alarms and individual channel equipment alarms
[8] Low Priority conditions include Medium Priority Systems Alarms and individual channel equipment alarms
[9] IEC 60601-1-8 also include specifications regarding the actual frequencies, harmonics and rise/fall times of Beeps

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3.1.14.3 Low Priority

Figure 7 illustrates the timing for a Low Priority Tones that shall be 1 Beep, with the Beep being 575 ± 3 Hz:

Figure 7 – Low Priority Audio Timing (not to scale)

Where: t_d = 125 to 250 mSec ± 1%

3.1.14.4 Audio Volume

The Alarm Volume shall control the loudness of the generated High and Medium Priority tones. The Alarm Volume setting is controllable by the User and has multiple selections with the minimum selection still audible (does not include mute/silence feature).

3.1.14.5 Audio Priority

If both Medium & High Priority conditions are present, only High Priority Tones shall be generated.

If both Low & Medium Priority conditions are present, only Medium Priority Tones shall be generated.

If only High Priority conditions are present, High Priority Tones shall be generated.

If only Medium Priority conditions are present, Medium Priority Tones shall be generated.

If only Low Priority conditions are present, Low Priority Tones shall be generated.

Once started (High or Medium) the Priority Tone sequence will complete the initial beeps (5 for High, 3 for low), e.g. if a High Priority condition exists only for 1 sec, 5 beeps will be generated. If a Medium Priority condition exists only for 1 sec, 3 beeps will be generated.

If a Medium Tone sequence is in progress (during the 3 beeps) and a High Priority condition becomes present (regardless of the duration), the following sequence will happen:

- The Medium Tone sequence is allowed to complete (3 beeps),
- Initiate High Priority Tone sequence (start 5 beep sequence);

If a High Tone sequence is in progress (during the 5 beeps), a Medium Priority condition is also present, and the High Priority condition is removed, the following sequence will happen:

- The High Tone sequence is allowed to complete (5 beeps),
- Initiate Medium Priority Tone sequence (start 3 beep sequence);

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3.1.15 Languages

The Monitor shall be able support numerous non-English languages. Certain text, on certain screens, need not be translated; Eng, Mfg & Srv Screens, as well as System log.

The factory default language shall be English.

The User may select for a list of Languages. The Monitor's memory will support numerous non-English Languages (including English).

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STATISTICAL METHODS FOR ASSESSING AGREEMENT BETWEEN TWO METHODS OF CLINICAL MEASUREMENT

J. Martin Bland, Douglas G. Altman

Department of Clinical Epidemiology and Social Medicine, St. George's Hospital Medical School, London SW17 ORE; and Division of Medical Statistics, MRC Clinical Research Centre, Northwick Park Hospital, Harrow, Middlesex

SUMMARY

In clinical measurement comparison of a new measurement technique with an established one is often needed to see whether they agree sufficiently for the new to replace the old. Such investigations are often analysed inappropriately, notably by using correlation coefficients. The use of correlation is misleading. An alternative approach, based on graphical techniques and simple calculations, is described, together with the relation between this analysis and the assessment of repeatability.

(*Lancet*, 1986; **i:** 307-310)

INTRODUCTION

Clinicians often wish to have data on, for example, cardiac stroke volume or blood pressure where direct measurement without adverse effects is difficult or impossible. The true values remain unknown. Instead indirect methods are used, and a new method has to be evaluated by comparison with an established technique rather than with the true quantity. If the new method agrees sufficiently well with the old, the old may be replaced. This is very different from calibration, where known quantities are measured by a new method and the result compared with the true value or with measurements made by a highly accurate method. When two methods are compared neither provides an unequivocally correct measurement, so we try to assess the degree of agreement. But how?

The correct statistical approach is not obvious. Many studies give the product-moment correlation coefficient (r) between the results of the two measurement methods as an indicator of agreement. It is no such thing. In a statistical journal we have proposed an alternative analysis, [1] and clinical colleagues have suggested that we describe it for a medical readership.

Most of the analysis will be illustrated by a set of data (Table 1) collected to compare two methods of measuring peak expiratory flow rate (PEFR).

SAMPLE DATA

The sample comprised colleagues and family of J.M.B. chosen to give a wide range of PEFR but in no way representative of any defined population. Two measurements were made with a Wright peak flow meter and two with a mini Wright meter, in random order. All measurements were taken by J.M.B., using the same two instruments. (These data were collected to demonstrate the statistical method and provide no evidence on the comparability of these two instruments.) We did not repeat suspect readings and took a single reading as our measurement of PEFR. Only the first measurement by each method is used to illustrate the comparison of methods, the second measurement being used in the study of repeatability.

PLOTTING DATA

The first step is to plot the data and draw the line of equality on which all points would lie if the two meters gave exactly the same reading every time (fig 1). This helps the eye in gauging the degree of agreement between measurements, though, as we shall show, another type of plot is more informative.

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PEFR MEASURED WITH WRIGHT PEAK FLOW AND MINI WRIGHT PEAK FLOW METER

	Wright peak flow meter		Mini Wright peak flow meter	
Subject	First PEFR (l/min)	Second PEFR (l/mi)	First PEFR (l/min)	Second PEFR (l/min)
1	494	490	512	525
2	395	397	430	415
3	516	512	520	508
4	434	401	428	444
5	476	470	500	500
6	557	611	600	625
7	413	415	364	460
8	442	431	380	390
9	650	638	658	642
10	433	429	445	432
11	417	420	432	420
12	656	633	626	605
13	267	275	260	227
14	478	492	477	467
15	178	165	259	268
16	423	372	350	370
17	427	421	451	443

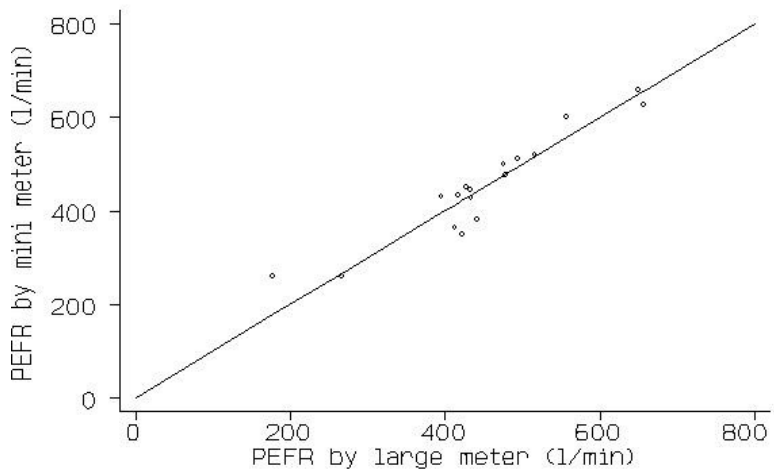

Fig 1. PEFR measured with large Wright peak flow meter and mini Wright peak flow meter, with line of equality.

INAPPROPRIATE USE OF CORRELATION COEFFICIENT

The second step is usually to calculate the correlation coefficient (r) between the two methods. For the data in fig 1, $r = 0.94$ ($p < 0.001$). The null hypothesis here is that the measurements by the two methods are not linearly related. The probability is very small and we can safely conclude that PEFR measurements by the mini and large meters are related. However, this high correlation does not mean that the two methods agree:

(1) r measures the strength of a relation between two variables, not the agreement between them. We have perfect agreement only if the points in fig 1 lie along the line of equality, but we will have perfect correlation if the points lie along any straight line.

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(2) A change in scale of measurement does not affect the correlation, but it certainly affects the agreement. For example, we can measure subcutaneous fat by skinfold calipers. The calipers will measure two thicknesses of fat. If we were to plot calipers measurement against half-calipers measurement, in the style of fig 1, we should get a perfect straight line with slope 2.0. The correlation would be 1.0, but the two measurements would not agree — we could not mix fat thicknesses obtained by the two methods, since one is twice the other.

(3) Correlation depends on the range of the true quantity in the sample. If this is wide, the correlation will be greater than if it is narrow. For those subjects whose PEFR (by peak flow meter) is less than 500 l/min, r is 0.88 while for those with greater PEFRs r is 0.90. Both are less than the overall correlation of 0.94, but it would be absurd to argue that agreement is worse below 500 l/min and worse above 500 l/min than it is for everybody. Since investigators usually try to compare two methods over the whole range of values typically encountered, a high correlation is almost guaranteed.

(4) The test of significance may show that the two methods are related, but it would be amazing if two methods designed to measure the same quantity were not related. The test of significance is irrelevant to the question of agreement.

(5) Data which seem to be in poor agreement can produce quite high correlations. For example, Serfontein and Jaroszewicz [2] compared two methods of measuring gestational age. Babies with a gestational age of 35 weeks by one method had gestations between 34 and 39.5 weeks by the other, but r was high (0.85). On the other hand, Oldham et al. [3] compared the mini and large Wright peak flow meters and found a correlation of 0.992. They then connected the meters in series, so that both measured the same flow, and obtained a "material improvement" (0.996). If a correlation coefficient of 0.99 can be materially improved upon, we need to rethink our ideas of what a high correlation is in this context. As we show below, the high correlation of 0.94 for our own data conceals considerable lack of agreement between the two instruments.

MEASURING AGREEMENT

It is most unlikely that different methods will agree exactly, by giving the identical result for all individuals. We want to know by how much the new method is likely to differ from the old: if this is not enough to cause problems in clinical interpretation we can replace the old method by the new or use the two interchangeably. If the two PEFR meters were unlikely to give readings which differed by more than, say, 10 l/min, we could replace the large meter by the mini meter because so small a difference would not affect decisions on patient management. On the other hand, if the meters could differ by 100 l/min, the mini meter would be unlikely to be satisfactory. How far apart measurements can be without causing difficulties will be a question of judgment. Ideally, it should be defined in advance to help in the interpretation of the method comparison and to choose the sample size.

The first step is to examine the data. A simple plot of the results of one method against those of the other (fig 1) though without a regression line is a useful start but usually the data points will be clustered near the line and it will be difficult to assess between-method differences. A plot of the difference between the methods against their mean may be more informative. Fig 2 displays considerable lack of agreement between the large and mini meters, with discrepancies of up to 80 l/min, these differences are not obvious from fig 1. The plot of difference against mean also allows us to investigate any possible relationship between the measurement error and the true value. We do not know the true value, and the mean of the two measurements is the best estimate we have. It would be a mistake to plot the difference against either value separately because the difference will be related to each, a well-known statistical artefact. [4]

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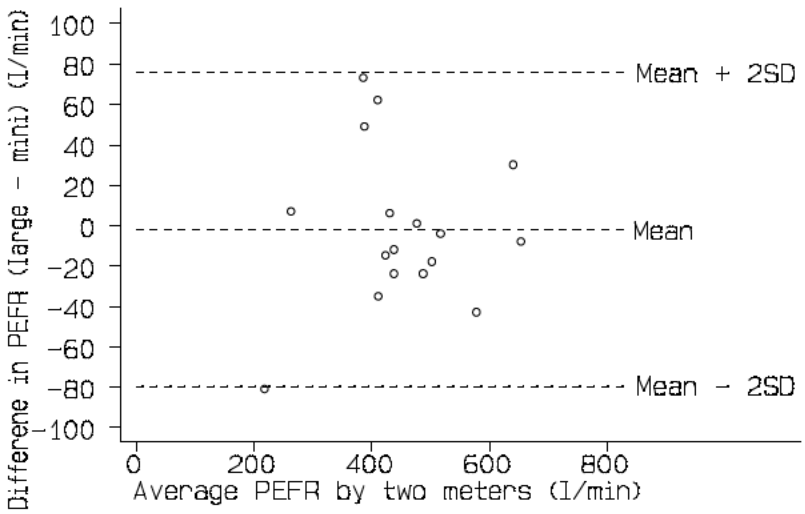

Fig 2. Difference against mean for PEFR data.

For the PEFR data, there is no obvious relation between the difference and the mean. Under these circumstances we can summarise the lack of agreement by calculating the bias, estimated by the mean difference $\bar{d}$ and the standard deviation of the differences (s). If there is a consistent bias we can adjust for it by subtracting $\bar{d}$ from the new method. For the PEFR data the mean difference (large meter minus small meter) is 2.1 l/min and s is 38.8 l/min. We would expect most of the differences to lie between $\bar{d}$ 2s and $\bar{d}+2s$ (fig 2). If the differences are Normally distributed (Gaussian), 95% of differences will lie between these limits (or, more precisely, between $\bar{d}$ 1.96s and $\bar{d}+1.96s$). Such differences are likely to follow a Normal distribution because we have removed a lot of the variation between subjects and are left with the measurement error. The measurements themselves do not have to follow a Normal distribution, and often they will not. We can check the distribution of the differences by drawing a histogram. If this is skewed or has very long tails the assumption of Normality may not be valid (see below).

Provided differences within $\bar{d} \pm 2s$ would not be clinically important, we could use the two measurement methods interchangeably. We shall refer to these as the "limits of agreement". For the PEFR data we get:

$$\bar{d} \quad 2s \qquad 2.1 \quad (2 \times 38.8) \qquad 79.7 \text{ l/min}$$

$$\bar{d} + 2s \qquad 2.1 + (2 \times 38.8) \qquad 75.5 \text{ l/min}$$

Thus, the mini meter may be 80 l/min below or 76 l/min above the large meter, which would be unacceptable for clinical purposes. This lack of agreement is by no means obvious in fig 1.

PRECISION OF ESTIMATED LIMITS OF AGREEMENT

The limits of agreement are only estimates of the values which apply to the whole population. A second sample would give different limits. We might sometimes wish to use standard errors and confidence intervals to see how precise our estimates are, provided the differences follow a distribution which is approximately Normal. The standard error of $\bar{d}$ is $\sqrt{s^2/n}$, where n is the sample size, and the standard error of $\bar{d}$ 2s and $\bar{d}+2s$ is about $\sqrt{3s^2/n}$. 95% confidence intervals can be calculated by finding the appropriate point of the t distribution with n 1 degrees of freedom, on most tables the columns marked 5% or 0.05,

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and then the confidence interval will be from the observed value minus t standard errors to the observed value plus t standard errors.

For the PEFR data $s = 38.8$. The standard error of $\bar{d}$ is thus 9.4, For the 95% confidence interval we have 16 degrees of freedom and $t = 2.12$. Hence the 95% confidence interval for the bias is $2.1 \quad (2.12 \times 9.4)$ to $2.1 + (2.12 \times 9.4)$, giving 22.0 to 17.8 l/min. The standard error of the limit $\bar{d} \quad 2s$ is 16.3 l/min. The 95% confidence interval for the lower limit of agreement is $79.7 \quad (2.12 \times 16.3)$ to $79.7 + (2.12 \times 16.3)$, giving 114.3 to 45.1 l/min. For the upper limit of agreement the 95% confidence interval is 40.9 to 110.1 l/min. These intervals are wide, reflecting the small sample size and the great variation of the differences. They show, however, that even on the most optimistic interpretation there can be considerable discrepancies between the two meters and that the degree of agreement is not acceptable.

EXAMPLE SHOWING GOOD AGREEMENT

Fig 3 shows a comparison of oxygen saturation measured by an oxygen saturation monitor and pulsed oximeter saturation, a new non-invasive technique. [5] Here the mean difference is 0.42 percentage points with 95% confidence interval 0.13 to 0.70. Thus pulsed oximeter saturation tends to give a lower reading, by between 0.13 and 0.70. Despite this, the limits of agreement (2.0 and 2.8) are small enough for us to be confident that the new method can be used in place of the old for clinical purposes.

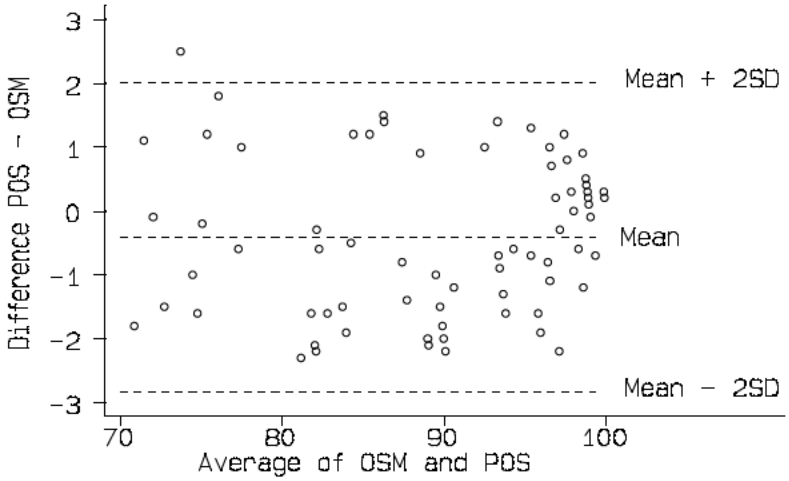

Fig 3. Oxygen saturation monitor and pulsed saturation oximeter

RELATION BETWEEN DIFFERENCE AND MEAN

In the preceding analysis it was assumed that the differences did not vary in any systematic way over the range of measurement. This may not be so. Fig 4 compares the measurement of mean velocity of circumferential fibre shortening (VCF) by the long axis and short axis in M-mode echocardiography. [6] The scatter of the differences increases as the VCF increases. We could ignore this, but the limits of agreement would be wider apart than necessary for small VCF and narrower than they should be for large VCF. If the differences are proportional to the mean, a logarithmic transformation should yield a picture more like that of figs 2 and 4, and we can then apply the analysis described above to the transformed data.

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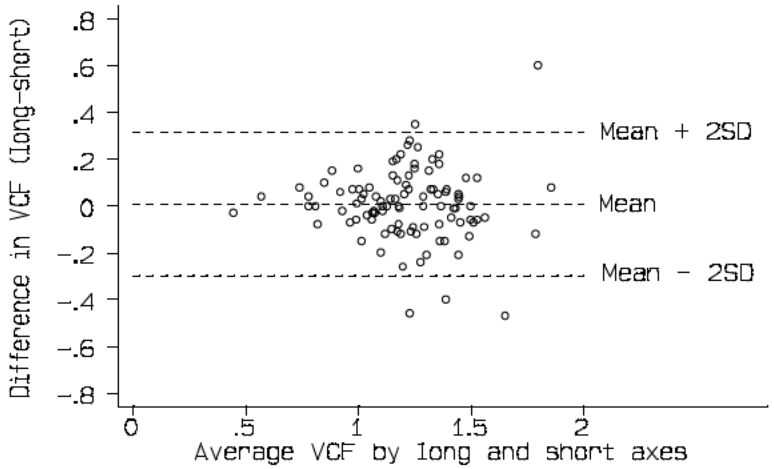

Fig 4. Mean VCF by long and short axis measurements.

Fig 5 shows the log-transformed data of fig 4. This still shows a relation between the difference and the mean VCF, but there is some improvement. The mean difference is 0.003 † on the log scale and the limits of agreement are 0.098 † and 0.106.† However, although there is only negligible bias, the limits of agreement have somehow to be related to the original scale of measurement. If we take the antilogs of these limits, we get 0.80 and 1.27. However, the antilog of the difference between two values on a log scale is a dimensionless ratio. The limits tell us that for about 95% of cases the short axis measurement of VCF will be between 0.80 and 1.27 times the long axis VCF. Thus the short axis measurement may differ from the long axis measurement by 20% below to 27% above. (The log transformation is the only transformation giving back-transformed differences which are easy to interpret, and we do not recommend the use of any other in this context.)

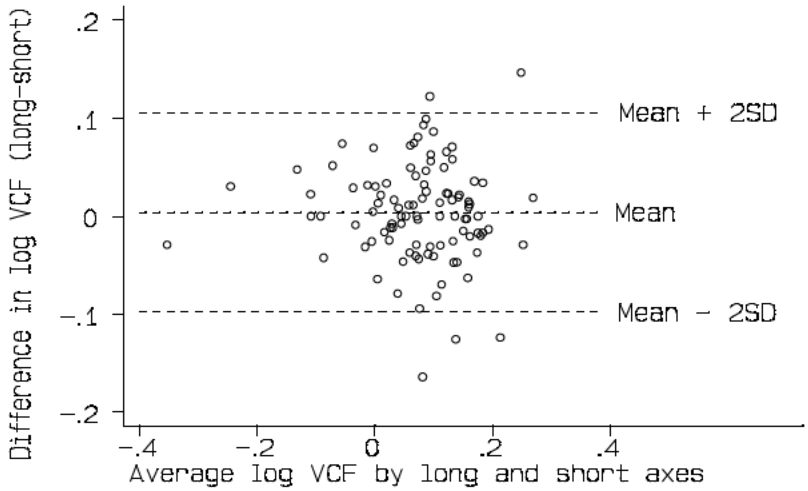

Fig 5. Data of fig 4 after logarithmic transformation.

† These numbers were incorrectly printed as 0.008, 0.226, and 0.243 in the *Lancet*. This mistake arose because when revising the paper we dithered over whether to use natural logs or logs to base 10 and got hopelessly confused.

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Sometimes the relation between difference and mean is more complex than that shown in fig 4 and log transformation does not work. Here a plot in the style of fig 2 is very helpful in comparing the methods. Formal analysis, as described above, will tend to give limits of agreement which are too far apart rather than too close, and so should not lead to the acceptance of poor methods of measurement.

REPEATABILITY

Repeatability is relevant to the study of method comparison because the repeatabilities of the two methods of measurement limit the amount of agreement which is possible. If one method has poor repeatability — i.e. there is considerable variation in repeated measurements on the same subject — the agreement between the two methods is bound to be poor too. When the old method is the more variable one, even a new method which is perfect will not agree with it. If both methods have poor repeatability, the problem is even worse.

The best way to examine repeatability is to take repeated measurements on a series of subjects. The table shows paired data for PEFR. We can then plot a figure similar to fig 2, showing differences against mean for each subject. If the differences are related to the mean, we can apply a log transformation. We then calculate the mean and standard deviation of the differences as before. The mean difference should here be zero since the same method was used. (If the mean difference is significantly different from zero, we will not be able to use the data to assess repeatability because either knowledge of the first measurement is affecting the second or the process of measurement is altering the quantity.) We expect 95% of differences to be less than two standard deviations. This is the definition of a repeatability coefficient adopted by the British Standards Institution. [7] If we can assume the main difference to be zero this coefficient is very simple to estimate: we square all the differences, add them up, divide by n, and take the square root, to get the standard deviation of the differences.

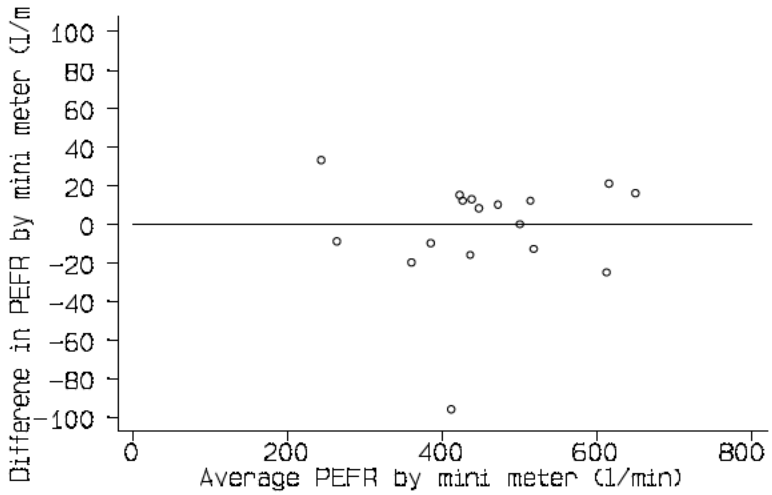

Fig 6. Repeated measures of PEFR using mini Wright peak flow meter.

Fig 6 shows the plot for pairs of measurements made with the mini Wright peak flow meter. There does not appear to be any relation between the difference and the size of the PEFR. There is, however, a clear outlier. We have retained this measurement for the analysis, although we suspect that it was technically unsatisfactory. (In practice, one could omit this subject.) The sum of the differences squared is 13479 so the standard deviation of differences between the 17 pairs of repeated measurements is 28.2 l/min. The coefficient of repeatability

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is twice this, or 56.4 l/min for the mini meter. For the large meter the coefficient is 43.2 l/min.

If we have more than two repeated measurements the calculations are more complex. We plot the standard deviation of the several measurements for that subject against their mean and then use one-way analysis of variance, [8] which is beyond the scope of this article.

MEASURING AGREEMENT USING REPEATED MEASUREMENTS

If we have repeated measurements by each of the two methods on the same subjects we can calculate the mean for each method on each subject and use these pairs of means to compare the two methods using the analysis for assessing agreement described above. The estimate of bias will be unaffected, but the estimate of the standard deviation of the differences will be too small, because some of the effect of repeated measurement error has been removed. We can correct for this. Suppose we have two measurements obtained by each method, as in the table. We find the standard deviation of differences between repeated measurements for each method separately, s_1 and s_2, and the standard deviation of the differences between the means for each method, s_D. The corrected standard deviation of differences, s_c, is $\sqrt{s_D^2 + \frac{1}{4}s_1^2 + \frac{1}{4}s_2^2}$. This is approximately $\sqrt{2s_D^2}$, but if there are differences between the two methods not explicable by repeatability errors alone (i.e. interaction between subject and measurement method) this approximation may produce an overestimate. For the PEFR, we have $s_D = 33.2$, $s_1 = 21.6$, $s_2 = 28.2$ ‡ l/min. s_c is thus $\sqrt{33.2^2 + \frac{1}{4} \times 21.6^2 + \frac{1}{4} \times 28.2^2}$ or 37.7 l/min. Compare this with the estimate 38.8 l/min which was obtained using a single measurement. On the other hand, the approximation $\sqrt{2s_D^2}$ gives an overestimate (47.0 l/min).

DISCUSSION

In the analysis of measurement method comparison data, neither the correlation coefficient (as we show here) nor techniques such as regression analysis [1] are appropriate. We suggest replacing these misleading analyses by a method that is simple both to do and to interpret. Further, the same method may be use to analyse the repeatability of a single measurement method or to compare measurements by two observers.

Why has a totally inappropriate method, the correlation coefficient, become almost universally used for this purpose?. Two processes may be at work here --- namely, pattern recognition and imitation. A likely first step in the analysis of such data is to plot a scatter diagram (fig 1). A glance through almost any statistical textbook for a similar picture will lead to the correlation coefficient as a method of analysis of such a plot, together with a test of the null hypothesis of no relationship. Some texts even use pairs of measurements by two different methods to illustrate the calculation of r. Once the correlation approach has been published, others will read of a statistical problem similar to their own being solved in this way and will use the same technique with their own data. Medical statisticians who ask "why did you use this statistical method?" will often be told "because this published paper used it". Journals could help to rectify this error by returning for reanalysis papers which use incorrect statistical techniques. This may be a slow process. Referees, inspecting papers in which two methods of measurement have been compared, sometimes complain if no correlation coefficients are provided, even when the reasons for not doing so are given.

‡ This was incorrectly printed as s_c in the *Lancet* and in *Biochimica Clinica*.

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Author(s): Josep L. Carrasco and Lluís Jover

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Estimating the Generalized Concordance Correlation Coefficient through Variance Components

Josep L. Carrasco* and Lluís Jover

Bioestadística, Departament de Salut Pública, Universitat de Barcelona,
Facultat de Medicina, Casanova, 143 08036 Barcelona, Spain
**email:* carrasco@medicina.ub.es

SUMMARY. The intraclass correlation coefficient (ICC) and the concordance correlation coefficient (CCC) are two of the most popular measures of agreement for variables measured on a continuous scale. Here, we demonstrate that ICC and CCC are the same measure of agreement estimated in two ways: by the variance components procedure and by the moment method. We propose estimating the CCC using variance components of a mixed effects model, instead of the common method of moments. With the variance components approach, the CCC can easily be extended to more than two observers, and adjusted using confounding covariates, by incorporating them in the mixed model. A simulation study is carried out to compare the variance components approach with the moment method. The importance of adjusting by confounding covariates is illustrated with a case example.

KEY WORDS: Agreement; Concordance correlation coefficient; Intraclass correlation coefficient; Mixed effects model; Variance components.

1. Introduction

Agreement between continuous data measured from different measurement methods has received a great deal of attention from the scientific community. The measurement methods can be multiple systems, processes, machines, or raters but, for the sake of simplicity, we refer to them as "observers" throughout the paper. A simple way to classify the procedures that measure agreement is to differentiate between aggregate and disaggregate approaches, where a disaggregate approach evaluates agreement for each component of the measurement model separately, for example, difference of means or error variances. An example of a disaggregate procedure is the structural equation model (Kelly, 1985; Cheng and Van Ness, 1999). On the other hand, an aggregate approach assesses agreement using a single measure as a concordance magnitude. The intraclass correlation coefficient (Pearson, 1901) and the concordance correlation coefficient (Lin, 1989) are two of the most popular aggregate procedures used to measure agreement when data are on a continuous scale.

The intraclass correlation coefficient (ICC) measures the amount of overall data variance due to between-subjects variability, while the concordance correlation coefficient (CCC) was defined by Lin (1989), based on the distance on the plane of each pair of data to the 45° line through the origin. The CCC has components of precision and accuracy. The disaggregate approach can also be evaluated, by assessing the precision and accuracy components separately (Lin et al., 2002). Since the ICC is defined using variance components, several expressions of ICC can be found (Bartko, 1966; Shrout and Fleiss, 1979) depending on the measurement model chosen. The ICC usually comes from a two-way analysis of variance, where observers and subjects are considered as effects. However, at the same time, this dependence of the ICC expression on the measurement model causes some confusion. Thus, the ICC was criticized as a measure of agreement among observers for two reasons: first, it allows duplicate readings to be interchangeable (Lin, 1989; Barnhart and Williamson, 2001), that is, it cannot measure lack of accuracy (difference of means) between observers measures; second, it gives a negative value when the paired readings are uncorrelated (Lin, 1989). We will argue that the ICC is a valid measure of agreement among observers and it can indeed take into account the difference of observer means, if it is suitably expressed.

The CCC is another, widely used agreement measure (Lin, 1992; Ruel et al., 1997; Calderone and Turcotte, 1998; Singh and Jones, 2002). It is interesting to note the differences and similarities between the coefficients. For the case of two observers, Nickerson (1997) found them practically identical, and Robieson (1999) found them to be asymptotically equivalent. Furthermore, a CCC for more than two observers is required (Lin, 1989; King and Chinchilli, 2001; Barnhart, Haber and Song, 2002) and, moreover, the CCC needs to be adjusted by confounding covariates (Barnhart and Williamson, 2001; King and Chinchilli, 2001). As a result of the comparison between the CCC and ICC, we will show that it is simple to adjust the CCC by covariates and obtain a CCC for more than two observers.

The article is structured as follows: in Section 2, the ICC and CCC are defined and compared. Section 3 contains the extension of CCC to more than two observers, the

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covariate-adjusted CCC, and some inference questions. In Section 4, moment-method and variance components procedures of CCC estimation are compared via a simulation study. Section 5 shows a case example involving the agreement between a manual and an automatic blood pressure device. In this example, the need for confounding covariate adjustment is illustrated by the inclusion of sex, age, and heart rate in the CCC estimation. Finally, the discussion and conclusions are included in Section 6.

2. Comparison of CCC and ICC

2.1 *Concordance Correlation Coefficient*

Lin (1989) defined the CCC for two observers, assuming data was distributed under a bivariate normal distribution; therefore, $(Y_1, Y_2) \sim \mathrm{MVN}(\boldsymbol{\mu}, \Sigma)$, where Y_1 and Y_2 are the array of measurements of each observer, $\boldsymbol{\mu} = (\mu_1\ , \mu_2)$ is the vector of the observer means, and

$$\boldsymbol{\Sigma} = \begin{pmatrix} \sigma_1^2 & \sigma_{12} \\ \sigma_{12} & \sigma_2^2 \end{pmatrix}$$

is the covariance matrix.

Lin based the CCC on the distance between Y_1 and Y_2 in relation to the concordance point. He used the expectation of the square difference, defining the CCC as

$$\rho_C = 1 - \frac{E\{(Y_1 - Y_2)^2\}}{E\{(Y_1 - Y_2)^2\} \text{ when } Y_1 \text{ and } Y_2 \text{ are uncorrelated}}$$
$$= \frac{2 \cdot \sigma_{12}}{\sigma_1^2 + \sigma_2^2 + (\mu_1 - \mu_2)^2}.$$

To build confidence intervals, Lin (1989) suggests using the inverse hyperbolic tangent transformation or Z-transformation, $Z_C = \tanh^{-1}(\rho_C) = 0.5 \cdot \ln\{(1 + \rho_C)/(1 - \rho_C)\}$, which improves the approximation to a Gaussian distribution. The standard error expression of $\hat{Z}_C$ was provided by Lin (1989, 2000), so the confidence interval estimation is made using the confidence interval of $\hat{Z}_C$, which is built using a standard normal distribution.

2.2 *Intraclass Correlation Coefficient*

Suppose a continuous variable is measured m times from n subjects by k observers or judges. The measurement model assumed is $Y_{ijl} = \mu + \alpha_i + \beta_j + e_{ijl}$ (Fleiss, 1986), where Y_{ijl} is the lth measurement made on individual i by observer j with $i = 1, \ldots, n$, $j = 1, \ldots, k$, and $l = 1, \ldots, m$; μ is the overall mean, α_i is the individual effect, β_j is the observer effect, and e_{ijl} is the random error. It is assumed that $\alpha_i \sim N(0, \sigma_\alpha^2)$ and $e_{ijl} \sim N(0, \sigma_e^2)$ and that the error term does not covary with any other component of the measurement model.

The general expression of ICC is $\rho_{\mathrm{ICC}} = \sigma_\alpha^2/\sigma_Y^2$ (Fleiss, 1986), where σ_Y^2 is the variance of Y_{ijl}. Depending on the nature of the observer effect, we will choose between two expressions of ICC: $\rho_{\mathrm{ICC}} = \sigma_\alpha^2/(\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2)$ if the observers are considered random and their effects distributed under a normal distribution $\beta_j \sim N(0, \sigma_\beta^2)$, or $\rho_{\mathrm{ICC},2} = \sigma_\alpha^2/(\sigma_\alpha^2 + \sigma_e^2)$ if the observers are considered as a fixed effect. It is obvious that ρ_{ICC} takes into account the differences in average among observers, whereas $\rho_{\mathrm{ICC},2}$ fails to do so.

The observer effect is considered as a random effect if agreement among a population of observers is desired. In that case, a random sample of observers is collected and ρ_{ICC} is used instead of $\rho_{\mathrm{ICC},2}$. However, following Shrout and Fleiss (1979): "When the judge variance is ignored, the correlation index can be interpreted in terms of rater consistency rather than rater agreement. Researchers of the rating process may choose between ρ_{ICC} and $\rho_{\mathrm{ICC},2}$ on the basis of which of these concepts they wish to measure." Therefore, to measure agreement among observers, ρ_{ICC} has to be used, even if the observer effect is fixed. In this case, the term σ_β^2 will be a sum of squares, $\sigma_\beta^2 = (k-1)^{-1} \sum_{j=1}^k \beta_j^2$, rather than a variance (Fleiss, 1986), where $\beta_j = \mu_j - \mu$ is the difference between the mean of observer j with respect to the overall mean, and k is the number of observers. The Z-transformation can be used to build a confidence interval for ICC, although Fleiss and Shrout (1978) suggested an approach based on the F-distribution when the observers are assumed to be normally distributed.

2.3 *How Different Are ICC and CCC?*

To compare the coefficients, we will assume that a continuous characteristic has been measured by k observers on n subjects, and that one measurement by observer and subject is taken ($m = 1$). Assuming that observers are a fixed effect, the following equalities are fulfilled

$$\sigma_\alpha^2 = \frac{2}{k \cdot (k-1)} \sum_{i=1}^{k-1} \sum_{j=i+1}^{k} \sigma_{ij};$$

$$\sigma_\beta^2 = \frac{1}{k \cdot (k-1)} \sum_{i=1}^{k-1} \sum_{j=i+1}^{k} (\mu_i - \mu_j)^2$$

and

$$\sigma_e^2 = \frac{2}{k \cdot (k-1)} \sum_{i=1}^{k-1} \sum_{j=i+1}^{k} \frac{1}{2}\left(\sigma_i^2 + \sigma_j^2 - 2\sigma_{ij}\right)$$
$$= \frac{1}{k} \sum_{i=1}^{k} \sigma_i^2 - \frac{2}{k \cdot (k-1)} \sum_{i=1}^{k-1} \sum_{j=i+1}^{k} \sigma_{ij}$$

where σ_i^2 and μ_i are the variance and mean of the measurements made by observer i, and σ_{ij} is the covariance between the measurements from observers i and j. Thus, the ICC can be expressed in terms of the variances, covariances, and means of the observers measurements, as

$$\rho_{\mathrm{ICC}} = \frac{\sigma_\alpha^2}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2} = \frac{2 \sum_{i=1}^{k-1} \sum_{j=i+1}^{k} \sigma_{ij}}{(k-1) \sum_{i=1}^{k} \sigma_i^2 + \sum_{i=1}^{k-1} \sum_{j=i+1}^{k} (\mu_i - \mu_j)^2}$$

which is exactly the same expression as the overall concordance correlation coefficient for k observers suggested in the works of Lin (1989), King and Chinchilli (2001) and Barnhart et al. (2002). Hence, the concordance correlation coefficient is the intraclass correlation coefficient when the observers are considered as a fixed effect.

This result implies that CCC can be estimated by variance components through a mixed effects model easily generalizable to more than two observers.

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Although the concordance correlation coefficient is no more than a particular intraclass correlation coefficient, throughout the article, we will refer to it as concordance correlation coefficient.

3. Concordance Correlation Coefficient Estimated by Variance Components

3.1 *Estimation of the CCC for k Observers*

CCC could be estimated either using variance components estimation methods (Searle, Casella, and McCulloch, 1992) or by estimating the variances, covariances, and means of the observer measurements, following Lin (1989).

Suppose $S_i^2, \bar{Y}_i$ and S_{ij} are the unbiased estimators of σ_i^2, μ_i and σ_{ij} respectively. If these estimates are used to estimate the components of CCC and their expectations are taken, we reach

$$E\left(\frac{2}{k\cdot(k-1)}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k} S_{ij}\right) = \frac{2}{k\cdot(k-1)}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}\sigma_{ij}$$

$$E\left(\frac{1}{k}\sum_{i=1}^{k} S_i^2\right) = \frac{1}{k}\sum_{i=1}^{k}\sigma_i^2$$

but, following Fleiss (1986),

$$E\left(\frac{1}{k\cdot(k-1)}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}(\bar{Y}_i-\bar{Y}_j)^2\right) = \frac{1}{k\cdot(k-1)}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}(\mu_i-\mu_j)^2+\frac{\sigma_e^2}{n},$$

where n is the number of subjects. Consequently, $\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}(\bar{Y}_i-\bar{Y}_j)^2$ is a biased estimator of $\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}(\mu_i-\mu_j)^2$, and the unbiased estimator is

$$\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}(\bar{Y}_i-\bar{Y}_j)^2-\frac{k\cdot(k-1)}{n}\hat{\sigma}_e^2 = \sum_{i=1}^{k-1}\sum_{j=i+1}^{k}(\bar{Y}_i-\bar{Y}_j)^2 - \frac{k\cdot(k-1)}{n}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}\left(S_i^2+S_j^2-2S_{ij}\right).$$

Obviously, this bias will be more or less important depending on the sample size and on the magnitude of the error variance; it will usually be quite negligible, but the unbiased estimator should be used:

$$\hat{\rho}_C = \frac{2\sum_{i=1}^{k-1}\sum_{j=i+1}^{k} S_{ij}}{(k-1)\sum_{i=1}^{k} S_i^2+\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}(\bar{Y}_i-\bar{Y}_j)^2-\frac{k\cdot(k-1)}{n}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}\left(S_i^2+S_j^2-2S_{ij}\right)}$$

3.2 *CCC Adjusted by Covariates*

A focal point to estimating any covariance-based index is covariate adjustment, particularly the covariates concerning subject effect. When an index based on variance components is estimated, we consider that variance of subject effect should only take into account the variability of the analysed measure, by removing other intersubject sources of variability (i.e., sex or age) that increase the estimated between-subjects variance. To achieve this objective, a method allowing subject-covariance adjustment is required.

Some procedures have been suggested to make this adjustment. Barnhart and Williamson (2001) proposed a covariate adjustment in CCC via generalized estimating equations, and King and Chinchilli (2001) give the expression of a stratified CCC.

Because the estimation of CCC using variance components of a mixed model has been demonstrated by means of the ICC, the adjustment by subject-covariates can be easily made by including these covariates in the model.

3.3 *Inference about CCC*

The CCC will be estimated using variance components of a mixed model with subjects as random effect and observers as fixed effect. Although $\hat{\rho}_C$ follows an asymptotic normal distribution (Lin, 1989), to build a $(1-\alpha)\%$ confidence interval, the inverse hyperbolic tangent transformation $\hat{Z}_C = \tanh^{-1}(\hat{\rho}_C) = 0.5\ln\{(1+\hat{\rho}_C)/(1-\hat{\rho}_C)\}$ can be used to accelerate the convergence to a normal distribution. In this case, first the confidence interval of Z_C will be estimated and then the hyperbolic tangent transformation will be applied to obtain a confidence interval for ρ_C.

The standard error of $\hat{Z}_C$ and $\hat{\rho}_C$ are approximated using the delta method (see the Appendix); then, the $\mathrm{Var}(\hat{\rho}_C)$ expression is

$$\frac{(1-\rho_C)^2\cdot\mathrm{Var}\left(\sigma_\alpha^2\right)+\left[\rho_C^2\cdot\left\{\mathrm{Var}\left(\sigma_\beta^2\right)+\mathrm{Var}\left(\sigma_e^2\right)+2\mathrm{cov}\left(\sigma_e^2,\sigma_\beta^2\right)\right\}\right]-\left[2\cdot(1-\rho_C)\cdot\rho_C\cdot\left\{\mathrm{cov}\left(\sigma_\alpha^2,\sigma_\beta^2\right)+\mathrm{cov}\left(\sigma_\alpha^2,\sigma_e^2\right)\right\}\right]}{\left(\sigma_\alpha^2+\sigma_\beta^2+\sigma_e^2\right)^2}$$

and $$\mathrm{Var}\left(\hat{Z}_C\right) \approx \frac{\mathrm{Var}(\hat{\rho}_C)}{(1+\rho_C)^2\cdot(1-\rho_C)^2}.$$

The expressions of the standard errors of variance components depend on the estimation method. Usually, this method will be a likelihood-based method, such as maximum likelihood or restricted maximum likelihood. Then, the variances and covariances of parameters will be approximated by the inverse of Fisher's information matrix, except for the case of σ_β^2, when the observers are considered a fixed effect. Here, the standard error can be approximated by (see the Appendix)

$$\mathrm{Var}(\hat{\sigma}_\beta^2) \approx \frac{4}{k^2\cdot(k-1)^2}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}\left\{(\bar{Y}_i-\bar{Y}_j)^2\cdot\mathrm{Var}(\bar{Y}_i-\bar{Y}_j)\right\} + \frac{\mathrm{Var}\left(\hat{\sigma}_e^2\right)}{(n\cdot m)^2}.$$

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For more details relating to methods of estimation for mixed effects models, we direct the reader to Searle et al. (1992).

Fleiss and Shrout (1978) give the expression of a confidence interval for ICC based on the F-distribution when the observers are considered as a random effect. This approach can also be used to make inferences about CCC. The $(1-\alpha)\%$ confidence interval will be provided by

$$\frac{k\cdot\sigma_\alpha^2+(1-F^*)\cdot\sigma_e^2}{F^*\left\{k\cdot\sigma_\beta^2+(k-1)\cdot\sigma_e^2\right\}+k\cdot\sigma_\alpha^2+\sigma_e^2}<\rho_C$$
$$<\frac{k\cdot F_*\sigma_\alpha^2+(F_*-1)\cdot\sigma_e^2}{k\cdot\sigma_\beta^2+(k-1)\cdot\sigma_e^2+F_*\left(k\cdot\sigma_\alpha^2+\sigma_e^2\right)}$$

where F^* and F_* are the $(1-\alpha/2)\%$ percentiles of an F distribution with $(n-1,\nu)$ and $(\nu\ ,n-1)$ degrees of freedom, respectively. Where

$$\nu=\frac{(k-1)\cdot(n-1)\cdot[k\cdot\hat\rho_{\rm ICC}\cdot F_r+n\cdot\{1+(k-1)\cdot\hat\rho_{\rm ICC}\}-k\cdot\hat\rho_{\rm ICC}]^2}{(n-1)\cdot k^2\cdot\hat\rho_{\rm ICC}^2\cdot F_r^2+[n\cdot\{1+(k-1)\cdot\hat\rho_{\rm ICC}\}-k\cdot\hat\rho_{\rm ICC}]^2}$$

and $F_r=1+(n\cdot\hat\sigma_\beta^2/\hat\sigma_e^2)$.

4. Simulation Study

To compare the CCC estimated by the usual moment method against the variance component method, we carried out a simulation study. Firstly, we compared the two estimation methods in the most common situation with two observers or measurement methods simulating 16 combinations of a bivariate normal distribution. We combined several values of differences of means, variances, and correlation, generating various values of CCC. From each situation, we collected 1000 random samples, estimating the CCC and its standard error using both moment-method and variance components procedures. Sample sizes of 20 and 60 subjects were considered. Table 1 shows the values used to generate each population, as well as the actual values of the CCC.

We compared the procedures in terms of accuracy and efficiency. The results are shown in Table 2. In this order, we calculated the mean of the estimates (column Mean of CCC estimates), the mean square error, MSE $=E\{(\hat\rho_C-$ Actual $\rho_C)^2\}$, the standard deviation of the estimates (column SE of CCC), and the mean of the estimated standard errors (column Mean of SE). We also analysed the empiric coverage of the confidence intervals. To build such intervals, we considered the asymptotic normal distribution of the CCC and the Z-transformation, as well as the procedure based on the F-distribution (Table 3).

To study the behaviour of the CCC estimation using variance components in the case of more than two observers, we used some results from Barnhart et al. (2002). In a simulation considering 4 observers, they estimated the CCC using generalized estimating equations and the U-statistics approach proposed by King and Chinchilli (2001). The situations considered were a multivariate normal distribution, with vector mean $\mu=(0.0\ 0.2\ 0.4\ 0.6)$, and a symmetric covariance matrix, with the elements of the diagonal equal to 1, and ρ in the off-diagonal, where ρ indicates Pearson's correlation coefficient taking values of 0.9, 0.7, and 0.5. A thousand random samples were selected and sample sizes of 25, 50, and 100 subjects were considered. The results obtained by Barnhart et al. (2002) are attached to the results using the variance components (Table 4).

In the simulation with two observers, we found a minimal bias in point estimation, as well as in standard error estimation. For point estimation, the bias grows when the value of the CCC decreases, and the bias is systematically greater in moment-method (MM) than in variance components (VC), confirming the bias of the MM estimator proposed by Lin (1989).

Both procedures give accurate estimates of the standard error, with the exception of the MM method when there is a difference between means, and the correlation is set to 0.99. In this case, the MM method fails, giving a standard error mean between 54.9% and 70.4% of the actual standard error. Regarding the variability of the estimates (SE of CCC in Table 2), the standard error of the estimates is systematically greater in the MM than the VC approach.

The coverage of the confidence intervals is correct compared to nominal coverage, but we must highlight combinations 9 and 13, where the MM approach fails to achieve the desirable coverage. This is linked to the fact that, in these combinations, the moment method underestimates the standard error.

Despite the fact that the coverage is correct with the asymptotic approach, the Z-transformation gives more accurate and steady coverage. The confidence intervals based on F approximations work quite well when there is no difference of means. When this component of variance appears, however, the F-approximation overestimates the nominal coverage.

Table 1
Combinations of parameters simulated

Comb.	μ_1	μ_2	σ_1^2	σ_2^2	ρ_{12}	ρ_C
1	100	100	100	100	0.99	0.99
2					0.9	0.9
3					0.7	0.7
4					0.5	0.5
5	100	100	100	125	0.99	0.9839
6					0.9	0.8944
7					0.7	0.6957
8					0.5	0.4969
9	100	105	100	100	0.99	0.8800
10					0.9	0.8000
11					0.7	0.6222
12					0.5	0.4444
13	100	105	100	125	0.99	0.8855
14					0.9	0.8050
15					0.7	0.6261
16					0.5	0.4472

μ_1 and μ_2 are the means, and σ_1^2 and σ_2^2 are the variances, of observers 1 and 2, respectively. ρ_{12} is Pearson's correlation coefficient, and ρ_C is the concordance correlation coefficient.

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Table 2
Simulation results

Comb.	Sample size	Actual CCC	Mean of CCC estimates		MSE × 10^5		SE of CCC (1)		Mean of SE (2)		(2)/(1)	
			MM	VC	MM	VC	MM	VC	MM	VC	MM	VC
1	20	0.99	0.9888	0.9891	0.25	0.24	0.0049	0.0048	0.0056	0.0054	1.143	1.125
	60	0.99	0.9896	0.9897	0.07	0.07	0.0026	0.0026	0.0028	0.0028	1.077	1.077
2	20	0.9025	0.8902	0.8923	25.85	24.82	0.0499	0.0493	0.0514	0.0499	1.030	1.012
	60	0.9025	0.8987	0.8994	6.19	6.1	0.0249	0.0247	0.0257	0.0254	1.032	1.028
3	20	0.7103	0.6884	0.6933	145.82	143.13	0.1203	0.1195	0.1219	0.1198	1.013	1.003
	60	0.7103	0.7004	0.7022	43.1	42.92	0.0657	0.0655	0.0668	0.0663	1.017	1.012
4	20	0.4947	0.4619	0.4682	327.9	314.04	0.1771	0.1744	0.1736	0.1711	0.980	0.981
	60	0.4947	0.4796	0.4816	104.5	103.92	0.1002	0.1003	0.0991	0.099	0.989	0.987
5	20	0.9833	0.981	0.9814	0.62	0.58	0.0073	0.0072	0.0078	0.009	1.068	1.250
	60	0.9833	0.9826	0.9827	0.15	0.15	0.0037	0.0037	0.0037	0.0046	1.000	1.243
6	20	0.89	0.8747	0.8773	35.3	33.3	0.0561	0.0551	0.0568	0.056	1.012	1.016
	60	0.89	0.8878	0.8886	7.54	7.34	0.0267	0.0265	0.0275	0.0279	1.030	1.053
7	20	0.6946	0.6764	0.6813	151.08	148.13	0.1215	0.1209	0.1245	0.1237	1.025	1.023
	60	0.6946	0.6887	0.6903	47.23	46.71	0.0684	0.0682	0.0681	0.0684	0.996	1.003
8	20	0.4985	0.4527	0.4591	318.53	308.23	0.173	0.1715	0.1742	0.1723	1.007	1.005
	60	0.4985	0.4797	0.4817	92.39	92.23	0.0946	0.0949	0.0985	0.0991	1.041	1.044
9	20	0.8801	0.8706	0.871	20.77	20.62	0.0446	0.0445	0.0245	0.0397	0.549	0.892
	60	0.8801	0.8771	0.8772	4.42	4.41	0.0208	0.0208	0.0132	0.0214	0.635	1.029
10	20	0.8013	0.7792	0.7828	62.03	59.62	0.076	0.0753	0.0796	0.0752	1.047	0.999
	60	0.8013	0.7941	0.7953	16.36	16.14	0.04	0.0399	0.0429	0.0408	1.073	1.023
11	20	0.6177	0.5972	0.6047	178.63	174.17	0.1314	0.1309	0.1336	0.1268	1.017	0.969
	60	0.6177	0.6149	0.6176	52.74	52.23	0.0723	0.0722	0.0754	0.0712	1.043	0.986
12	20	0.4344	0.4218	0.4306	250.78	242.04	0.1568	0.155	0.1663	0.1616	1.061	1.043
	60	0.4344	0.4278	0.4309	85.43	84.88	0.091	0.0912	0.0963	0.0937	1.058	1.027
13	20	0.8867	0.8776	0.8783	17.31	17.13	0.0409	0.0408	0.028	0.0394	0.685	0.966
	60	0.8867	0.883	0.8832	4.6	4.58	0.0213	0.0213	0.015	0.0214	0.704	1.005
14	20	0.8036	0.7883	0.7921	62.64	60.33	0.0774	0.0766	0.0783	0.0742	1.012	0.969
	60	0.8036	0.798	0.7993	15.79	15.52	0.0391	0.039	0.0429	0.041	1.097	1.051
15	20	0.6343	0.6113	0.6191	165.47	162.39	0.1279	0.1273	0.1312	0.1256	1.026	0.987
	60	0.6343	0.6264	0.6292	47.35	47.25	0.0688	0.0687	0.0743	0.0712	1.080	1.036
16	20	0.4487	0.4259	0.4349	235.08	227.65	0.1519	0.1505	0.1666	0.1631	1.097	1.084
	60	0.4487	0.4405	0.4436	84.59	84.56	0.0918	0.0919	0.0959	0.0941	1.045	1.024

The terms MM and VC refer to moment-method and variance components method, respectively.

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Table 3

Percentage of cover of the confidence intervals. Column n shows the sample size. The nominal coverage is 95%. The combinations simulated are shown in Table 1.

		Moment method		Variance components		
Comb	n	Asymptotic	Z-trans.	Asymptotic	Z-trans.	F
1	20	94.8	96.2	94.5	96.2	97.1
	60	96.1	96.1	96.1	95.9	96.5
2	20	91.5	93.7	90.7	93.8	94.1
	60	96.1	94.9	94.1	95.0	95.5
3	20	91.3	94.9	89.9	94.8	95.2
	60	94.1	95.9	92.9	95.6	95.8
4	20	91.8	94.4	91.9	94.7	95.2
	60	93.2	93.9	93.1	93.8	94.0
5	20	96.1	95.5	98.3	98.3	98.8
	60	96.8	94.2	98.8	97.5	97.6
6	20	95.6	94.7	94.9	94.1	94.6
	60	94.7	94.6	94.7	94.8	94.8
7	20	93.8	95.5	92.9	95.4	96.4
	60	94.4	94.9	94.4	95.1	95.4
8	20	93.2	94.0	93.4	94.2	95.5
	60	95.6	95.7	95.8	95.8	96.1
9	20	74.6	76.1	94.8	94.5	99.8
	60	78.8	78.0	96.2	94.7	100.0
10	20	95.1	94.6	93.7	94.2	99.8
	60	95.2	96.1	94.6	95.4	100.0
11	20	93.9	94.0	92.6	93.8	98.6
	60	94.7	95.6	92.1	94.5	99.9
12	20	92.8	95.8	92.4	95.2	97.8
	60	95.4	95.2	94.7	95.3	97.8
13	20	82.7	82.5	94.4	94.0	100.0
	60	84.6	84.0	94.1	95.1	100.0
14	20	93.5	94.4	92.9	93.6	99.3
	60	96.1	96.1	96.1	95.7	100.0
15	20	92.5	94.3	91.5	93.8	97.7
	60	94.5	95.7	93.1	95.0	99.3
16	20	94.4	96.1	94.7	95.6	97.3
	60	94.1	96.4	93.7	95.8	98.1

In the simulation with more than two observers, there is a bias in GEE and U-statistics. This may be attributable to the use of the CCC biased estimator (Section 2). Standard errors are estimated with more precision in the variance components method, which improves coverage of confidence intervals in most combinations simulated.

5. Blood Pressure Devices Data

The importance of adjusting the concordance correlation coefficient by subject-covariates is shown by way of an example. To compare a handle mercury sphygmomanometer device against an OMRON 711 automatic device, a sample of 384 subjects was collected in the area of Girona (Catalonia, Spain). Systolic and diastolic blood pressure were measured simultaneously twice by each instrument, although we will only use the systolic blood pressure in the example. Sex, age, and heart rate of each subject were measured as covariates. Sex was coded as 0 for males and 1 for females, whereas age and heart rate were taken as continuous variables.

First, we fit a mixed effects model via REML, with subjects as random effect and measurement instruments as fixed effect. The resulting variance components are (Table 5) $\hat{\sigma}^2_\alpha = 380.187, \hat{\sigma}^2_e = 52.867,$ and $\hat{\sigma}^2_\beta = \{(-2.174)^2/2\} - \{52.867/(384 \cdot 2)\} = 2.295$, giving a CCC of $\hat{\rho}_C = 0.8733$.

The asymptotic variance-covariance matrix of the between-subjects, observers and error variance components is

$$\sum(\alpha, \beta, e) = \begin{pmatrix} 808.50 & 0.0016 & -1.2152 \\ & 0.6510 & -0.0063 \\ & & 4.86 \end{pmatrix}.$$

We estimate a 95% confidence interval for ρ_C using the Z-transformation. The resulting confidence interval is [0.8531; 0.8908]. The CCC estimate indicates a high level of agreement between both instruments. Since ($\hat{\sigma}^2_e \gg \hat{\sigma}^2_\beta$), the disagreement is principally due to random error, rather than inaccuracy.

Then we consider sex as a potential confounding subject-covariate. Figure 1 shows a scatter plot of the systolic pressure measures of each instrument by sex. It seems that there is a shift depending on sex: males tend to have greater values than females. Table 5 shows the estimate for sex that is significantly different from 0. If sex is included in the model, the variance components become $\hat{\sigma}^2_\alpha = 363.024$, $\hat{\sigma}^2_e = 52.867$ and $\hat{\sigma}^2_\beta = 2.295$, giving a CCC estimate of $\hat{\rho}_C = 0.8681$; this is slightly lower than the former CCC. Now, the asymptotic variance-covariance matrix of the random effects is

$$\sum(\alpha, \beta, e) = \begin{pmatrix} 741.45 & 0.0016 & -1.2154 \\ & 0.6510 & -0.0063 \\ & & 4.86 \end{pmatrix}.$$

Only the variance of $\hat{\sigma}^2_\alpha$ is modified, becoming a more precise estimate. Now, the 95% confidence interval for CCC is [0.8472; 0.8863].

Regarding the variance components estimates, between-observers and error variances remain the same, and between-subjects variance decreases, which in turn lowers CCC. This is the consequence of controlling by confounding subject-covariates. The difference of means between sexes increases the between-subjects variance (i.e., the covariance between instruments; see Figure 1) and so the concordance is overestimated. This is a well-known issue concerning measures that depend on covariance (Atkinson and Neville, 1997), as with Pearson's correlation coefficient.

Finally, we fit the model using the remaining covariates: age and heart rate. The variance components become $\hat{\sigma}^2_\alpha = 221.391, \hat{\sigma}^2_\beta = 2.295$, and $\hat{\sigma}^2_e = 52.867$, and the CCC estimate is $\hat{\rho}_C = 0.8005$. The asymptotic variance-covariance matrix of the variance components is now

$$\sum(\alpha, \beta, e) = \begin{pmatrix} 289.99 & 0.0016 & -1.2140 \\ & 0.6510 & -0.0063 \\ & & 4.86 \end{pmatrix}.$$

The 95% confidence interval for the CCC is [0.7709; 0.8267]. Though the value of CCC is still indicating a good agreement between both procedures, the CCC adjusted by covariates is quite lower than the former unadjusted CCC.

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Table 4
Results of the simulations for more than two observers

True ρ	True ρ_C	Sample size	Method	Mean	S.D.	Mean S.E.	95% coverage (%)[a]	95% coverage (%)[b]
0.5	0.469	100	GEE	0.464	0.0517	0.0492	93.8	
			U-Stat	0.464	0.0517	0.0491	93.8	
			VC	0.473	0.0477	0.0502	95.9	96.1
		50	GEE	0.459	0.0702	0.0679	93.1	
			U-Stat	0.459	0.0702	0.0679	93.1	
			VC	0.465	0.0746	0.0709	92.6	93.7
		25	GEE	0.449	0.1001	0.0906	89.5	
			U-Stat	0.449	0.1001	0.0904	89.4	
			VC	0.462	0.1003	0.1001	92.9	94.1
0.7	0.656	100	GEE	0.651	0.0410	0.0398	93.1	
			U-Stat	0.651	0.0410	0.0398	93.2	
			VC	0.659	0.0380	0.0398	94.8	95.3
		50	GEE	0.646	0.0580	0.0549	92.3	
			U-Stat	0.646	0.0580	0.0550	92.4	
			VC	0.652	0.0605	0.057	92.6	92.2
		25	GEE	0.635	0.0841	0.0753	90.4	
			U-Stat	0.635	0.0841	0.0756	90.5	
			VC	0.646	0.0844	0.0815	93.6	93.8
0.9	0.844	100	GEE	0.840	0.0226	0.0211	92.4	
			U-Stat	0.840	0.0226	0.0216	92.7	
			VC	0.844	0.0210	0.0211	95.0	95.5
		50	GEE	0.836	0.0315	0.0300	93.9	
			U-Stat	0.836	0.0315	0.0307	94.2	
			VC	0.840	0.0339	0.0308	92.7	92.5
		25	GEE	0.828	0.0498	0.0419	91.2	
			U-Stat	0.828	0.0498	0.0428	91.6	
			VC	0.837	0.0466	0.0449	94.0	94.0

[a] Using $\hat{\rho}_C \pm 1.96 \cdot S.E.(\hat{\rho}_C)$.
[b] Using the Z-transformation.

6. Discussion

In this article, we have shown that the intraclass correlation coefficient is a useful measure of agreement among observers if the suitable expression of ICC is chosen. If the observers are a fixed effect, the contribution of the variability of the observers means to the ICC will be a sum of squares rather than a variance. If this source of variability is not included in the ICC, we will be measuring consistency among observers instead of agreement (Shrout and Fleiss, 1979), where consistency means that we are only interested in studying the lack of precision, ignoring systematic differences among observers. On the other hand, the fact that ICC could take a negative value is related to the estimation process used: if this process allows a negative between-subjects variance estimate,

Table 5
Estimates of the mixed models. The values of random effects are variances, whereas point estimate and standard error (between brackets) are shown for fixed effects.

	Effects	Model 1	Model 2	Model 3
Random	Individual	380.187	363.024	221.391
	Error	52.867	52.867	52.867
Fixed	Intercept	133.369	137.713	84.864
		(1.029)	(1.427)	(5.061)
	Instrument	−2.174	−2.174	−2.174
		(0.371)	(0.371)	(0.371)
	Sex	–	−8.510	−9.496
			(1.980)	(1.585)
	Age	–	–	0.817
				(0.057)
	Heart rate	–	–	0.194
				(0.069)
Log likelihood		−5876.413	−5865.769	−5778.271

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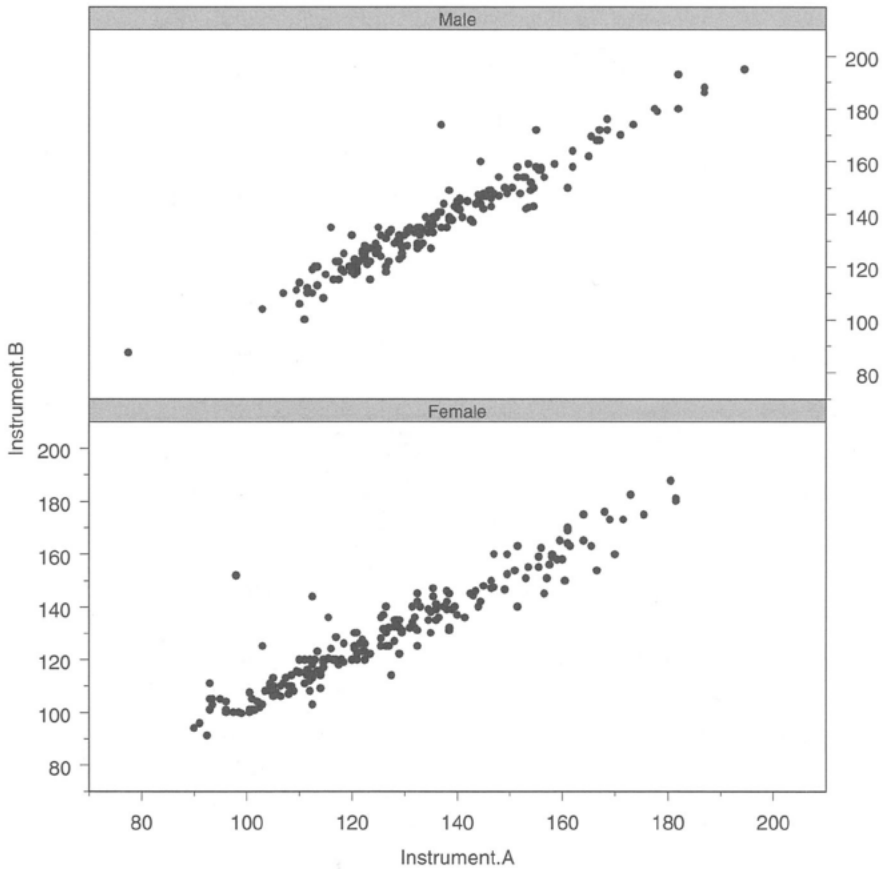

Figure 1. Scatter plot of systolic blood pressure measured using both measurement instruments by sex. Instrument A is the automatic device, whereas instrument B is the handle device.

then the ICC will be negative, but in that case, the covariance between observers would also be negative, as well as the CCC.

The concordance correlation coefficient was originally introduced as a different index from the ICC, but we have shown that the CCC is identical to the ICC when the observers are a fixed effect and agreement among observers is desired. How Lin (1989) arrives at the expression of CCC is more intuitive and easier to understand than ICC, because the idea of measuring departures from the concordance line is very attractive. One important characteristic of the CCC found by Lin (1989) is the decomposition of the CCC into meaningful precision and accuracy components. This can also be done using the variance components approach via the observers and error variances. The observers variance measures the lack of agreement due to inaccuracy, whereas the error variance is related to precision. In the example, the error variance was much greater than the observer variance, thus the lack of agreement was mainly due to lack of precision.

Although considering observers as a fixed effect is the most common situation in an agreement assay, estimating agreement in a population of observers or measurement methods may be desired; in this case, a random sample of observers should be collected and observers should be considered as a random effect. In this situation, even if the point estimate of the CCC was correct (correcting the bias), the standard error, as it was defined by Lin (1989, 2000), would not take into account the variability due to observer sampling.

We have seen that there are two ways to estimate the CCC: the method proposed by Lin, based on observers sample moments, and the other based on variance components. It has also been shown that the moment method provides a biased estimation of between-observers variability, which produces a biased CCC. This bias can be seen by comparing the mean of estimates in the simulation study, where the estimates based on variance components are systematically closer to the true value than the moment method estimates.

Via the simulation study, it has been shown that the variance components estimation of the CCC is a good approach, giving accurate point estimates, as well as standard errors. The Z-transformation is a useful approach to building confidence intervals that improves the asymptotic convergence of the CCC to a normal distribution, while the method based on the F-distribution seems to overestimate the nominal cover, especially when there is a difference between observer means. The poor performance of the method based on the F-distribution is due to this method considering observers as a random effect, so this method should be avoided if the observers are not a random sample from a larger population.

Furthermore, estimating the CCC with variance components using a mixed effects model allows the CCC to be easily extended for more than two observers, and to be adjusted by potentially confounding subject-covariates. The relevance

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of confounding subject-covariate adjustment has been noted in the example. In general, including confounding covariates will reduce the range of the variable in study and, therefore, decrease the CCC estimate. Conversely, if the confounding covariates are not included in the model, a higher agreement than the real agreement will be observed. The estimation of the variability between subjects, or covariance between observers, is a very important issue when a covariance-based index is used. The researcher has to achieve an estimate representative of the true variability of the measure between subjects. This implies knowledge of the population, as well as the range of measurements, when the agreement has to be measured (Lin and Chinchilli, 1997).

Other procedures have been proposed to obtain a CCC adjusted by subject-covariates. Barnhart and Williamson (2001) proposed three sets of generalized estimation equations to calculate estimations, and King and Chinchilli (2001) give the expression for an overall CCC and a stratified CCC. Nevertheless, incorporating the subject-covariates in mixed effects models seems easier to implement and to understand.

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Résumé

Le coefficient de corrélation intraclasse (ICC) et le coefficient de corrélation de concordance (CCC) sont deux des mesures de concordance les plus répandues pour des variables mesurées sur une échelle continue. Nous démontrons ici que ICC et CCC sont une même mesure de concordance estimée de deux façons: par composants de la variance, et par la méthode des moments. Nous proposons d'estimer le CCC en utilisant les composants de la variance d'un modèle à effets mixtes au lieu de l'habituelle méthode des moments. Par l'approche des composants de la variance, le CCC peut aisément être étendu à plus de deux observateurs et ajusté sur des covariables de confusion en incorporant celles-ci dans le modèle mixte. Une étude de simulation est menée pour comparer l'approche par composants de la variance à celle de la méthode des moments. La valeur de l'ajustement sur des variables de confusion est illustrée par un exemple.

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Appendix

To approximate the variance of $\hat{\rho}_C$, the delta method is used. Given that the derivatives with respect to $\rho_C = \sigma_\alpha^2/(\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2)$ are

$$\frac{\partial \rho_C}{\partial \sigma_\alpha^2} = \frac{1-\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}$$

$$\frac{\partial \rho_C}{\partial \sigma_\beta^2} = -\frac{\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}$$

$$\frac{\partial \rho_C}{\partial \sigma_e^2} = -\frac{\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}$$

then

$$\begin{aligned}
\mathrm{Var}(\hat{\rho}_C) \approx{}& \left(\frac{1-\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}\right)^2 \mathrm{Var}\left(\sigma_\alpha^2\right) + \left(-\frac{\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}\right)^2 \mathrm{Var}\left(\sigma_\beta^2\right) + \left(-\frac{\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}\right)^2 \mathrm{Var}\left(\sigma_e^2\right) \\
&+ 2\cdot\left(\frac{1-\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}\right)\left(-\frac{\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}\right)\cdot \mathrm{cov}\left(\sigma_\alpha^2, \sigma_\beta^2\right) + 2\cdot\left(-\frac{\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}\right)\left(-\frac{\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}\right)\mathrm{cov}\left(\sigma_e^2, \sigma_\beta^2\right) \\
&+ 2\cdot\left(\frac{1-\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}\right)\left(-\frac{\rho_C}{\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2}\right)\mathrm{cov}\left(\sigma_\alpha^2, \sigma_e^2\right) \\
={}& \frac{(1-\rho_C)^2\cdot \mathrm{Var}\left(\sigma_\alpha^2\right) + \left[\rho_C^2\cdot\left\{\mathrm{Var}\left(\sigma_\beta^2\right) + \mathrm{Var}\left(\sigma_e^2\right) + 2\mathrm{cov}\left(\sigma_e^2, \sigma_\beta^2\right)\right\}\right] - \left[2\cdot(1-\rho_C)\cdot\rho_C\cdot\left\{\mathrm{cov}\left(\sigma_\alpha^2, \sigma_\beta^2\right) + \mathrm{cov}\left(\sigma_\alpha^2, \sigma_e^2\right)\right\}\right]}{\left(\sigma_\alpha^2 + \sigma_\beta^2 + \sigma_e^2\right)^2}
\end{aligned}$$

If the Z-transformation is used, $Z = 0.5\log(1+\rho_C)/(1-\rho_C)$, the standard error, can be approximated in the same way; then

$$\mathrm{Var}(Z) \approx \left(\frac{\partial Z}{\partial \rho_C}\right)^2 \cdot \mathrm{Var}(\rho_C) = \frac{\mathrm{Var}(\rho_C)}{(1+\rho_C)^2\cdot(1-\rho_C)^2}.$$

The standard errors of the variance components will depend on the method of estimation, but when the observers were a fixed effect the quantity, σ_β^2 will be a sum of squares

$$\sigma_\beta^2 = \frac{1}{k\cdot(k-1)}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}(\mu_i - \mu_j)^2$$

estimated by

$$\hat{\sigma}_\beta^2 = \frac{1}{k\cdot(k-1)}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}(\bar{Y}_i - \bar{Y}_j)^2 - \frac{\hat{\sigma}_e^2}{n\cdot m}.$$

Then, the variance of $\hat{\sigma}_\beta^2$ is provided by

$$\begin{aligned}
\mathrm{Var}(\hat{\sigma}_\beta^2) = {}& \frac{4}{k^2\cdot(k-1)^2}\sum_{i=1}^{k-1}\sum_{j=i+1}^{k}\left\{(\bar{Y}_i - \bar{Y}_j)^2\cdot\mathrm{Var}(\bar{Y}_i - \bar{Y}_j)\right\} \\
&+ \frac{\mathrm{Var}\left(\hat{\sigma}_e^2\right)}{(n\cdot m)^2}
\end{aligned}$$

The covariance between $\hat{\sigma}_\beta^2$ and the other variance components depends on method estimation. If the model is estimated via REML (Searle et al., 1992), the covariances are provided by

$$\mathrm{cov}\left(\hat{\sigma}_\alpha^2, \hat{\sigma}_\beta^2\right) = \frac{1}{k\cdot n\cdot m^2}\mathrm{Var}\left(\hat{\sigma}_e^2\right)$$

and

$$\mathrm{cov}\left(\hat{\sigma}_\beta^2, \hat{\sigma}_e^2\right) = -\frac{1}{n\cdot m}\mathrm{Var}\left(\hat{\sigma}_e^2\right).$$

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ORIGINAL ARTICLE

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Arterial fraction of cerebral blood volume in humans measured by positron emission tomography

Hiroshi Ito, Iwao Kanno, Hidehiro Iida, Jun Hatazawa, Eku Shimosegawa, Hajime Tamura and Toshio Okudera

Department of Radiology and Nuclear Medicine, Akita Research Institute of Brain and Blood Vessels

In quantitative functional neuroimaging with positron emission tomography (PET) and magnetic resonance imaging (MRI), cerebral blood volume (CBV) and its three components, arterial, capillary, and venous blood volumes are important factors. The arterial fraction for systemic circulation of the whole body has been reported to be 20–30%, but there is no report of this fraction in the brain. In the present study, we estimated the arterial fraction of CBV with PET in the living human brain. $C^{15}O$ and dynamic $H_2{}^{15}O$ PET studies were performed in each of seven healthy subjects to determine the CBV and arterial blood volume (V_a), respectively. A two-compartment model (influx: K_1, efflux: k_2) that takes V_a into account was applied to describe the regional time-activity curve of dynamic $H_2{}^{15}O$ PET. K_1, k_2 and V_a were calculated by a non-linear least squares fitting procedure. The V_a and CBV values were 0.011 ± 0.004 m*l*/m*l* and 0.031 ± 0.003 m*l*/m*l* (mean ± SD), respectively, for cerebral cortices. The arterial fraction of CBV was 37%. Considering the limited first-pass extraction fraction of $H_2{}^{15}O$, the true arterial fraction of CBV is estimated to be about 30%. The estimated arterial fraction of CBV was quite similar to that of the systemic circulation, whereas it was greater than that (16%) widely used for the measurement of cerebral metabolic rate of oxygen ($CMRO_2$) using PET. The venous plus capillary fraction of CBV was 63–70% which is a important factor for the measurement of $CMRO_2$ with MRI.

Key words: cerebral blood volume, artery, vein, human, brain, PET

INTRODUCTION

Quantitative functional neuroimaging with positron emission tomography (PET) and magnetic resonance imaging (MRI) has been widely used to investigate the neurophysiology and the pathophysiology of cerebrovascular and neuropsychiatric diseases. For such quantitative imaging, cerebral blood volume (CBV) is an important factor. The CBV in a brain region is the sum of three components, i.e., the arterial, capillary, and venous blood volumes.[1–3] The fractions of these component are needed for quantitative functional imaging with PET and MRI, but there has been no report of these fractions in the brain.

Since regional intravascular radioactivity in the brain contributes to the regional radioactivity measured by PET,[4] the correction of intravascular radioactivity is needed in quantitative PET analysis.[1] The CBV can be measured by ^{15}O-labeled carbon monoxide ($C^{15}O$) and PET.[5] Nevertheless when a tracer that has a relatively high first-pass extraction fraction is used, the radioactivity concentration in the arterial blood differs from that in the capillary and venous blood.[3] For such tracers, determination of the arterial fraction of CBV is necessary for correction of intravascular radioactivity.[2]

Whereas the blood oxygenation level dependent (BOLD) contrast measured by functional magnetic resonance imaging (fMRI) has been used as an indicator of neuronal activity,[6] the measurement of the cerebral metabolic rate of oxygen ($CMRO_2$) by means of BOLD contrast has recently been reported.[7] Since the concentration

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For reprint contact: Hiroshi Ito, M.D., Department of Radiology and Nuclear Medicine, Akita Research Institute of Brain and Blood Vessels, 6–10 Senshu-kubota-machi, Akita 010–0874, JAPAN.

E-mail: hito@akita-noken.go.jp

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of oxygenated blood in venous and capillary blood is the main contributor to BOLD contrast,[6,8] the venous plus capillary fraction of CBV is an important factor for the measurement of $CMRO_2$ by means of BOLD contrast with fMRI.[7–9]

^{15}O-labeled water ($H_2{}^{15}O$) is a tracer that can freely diffuse through the blood-brain barrier. After intravenous infusion of $H_2{}^{15}O$, the radioactivity concentration in the capillary and venous blood is same as that in the brain tissue,[10] but it differs from that in the arterial blood. The radioactivity concentration in the arterial blood can be differentiated on a regional time-activity curve by kinetic analysis with a two-compartment model that takes into account the contribution of radioactivity from the arterial blood in a region of interest. Such a two-compartment model has been used to calculate the blood flow and arterial blood volume in myocardium using $H_2{}^{15}O$.[11] Recently this two-compartment model has been applied to describe the regional time-activity curve of $H_2{}^{15}O$ in the brain.[3] With this model, the arterial blood volume in a brain region can be calculated from dynamic $H_2{}^{15}O$ PET data.

In the present study we estimated the arterial fraction of CBV by means of PET in the living human brain. Both $C^{15}O$ and $H_2{}^{15}O$ PET studies were performed in each of seven healthy subjects. The CBV and arterial blood volume were determined from $C^{15}O$ and $H_2{}^{15}O$ PET studies, respectively.

MATERIALS AND METHODS

Theory

The CBV (m*l*/m*l*) in a brain region is assumed to be the sum of the three components as follows.[1–3]

$$CBV = V_a + V_c + V_v \qquad \text{(Eq. 1)}$$

where V_a is the arterial blood volume (m*l*/m*l*), V_c is the capillary blood volume (m*l*/m*l*), V_v is the venous blood volume (m*l*/m*l*).

To describe the kinetics of $H_2{}^{15}O$ in the brain, the two-compartment model that takes V_a into account (V_a model, Fig. 1) is used. According to this model, the radioactivity concentration in a brain region can be expressed as follows.[3,11]

$$C_b(t) = K_1 \cdot C_a(t) \otimes e^{-k_2 \cdot t} + V_a \cdot C_a(t) \qquad \text{(Eq. 2)}$$

where $C_b(t)$ is the radioactivity concentration in a brain region, $C_a(t)$ is the radioactivity concentration in the arterial whole blood (arterial input function), K_1 is the influx rate constant (m*l*/m*l*/min) and k_2 is the efflux rate constant (min^{-1}). The influx rate constant K_1 corresponds to the cerebral blood flow (CBF). The K_1/k_2 ratio is defined as the distribution volume (V_d, m*l*/m*l*).

Subjects

The study was approved by the Ethics Committees of Akita Research Institute of Brain and Blood Vessels. Seven healthy volunteers including 4 men and 3 women (age range, 22–61 yr; average, 49.1 yr) were recruited and gave written informed consent. The subjects were determined to be healthy based on their medical history, physical examination, blood screening analysis and MRI of the brain.

PET procedure

The PET system used was Headtome V (Shimadzu Corp., Kyoto, Japan)[12] which provides 47 sections with a center to center distance of 3.125 mm. The intrinsic spatial resolution was 4.0 mm full width at half maximum (FWHM) in-plane and 4.3 mm FWHM axially. With a Butterworth filter, the reconstructed in-plane resolution was approximately 8 mm FWHM.

$C^{15}O$ study

To measure the CBV, a $C^{15}O$ PET study was performed.[5] The static PET scan was started 3 minutes after 1 minute of continuous inhalation of $C^{15}O$ gas (approximately 5 GBq by mouth). The scan time was 4 minutes. Three arterial blood samples were taken during PET scanning. The transmission scanning for attenuation correction was performed just before $C^{15}O$ PET scanning.

$H_2{}^{15}O$ study

After the $C^{15}O$ PET study, 360-second dynamic scanning was performed following continuous intravenous infusion of $H_2{}^{15}O$ over 2 minutes. The scan sequence consisted of six 5-sec frames, six 15-sec frames and eight 30-sec frames. The dose of radioactivity was 1.1 to 1.4 GBq at the start of the scanning. The arterial input function was obtained by continuous measurement of arterial whole blood radioactivity with a beta probe. Dispersion and delay occurring in the beta detector system and in the internal-arterial line were corrected according to the methods previously reported.[13,14] The dispersion was corrected by deconvolution with a single exponential function assuming the dispersion time constant to be 4 sec. The delay was corrected by means of a non-linear curve fitting to the time-activity data of the whole brain (gantry coincidence curve of PET scanner) with a single-tissue compartment model that takes the delay into account. Two blood samples were taken at the beginning and at the end of scanning to measure the arterial CO_2 gaseous pressure. A head fixation system with individual molds for each subject was used to minimize head movement over the period of the PET measurements.

Regions of interest

Regions of interest (ROIs) were drawn on the PET images. ROIs were defined for four neocortical regions representing the frontal, temporal, parietal, and occipital lobe. The ROIs were elliptical in shape with a short axis of 16 mm and long axis of 32 mm. Each ROI was drawn

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in three adjacent sections, and data were pooled to obtain the average radioactivity concentration for the whole volume of interest. To obtain regional time-activity curves, regional radioactivity was calculated for each frame, corrected for decay and plotted against the time.

Kinetic analysis

The two-compartment model that takes V_a into account (V_a model, Fig. 1) was used to describe the $H_2{}^{15}O$ time-activity curves for each region. The rate constants and V_a were estimated by non-linear curve fitting to the regional time-activity curves in a least-squares manner.[15] The model equation solved in the convolution integral procedure (Eq. 2) was used for this analysis. The two-compartment model assuming V_a to be zero (NoV_a model) which has widely been used to calculate CBF[16,17] was also used

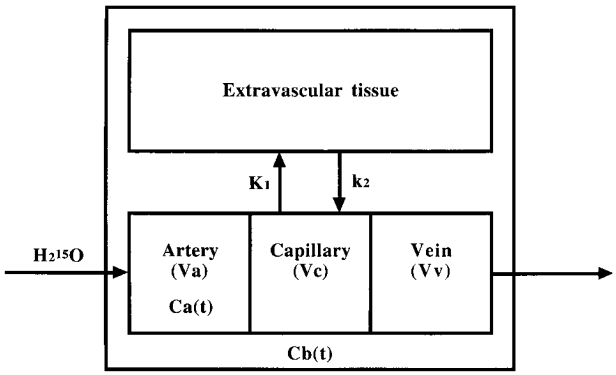

Fig. 1 Two-compartment model taking V_a into account (V_a model) to describe the kinetics of $H_2{}^{15}O$ in the brain.

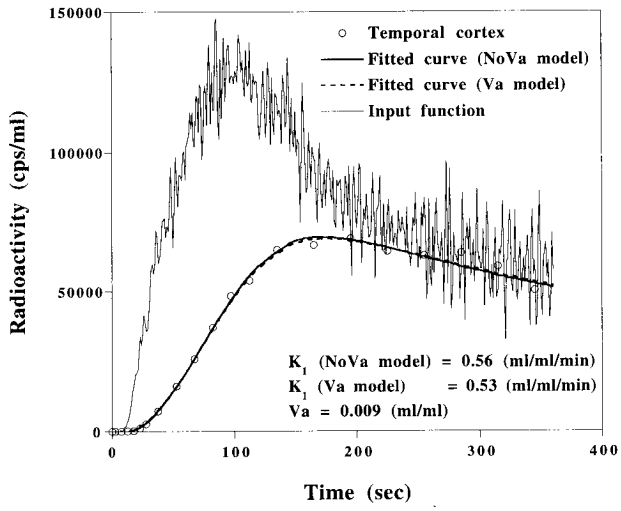

Fig. 2 Typical time-activity data for a cerebral cortical region and fitted curves in both the V_a and NoV_a model.

Table 1 The K_1, V_d and Akaike information criterion (AIC) values obtained by kinetic analyses for $H_2{}^{15}O$ PET

Region	NoV_a model			V_a model			
	K_1 (ml/ml/min)	V_d (ml/ml)	AIC	K_1 (ml/ml/min)	V_d (ml/ml)	AIC	V_a (ml/ml)
Frontal cortex	0.47 ± 0.10‡	0.74 ± 0.06	334 ± 12†	0.45 ± 0.10	0.74 ± 0.05	327 ± 8	0.009 ± 0.005
Temporal cortex	0.52 ± 0.06†	0.76 ± 0.06	341 ± 8†	0.48 ± 0.08	0.76 ± 0.05	333 ± 8	0.013 ± 0.007
Occipital cortex	0.51 ± 0.06†	0.74 ± 0.05	345 ± 12†	0.49 ± 0.06	0.74 ± 0.05	337 ± 13	0.009 ± 0.004
Parietal cortex	0.49 ± 0.08†	0.75 ± 0.03	338 ± 14‡	0.45 ± 0.09	0.75 ± 0.03	329 ± 12	0.014 ± 0.006
Cerebral cortices*	0.50 ± 0.07†	0.75 ± 0.04	340 ± 9†	0.47 ± 0.08	0.75 ± 0.03	332 ± 8	0.011 ± 0.004

Values are mean ± SD

*Average of frontal, temporal, occipital and parietal cortices

Significant difference in comparison to the V_a model (paired t-test): †$p < 0.01$, ‡$p < 0.05$

Table 2 The CBV, V_a, $V_v + V_c$ (= CBV − V_a) and arterial and venous plus capillary fraction of CBV (V_a/CBV, $V_v + V_c$/CBV)

Region	CBV (ml/ml)	V_a (ml/ml)	$V_v + V_c$ (ml/ml)	V_a/CBV	$(V_v + V_c)$/CBV
Frontal cortex	0.025 ± 0.004	0.009 ± 0.005	0.016 ± 0.006	0.37 ± 0.23	0.63 ± 0.23
Temporal cortex	0.032 ± 0.002	0.013 ± 0.007	0.019 ± 0.006	0.40 ± 0.21	0.60 ± 0.21
Occipital cortex	0.038 ± 0.006†§	0.009 ± 0.004	0.029 ± 0.005†§§	0.24 ± 0.10	0.76 ± 0.10
Parietal cortex	0.030 ± 0.003‡**	0.014 ± 0.006	0.016 ± 0.006**	0.47 ± 0.20	0.53 ± 0.20
Cerebral cortices*	0.031 ± 0.003	0.011 ± 0.004	0.020 ± 0.002	0.37 ± 0.11	0.63 ± 0.11

Values are mean ± SD

*Average of frontal, temporal, occipital and parietal cortices

Significant difference in comparison to the frontal cortex (paired t-test): †$p < 0.01$, ‡$p < 0.05$

Significant difference in comparison to the temporal cortex (paired t-test): §$p < 0.01$, §§$p < 0.05$

Significant difference in comparison to the occipital cortex (paired t-test): **$p < 0.01$

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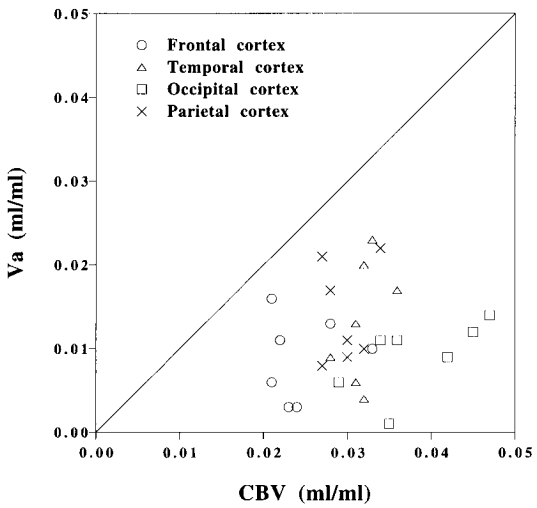

Fig. 3 The correlation between CBV and V_a.

to describe the time-activity curves. To compare the two models statistically, methods, the Akaike information criterion[18] and F-statistics[19] were used. Values are shown as mean ± SD.

RESULTS

Typical time-activity data for a cerebral cortical region and fitted curves determined by both the V_a and NoV_a models are shown in Figure 2. The regional time-activity data were well described by both models. The results of kinetic analyses for $H_2{}^{15}O$ PET are given in Table 1. The mean K_1 values obtained from the NoV_a model were significantly overestimated by 6% compared with those from the V_a model. The mean V_d values in the two models were identical. The Akaike information criteria (AIC) in the V_a model were significantly smaller than those in the NoV_a model, indicating the V_a model to be the preferred model. F-statistics also showed the V_a model to be preferred for each time-activity curve. Good correlation was observed in K_1 values was observed between the V_a and NoV_a models ($Y = 0.93X + 0.06$: X, V_a model; Y, NoV_a model; $r = 0.98$). The range of P_aCO_2 was 37.9 to 43.2 mm Hg for all subjects.

The CBV, V_a, and venous plus capillary blood volume ($V_v + V_c = CBV - V_a$, Eq. 1) values are given in Table 2. The average cerebral cortices CBV, V_a and $V_v + V_c$ were 0.031 ± 0.003 (m*l*/m*l*), 0.011 ± 0.004 (m*l*/m*l*) and 0.020 ± 0.002 (m*l*/m*l*), respectively. The arterial fraction of CBV (V_a/CBV) was 37 ± 11% that of the cerebral cortical average. The venous plus capillary fraction ($V_v + V_c$/CBV) was 63 ± 11%. The CBV value of the occipital cortex was significantly higher and the CBV value of the frontal cortex was significantly lower than the CBV value in the other regions. There were no significant differences between the regions in V_a values. No correlation between CBV and V_a was observed (Fig. 3).

DISCUSSION

Arterial fraction of cerebral blood volume

This is the first study to estimate the arterial fraction of CBV in the living human brain. The arterial fraction of CBV was 37% for the cerebral cortices (Table 2). This fraction was slightly greater than the arterial blood volume fraction for the systemic circulation of the whole body, which has been reported to be 20–30%.[20] In the measurement of $CMRO_2$ with a bolus inhalation of ^{15}O-labeled molecular oxygen ($^{15}O_2$) with PET, the arterial fraction of CBV is necessary for correction of intravascular radioactivity since the first-pass extraction fraction of $^{15}O_2$ is relatively high (about 40%).[2] According to the literature, the arterial fraction of CBV has been assumed to be 16% for this correction,[2] but this value was not for the brain. When an arterial fraction of 37% is used instead of 16%, the calculated $CMRO_2$ will be lowered. No correlation between CBV and V_a was observed (Fig. 3), indicating that V_a might be independent of CBV, but variations in V_a were larger than those of CBV since V_a is sensitive to statistical noise.

$H_2{}^{15}O$ is a tracer that can freely diffuse through the blood-brain barrier but, in fact, the capillary permeability-surface product of $H_2{}^{15}O$ is not infinite, indicating that the first-pass extraction fraction of $H_2{}^{15}O$ (E) is less than 1.[21,22] Since radioactivity in the capillary and vein become higher than that in the brain tissue when E is less than 1,[3] V_a is greater than the true intravascular volume of the artery. The V_a value obtained in the present study therefore includes a part of the intravascular volume of the capillary and vein. The true arterial fraction of CBV (X) is expressed with the first-pass extraction fraction of $H_2{}^{15}O$ (E) and estimated arterial fraction (37%) as follows:

$$X + (1 - X) \cdot (1 - E) = 0.37$$

Assuming E to be 0.9,[21,22] the true arterial fraction of CBV (X) will be 30%.

In the present study the small- to large-vessel hematocrit ratio was assumed to be 0.85, in order to calculate the CBV according to the method reported,[5] but this ratio has also been reported to be 0.69 as measured by PET in the human brain.[23] When the hematocrit ratio of 0.69 is used instead of 0.85, the CBV will become greater. The hematocrit ratio might not be uniform in the brain, and individual variation might exist. These may also cause errors in the determination of CBV. In addition, changes in cerebral hematocrit with cerebrovascular disease have been reported.[24]

Venous plus capillary fraction of cerebral blood volume

The venous plus capillary fraction of CBV was 63% for the cerebral cortices (Table 2). Considering limited first-pass extraction fraction of $H_2{}^{15}O$, the true venous plus capillary fraction of CBV is estimated to be about 70% as

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mentioned above. Since the capillary bed is smaller in volume than the noncapillary bed, this fraction represents mainly the venous fraction.[2,8] The measurement of $CMRO_2$ using BOLD contrast with fMRI has recently been reported.[7] Since the concentration of oxygenated blood in venous and capillary blood is the main contributor to BOLD contrast,[6,8] the venous plus capillary fraction of CBV is a important factor for the measurement of $CMRO_2$ using BOLD contrast with fMRI.[7–9] The estimated value of venous plus capillary fraction of CBV in the present study can be used for such a measurement.

Comparison of the V_a and NoV_a models

Although the regional time-activities were well described by both the V_a and NoV_a models (Fig. 2), the AICs in the V_a model were significantly smaller than those in the NoV_a model, indicating the V_a model to be the preferred model.[3] F-statistics also showed the V_a model to be preferred. The K_1 obtained from the NoV_a model was significantly overestimated by 6% compared with K_1 from the V_a model, whereas the V_d was identical in the two models (Table 1) but a good correlation in K_1 values was observed between the V_a and the NoV_a models. Since V_a was small, the overestimation of K_1 for the NoV_a model which has widely been used to calculate CBF[16,17] would be small.

CONCLUSION

The arterial fraction of CBV was 37%. Considering a limited first-pass extraction fraction of $H_2{}^{15}O$, the true arterial fraction of CBV is estimated to be about 30%. This fraction quite similar to that for the systemic circulation of the whole body but higher than that widely used for the correction of intravascular radioactivity in the measurement of $CMRO_2$ with $^{15}O_2$ and PET. The venous plus capillary fraction of CBV was 63–70% which is an important factor for the measurement of $CMRO_2$ using BOLD contrast with fMRI.

ACKNOWLEDGMENTS

The assistance of the members of the Akita Research Institute of Brain and Blood Vessels in performing the PET experiments is gratefully acknowledged.

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Animal Study Summary
Validation Study for Tissue Oxygenation with INVOS System

Objectives

An animal tissue study was performed in the research labs of the Miller School of Medicine at the University of Miami with principal investigator Marco Ricci, MD. The objectives of the study were:

- To evaluate the accuracy of the INVOS System as compared to co-oximetry of blood samples when used on tissues other than the brain
- To compare the performance of the INVOS System with the Hutchinson InSpectra device (K042020)
- To compare the performance of the INVOS adult and pediatric sensors in a homogeneous tissue model

Methods

Selective perfusion of the hind leg in a porcine model was used to create varying levels of blood oxygen saturation, blood flow and hematocrit in skeletal muscle tissue. Four young swine weighing 30-40 kg were used to create the model. Each pig was anesthetized, intubated and artificially ventilated and the right hind leg was surgically removed and selectively perfused via the femoral artery and vein using a roller pump, oxygenator and venous reservoir. Sensors from the INVOS System and the Hutchinson InSpectra were placed in various locations on the limb and readings were obtained and stored on floppy disk. Blood oxygenation was varied by adjusting the oxygen/nitrogen mixture going to the oxygenator. Readings were obtained over a range of 5% to 95% oxygen saturation at hemoglobin concentrations ranging from 6 to 12 g/dl. Blood flows were essentially constant at 200 ml/min, but were also varied between 60 to 300 ml/min. Blood samples were drawn from the arterial and venous circuits at the end of each oxygenation step and were analyzed on an IL-682 co-oximeter to determine SaO2 and SvO2. The INVOS readings at the time of each sample were then compared to these readings to determine absolute and trend accuracy.

Investigators

The study director was Pierluca Lombardi, MD, Postdoctoral Associate, Division of Cardiothoracic Surgery, University of Miami School of Medicine.
Additional Investigators were:

- Jennifer Zuccarelli, MS
- Mark Martin, CCP

None of the investigators has any interest in Somanetics Corporation.

IACUC Certification

The Investigational Animal Care and Use Committee of the University of Miami School of Medicine reviewed the study protocol number 05-185 and granted approval on August 11, 2005.

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Statistical Tests and Procedures
INVOS readings were compared to the estimate of field saturation in the limb (25% arterial saturation + 75% venous saturation) as was performed in earlier INVOS cerebral validation studies (K971628 and K001842). Field saturation is the saturation of blood in a region of tissue and is comprised of both arterial oxygen saturation and venous oxygen saturation combined in a ratio equal to the presumed blood volume ratio of the arterial and venous compartments. Comparisons were made between absolute readings and also transitions where values were changing over time and the change between steps was calculated for both the INVOS and blood samples. Pearson's correlation coefficient was used to determine the agreement, and bias and precision were calculated to quantify accuracy. A Bland-Altman plot was used to show agreement between the two measures.

Sample Description
Four pigs were reserved for the study. All four were anesthetized and had the right hind limb removed and selectively perfused. The first pig was subject to extensive bleeding which was exacerbated by a small volume of blood reserved from the pig for priming the pump. This kept the hemoglobin concentration below 6 g/dl for most of the study. Therefore this pig's data was not used in the final analysis.

Pigs two and three were successfully operated on and provided the data for the study. Sufficient blood was removed from the pig to prevent severe hemodilution in the pump circuit, and hemoglobin concentrations remained above 6.9 g/dl for both of the perfused limbs.

Pig four experienced extensive bleeding from the musculature at the hip during leg resection. In the process of cauterizing the bleeding vessels after limb removal, the leg was turned over several times and manipulated by the surgeon. At some time during this manipulation, the venous cannula became kinked, blocking venous outflow. Subsequently, the femoral vein clotted such that nothing could be done to improve venous flow. Even replacement of the venous cannula did not improve the situation and this pig was also rejected from the study.

Data exclusion
Other than the rejection of pigs 01 and 04 as described above, there were no problems with obtaining or analyzing blood samples on the co-oximeter. Two practice blood draws were performed on pig 03 before data storage was initiated due to suspected problems with the arterial-venous manifold connections. After replacing the manifold, an additional 13 samples were drawn.

Initial resection of the limb was performed with the pig in the supine position and incisions were made on the ventral abdomen along the flank fold. The adductor muscles were then separated and the incision made longer and deeper until the femoral artery and vein were located. Additional muscle and tissue resection continued until the limb was almost freed from the animal. Bleeding during this time was controlled as best as possible by vessel ligation and cautery, however, some blood was lost. Because of the position of the animal, this blood tended to drain downward into the space between the

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dorsal musculature and dermis. While most of this blood oozed out of the dorsal space once the limb was free, a thin layer remained.

This remaining blood was not part of the circulatory system and remained static during the study. Because there was little or no oxygen extraction, the saturation of this sequestered blood remained relatively constant or declined slowly. The near-infrared light had to pass through this layer of sequestered blood whose concentration was 100% unlike the concentration of blood in tissue, which ranges from 1-10%. Therefore, a portion of the total absorption of light was caused by the sequestered, unchanging blood. This resulted in a variable amount of interference with the NIRS signal depending on the thickness of the layer of blood, its inherent oxygen saturation, and how close to the incision site the sensors were placed. As stated in the precautions for the INVOS System, the sensor is not to be placed over pooled blood.

While no data has been excluded for this reason, the data from sensors placed on the lower limb (distal) away from the pooled blood is presented in a separate analysis. Data from all of the sensors is also presented to show machine linearity and repeatability. The distal sensors tracked blood oxygen saturation extremely well over a range of 5 to 93% saturation while the others show a reduced sensitivity to change, similar to the performance of the Hutchinson InSpectra on Pig 03, which was also placed near the surgical site. After becoming aware of this reduced sensitivity, more sensors were placed as far as possible from the incision site in Pig 03 as opposed to Pig 02.

Results

A total of 23 blood samples were drawn, including 10 in Pig 02 and 13 in Pig 03. All samples were analyzed successfully on the co-oximeter. All data on Pigs 02 and 03 was recorded successfully to disk drive and was available for analysis. The Hutchinson InSpectra serial number 0000005-2000 malfunctioned during the study of Pig 02 and was replaced with another unit, serial number 2002A01029 for the Pig 03 study. This unit appeared to function normally. Data was analyzed for individual sensors, as a group and also for the two sensors farthest from the bleeding site.

Individual Sensor Correlations

Individual sensor correlations with blood samples were excellent as shown in Table 1 and in the Study Data Appendix A8. Correlation r^2 ranged from 0.73 to 0.98 ($r = 0.85$ to 0.99) and r^2 averaged 0.93 ± 0.08 (mean ± SD). Slope ranged from 0.31 to 83 with the highest slopes found in the sensors farthest away from the pooled stagnant blood. The slopes for Pig 02 averaged 0.46 ± 0.25 while those for Pig 03 (where more sensors were placed farther from the incision) averaged 0.62 ± 0.14. The two sensors placed farthest from the incision had slopes that averaged 0.8 ± 0.05 illustrating the increased sensitivity when no pooled blood was present in the photon path.

Table 1: Descriptive data for individual sensors

	r^2	r	Slope	Intercept
Mean	0.93	0.96	0.54	20.66
Std Dev	0.08	0.05	0.20	8.80
Min	0.73	0.85	0.31	6.18
Max	0.98	0.99	0.83	30.60

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Absolute Accuracy

The absolute agreement between noninvasive spectroscopic measurements of skeletal muscle tissue blood oxygen saturation is shown in Figure 1. This represents two sensors placed farthest from the site of surgery and therefore with the least volume of pooled, stagnant blood. The data represents one pediatric sensor for Pig 02 and an adult sensor for Pig 03. Figure 2 depicts the agreement between the predicate device, the Hutchinson InSpectra and blood sample analysis from K963903 for comparison.

Figure 1: Absolute agreement, INVOS rSO2 vs. fSO2

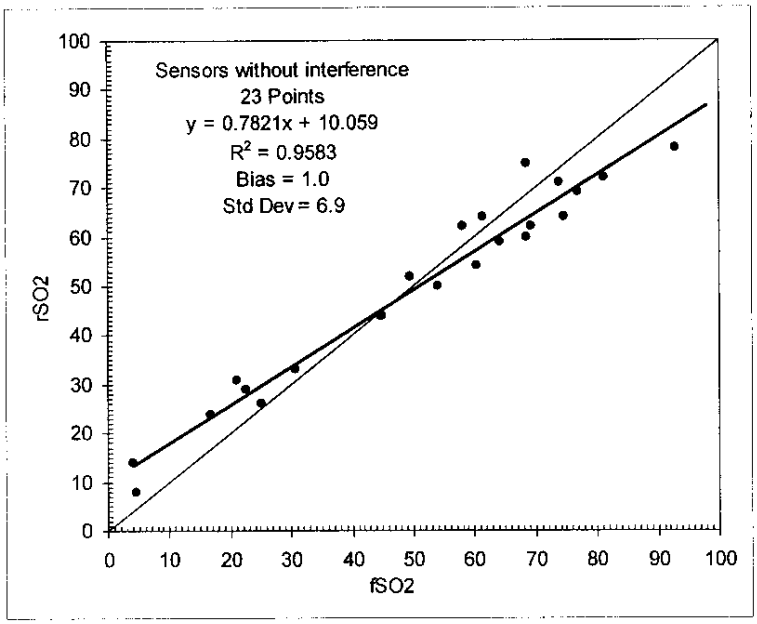
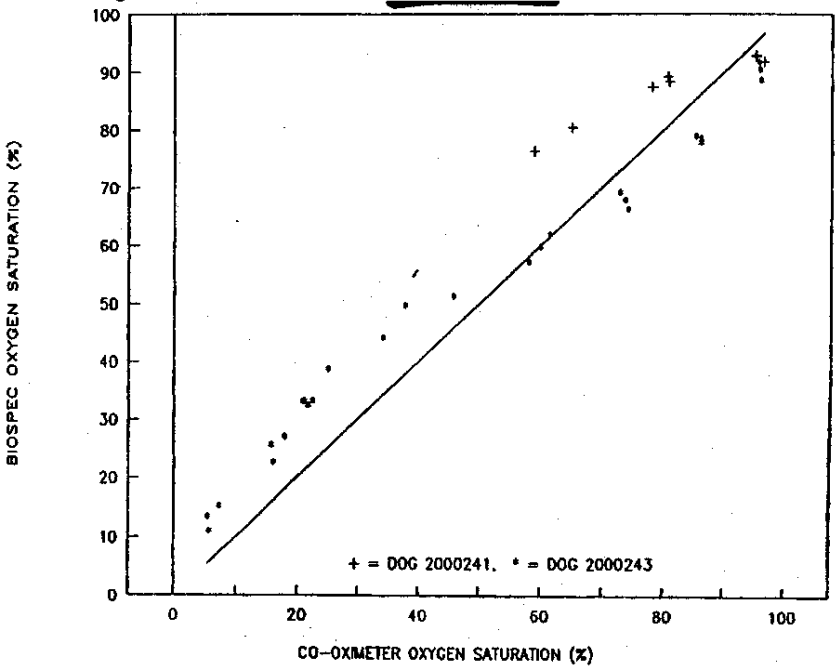


Figure 2: Absolute agreement, Hutchinson InSpectra vs. blood samples (from K963903)



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Bias was 1 and standard deviation was 6.9, which was superior to the predicate Hutchinson InSpectra at 3.4 and 8.0 (K963903).

Figure 3 depicts the absolute accuracy in a Bland-Altman graph of difference versus average. The mean bias is shown as a solid line while the two standard deviation limits are depicted as dashed lines on the graph. Transition accuracy is shown in Figure 5.

Figure 3: Bland-Altman graph of measurement differences versus averages

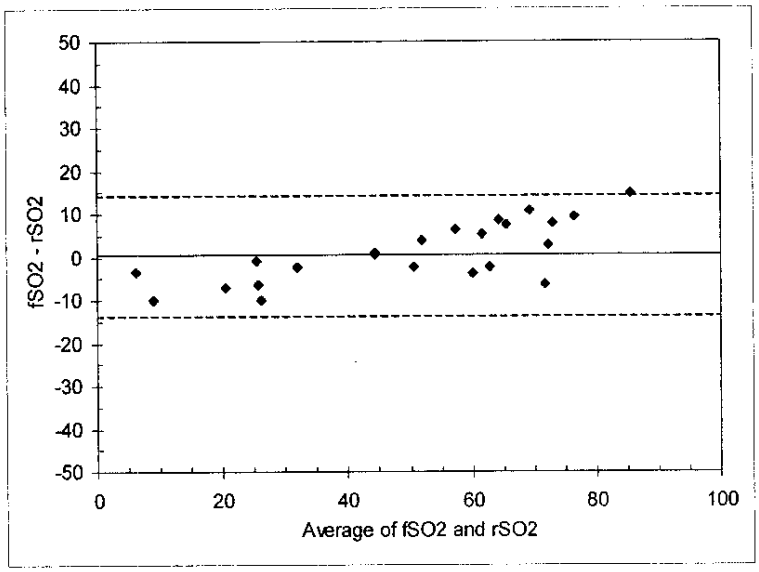
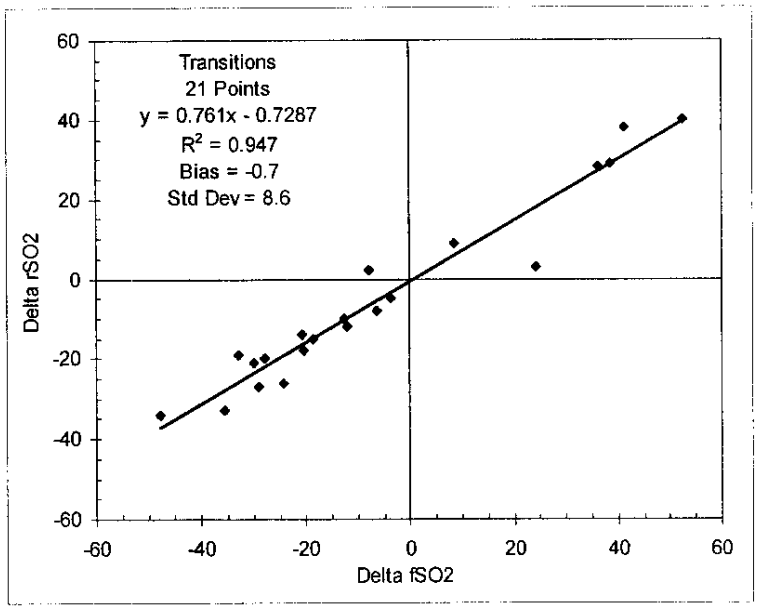


Figure 4: Transition accuracy, change in rSO2 versus change in fSO2



The transition accuracy is also presented in a Bland-Altman graph, Figure 5.

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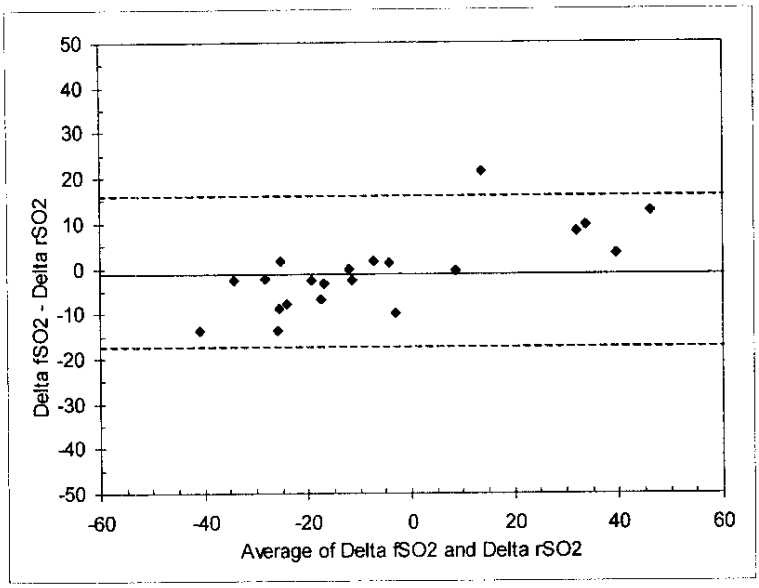
Figure 5: Bland-Altman graph of transition differences versus averages



Group Data

Pooled data from all sensors during all blood draws showing agreement between INVOS values and co-oximeter analyzed fSO2 is presented in Figure 6. This data is also presented in a Bland-Altman graph showing measurement differences versus average of the readings in Figure 7.

Figure 6: INVOS rSO2 values vs. Co-oximeter determined fSO2

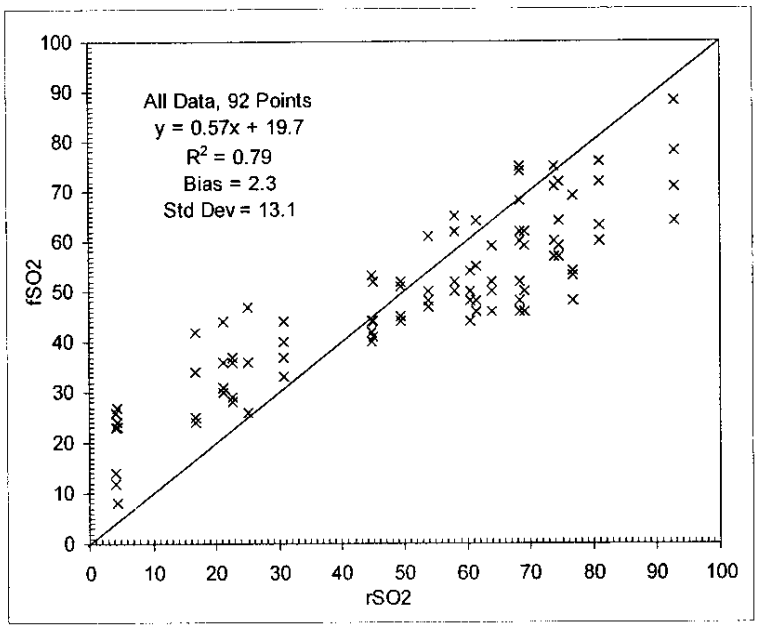


Figure 7: Bland-Altman graph of measurement differences vs. averages

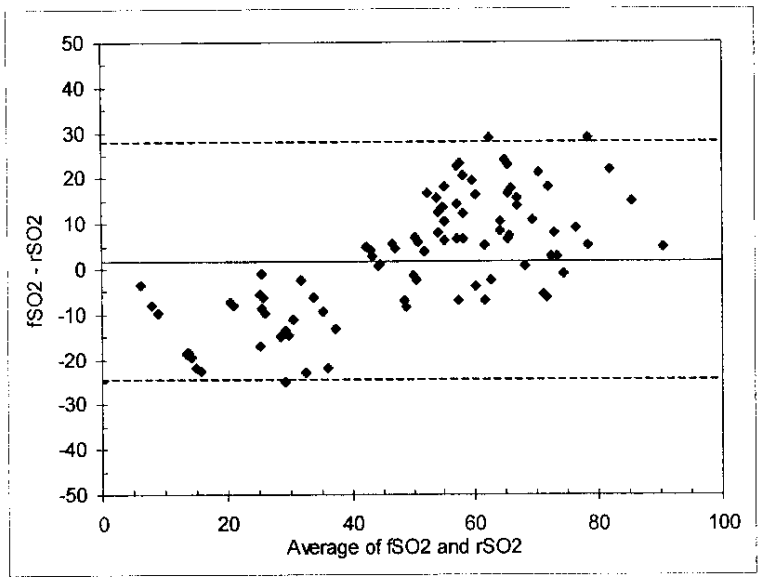


Figure 8 depicts the transition accuracy of all sensors during changes in oxygen saturation at each step of the study. This includes sensors where sensitivity to changes was blunted by the presence of pooled blood. Figure 9 depicts the same data in a Bland-Altman plot.

Figure 8: Transitions of rSO2 versus transitions of fSO2

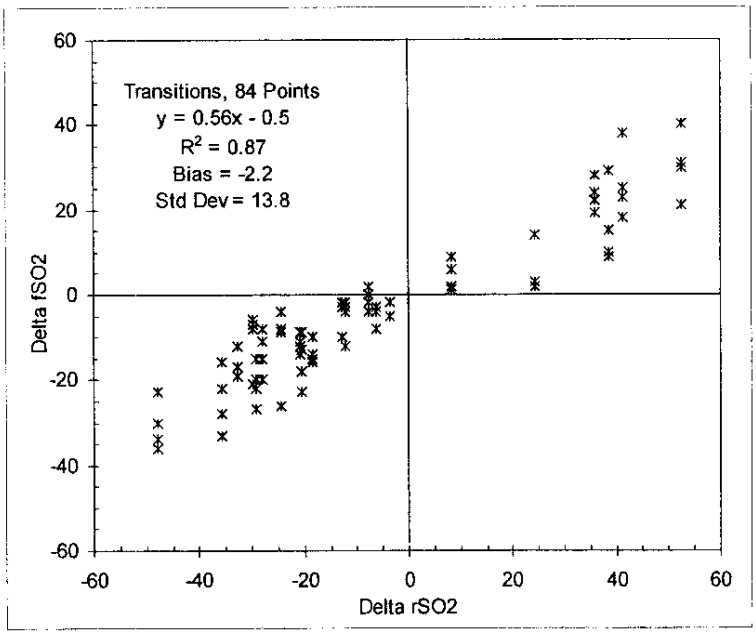
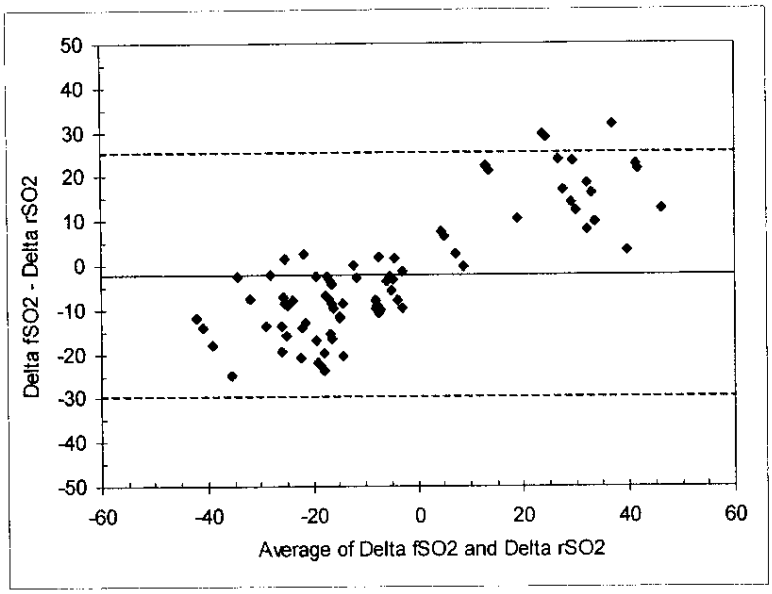


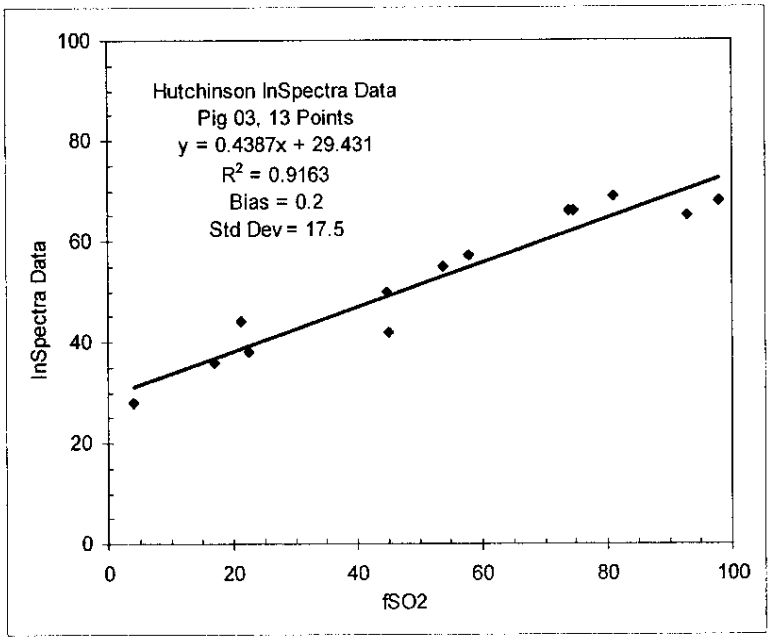
Figure 9: Bland-Altman graph of transition differences vs. averages



Comparison with Hutchinson InSpectra

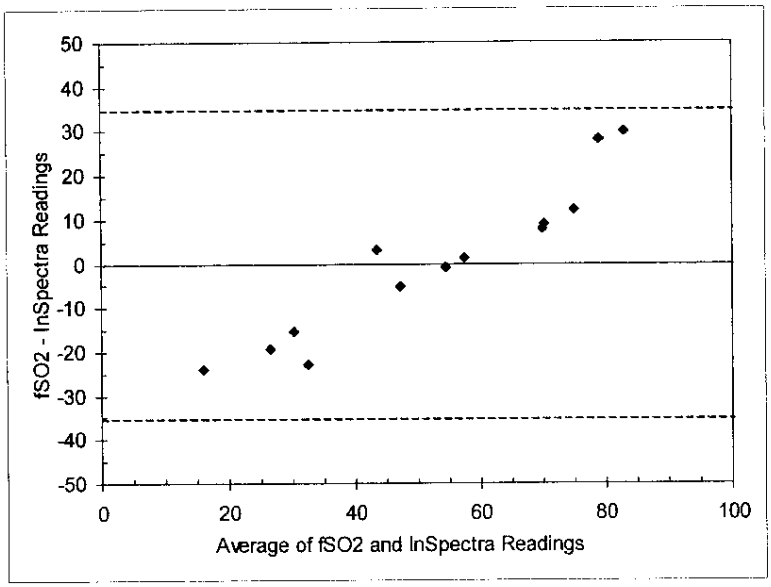
A Hutchinson InSpectra device with 25 mm probe was used to collect data during the study. The probe was placed on the flank of the limb close to an INVOS sensor for direct comparison. The device failed during the study of Pig 02 (S/N 0000005-2000) and was replaced with another unit, serial number 2002A01029 for Pig 03. Absolute accuracy data for the Pig 03 study is presented in Figure 10. It was also affected by the pooled blood close to the surgical site.

Figure 10: Absolute accuracy data from Pig 03, Hutchinson InSpectra data versus blood samples.



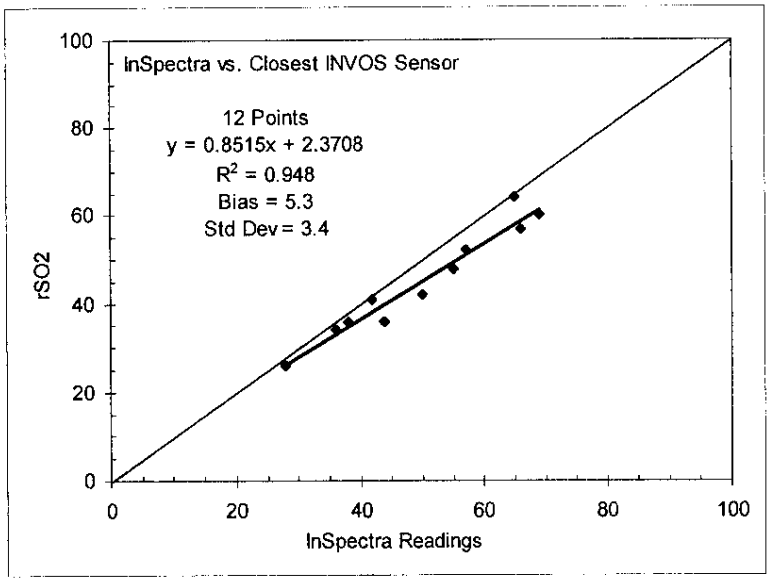
The data from Figure 10 is also plotted in a Bland-Altman graph, Figure 11.

Figure 12: Bland-Altman graph of InSpectra absolute agreement with blood samples



We assume the InSpectra was subject to the same effect of pooled blood as was seen by the INVOS System. Comparing the data from the InSpectra and the closest INVOS sensor, the agreement is quite strong, depicted in Figure 12, indicating that both devices were measuring the same phenomena.

Figure 12: InSpectra data versus the data from the closest INVOS sensor



Pediatric Versus Adult Sensors
Both pediatric and adult sensors were used on the perfused limbs of both animals. It was hypothesized that the differences in the algorithms used for the pediatric and adult sensors would be minimized when they are used on mostly homogeneous skeletal muscle tissue. Following analysis, this was found to be true.

Mean difference between adult and pediatric sensors placed close to each other was –1.76 ± 7.4 (mean ± SD). This bias difference would not be considered clinically significant when used on patients. Therefore, we assume that based on a homogeneous skeletal muscle tissue sample, the pediatric and adult sensors are interchangeable.

Discussion
The study involved selective perfusion of an isolated porcine limb while varying blood oxygen saturation over a wide range and comparing INVOS System readings with co-oximeter blood sample analysis. There were no technical issues with either of the INVOS Systems and both oximeters and all eight sensors worked perfectly during the study. While the first and last pig were rejected for technical reasons, all data from pigs 02 and 03 were collected and analyzed and are presented here.

Agreement between the distal sensors on each limb was excellent over a range of 5% to 93% blood oxygen saturation and a range of 7 to 9.9 g/dl Hb concentration. The correlation coefficient r^2 was 0.96 with a bias and SD of 1.0 and 6.9 respectively. This was superior to the Hutchinson InSpectra device study of isolated canine limbs (K963903) which demonstrated bias and SD of 3.4 and 8.0 respectively. Trend accuracy was also very good with a bias of –0.7 and SD of 8.6.

The distal sensors were chosen because they had the least amount of contamination caused by accumulated stagnant blood resulting from the limb resection. Even a thin layer of this blood at 100% concentration has a considerable effect on spectroscopic measurements of skeletal muscle tissue which has a blood concentration of only 1% to 10%.

Individual sensor correlations were also very strong, averaging an r^2 of 0.93 (0.08 SD) over all eight sensors. This strong agreement demonstrates good linearity and repeatability of the sensors and oximeter system.

While the predicate Hutchinson InSpectra device malfunctioned during the first limb experiment (Pig 02), a second unit appeared to function normally during the second experiment (Pig 03). In this second experiment, correlation between the InSpectra and the closest INVOS sensor was very strong, $r^2 = 0.92$ over 13 points and over a range of 5% to 93% blood oxygen saturation.

Additionally, no clinically significant differences were found between the adult and pediatric sensors and algorithms when used on relatively homogeneous skeletal muscle tissue. Sensors that were placed close to each other showed a high level of agreement with a mean bias of –1.76.

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Conclusions

Based on the study results, the INVOS System was able to measure changes in blood oxygen saturation in an isolated perfused porcine limb over a wide range of oxygen saturation when hemoglobin concentration was in the range typically encountered in patients. Performance during measurements of skeletal muscle tissue was very consistent across sensors and over time. When the sensors were located in areas of little or no blood contamination, agreement with blood samples analyzed on a co-oximeter was excellent with a bias of only one point and a standard deviation less than 7.

When the closest INVOS sensor was compared to the predicate Hutchinson InSpectra device, agreement was also excellent with a correlation r^2 of 0.92 (13 points) over a range of 5% to 93% blood oxygen saturation.

The performance of the adult and pediatric sensors and algorithms was comparable over both legs, over the entire range of blood oxygen saturation and with hemoglobin concentrations in a range that would be encountered in patients. Mean bias between the measurements was less than 2 points, an amount that would not be considered clinically significant. Therefore, the adult and pediatric sensors can be considered interchangeable for skeletal muscle tissue monitoring.

In conclusion, we have shown that the INVOS System performed in a manner that was substantially equivalent to the predicate INVOS 5100 used for cerebral monitoring and the Hutchinson InSpectra device. Results of the comparison against blood sample oxygen saturation in this study show that the INVOS System had a higher degree of accuracy when compared with the Hutchinson InSpectra device in their canine study described in K963903.

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K102715

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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter:	Nonin Medical, Inc.
Contact Person:	Lori M. Mitchell RN, BSN Clinical/Regulatory Specialist Nonin Medical, Inc. 13700 1st Ave. North Plymouth, MN 55441-5443
Date Prepared:	September 17, 2010
Trade Name:	Model 7600 Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA)
Classification Name: and Number:	Class II, 21 CFR 870.2700
Product Code:	MUD
Predicate Device(s):	Nonin's Model 7600 4-Channel Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA) are substantially equivalent to the Nonin Medical, Model 7600 Regional Oximeter System (K090807), CAS Medical, Fore-Sight® Cerebral Oximeter MC-2000 (K091452), Somanetics Corporation, INVOS® Model 5100B Adult/Pediatric Cerebral Oximeter (K051274).
Device Description:	Nonin's® Model 7600 4-Channel Regional Oximeter System with Equanox™ Technology and Bluetooth® Wireless Technology and compatible sensors (8004CA, 8000CA) continuously monitor and record the mixed arterial/venous blood oxygen levels through non-invasive near-infrared spectroscopy sensors. The system is comprised of three subsystems; sensor, patient oximetry device (pod) and 4-channel display unit.

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The sensor allows light absorption measurements at various wavelengths in the near-infrared spectrum (approximately 700 to 900 nanometers). The sensor is approximately 1.5 by 3 inches.

The sensors plug into the patient oximetry device (pod) which controls the light emitted from the sensor LEDs and measures the light returning to the sensor photodiodes. From these measurements, the pod determines specific absorption values and calculates the mixed arterial/venous oxygen saturation values. The pods then communicate the regional oxygen saturation readings and other data to the display unit.

The 4-channel display unit displays absolute real-time regional hemoglobin oxygen saturation (rSO_2) numeric data and trend lines. It is a battery-backed, mains powered device equipped with audio and visual alarm indicators. Real-time data and playback output is accomplished through a Bluetooth transceiver module.

Intended Use:

Model 7600 4-Channel Regional Oximeter System:

Nonin's non-invasive Model 7600 4-Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult or pediatric patients weighing greater than 88 pounds (>40 kilograms). It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Model 8004CA Regional Sensor:

The 8004CA Single-Patient use, Non-Sterile, Disposable Sensor is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (>40 kilograms). The sensor may be repositioned or replaced with another 8004CA sensor without baseline re-establishment. It is intended for use in environments including the operating

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room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Model 8000CA Regional Sensor:

The 8000CA Single-Patient use, Non-Sterile, Disposable Sensor is intended for use as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (>40 kilograms). The sensor may be repositioned or replaced with another 8000CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Functional and Safety Testing:

Nonin's Model 7600 4-Channel Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA) have successfully undergone extensive performance, electromagnetic, safety, clinical, environmental, and software testing to ensure that it has appropriate functional features and is substantially equivalent to the predicate devices.

Conclusion:

Nonin's Model 7600 4-Channel Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA) are substantially equivalent to the Nonin Medical, Model 7600 Regional Oximeter System (K090807), CAS Medical, Fore-Sight® Cerebral Oximeter MC-2000 (K091452), Somanetics Corporation, INVOS® Model 5100B Adult/Pediatric Cerebral Oximeter (K051274).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Lori M. Mitchell
Clinical/Regulatory Specialist
Nonin Medical, Incorporated
13700 1st Avenue North
Plymouth, Minneapolis 55441-5443

DEC 1 7 2010

Re: K102715
Trade/Device Name: Nonin Medical, Inc. Model 7600 4-Channel Regional Oximeter With Equanox™ Technology and Bluetooth® Wireless Technology and Compatible Regional Sensors (Models 8004CA and 80000CA)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: September 17, 2010
Received: September 20, 2010

Dear Ms. Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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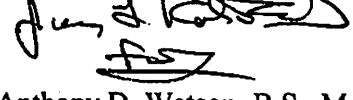
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(K) Number: K102715

Device Name:

Nonin Medical, Inc. Model 7600 4-Channel Regional Oximeter with Equanox™ Technology and Bluetooth® Wireless Technology and compatible Regional Sensors (Models 8004CA and 8000CA)

Indications for Use:

Model 7600 Regional Oximeter System:

Nonin's non-invasive Model 7600 4-Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult or pediatric patients weighing greater than 88 pounds (40 kilograms). It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Model 8004CA Regional Sensor:

The 8004CA Single-Patient use, Non-Sterile, Disposable Sensor is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (>40 kilograms). The sensor may be repositioned or replaced with another 8004CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Model 8000CA Regional Oximeter Sensor:

The 8000CA Single-Patient use, Non-Sterile, Disposable Sensor is intended for use as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood underneath the sensor of adult and pediatric patients weighing greater than 88 pounds (>40 kilograms). The sensor may be repositioned or replaced with another 8000CA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102715

Division Director

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Meta-Analysis in Clinical Trials*

Rebecca DerSimonian and Nan Laird

ABSTRACT: This paper examines eight published reviews each reporting results from several related trials. Each review pools the results from the relevant trials in order to evaluate the efficacy of a certain treatment for a specified medical condition. These reviews lack consistent assessment of homogeneity of treatment effect before pooling. We discuss a random effects approach to combining evidence from a series of experiments comparing two treatments. This approach incorporates the heterogeneity of effects in the analysis of the overall treatment efficacy. The model can be extended to include relevant covariates which would reduce the heterogeneity and allow for more specific therapeutic recommendations. We suggest a simple noniterative procedure for characterizing the distribution of treatment effects in a series of studies.

KEY WORDS: *random effects model, heterogeneity of treatment effects, distribution of treatment effects, covariate information*

INTRODUCTION

Meta-analysis is defined here as the statistical analysis of a collection of analytic results for the purpose of integrating the findings. Such analyses are becoming increasingly popular in medical research where information on efficacy of a treatment is available from a number of clinical studies with similar treatment protocols. If considered separately, any one study may be either too small or too limited in scope to come to unequivocable or generalizable conclusions about the effect of treatment. Combining the findings across such studies represents an attractive alternative to strengthen the evidence about the treatment efficacy.

The main difficulty in integrating the results from various studies stems from the sometimes diverse nature of the studies, both in terms of design and methods employed. Some are carefully controlled randomized experi-

Yale University, School of Medicine, New Haven, Connecticut (R.D.); Harvard University, School of Public Health, Boston, Massachusetts (N.L.)

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Address reprint request to: Rebecca DerSimonian, Yale University School of Medicine, P.O. Box 3333, New Haven, CT 06510.

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ments while others are less well controlled. Because of differing sample sizes and patient populations, each study has a different level of sampling error as well. Thus one problem in combining studies for integrative purposes is the assignment of weights that reflect the relative "value" of the information provided in a study. A more difficult issue in combining evidence is that one may be using incommensurable studies to answer the same question. Armitage [1] emphasizes the need for careful consideration of methods in drawing inferences from heterogeneous but logically related studies. In this setting, the use of a regression analysis to characterize differences in study outcomes may be more appropriate [2].

This paper discusses an approach to meta-analysis which addresses these two problems. In this approach, we assume that there is a distribution of treatment effects and utilize the observed effects from individual studies to estimate this distribution. The approach allows for treatment effects to vary across studies and provides an objective method for weighting that can be made progressively more general by incorporating study characteristics into the analysis. We illustrate the use of this model in several examples, and based on the empirical evidence, suggest a simple noniterative procedure for testing and estimation.

DATABASE

In a systematic search of the first ten issues published in 1982 of each of four weekly journals (*NEJM, JAMA, BMJ,* and *Lancet*), Halvorsen [3] found only one article (out of 589) that considered combining results using formal statistical methods. Our data consist of an ad hoc collection of such articles from the medical literature found through references provided by colleagues and through bibliographic references in articles already located [4–11]. The method we propose applies to several additional articles that have come to our attention since our original analyses [12–14].

We examine in detail eight review articles each reporting results from several related trials. Each review pools the results from the relevant trials in order to evaluate the efficacy of a certain treatment for a specified medical condition. In most of these reviews the original investigators pool the results from the relevant trials and estimate an overall treatment effect without first checking whether the treatment effect across the trials is constant. Others exclude some trials and combine the results only from trials that are similar in design and implementation. The investigators who do check for homogeneity of treatment effect before pooling use different criteria to assess this homogeneity. With two exceptions [6,11], the reviews consider randomized trials only. The two reviews that include nonrandomized studies analyze the data from the two groups of studies (randomized and nonrandomized) separately. In this study, we restrict our attention to the results of randomized trials only. We first describe the eight reviews identifying each by its first author, and in Table 1 summarize the methods used in each review:

Winship: A review of eight trials that compare the healing rates in duodenal ulcer patients treated with cimetidine or placebo therapy [4].

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Table 1 The Methods and Outcome Measures Used in the Original Reviews

	Outcome measure	Overall effect estimate	Test of homogeneity
Winship	difference in proportions	pooled raw data	———
Conn	difference in proportions	pooled raw data	———
Miao	difference in proportions	weighted average	Chi-Square Test (Q_w)
DeSilva	relative risk	Mantel–Haenszel estimate for pooled relative risk	———
Stjernsward	difference in proportions	minimum and maximum	———
Baum	difference in proportions	pooled raw data	Gilbert, McPeek, and Mosteller estimate of variance [15]
Peto	difference in proportions	———	Mentions lack of heterogeneity
Chalmers	difference in proportions	unweighted average	———

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Conn: A review of nine trials that compare the survival rates in alcoholic hepatitis patients with steroids or control therapy [5].

Miao: A review of six trials that compare gastric with sham freezing in the treatment of duodenal ulcer [6]. In addition, this review considers 14 observational and two controlled but nonrandomized studies.

DeSilva: A review of six trials that evaluate the effect of lignocaine on the incidence of ventricular fibrillation in acute myocardial infarction [7]. This study originally considered 15 trials but because the trials vary widely in treatment schedules and doses, some criteria for adequacy of treatment are established and only six trials that fulfill these requirements are analyzed.

Stjernsward: A review of five trials that compare the 5-year survival rates of patients with cancer of the breast treated with surgery plus radiotherapy or surgery alone [8].

Baum: A review of 26 trials that evaluate the efficacy of antibiotics in the prevention of wound infection following colon surgery [9].

Peto: A review of six trials that evaluate the efficacy of aspirin in the prevention of secondary mortality in persons recovered from myocardial infarction [10].

Chalmers: A review of a number of trials that evaluate the efficacy of anticoagulants in the treatment of acute myocardial infarction [11]. Data from 18 surveys employing historical controls (HCT), eight studies employing alternately assigned controls (ACT), and six randomized controlled trials (RCT) are given. Three endpoints, total case fatality rates, case fatality rates excluding early deaths, and thromboembolism rates are considered, although not all studies report all three endpoints. Here we consider thromboembolism and total case fatality rates in the RCTs only. The results from randomized trials are compared to those of nonrandomized ones (HCTs and ACTs) in Laird and DerSimonian [16].

METHODS

We consider the problem of combining information from a series of k comparative clinical trials, where the data from each trial consist of the number of patients in treatment and control groups, n_T and n_C, and the proportion of patients with some event in each of the groups, r_T and r_C. Letting i index the trials, we assume that the numbers of patients with the event in each of the study groups are independent binomial random variables with associated probabilities p_{Ti} and p_{Ci}, $i = 1, \ldots, k$. The basic idea of the random effects approach is to parcel out some measure of the observed treatment effect in each study, say y_i, into two additive components: the true treatment effect, θ_i, and the sampling error, e_i. The variance of e_i is the sample variance, s_i^2, and is usually calculated from the data of the ith observed sample. The true treatment effect associated with each trial will be influenced by several factors, including patient characteristics as well as design and execution of the study. To explicitly account for the variation in the true effects, the model assumes

$$\theta_i = \mu + \delta_i$$

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where θ_i is the true treatment effect in the ith study, μ is the mean effect for a population of possible treatment evaluations, and δ_i is the deviation of the ith study's effect from the population mean. We regard the trials considered as a sample from this population and use the observed effects to estimate μ as well as the population variance [$\mathrm{var}(\delta) = \Delta^2$]. Here, Δ^2 represents both the degree to which treatment effects vary across experiments as well as the degree to which individual studies give biased assessments of treatment effects.

The model just described can thus be characterized by two distinct sampling stages. First we sample a study from a population of possible studies with mean treatment effect μ and variance in treatment effects of Δ^2. Then we sample observations in the ith study with underlying treatment effect θ_i.

One issue which deserves some attention is the specification of treatment effect, θ_i. Three commonly used measures are the risk difference, $p_{Ti} - p_{Ci}$, the relative risk, p_{Ti}/p_{Ci}, and the relative odds, $[p_{Ti}/(1 - p_{Ti})/p_{Ci}/(1 - p_{Ci})]$. The relative odds is popular because of its suitability in retrospective or case control studies, and because it has some interesting mathematical properties. In particular, if we assume a constant relative odds ($\theta_i = \mu$ or $\Delta^2 = 0$), then the Mantel–Haenszel statistic is optimal for testing H_0: $\mu = 1$, and there is considerable literature on efficient estimates of μ and on methods for testing H_0: $\theta_1 = \theta_2 = \ldots = \theta_k$. Despite these advantages, the relative odds (and the closely related relative risk) suffers in interpretability. By far the most intuitively appealing measure for trials of clinical efficacy is the risk difference, since it measures actual gains which can be expected in terms of percentages of patients treated. Besides relevance of the measure and statistical efficiency, it is also desirable to choose a measure which is nearly constant over studies, so that the effect of heterogeneity is minimized. Unless there is no treatment effect at all ($p_{Ti} = p_{Ci}$ for all i), constancy of treatment effect in one scale (say $p_{Ti}/p_{Ci} = A$ for all i) implies variation across studies in another ($p_{Ti} - p_{Ci}$, say). Thus it is conceivable that the wrong choice of scale could imply heterogeneity in treatment effects which would not exist if a different measure were used. However, this is not likely to happen in practice unless there is a very wide range in the control rates (p_{Ci}) or all the rates are very close to zero (or one). In such cases, one might want to do the analysis in both the relative odds and risk difference scales.

HOMOGENEITY OF TREATMENT EFFECT

To evaluate constancy of treatment effect across strata, we use a large sample test based on the statistic $Q = \sum_i w_i(y_i - \bar{y}_w)^2$, where y_i is the ith treatment effect estimate, $\bar{y}_w = \sum_i w_i y_i / \sum_i w_i$ is the weighted estimator of treatment effect, and w_i is the inverse of the ith sampling variance. The test statistic Q is the sum of squares of the treatment effect about the mean where the ith square is weighted by the reciprocal of the estimated variance. Under the null hypothesis, Q is approximately a χ^2 statistic with $k - 1$ degrees of freedom; thus, when each study has a large sample size relative to the number of strata, Q may be used to test H_0: $\Delta^2 = 0$.

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When y_i is a difference in proportions, $r_{Ti} - r_{Ci}$, we estimate the sampling variance in the ith study, s_i^2, by

$$s_i^2 = r_{Ti}(1 - r_{Ti})/n_{Ti} + r_{Ci}(1 - r_{Ci})/n_{Ci}, \tag{1}$$

and use $Q_w = \sum_i w_i(y_i - \bar{y}_w)^2$ to test constancy of treatment effect.

The weights in Q may vary according to the assumptions made about the sampling variances. For instance, when the sampling variances can be assumed to be equal, then w_i, $i = 1, \ldots, k$, is the inverse of a common sampling variance s^2. One review [9], which includes a qualitative assessment of homogeneity of treatment effect, uses the method of Gilbert et al. [15] to estimate the magnitude of the variation across the differences in proportions. Since the method of Gilbert et al. for estimating the variation in treatment effects assumes a common sampling variance, we calculate Q_u, the analogue of Q_w, assuming equal sampling variances. Here, the treatment effect is again the difference in proportions, but

$$w_i = s^{-2}, \qquad i = 1, \ldots, k,$$

where

$$s^2 = \sum_i s_i^2/k,$$

and s_i^2 is defined in equation (1).

We also use the Q statistic for testing homogeneity in the relative odds scale. In this scale,

$$Q_L = \sum_i w_i (y_i - \bar{y}_w)^2$$

where

$$y_i = \ln [r_{Ti}(1 - r_{Ci}) / r_{Ci}(1 - r_{Ti})],$$

$$w_i = s_i^{-2}, \qquad \bar{y}_w = \sum_i w_i y_i / \sum_i w_i,$$

and

$$s_i^2 = [n_{Ti} r_{Ti}(1 - r_{Ti})]^{-1} + [n_{Ci} r_{Ci}(1 - r_{Ci})]^{-1}.$$

In the large sample case, Q_L is analogous to the goodness-of-fit test in logistic models [17]. An alternate test statistic for assessing homogeneity is the likelihood ratio test which is computationally more cumbersome than the Q statistic used here [18].

ESTIMATION AND COMPUTATION

Most of the reviews consider the differences in proportions as a measure of treatment effect (Table 1). For estimating μ and Δ^2 we also restrict our attention to this scale.

When $\Delta^2 \neq 0$, Q_w is used to derive a noniterative estimate of Δ^2 by equating the sample statistic with the corresponding expected value. This yields a weighted estimator

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$$\Delta_w^2 = \max\{0, \{Q_w - (k-1)\} / [\sum_i w_i - (\sum_i w_i^2 / \sum_i w_i)]\},$$

where Q_w, $\bar{y}_w$, w_i are as described above. The weighted least squares or Cochran's [19] semiweighted estimator of μ is

$$\mu_w = \sum_i w_i^* y_i / \sum_i w_i^*, \tag{2}$$

where

$$w_i^* = (w_i^{-1} + \Delta_w^2)^{-1}. \tag{3}$$

The asymptotic standard error of μ_w is

$$\text{s.e.}(\mu_w) = (\sum_i w_i^*)^{-1/2}. \tag{4}$$

When the sampling variances are assumed to be equal, these equations reduce to:

$$\Delta_u^2 = \max[0, \{\sum_i (y_i - \bar{y})^2 / (k-1)\} - s^2],$$

$$\mu_u = \bar{y},$$

and

$$\text{s.e.}(\mu_u) = [(s^2 + \Delta_u^2) / k]^{1/2},$$

where

$$\bar{y} = \sum_i y_i / k \quad \text{and} \quad s^2 = \sum_i s_i^2 / k.$$

Rao et al. [20] derive Δ_u^2 from an unweighted sum of squares procedure and show that it is also the Minque estimator when the sampling variances are all equal. The unweighted mean, μ_u, is equivalent to the estimate of the treatment effect in reviews that use the average difference in proportions to assess the overall treatment efficacy.

With an additional assumption that y_i is $N(\theta_i, s_i^2)$ and θ_i is $N(\mu, \Delta^2)$, we also compute maximum likelihood (ML) and restricted maximum likelihood (REML) estimates and compare them to the noniterative ones. The maximum likelihood estimates of the unknown parameters are those values that maximize the probability density function of the data. In REML estimation, the likelihood to be maximized is slightly modified to adjust for μ and Δ^2 being estimated from the same data. The REML estimators are the iterative equivalents of the weighted estimators above. Both ML and REML estimates of μ and its s.e. take the form given in equations (2) and (4) with weights given in (3), but differ in the way Δ^2 is estimated.

The ML estimating equations are given in Rao et al. [20] and the REML equations are reviewed by Harville [21]. For implementing the ML or REML procedures, we use the EM algorithm [22] which is an iterative procedure for computing maximum likelihood estimates appropriate when the observations can be viewed as incomplete data.

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RESULTS

Homogeneity of Treatment Effect

We present the statistics for testing homogeneity of treatment effect in Table 2. For these reviews Q_w, the weighted statistic in the difference scale, and Q_L, the analogous statistic in the log odds scale, imply similar conclusions about the constancy of treatment effect. The assumption of homogeneity holds in the reviews by DeSilva [7], Stjernsward [8], Peto [10], and in Chalmers' [11] randomized controlled trials (case fatality rates). In the remaining five sets of trials, the evidence suggests heterogeneity of treatment effect irrespective of the scale of measurement.

The review by Peto [10] mentions lack of heterogeneity in treatment effects across trials. For this review, the Q_u statistic supports the homogeneity assumption (p value = 0.65), whereas both Q_w and Q_L support that assumption only marginally (p value = 0.12). Baum et al. [9] estimate the variability in treatment differences using the method of Gilbert et al. [15] and conclude that relative to within study variation (assumed equal for all studies), between study variation is negligible. This qualitative assessment is not consistent with the results of Table 2 where a common treatment effect across the trials in this review does not seem to hold in either scale of measurement. The third review which includes a test of homogeneity before pooling the results [6] uses a slightly modified version of Q_w to test this hypothesis and the conclusion of lack of homogeneity agrees with the result in Table 2.

As in the review by Peto [10], Q_u and Q_w imply different conclusions about the homogeneity of treatment effect in the review by Winship [4]. In this review also, the method assuming equal weights (Q_u) implies homogeneity of effect while the weighted one implies the opposite.

These results emphasize that the variation in the treatment effect across several trials is often not negligible and should be incorporated into the anal-

Table 2 Test of Homogeneity[a]

	df[c]	Q_w[d]	Q_L[e]	Q_u[f]
Winship	7	15.2[b]	15.6[b]	7.9
Conn	8	15.6[b]	20.6[b]	19.3[b]
Miao	5	21.7[b]	18.8[b]	20.9[b]
DeSilva	5	9.1	4.4	7.3
Stjernsward	4	2.1	2.2	2.7
Baum	25	40.4[b]	35.2[b]	35.3[b]
Peto	5	9.0	9.2	3.5
Chalmers				
Thromboembolism	5	12.3[b]	10.3[b]	10.6[b]
Case fatality rates	5	3.5	2.4	1.8

[a]Figures in Tables 2–4 are based on data available at the time of review publication.

[b]p value <0.10.

[c]Degrees of freedom.

[d]Q statistic in difference scale (unequal weights).

[e]Q statistic in log odds scale (unequal weights).

[f]Q statistic in difference scale (equal weights).

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ysis of the overall treatment efficacy. Lack of homogeneity holds both when the treatment effect is the difference in proportions and when it is the log odds. The unweighted statistic which assigns an equal weight to each study may not be appropriate for testing homogeneity when differences in sample sizes and/or underlying proportions across studies are large.

Estimation

For all four methods of estimation we present estimates of μ and its s.e. in Table 3, and estimates of Δ^2 in Table 4. The estimates of Δ^2, and s.e. ($\hat{\mu}$) are quite similar in the weighted noniterative method, maximum likelihood, and restricted maximum likelihood procedures. The Δ^2s from these three methods are zero or nearly so in the reviews by DeSilva [7], Stjernsward [8], Peto [10], and Chalmers' [11] randomized trials (case fatality rates). These same reviews have Q statistics that are small relative to their degrees of freedom (Table 2). The weighted method and the REML estimation procedures consistently yield slightly higher values of Δ^2 than the ML procedure. This is because both these procedures adjust for μ and Δ^2 being estimated from the same data whereas the ML procedure does not. The estimates of μ and its s.e. from these three procedures are expected to be similar since the estimates of Δ^2 are almost equal.

Comparing the unweighted method of moments with the other three methods, we find that the estimates for Δ^2 from this method differ, and sometimes differ widely, from the estimates of the other three methods but without any consistent pattern. The estimates of μ and its s.e. from the unweighted method also differ from the estimates of the other three methods and these differences are not necessarily due to the differences in Δ^2s. In Chalmers' [11] randomized trials (case fatality rates), for instance, even when Δ^2 is zero for all four methods, the estimate of μ is 0.042 (s.e. = 0.024) for the unweighted method while it is 0.029 (s.e. = 0.012) for the other three methods. The original reviewers report the unweighted average of the observed rate differences

Table 3 Estimated Overall Effects and Their Standard Errors[a]

	μ_u[b]	μ_w[c]	μ_M[d]	μ_R[e]
Winship	0.406 (0.046)	0.389 (0.058)	0.384 (0.053)	0.387 (0.056)
Conn	0.102 (0.092)	0.075 (0.072)	0.070 (0.063)	0.073 (0.069)
Miao	0.077 (0.125)	0.094 (0.111)	0.095 (0.106)	0.093 (0.118)
DeSilva	0.026 (0.019)	0.027 (0.019)	0.026 (0.017)	0.027 (0.019)
Stjernsward	0.046 (0.020)	0.041 (0.018)	0.041 (0.018)	0.041 (0.018)
Baum	0.203 (0.031)	0.208 (0.026)	0.208 (0.025)	0.208 (0.026)
Peto	0.018 (0.008)	0.015 (0.008)	0.014 (0.008)	0.015 (0.008)
Chalmers				
Thromboembolism	0.102 (0.036)	0.079 (0.020)	0.078 (0.017)	0.078 (0.020)
Case fatality rates	0.042 (0.024)	0.029 (0.012)	0.029 (0.012)	0.029 (0.012)

[a]Figures in parentheses represent the standard errors of the corresponding estimates.

[b]Noniterative estimates with equal weights.

[c]Noniterative estimates with weights to reflect unequal variances.

[d]Maximum likelihood estimates.

[e]Restricted maximum likelihood estimates.

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Table 4 Estimated Variation in the True Effects

	Δ_u^{2a}	Δ_w^{2b}	Δ_M^{2c}	Δ_R^{2d}
Winship	0.0020	0.0137	0.0096	0.0117
Conn	0.0442	0.0208	0.0112	0.0176
Miao	0.0716	0.0540	0.0482	0.0638
DeSilva	0.0007	0.0009	0.0006	0.0009
Stjernsward	0	0	0	0
Baum	0.0072	0.0062	0.0049	0.0057
Peto	0	0.0002	0.0002	0.0002
Chalmers				
Thromboembolism	0.0041	0.0012	0.0007	0.0012
Case fatality rates	0	0	0	0

[a]Noniterative estimates with equal weights.

[b]Noniterative estimates with weights to reflect unequal variances.

[c]Maximum likelihood estimates.

[d]Restricted maximum likelihood estimates.

(0.042) as an estimate of overall treatment efficacy. The weighted estimate of the treatment effect which weights the observed effects in relation to sample size is lower than the unweighted average, since some of the larger studies have smaller estimated treatment effects.

DISCUSSION

We have used a simple random effects model for combining evidence, and applied it to characterize the distribution of treatment effects in a series of studies. The model is useful both in summarizing the data and in illustrating the different kinds of results which one obtains from randomized and nonrandomized studies. In general, studies with greater potential for bias, such as uncontrolled or nonrandomized ones, show greater treatment effect as well as greater heterogeneity [2,16].

One important finding that emerges from this investigation is that heterogeneity of treatment effects across studies is common and should be incorporated into the analysis. The random effects model incorporates this heterogeneity, however small, in the analysis of the overall efficacy of the treatment. The method estimates the magnitude of the heterogeneity, and assigns a greater variability to the estimate of overall treatment effect to account for this heterogeneity. In principle, we can extend the model to include pertinent covariate information [2]. Utilizing covariate information may substantially reduce the heterogeneity of effects and thus allow for more specific therapeutic recommendations. This is often difficult in practice, however, since covariate information may be missing for some studies. Improvement in publication standards for medical reporting and further methodological work for handling missing covariate information are needed to strengthen our ability to combine results from clinical studies.

For estimating the overall treatment effect and the variation of effects across studies, our results suggest that the weighted noniterative method is an attractive procedure because of the comparability of its estimates with those of the maximum likelihood methods and because of its relative simplicity. On

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the other hand, the unweighted method which ignores differences in sample sizes yields estimates that often differ from the estimates of the other methods.

A problem in pooling data we have not addressed here is that of publication bias. This problem relates to studies being executed, but not reported, usually because treatment effect has not been found. Reviewers generally recount those studies that appear to be worthwhile and discount those that are unpublished or are not in agreement with a favored group of studies. The method we describe here represents a systematic, quantitative pooling of available data to resolve controversies about a treatment effect. With each individual controversy, unpublished information may be elicited and along with recent findings the method can be used to update the results.

In all our work we assume that the sampling variances are known, although in reality we estimate them from the data. Further research needs to be done in this area as there are alternative estimators that might be preferable to the ones we use. For instance, if the sample sizes in each study are small, then sampling variances based on pooled estimates of the proportions in the treatment and control groups might be better than the ones based on estimates of proportions from the individual studies. Another alternative is to shrink the individual proportions towards a pooled estimate before calculating the variances. Further investigation is needed before one single method emerges as superior.

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ESTIMATION OF THE LINEAR RELATIONSHIP BETWEEN THE MEASUREMENTS OF TWO METHODS WITH PROPORTIONAL ERRORS

KRISTIAN LINNET

The Department of Clinical Chemistry, KK 7642, Rigshospitalet, University of Copenhagen, Blegdamsvej 9, DK-2100 Copenhagen, Denmark

SUMMARY

The linear relationship between the measurements of two methods is estimated on the basis of a weighted errors-in-variables regression model that takes into account a proportional relationship between standard deviations of error distributions and true variable levels. Weights are estimated by an iterative procedure. As shown by simulations, the regression procedure yields practically unbiased slope estimates in realistic situations. Standard errors of slope and location difference estimates are derived by the jackknife principle. For illustration, the linear relationship is estimated between the measurements of two albumin methods with proportional errors.

INTRODUCTION

When the measurements of the same compound using two different methods are to be compared, it is commonplace to estimate a linear relationship between the measurements. If the slope of the line deviates significantly from unity, a proportional systematic error exists between the measurements of the two methods. A systematic proportional error may arise if the concentrations of the calibrator of one of the methods deviate by a common factor from those of the other method. A constant systematic error is present if the line does not pass through the origin (0, 0). For example, such an error may be caused by insufficient background correction in photometry or counts of radioactivity for one of the methods. Various statistical methods are available for estimation of a linear relationship.[1–3] A review of method comparison studies published in '*Clinical Chemistry*' over the first three months of 1988 revealed that ordinary least-squares regression analysis was used in 46 out of 50 cases. Deming's procedure[4] was applied in the remaining studies. Ordinary least-squares regression analysis presupposes that one of the methods is without random measurement error, and that the standard deviation of the error distribution of the other method is constant throughout the measurement range.[1] These assumptions are almost never fulfilled, because both methods are usually subject to random measurement errors, and the standard deviations of the error distributions are more likely to be proportional to the variable level than constant.[5,6] Violation of the first assumption causes a downwards bias of the slope estimate, the magnitude of which depends on the relation between the dispersion of the errors and the dispersion of the true values of the variables. In practice, the problem is more acute when the dispersion of the true values of the variables is small. Table I displays the ranges of serum concentrations of a series of clinical chemical compounds, expressed as 95 per cent reference

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Table I. 95 per cent reference intervals for serum concentrations of some common clinical chemical analytes

	Units	95 per cent reference interval Lower limit	Upper limit	Ratio (upper/lower)
Electrolytes				
Sodium	mmol/l	136	146	1·1
Calcium	mmol/l	2·10	2·55	1·2
Potassium	mmol/l	3·2	4·5	1·4
Metabolites				
Glucose	mmol/l	3·9	5·8	1·5
Creatinine	μmol/l	44	106	2·4
Urea	mmol/l	1·2	3·0	2·5
Enzymes				
Lactate dehydrogenase	U/l	45	90	2·0
Amylase	U/l	25	125	5·0
Creatine kinase	U/l	12	80	6·7
Proteins				
Albumin	μmol/l	550	810	1·5
Transferrin	μmol/l	22	49	2·2
Immunoglobulin M	mg/l	400	3450	8·6
Hormones				
Triiodothyronine	nmol/l	1·9	3·0	1·6
Estradiol	pmol/l	40	1800	45·0
Follicle stimulating hormone	IU/l	4	250	62·5

intervals for healthy subjects.[7] Electrolytes, some metabolites, and the serum protein albumin have limited ranges with ratios between upper and lower interval limits varying from 1·1 to 1·5. Although the ranges may be expanded somewhat by inclusion of specimens from diseased subjects, a slope bias problem may remain in connection with ordinary least-squares regression analysis. For example, suppose that the linear relationship between the measurements of two albumin methods is estimated by ordinary least-squares regression analysis and a range ratio of three is assumed with a uniform distribution of true values on the interval. This situation may be accomplished by sampling specimens from equal groups of healthy and diseased subjects. If, in addition, proportional measurement error with coefficient of variation of 0·05 is assumed for both methods then simulations show that the slope bias is $-0{\cdot}030$ for single measurements and $-0{\cdot}014$ for duplicate measurements of each specimen by both methods. The problem is overcome by using a regression model that takes into account random measurement errors for both methods. The appropriate procedure, which is called a functional or structural relationship model or an errors-in-variables regression method in the statistical literature,[2,8] has been termed in clinical chemistry Deming's method.[4] However, the method is based on the assumption of constant measurement errors, and, accordingly, is not optimal for the situation with proportional errors. The efficiency of Deming's method will be low, when estimating the linear relationship between substances such as hormones, which may have very wide distributions of serum concentrations (Table I). Furthermore, estimation of standard errors of parameter estimates[2] will not be correct. Special procedures[9,10] have been introduced for situations with heteroscedastic error distributions, but these methods are very complicated and not well-suited for clinical chemical problems. In this paper, a weighted modification of Deming's method is presented. The method is efficient for situations with proportional measurement errors, and standard errors are

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Records processed under FOIA Request #2014-4955; Released by CDRH on 12-8-2015

correctly estimated by the jackknife method. The assumptions of the method are checked using a plot of residuals.

ESTIMATION OF THE LINEAR RELATIONSHIP BETWEEN THE MEASUREMENTS OF TWO METHODS WITH CONSTANT ERRORS

We distinguish between true (X_i) and observed (x_i) values for a compound measured by a chemical method. 'True' should here be understood as the average value of an indefinite number of repeated measurements of a specimen by the method, that is the expected value. Given two measurement methods for a compound, we have:

$$x_i = X_i + \varepsilon_i$$
$$y_i = Y_i + \delta_i.$$

The error terms ε_i and δ_i are supposed to be independent Normal variables with expected values zero. In clinical chemistry, the standard deviations of the distributions of the error terms are known as the analytical standard deviations. On the basis of a series of k paired measurements (x_i, y_i) from the two methods, a linear relationship is estimated by

$$\hat{Y}_i = a_0 + b\hat{X}_i = a + b(\hat{X}_i - \bar{X}). \tag{1}$$

The circumflex denotes *estimates* of the true values.

Suppose that the error variances $V(\varepsilon)$ and $V(\delta)$ are constant, and that their ratio $\lambda = V(\varepsilon)/V(\delta)$ is known. A set of k paired observations (x_i, y_i) are available for estimation of the linear relationship. Using a least-squares approach,[11] the sum of squares

$$S = \sum_{i=1}^{k} [(x_i - \hat{X}_i)^2 + \lambda(y_i - \hat{Y}_i)^2]$$

is minimized. This corresponds to minimizing the sum of squared deviations from the line at an angle determined by λ. For comparison, in an ordinary least-squares regression analysis, the sum of squared deviations in the vertical direction is minimized. In order to obtain a solution, the following sums are computed for all k pairs:[11]

$$u = \sum (x_i - \bar{x})^2, \qquad q = \sum (y_i - \bar{y})^2, \qquad p = \sum (x_i - \bar{x})(y_i - \bar{y}).$$

It can be shown that the slope estimate is

$$b = \{(\lambda q - u) + \sqrt{[(u - \lambda q)^2 + 4\lambda p^2]}\}/2\lambda p$$

and

$$a = \bar{y}.$$

In the equation for the line, $\bar{x}$ is substituted for $\bar{X}$. This is Deming's regression method,[4] also known as a structural or functional relationship model.[2] 'Structural' is for the case where the true values X and Y are random variables, whereas in a functional relationship X and Y are supposed fixed. The distinction is analogous to the two situations in ordinary least-squares regression analysis.[1] In practical situations, the distinction is of minor importance, because the computations are identical for the two cases.

The null hypothesis of identity that $Y = X$, is tested by the t-tests:

$$t = (b - 1)/\widehat{\mathrm{SE}}(b)$$
$$t = (a - \bar{x})/\widehat{\mathrm{SE}}(a - \bar{x}).$$

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The latter t-test is a test of location difference which is independent of the test of the slope. This represents a more simple statistical analysis than testing whether the intercept deviates from zero.[1] Computation of the standard errors by the jackknife method is explained in a later section.

ESTIMATION OF THE LINEAR RELATIONSHIP BETWEEN THE MEASUREMENTS OF TWO METHODS WITH PROPORTIONAL ERRORS

If the error variances are assumed proportional to the squares of the average of the true values, then

$$V(\varepsilon_i) = f_x^2\,[(X_i + Y_i)/2]^2$$
$$V(\delta_i) = f_y^2\,[(X_i + Y_i)/2]^2.$$

Under this assumption, $\lambda = V(\varepsilon_i)/V(\delta_i) = f_x^2/f_y^2$ is constant. A weighted modification of the slope estimation procedure is to minimize the sum of squares

$$S_w = \sum_{i=1}^{k} [w_i(x_i - \hat{X}_i)^2 + \lambda w_i(y_i - \hat{Y}_i)^2]$$

where the weights

$$w_i = 1/[(X_i + Y_i)/2]^2$$

are inversely proportional to the error variances, and

$$\hat{Y}_i = a + b(\hat{X}_i - \bar{X}_w).$$

Denoting

$$\bar{x}_w = \sum_i w_i x_i \Big/ \sum_i w_i, \qquad \bar{y}_w = \sum_i w_i y_i \Big/ \sum_i w_i,$$

$$u_w = \sum_i w_i(x_i - \bar{x}_w)^2, \qquad q_w = \sum_i w_i(y_i - \bar{y}_w)^2,$$

$$p_w = \sum_i w_i(x_i - \bar{x}_w)(y_i - \bar{y}_w),$$

the slope estimate is

$$b = \{(\lambda q_w - u_w) + \sqrt{[(u_w - \lambda q_w)^2 + 4\lambda p_w^2]}\}/2\lambda p_w$$

and

$$a = \bar{y}_w.$$

In the equation for the line $\bar{x}_w$ is substituted for $\bar{X}_w$.

SIMULATIONS

The unweighted and weighted estimation procedures were evaluated by a simulation which mimics the problem of estimating a linear relationship between the measurements of two albumin methods. According to Table I, the measurement range extends from 550 to 810 μmol/l for 95 per cent of a healthy population. Liver disease causes a decrease of the serum concentrations. Thus, supposing that specimens from both diseased and healthy subjects are included, we may have

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Table II. Simulated estimation of the slope of the linear relationship between two albumin methods using alternative Deming models. 5000 simulation runs for each case

f_x	f_y	λ		Unweighted	True weight	Estimated weight	Iterative estimated weight
0·05	0·05	1	$\bar{b}$	1·000	1·000	1·000	1·001
			SE(b)	0·025	0·021	0·021	0·021
0·05	0·15	$1/3^2$	$\bar{b}$	1·001	1·000	0·990*	1·000
			SE(b)	0·057	0·048	0·049	0·048
0·15	0·05	3^2	$\bar{b}$	1·001	1·001	1·012*	1·001
			SE(b)	0·058	0·049	0·050	0·048

* Different from 1 ($P < 0·001$)

specimens with concentrations varying from about 250 to 800 μmol/l, giving a range ratio of about 3. In order to estimate λ, we suppose that duplicate measurements are performed by each method, and that the mean values enter the statistical computations. Thus the k pairs $(\bar{x}_i = (x_{1i} + x_{2i})/2, \bar{y}_i = (y_{1i} + y_{2i})/2)$ are used for the simulation. The constant f_x^2 is estimated by

$$\hat{f}_x^2 = \left\{ \sum_i (x_{1i} - x_{2i})^2 / [(\bar{x}_i + \bar{y}_i)/2]^2 \right\} \Big/ 2k$$

with a similar expression for $\hat{f}_y^2$, and finally

$$\hat{\lambda} = \hat{f}_x^2 / \hat{f}_y^2.$$

Pseudo-random Normal numbers were generated by the NAG routine GO5DDF[12] according to the stated model in which the null hypothesis $Y = X$ was supposed. A uniform distribution of true values is assumed. This generated two random numbers x_{1i} and x_{2i} for X_i and two y_{1i} and y_{2i} for Y_i. The results of 5000 simulation runs, assuming $k = 50$, are summarized in Table II. For $f_x = f_y = 0·05$, both the unweighted and the weighted method yield unbiased slope estimates, but the standard error of the slope estimated by the weighted procedure is smallest. The shown standard errors are the standard deviations of the distributions of b for the simulation runs. The same pattern is observed for $\lambda = 1/3^2$ and 3^2, respectively, and where the coefficient of variation for one of the methods has been assumed equal to 0·15.

Although the weighted Deming method appears to be a straightforward procedure, there is a problem concerning the weights. In the simulation example the true weights

$$w_i = [(X_i + Y_i)/2]^{-2}$$

were used. In real situations, only *estimates* of the weights are available:

$$\hat{w}_i = [(\bar{x}_i + \bar{y}_i)/2]^{-2}$$

because the true values X_i and Y_i are unknown. Column 3 of Table II shows that the weighted Deming method with *estimated* weights yields biased slope estimates for λ values different from unity.

A possible way to resolve the problem is to try to get better estimates of the true values than those provided by the directly measured values. We may obtain an initial estimate of the linear relationship by using the unweighted method, that is by setting $w_i = 1$. According to Mandel,[11] we may derive estimates of the true values $(\hat{X}_i; \hat{Y}_i)$ for each point $(\bar{x}_i, \bar{y}_i)$ by a projection onto the

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line. Denoting

$$d_i = \bar{y}_i - (a_0 + b\bar{x}_i)$$

we have

$$\hat{X}_i = \bar{x}_i + \hat{\lambda} b d_i/(1 + \hat{\lambda} b^2)$$
$$\hat{Y}_i = \bar{y}_i - d_i/(1 + \hat{\lambda} b^2).$$

We may now re-estimate the line using the weights

$$\hat{w}_i = [(\hat{X}_i + \hat{Y}_i)/2]^{-2}$$

and λ is also re-estimated by substituting $\hat{X}_i$ for $\bar{x}_i$ and $\hat{Y}_i$ for $\bar{y}_i$ in the formulae for $\hat{f}_x^2$ and $\hat{f}_y^2$. It is usual to iterate the procedure to obtain even better estimates of the true values. It turned out that the slope estimate usually converged towards a target value with successive differences of less than 10^{-4} within 3 to 4 iterations. Column 4 of Table II shows that this iterative method yields slope estimates with a negligible bias for the given situation, and that the standard error is almost identical to that of the true weight based method. Thus, this method seems suitable for estimation of the linear relationship between the two albumin methods under the given conditions.

The iterative method was also evaluated by a further series of simulations. These studies showed that the method was subject to a small bias of the slope estimate, the magnitude of which depended on the sample size and the ratio between the coefficients of variation of the error and true value distributions (the coefficient of variation of the error distribution refers to the error distribution of the means of duplicate measurements). In practice, these ratios are unlikely to exceed 0·25. For simulation with ratios not exceeding 0·25, slope biases of 0·0056 (sample size 20) to 0·0012 (sample size 100) were recorded. Simulation examples with fixed as well as random true values were also performed. The true values were assumed distributed according to Normal or log-Normal distributions and λ ranged from 10^{-2} to 10^2. The observed decrease of bias with increasing sample size suggests that the method is asymptotically unbiased. Further, the almost identical standard errors of the slope estimates based on true and iteratively estimated weights, respectively, suggests that the iterative method is asymptotically efficient (Table II).

The relative advantage of the weighted over the unweighted approaches depends on the degree of heteroscedasticity. Given a uniform distribution of true variables on the interval [1, 5], the variance of the slope estimate of the weighted approach equals 0·60 times that of the unweighted method for a sample size of 100. Simulations show that this relation is 0·49 for the interval [1, 10], dropping to 0·25 for the interval of [1, 100].

STANDARD ERRORS OF ESTIMATES

Assuming homoscedastic, Normally distributed measurement errors, expressions have been derived for the asymptotic standard error of the slope estimate.[2,8,13] However, it is difficult to derive a formula for the standard deviation, even if the Normality of error distributions are presumed, for the heteroscedastic case. Therefore, a non-parametric alternative such as the jackknife method seems appropriate.[13-15] We compute b^i = the slope based on the subset $\{(x_j; y_j)\}$ which does not contain $(x_i; y_i)$.

$$b_i = kb - (k-1)b^i \qquad \text{(the } i\text{the pseudovariate, } i = 1, \ldots, k)$$

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where b is the slope estimated from the complete data set.

$$\tilde{b} = \sum_{i=1}^{k} b_i/k \qquad \text{(the jackknifed estimator)}$$

$$V_j(b) = \sum_{i=1}^{k} (b_i - \tilde{b})^2/(k-1)$$

$$\widehat{\mathrm{SE}}(b) = \sqrt{(V_j(b)/k)}.$$

Notice that this method allows for the uncertainty of the λ estimate, for example, based on duplicate measurements, because λ estimates based on the subsets are used for calculation of the pseudo-variates. In a similar way we can obtain a jackknife estimate of $\widehat{\mathrm{SE}}(a - \bar{x}_w)$.

The jackknife method for estimation of standard errors was evaluated by simulation assuming the model of the previously mentioned albumin example. Given a nominal significance level of 0·05 for test of slope deviation from unity and location difference, we expect 100 rejections out of 2000 simulation runs under the null hypothesis. The actual numbers of rejections were 103 and 100 for slope deviation and location difference, respectively. The overall number of rejections of the null hypothesis was 199. Other simulation examples also revealed good agreement between observed and expected rejection frequencies. Thus, the jackknife method seems to operate satisfactorily.

Finally, a variance ratio test for the regression model may be considered. If λ is known in advance and duplicate measurements are performed, independent estimates of the proportionality factors of the error variances can be obtained. From the dispersion of $\bar{x}_i$ and $\bar{y}_i$ about the line, we have[11]

$$\hat{f}_x'^2 = \{\lambda/[(k-2)(1+\lambda b^2)]\} \sum_i d_i^2/[(\hat{X}_i + \hat{Y}_i)/2]^2$$

$$\hat{f}_y'^2 = \hat{f}_x'^2/\lambda$$

where d_i is the vertical distance of a point from the line. The ratios between these estimates and those founded on the duplicate measurements, as described in the previous section ($\hat{f}_x^2/2$ and $\hat{f}_y^2/2$; the denominator 2 is used because we are dealing with $\bar{x}_i$ and $\bar{y}_i$) can be related to the critical value of the variance ratio statistic, with $(k-2)$ degrees of freedom for the numerator and k for the denominator. In most real examples, however, λ is not known in advance, but it is estimated from duplicate measurements. Under this condition, the two variance estimates are not independent, and the variance ratio test is not exact.

AN EXAMPLE FROM CLINICAL CHEMISTRY

In the previous sections, the problem of estimating a linear relationship between the measurements of two albumin methods has served as a model for the simulation studies. Now a concrete data example is considered. In the laboratory, two methods are available for determination of serum concentrations of albumin. Both methods are based on an antigen–antibody reaction, but they differ with respect to various technical details. A study is undertaken to evaluate whether there is any systematic difference between the measurements by the two methods. It is considered that a slope deviation of $\Delta\beta = 0{\cdot}1$ should be detected with a high probability, say 0·95 or higher. A type I error of 0·025 is chosen, because together with the same type I error for the test of location difference, the overall type I error becomes 0·05,. As mentioned previously, coefficients of

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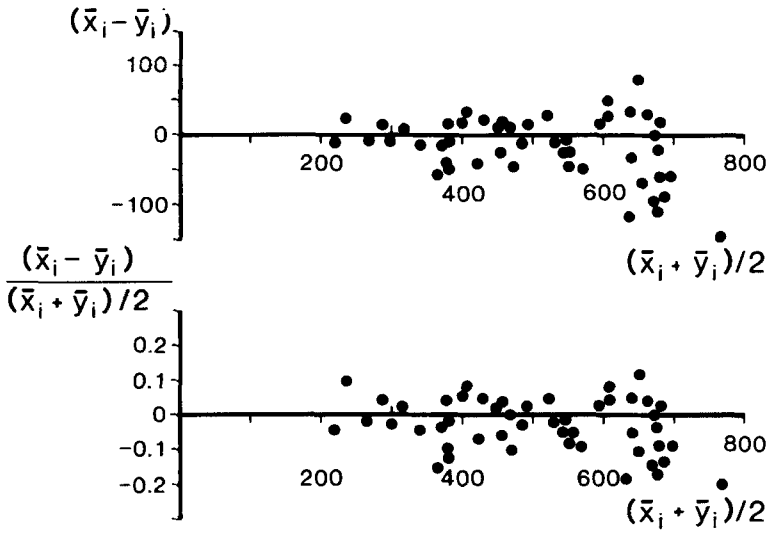

Figure 1. Absolute (top) and relative (bottom) differences between albumin measurements by two methods plotted against the average levels. The unit on the abscissa is μmol/l

variation of about 0·05 are expected for the error distributions, or $0{\cdot}05/\sqrt{2} = 0{\cdot}035$ for the means of duplicate measurements. Given these data together with an assumption of a uniform distribution over the interval 250–800 μmol/l, the power is determined as 0·98 for a sample size of 50, using jackknife standard errors from a 1000 runs. This suggests that approximately 50 observations are reasonable for this study. Duplicate measurements of 49 serum specimens by each method were actually carried out. Plots of absolute and relative differences between the measurements by the two methods against the average levels suggested proportional errors (Figure 1). Plots of differences between duplicate measurements by each method pointed in the same direction (Figure 2). These plots suggest that the weighted estimation procedure is appropriate. For comparison, both an unweighted and weighted regression analysis were performed. The equation for the line estimated by unweighted procedure is

$$\begin{aligned}\hat{Y}_i &= 515{\cdot}95 + 1{\cdot}0877(\hat{X}_i - 499{\cdot}1429)\\ &= -26{\cdot}99 + 1{\cdot}0877\,\hat{X}_i\end{aligned}$$

and by the weighted method:

$$\begin{aligned}\hat{Y}_i &= 417{\cdot}35 + 1{\cdot}0713(\hat{X}_i - 407{\cdot}37)\\ &= -19{\cdot}06 + 1{\cdot}0713\,\hat{X}_i.\end{aligned}$$

In this particular example, there is only a small difference between the two types of estimates, and so only the line estimated by the weighted method is shown in Figure 3, together with the line of identity. The estimates for f_x^2, f_y^2 and λ were 0·001681, 0·005641 and 0·298, respectively. These correspond to coefficients of variation of 0·041 and 0·074.

A plot of weighted residuals

$$r_i = \mathrm{sign}\,[\hat{w}_i(\bar{x}_i - \hat{X}_i)^2 + \hat{w}_i\hat{\lambda}(\bar{y}_i - \hat{Y}_i)^2]^{1/2}$$

against $(\hat{X}_i + \hat{Y}_i)/2$ is displayed in Figure 4. The sign of r_i is identical with the sign of the vertical

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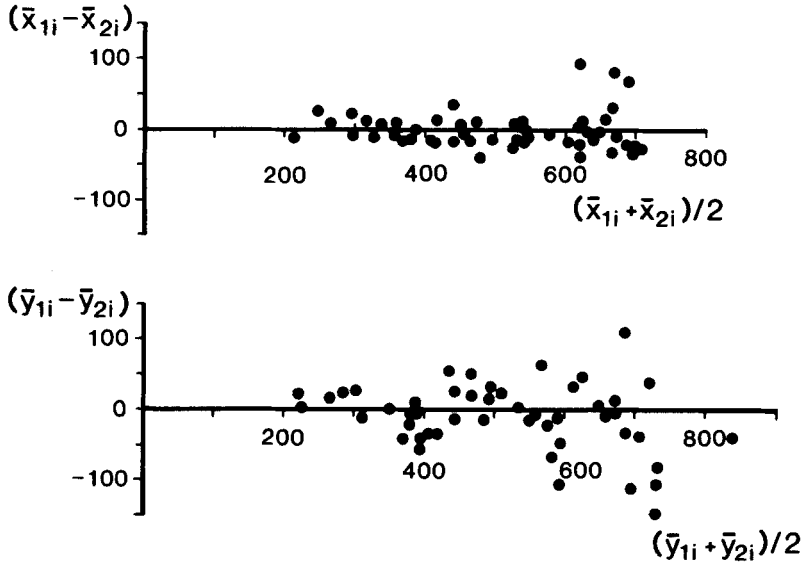

Figure 2. Absolute difference between duplicate measurements by the methods plotted against the means of the measurements

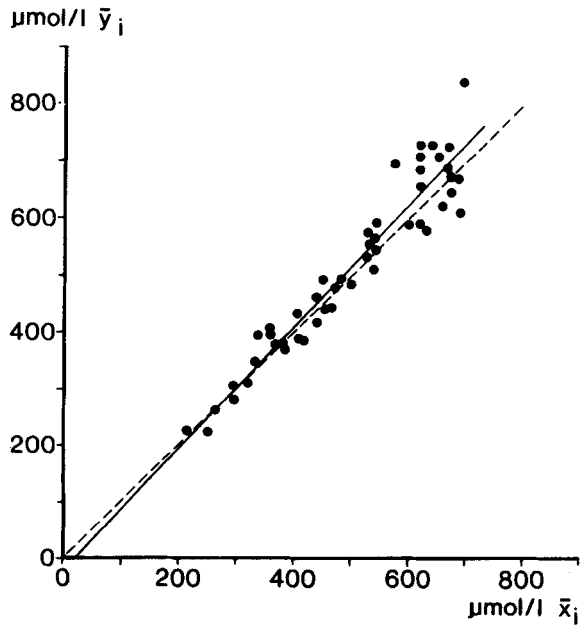

Figure 3. $(\bar{x}_i, \bar{y}_i)$ plot for the albumin example with the estimated regression line using the weighted Deming method (——). The line of identity is $Y = X$ (– – –)

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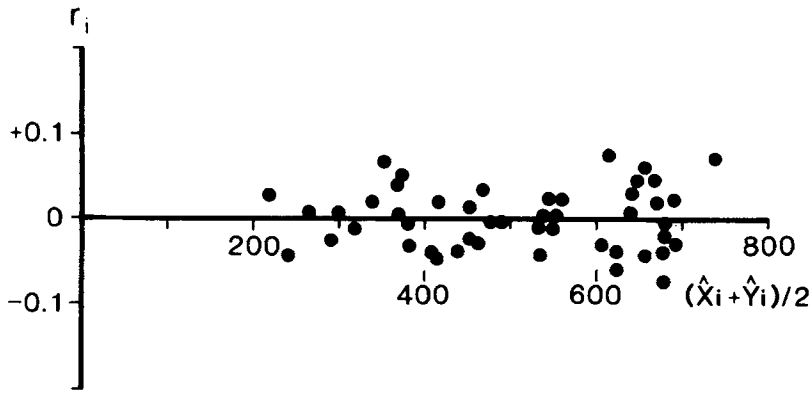

Figure 4. A plot of weighted residuals (r_i) against $(\hat{X}_i + \hat{Y}_i)/2$

distance d_i from the line. A fairly homogeneous scatter is observed, supporting the hypothesis of a linear relationship between X and Y with a proportional measurement error.

We proceed with tests for slope deviation from unity and location difference, using jackknife standard errors, then

$$t = (b - 1)/\widehat{\mathrm{SE}}(b) = 0{\cdot}0713/0{\cdot}0399 = 1{\cdot}79$$

and

$$t = (a - \bar{x}_w)/\widehat{\mathrm{SE}}(a - \bar{x}_w) = (417{\cdot}35 - 407{\cdot}37)/4{\cdot}8201 = 2{\cdot}07.$$

Given a significance level of 0·025 for each test, corresponding to $t = 2{\cdot}32$, we do not reject the null hypothesis of identity of the methods.

DISCUSSION

Estimation of the linear relationship between the measurements of two methods, both of which are subject to errors that depend on the variable levels, is a common problem in clinical chemistry and other fields of medicine. Although the focus has been on proportional measurement errors, other relationships might also be considered, particularly for immunoassays. Computer programs have been developed for estimation of variance functions on the basis of maximum likelihood theory.[16–18] In order to preserve the condition that λ is constant, however, one has to operate with a common form of the functions for both assays.

In this presentation, focus has been on clinical chemical problems, in which replicate measurements are available, so that the error variances and their ratio can be estimated. In clinical medicine, replicate measurements are not always attainable. If technical considerations make a variance ratio of one plausible, the analysis may be carried out on this basis. A plot of the differences $(y_i - x_i)$ against $(x_i + y_i)/2$ may suggest whether a weighted or an unweighted analysis is appropriate.

Comparison of methods on the basis of an estimated linear relationship yields more information than is achieved by merely testing for a location difference.[19,20] In clinical chemistry, one is *not* just interested in testing the null hypothesis of identity. If the null hypothesis is rejected, a recalibration of one of the methods is frequently performed in order to eliminate systematic

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measurement differences. For this purpose, estimation of both slope and location difference is necessary.

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Evaluation of Regression Procedures for Methods Comparison Studies

Kristian Linnet

Using simulation, I evaluated five regression procedures that are used for analyzing methods comparison data: ordinary least-squares regression analysis, weighted least-squares regression analysis, the Deming method, a weighted modification of the Deming method, and a rank procedure. I recorded the following performance measures: plus or minus bias of the slope estimate, the root mean squared error of the slope estimate, and correctness of hypothesis testing. I evaluated the unweighted regression procedures by using a simulated comparison of two electrolyte methods; only the Deming method gave unbiased slope estimates. Using the jackknife method, a computer program that estimates the standard error, I showed that hypothesis testing was correct for the Deming method. I used all regression procedures on data from a simulated comparison of two measurement methods with proportional analytical errors dispersed over one decade. Bias of the slope estimates was not a problem for these cases. The weighted least-squares regression analysis and the weighted Deming method were most efficient (lowest root mean squared error); the other procedures required 1.6 to 2.2 times as many observations to attain the same precision for the slope estimate. Hypothesis testing was correct by the weighted Deming method with the jackknife principle for standard error computation; the other methods rejected the null hypothesis 1.4 to 4.4 times too frequently. In conclusion, it is preferable to use an alternative to ordinary least-squares regression analysis for methods comparison studies.

Indexing Terms: *statistics* · *intermethod comparison*

It is often necessary in clinical chemistry to look for a systematic difference between the measurements of two methods. To do this, a set of samples is analyzed by both methods and, on the basis of a regression analysis, any systematic difference is evaluated. Ordinary least-squares regression analysis, which is readily available in pocket calculators and statistical packages (*1*), is commonly used. This procedure presumes that the measurements for one of the methods are without random error, i.e., the analytical standard deviation is zero, and that the analytical standard deviation for the other method is constant throughout the measurement range. Both assumptions are rarely fulfilled. Therefore, it is reasonable to consider alternatives to ordinary least-squares regression analysis for evaluation of methods comparison data. In weighted least-squares regression analysis (*2*), the analytical standard deviation for the method that is subject to random errors need not be constant. The Deming procedure (*3–10*) realistically assumes that the measurements by both methods are subject to random errors, and a weighted modification of the Deming method (*11*) takes into account nonconstant analytical standard deviations for both methods. For example, it can be assumed that both methods are subject to proportional measurement errors (constant coefficients of variation), which is a very common situation in clinical chemistry. Finally, a regression procedure based on the rank principle, which also takes random errors for both methods into account, may be considered (*12–14*). In this paper, I evaluate the regression procedures mentioned above, using simulations of typical situations in clinical chemistry. I focus on the shortcomings of ordinary least-squares regression analysis, and how these can be overcome by using an alternative procedure.

Department of Clinical Biochemistry KB 76.4.2, Rigshospitalet University Hospital, Tagensvej 20, DK-2200 Copenhagen N, Denmark.

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Comparison of Two Clinical Chemistry Methods by Regression Analysis

Because every method in clinical chemistry is subject to some random measurement error, we must distinguish between the measured value (x_i) and the true or target value (X_i). The latter is the average of all the values that we would obtain if we repeated the measurement of a given sample an indefinite number of times. A particular measured value is likely to deviate from the target value by some small "random" amount (ϵ or δ). Given two clinical chemistry methods, we have for the ith sample

$$x_i = X_i + \epsilon_i$$

$$y_i = Y_i + \delta_i$$

The standard deviation of the dispersion of measured values about the target value is the analytical standard deviation (Figure 1). The analytical standard deviation may be constant, i.e., independent of the target value, but usually it increases with increasing target values. For many compounds, the analytical standard deviation is approximately proportional to the concentration level, corresponding to a constant coefficient of variation (Figure 2*a*) (*15*). In some cases, e.g., hormone assays, the analytical standard deviation becomes constant in the low range, resulting in an increased coefficient of variation in this area (Figure 2*b*) (*16*). One must consider the relation between analytical standard deviation and concentration value when one chooses the best regression analysis for a method comparison study (see below).

From a set of paired measured values $\{(x_i; y_i)\}$ the relation between the target values $\{(X_i; Y_i)\}$ is to be elucidated. The null hypothesis of no difference (H_o)

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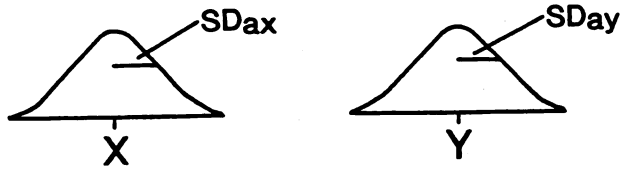

Fig. 1. Distributions of measured values about the target values
The analytical standard deviations SD_{ax} and SD_{ay} are schematically shown

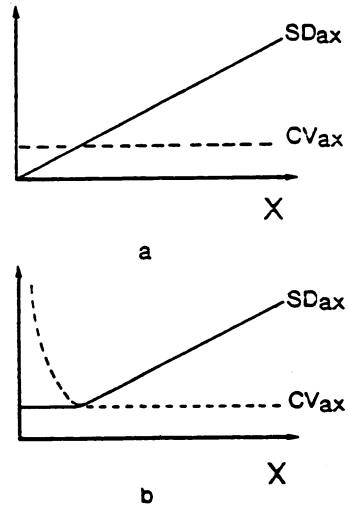

Fig. 2. Examples of relations between analyte concentration (X), analytical standard deviation (SD_{ax}), and coefficient of variation (CV_{ax})

$$H_0: Y_i = \alpha_0 + \beta X_i \quad (\alpha_0; \beta) = (0; 1)$$

is tested against the alternative hypotheses (H_{a1} and H_{a2}):

H_{a1}: A linear relationship exists between X and Y.

$$Y_i = \alpha_0 + \beta X_i \quad (\alpha_0; \beta) \neq (0; 1)$$

H_{a2}: Y is a nonlinear function of X or totally independent of X.

The hypotheses are evaluated by some type of regression analysis, supported by graphical plots. If a linear relationship seems plausible from graphical plots or statistical tests of linearity, we must decide between H_0 and H_{a1}. By determining whether the slope deviates significantly from 1 (proportional systematic error) and whether α_0 is different from 0 (constant systematic error), we decide between these two hypotheses.

Each regression method requires certain assumptions concerning data distribution and analytical errors. If these assumptions are violated, the statistical analysis may be incorrect or nonoptimal. The regression method that requires the simplest computations, ordinary least-squares regression analysis, relies on the most rigid assumptions, whereas the more complicated methods operate with assumptions that are more likely to be fulfilled in reality (*Appendix*).

Ordinary least-squares regression analysis requires that one of the methods (corresponding to x) is without random measurement error, that the measurement errors of the other method (y) have a gaussian distribution at a given level, and that the standard deviation is constant throughout the measurement range (Figure 3) (*1*). The computation of an ordinary least-squares regression analysis is based on minimization of the squared deviations from the line in the vertical direction. It can be shown that this procedure is optimal under the stated conditions.

Weighted least-squares regression analysis (*Appendix*) (*2*) allows for a nonconstant standard deviation for the y method, but it is still presumed that the x method is without random measurement error. Weights are introduced that are inversely proportional to the squared analytical standard deviation of y measurements at a given concentration. For example, the procedure can be applied to the case with a proportional analytical standard deviation for y (constant coefficient of variation). The sum of weighted squared deviations from the line in the vertical direction is minimized. In the situation with proportional analytical standard deviation, the weights reduce the influence of observations at high concentrations. This is reasonable because the analytical standard deviation, and thus the uncertainty, increases with the concentration. The result is a more precise estimation of the regression line.

The Deming method (*Appendix*) (*3–10*) allows measurement errors for both methods, requiring that the ratio between the analytical standard deviations is known. The Deming method is primarily used when analytical standard deviations are constant. The sum of squared deviations from the line at an angle determined by the ratio between the standard deviations is minimized (Figure 4). Various procedures for estimation of standard errors of slope and intercept have been suggested (*5, 10*). If a computerized method such as the jackknife method is used, gaussian error distributions need not be assumed; i.e., the procedure becomes nonparametric (*11*).

A weighted modification of the Deming method takes into account nonconstant measurement errors for both methods (*Appendix*) (*11*). It still has to be presumed that the ratio between the analytical standard deviations is constant. This is true for the common situation with proportional analytical standard deviations (constant coefficients of variation) for both methods [and strictly, a regression line passing through (0; 0)]. The sum of

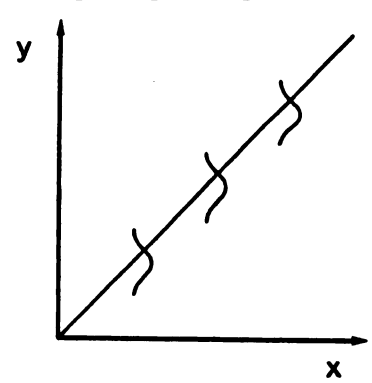

Fig. 3. The model assumed in ordinary least-squares regression analysis: no error in x and constant gaussian error distribution for y
In this example, the regression line is coinciding with the line of identity

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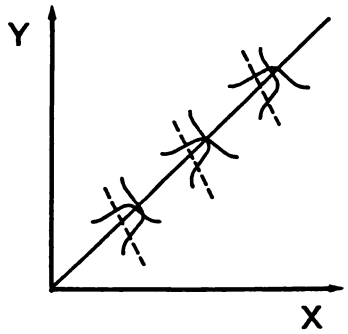

Fig. 4. The model assumed in the Deming regression procedure
The regression line is estimated by minimization of squared distances to the line at an angle determined by the ratio of the analytical standard deviations for the two methods

weighted squared deviations at an angle to the line is minimized.

Finally, a nonparametric rank method developed by Passing and Bablok is evaluated (*Appendix*) (*12–14*). The slope of the regression line is calculated as the median of all possible slopes. This estimation principle makes the method robust towards outliers, which is the main advantage of the method. Measurement errors for both chemistry methods are partially taken into account. Passing and Bablok claim that this method can be used when errors are proportional.

Performance of the Regression Methods

To compare the regression methods, I used each regression analysis in two simulated methods comparison studies; one compared two methods for determination of an electrolyte, and the second, two methods for determination of a metabolite.

Electrolyte Study

Serum concentrations of electrolytes are tightly regulated, which means that the range of concentrations is very small in healthy individuals, and deviations associated with disease are small to moderate. For example, the ratio between the upper and lower reference limits (range ratio) for serum sodium is 146 mmol/L:136 mmol/L = 1.07 (*17*). In a study that included samples from diseased subjects, Cornbleet and Gochman (*5*) found a range ratio of 1.15 for serum sodium. For my model I suppose a gaussian distribution of target values with a mean of 135.5 mmol/L and a standard deviation of 3.8 mmol/L. If the minimum and maximum values are 2.5 standard deviations below and above the mean, respectively, the range ratio is 1.15 (145 mmol/L:126 mmol/L). The analytical coefficients of variation are supposed to be 0.01 and 0.015 for methods 1 (x) and 2 (y), respectively. For this case, it makes little difference whether we suppose constant or proportional analytical errors; I selected constant analytical errors with the above-mentioned coefficients of variation at the mean value. Consequently, I did not need to use the weighted least-squares regression analysis or the weighted Deming method. To test the null hypothesis, that the target values for the two methods are identical, I selected a sample size of 50 duplicate measurements by each method. Using duplicate measurements, one can estimate the analytical standard deviations and compute their ratio. This ratio is then used for computing the slope by the Deming method. In the simulation process, pseudorandom gaussian numbers are generated according to the specified model and regression equations are calculated. By repeating the procedure many times (=nrun), e.g., 2000–5000 times, one obtains various performance measures for each regression method. These are listed in Table 1. The average slope ($\bar{b}$) indicates whether the slope estimate is biased or not. The root mean squared error (RMSE)

$$\mathrm{RMSE} = \sqrt{\Sigma(b-1)^2/\mathrm{nrun}} = \sqrt{\mathrm{BIAS}^2 + \mathrm{SE}^2}$$

is an estimate of the total error of the slope and includes both the random error, i.e., the standard deviation of the dispersion of b around $\bar{b}$, and the systematic error or bias. The *real* standard error of the slope [SE($\bar{b}$ − 1)] is the standard error observed in the simulation study, i.e., the standard deviation for the distribution of b in the simulation runs. The average *estimated* standard error of the slope, on the other hand, refers to the standard error derived by statistical analysis. In each simulation run, an estimated standard error is computed so as to carry out a test of the null hypothesis. A prerequisite for a correct test is that the estimated standard error, on average, agrees with the real one. In the rank method, hypothesis testing is carried out in another way, and no average estimated standard error is given. Lastly, I evaluated the performance of hypothesis testing by comparing the observed and expected number of rejections of the null hypothesis. Under the null hypothesis, we expect 50 rejections out of 1000 trials, given a nominal type I error of 0.05. Any deviation from this number may be expressed as a factor. For example, if 100 rejections are recorded, the factor is

$$f = 100/50 = 2$$

The ideal hypothesis test factor is, of course, 1. Figure 5 shows the average regression lines obtained by the three procedures for this example. The scatter points of one simulation run are also shown.

Ordinary least-squares regression analysis and the

Table 1. Performance Characteristics of Three Regression Procedures for a Simulated Comparison of Two Electrolyte Methods

	Least-Squares reg. anal.[a]	Deming reg. anal.	Rank reg. anal.
Average slope ($\bar{b}$)	0.940[b]	1.001	1.031[b]
Root mean squared error	0.088	0.069	0.072
Real SE(b)	0.064	0.069	0.065
Average estimated SE(b)	0.058	0.070	—
Hypothesis test factor (f)	4.1	1.0	3.8

The true slope β is equal to 1. Sample size: 50 duplicate measurements by each method. Based on 2000–5000 simulation runs.
[a] Ordinary least-squares regression analysis.
[b] Significantly different from 1 (P <0.001).

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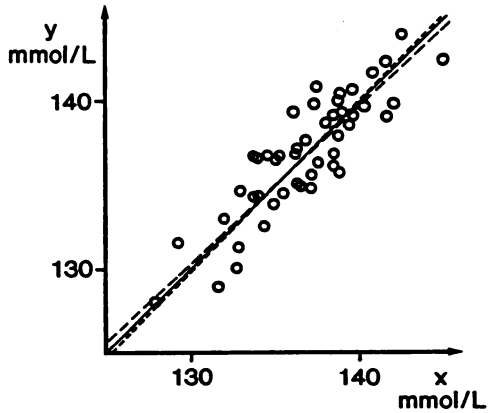

Fig. 5. The simulated electrolyte case

Fifty scatter points (means of duplicate measurements by each method) are shown for one simulation run. The regression lines are averages of 5000 simulation runs. (——) the Deming procedure; (— —) ordinary least-squares regression analysis; (- - -) the rank procedure

rank method yield biased slope estimates, $\bar{b} = 0.94$ and 1.03, respectively, whereas the Deming method is without bias. The negative bias of the ordinary least-squares method is simply the squared ratio of the coefficients of variation of x errors and target value distributions ($0.01^2 \cdot 0.5/0.028^2 = 0.06$; the factor 0.5 enters because we have duplicate measurements). This example and other similar simulations show that the rank method does not provide unbiased slope estimates if the analytical standard deviations for methods 1 and 2 are different. This conclusion is also apparent from the study by Bablock and Pässing (*13*). For both ordinary least-squares regression analysis and the rank procedure, I have observed that a biased slope estimate is accompanied by a biased intercept.

The root mean squared error is smallest for the unbiased Deming method. The jackknife principle of estimating the standard error results in correct hypothesis testing [hypothesis test factor (f) = 1.0]. In contrast, the null hypothesis is rejected too frequently by the other two procedures, $f = 3.8$ and 4.1, corresponding to rejection frequencies of ~20%. This is caused partly by bias and partly by incorrect estimation of the standard error.

Metabolite Study

Metabolites include commonly measured substances such as glucose, urea, and urate. The serum concentrations of these substances vary more than those of electrolytes, resulting in larger range ratios. I compared two methods for glucose determination and supposed that the glucose concentrations extended from 2.5 to 25 mmol/L, corresponding to a range ratio of 10. I assumed that a majority of the samples came from healthy subjects or patients with moderately elevated glucose concentrations; thus three-quarters of the observations were located on the lower half and one-quarter on the upper half of the interval (Figure 6). The measurement errors were proportional to the concentrations, with coefficients of variation of $CV_1 = 0.05$ (x) and $CV_2 = 0.075$ (y). The sample comprised 50 duplicate observa-

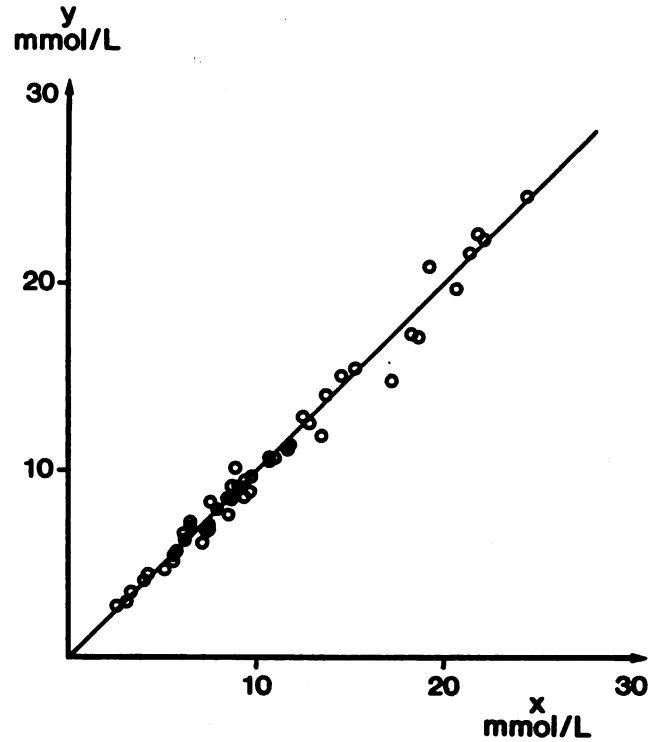

Fig. 6. The simulated metabolite case

Fifty scatter points are shown for one simulation run. The *solid line* is the diagonal, which corresponds to the nearly coinciding average regression lines of each of the five methods

tions. The simulations show that ordinary and weighted least-squares regression analyses yield slope estimates with a negligible bias ($\bar{b} = 0.996$ and 0.993) (Table 2). The analytical coefficient of variation of method 1 is small when compared with the coefficient of variation of the target value distribution. However, ordinary least-squares regression analysis is not appropriate because the hypothesis testing is inaccurate; an actual type I error exceeds the nominal one by a factor of $f = 4.4$. This is caused by an underestimation of the standard error of the slope by ~40%, as evident from the simulation study. The weighted procedure performs better, with an error factor of $f = 1.7$. In addition, the slope, as calculated by the weighted procedure, has a smaller root mean squared error than it would if it were calculated by the ordinary least-squares regression analysis.

The Deming and the weighted Deming methods give unbiased slope estimates, as expected, and the rank method has only a negligible bias ($\bar{b} = 1.002$). The weighted Deming method performs hypothesis testing correctly, whereas the unweighted procedure and the rank method have moderately increased type I errors (f = 1.4 and 1.6, respectively). The average estimated standard error of the unweighted Deming procedure is correct, but the distribution of the test statistic does not conform exactly to the t-distribution, affecting the hypothesis testing. The weighted Deming method is more efficient than the unweighted modification, as indicated by the root mean squared error, and the rank method has an intermediate efficiency.

For comparison, Table 2 shows the number of obser-

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Table 2. Simulated Comparison of Two Glucose Methods

	Ordinary least-squares reg. anal.	Weighted least-squares reg. anal.	Deming reg. anal.	Weighted Deming reg. anal.	Rank reg. anal.
Average slope ($\bar{b}$)	0.996[a]	0.993[a]	1.001	1.000	1.002[a]
Root mean squared error	0.028	0.019	0.028	0.018	0.023
Real SE(b)	0.028	0.018	0.028	0.018	0.022
Average estimated SE(b)	0.018	0.016	0.028	0.018	—
Hypothesis test factor (f)	4.4	1.7	1.4	1.0	1.6
Sample sizes yielding the same precision of slope estimate, n	210	100	220	100	160

$\beta = 1$, $CV_1 = 0.05$, $CV_2 = 0.075$, 50 duplicate measurements, and 2000–5000 simulation runs.
[a] Significantly different from 1 ($P < 0.001$).

vations required by each of the methods to obtain slope estimates that have the same precision. Weighted least-squares regression analysis and the weighted Deming method each require a sample size of 100, with the other methods demanding up to 2.2 times as many observations.

Performance of Regression Methods in the Presence of Outliers and Nongaussian Error Distributions

In the previous section, I considered ideal situations, i.e., cases with gaussian error distributions and no outliers. Because skew error distributions and outliers may occur in real cases, it is relevant to evaluate the regression methods under these conditions. I compared the weighted Deming procedure, which is based on the least-squares computation principle, with the rank method. The least-squares computation procedure is sensitive towards outliers, in contrast to the rank principle, where a median value serves as a slope estimate.

I investigated the impact of outliers by using the metabolite model and introducing an outlier randomly in 1 of 50 observations. Here, an outlier is considered as an observation for which the target value deviates from the value expected under the given hypothesis. Under the null hypothesis, we expect $x_i = y_i$, but for the outlier the relation is $x_i = y_i + d$, where d is some constant. The target value of the outlier is shifted by one to eight analytical standard deviations at the given value from the identity line. The slope is estimated in each simulation run, and the root mean squared error is recorded for 1000–5000 repetitions. For the weighted Deming method, I calculated the root mean squared error both with and without application of a rejection rule for outliers. For each pair of observations (x_i, y_i), I calculated the standardized deviation from the estimated regression line, and if this deviation exceeded three standard deviations of the distribution of deviations, I rejected the observation (*11*). If a rejection rule is not used, the root mean squared error for the slope estimate of the weighted Deming method increases steadily as outlier deviation increases, whereas the root mean squared error of the rank method is almost unaffected (Figure 7). When the rejection rule is applied, however, the root mean squared error of the weighted Deming method increases only moderately up to a maximum and then declines towards the starting value. For all outlier positions, the root mean squared error of the weighted Deming procedure is smaller than that of the rank method. No rejection rule for outliers is specified for the rank method (*12*). Actually, identification of outliers is important, because they may indicate the presence of special matrix effects or interferents.

Skew measurement error distributions may be modeled by log-gaussian distributions (Figure 8). The coef-

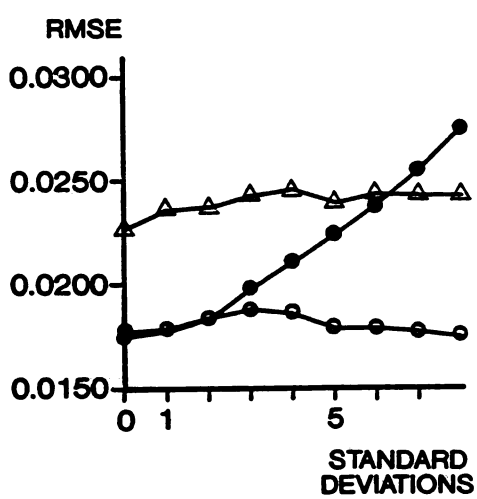

Fig. 7. The root mean squared error (*RMSE*) of the slope estimate as a function of outlier deviation expressed in standard deviations
●, the weighted Deming procedure; ○, the weighted Deming procedure with outlier rejection; △, the rank procedure

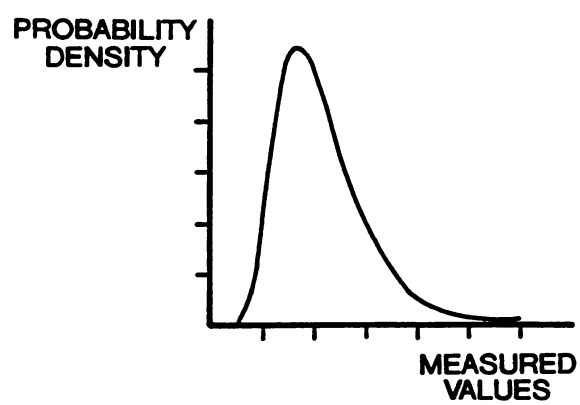

Fig. 8. The shape of the skew measurement error distributions
The coefficient of skewness is 1.3

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ficient of skewness is 1.3 for this example. Table 3 gives average slopes, root mean squared errors, standard errors, and hypothesis test factors for the metabolite case with skew error distributions. Bias was not important for either method. The root mean squared error of the weighted Deming method is smaller than that of the rank method, and $f = 1$ only for the weighted Deming method.

Discussion

Ordinary least-squares regression analysis is the simplest regression method and by far the most widely used one for methods comparison studies. However, modern computer technology has made more complicated methods generally accessible because computations can be automated. Therefore, it appears reasonable to evaluate whether more complicated regression methods offer advantages over ordinary least-squares regression analysis. Earlier, we noted that apart from the electrolyte case, ordinary least-squares regression analysis gives a slope estimate with only a modest bias, even though both analytical methods are subject to random measurement errors. A more serious problem is that hypothesis testing is unreliable when errors are proportional. For the metabolite case studied here, the standard error of the slope was on average underestimated by 40%, and thus the null hypothesis was rejected too frequently and confidence intervals were underestimated. Also, the efficiency of ordinary least-squares regression analysis may be low for large range ratios when there are proportional errors.

Weighted least-squares regression analysis is efficient for the metabolite case, and the bias is small. Hypothesis testing is better than for ordinary least-squares regression analysis, but the type I error is still somewhat high because the random measurement errors of x are neglected. Simulations show that if x is without error, hypothesis testing becomes correct.

The unweighted Deming method yields an unbiased slope estimate in both the metabolite and electrolyte method comparisons and, with use of the jackknife principle, hypothesis testing becomes correct for the electrolyte case with constant analytical standard deviations. Cornbleet and Gochman (*5*) suggest estimating the standard error of the slope by using the same formula as for ordinary least-squares regression analysis. Using this simple principle, I found that hypothesis testing was not as good as that achieved by using the jackknife method to derive standard errors ($f = 1.5$ for the electrolyte case and 3.8 for the metabolite case, compared with $f = 1.0$ and 1.4, respectively, for the jackknife method).

Table 3. Performance of the Weighted Deming and the Rank Regression Procedures on Skew Error Distributions

	Weighted Deming reg. anal.	Rank reg. anal.
Average slope ($\bar{b}$)	1.000	0.997[a]
Root mean squared error	0.017	0.022
Real SE(b)	0.017	0.022
Average estimated SE(b)	0.017	—
Hypothesis test factor (f)	1.0	2.2

[a] Significantly different from ($P < 0.001$).

Given proportional measurement errors for both methods, the weighted Deming method is more efficient than the usual unweighted approach. The larger the range ratio, the greater the advantage. For a range ratio of 10, the weighted approach requires less than half the sample size of the unweighted one to provide a slope estimate with the same precision. Achieving high precision for the slope estimate is as important as eliminating bias. In a particular methods comparison study, the slope estimate is likely to be within plus or minus two standard errors from the true, unknown slope value. Thus, if an unbiased slope estimate has a low precision, perhaps caused by the use of nonoptimal regression technique, the result may still deviate considerably from the true value.

For both modifications of the Deming method, it is presumed that the ratio (λ) between the analytical standard deviations is constant. This condition is satisfied if both standard deviations are constant, i.e., independent of the concentration, or if both methods have a constant coefficient of variation and a proportional relationship exists between the methods ($\alpha_0 = 0$). Although in reality λ is often not constant, it is frequently approximated. If the ratio is not quite constant, a small bias may arise. Studies have shown that the Deming model is robust towards misspecification of λ (*18*). The bias is, at most, of the same order of magnitude as that of ordinary or weighted least-squares regression analysis.

The rank method of Passing and Bablok (*12–14*) gives an unbiased slope estimate under the null hypothesis only if the analytical standard deviations for the two methods to be compared are of equal size. Hypothesis testing is not correct for the rank method, and because the rank method is, in principle, an unweighted method, it is not optimal for the case with proportional errors. The advantage of the method is its resistance towards outliers, but the method needs further development to eliminate the inadequacies revealed by the simulations performed here.

In a time when there is an increasing focus on accuracy in analytical methods, the choice of an optimal regression technique for methods comparison studies is important. For example, an inaccuracy of <3% has been recommended for cholesterol measurement methods in clinical laboratories (*19*). If an inappropriate or nonoptimal regression procedure is used to analyze the data for a cholesterol methods comparison study, a bias of perhaps 1% or an unnecessarily large standard error for the slope estimate may soon become critical.

Appendix

Computation Principles for the Regression Methods

Ordinary least-squares regression analysis (*1*). On the basis of k paired observations (x_i; y_i), the regression line is estimated from sums of squared deviations and cross-products:

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$$u = \sum (x_i - \bar{x})^2; \quad q = \sum (y_i - \bar{y})^2;$$

$$p = \sum (x_i - \bar{x})(y_i - \bar{y})$$

$$\mathrm{b} = p/u; \quad \mathrm{a} = \bar{y}$$

$$\hat{Y}_i = \mathrm{a} + \mathrm{b}(x_i - \bar{x}) = \mathrm{a}_0 + \mathrm{b}x_i; \quad (\mathrm{a}_0 = \mathrm{a} - \mathrm{b}\bar{x})$$

The caret of $\hat{Y}_i$ denotes that we obtain an estimate of the "true" value for a given x_i.

The standard deviation for the distribution about the line is as follows:

$$\mathrm{SD}y \cdot x = \sqrt{\sum (y_i - \hat{Y}_i)^2/(k-2)}$$

The standard errors of a and b are as follows:

$$\mathrm{SE(a)} = \mathrm{SD}y \cdot x/\sqrt{k}$$

$$\mathrm{SE(b)} = \mathrm{SD}y \cdot x/\sqrt{u}$$

The null hypothesis of identity is tested by two independent t-tests:

$$t = (\mathrm{a} - \bar{x})/\mathrm{SE(a)}; \quad t = (\mathrm{b} - 1)/\mathrm{SE(b)}$$

Weighted least-squares regression analysis (2). In principle, weights (w_i) are introduced in computations of sums of squared deviations and cross-products. The weights are inversely proportional to the squared analytical standard deviation of y at a given value. It is usual to assume that the analytical standard deviation is a function [$h(\cdot)$] of the "true" concentration ($= x$), i.e.,

$$\mathrm{SD}_{ay} = ch(x_i)$$

where c is a proportionality factor. Then

$$w_i = 1/[h(x_i)]^2$$

If it is plausible from experimental data to assume that the coefficient of variation is constant, we have $\mathrm{SD}_{ay} = c\,x_i$ (supposing that $\alpha_0 = 0$) and $w_i = 1/x_i^2$. For some analytes (as shown in Figure 2*b*), the analytical standard deviation becomes constant in the low region, below a limit L. We then have that $\mathrm{SD}_{ay} = c\,L$ for $x_i < L$ and $\mathrm{SD}_{ay} = c\,x_i$ for $x_i > L$. Correspondingly, $w_i = 1/L^2$ for $x_i \leq L$ and $w_i = 1/x_i^2$ for $x_i > L$.

The regression line is estimated as follows:
Weighted averages are computed:

$$\overline{x_w} = \sum w_i x_i / \sum w_i$$

$$\overline{y_w} = \sum w_i y_i / \sum w_i$$

Weighted squared deviations and cross-products are summed:

$$u_w = \sum w_i (x_i - \overline{x_w})^2; \; q_w = \sum w_i (y_i - \overline{y_w})^2$$

$$p_w = \sum w_i (x_i - \overline{x_w})(y_i - \overline{y_w})$$

Slope and location parameters are determined:

$$\mathrm{b} = p_w/u_w; \quad \mathrm{a} = \overline{y_w}$$

The line is estimated:

$$\hat{Y}_i = \mathrm{a} + \mathrm{b}(x_i - \overline{x_w}) = \mathrm{a}_0 + \mathrm{b}x_i \; (\mathrm{a}_0 = \mathrm{a} - \mathrm{b}\overline{x_w})$$

The proportionality factor (c) for the standard deviation about the line is computed:

$$c = \sqrt{\sum (y_i - \hat{Y}_i)^2 w_i/(k-2)}$$

The standard errors of a and b are determined:

$$\mathrm{SE(a)} = c/\sqrt{k}; \quad \mathrm{SE(b)} = c/\sqrt{u_w}$$

The null hypothesis of identity is tested by two independent t-tests:

$$t = (\mathrm{a} - \overline{x_w})/\mathrm{SE(a)}; \quad t = (\mathrm{b} - 1)/\mathrm{SE(b)}$$

The Deming regression analysis (also called: errors-in-variables regression analysis, a structural or functional relationship model) (*3–11*). In addition to the sums of squared deviations and cross-products, the ratio between the squared analytical standard deviations for the methods is needed:

$$\hat{\lambda} = \mathrm{SD}_{ax}^2/\mathrm{SD}_{ay}^2$$

Assuming constant standard deviations and given duplicate measurements (x_{1i} and x_{2i}; y_{1i} and y_{2i}), the analytical standard deviations are estimated as

$$\mathrm{SD}_{ax}^2 = (1/2k) \sum (x_{1i} - x_{2i})^2$$

$$\mathrm{SD}_{ay}^2 = (1/2k) \sum (y_{1i} - y_{2i})^2$$

The regression line is estimated as follows:

$$\mathrm{b} = \left[(\hat{\lambda}q - u) + \sqrt{(u - \hat{\lambda}q)^2 + 4\hat{\lambda}p^2} \right] / 2\hat{\lambda}p$$

$$\mathrm{a} = \bar{y}$$

$$\hat{Y}_i = \mathrm{a} + \mathrm{b}(\hat{X}_i - \bar{x}) = \mathrm{a}_0 + \mathrm{b}\hat{X}_i; \quad (\mathrm{a}_0 = \mathrm{a} - \mathrm{b}\bar{x})$$

Rather complicated methods for computation of standard errors are given in the theoretical statistical literature (*10*). I used the computerized jackknife method (*11*), which has the advantage of being distribution-free.

Weighted Deming regression analysis. In the weighted Deming regression analysis, weights (w_i) are introduced

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in computations of sums of squared deviations and cross-products, and the slope is calculated as described in the previous section (*11*). The weights are inversely proportional to the squared analytical standard deviations at a given value. Supposing that the analytical standard deviations are functions of the true concentration, we have

$$SD_{ax} = f_x h_x(X); \quad SD_{ay} = f_y h_y(Y)$$

To use a weighted modification of the Deming method, we must assume that the ratio SD_{ax}^2/SD_{ay}^2 is a constant ($= \lambda$). Given a proportional relationship between analytical standard deviations and concentrations, perhaps truncated at some lower limit L, and $\alpha_o = 0$, this condition holds true. Keeping in mind the symmetry of this model, we may then express the weights as

$$w_i = 1/[(X_i + Y_i)/2]^2$$

Because X_i and Y_i are unknown true values, we have to use estimates, which can be obtained by an iterative procedure, described in detail in reference *11*:

$$\hat{w}_i = 1/[(\hat{X}_i + \hat{Y}_i)/2]^2$$

Actually, it is possible that the most precise estimate may be the inverse of a weighted average of the estimated true values, i.e., $1/[(\hat{X}_i + \lambda\hat{Y}_i)/(1 + \hat{\lambda})]^2$. In the simulations performed here, only the simple average has been used.

The regression line is estimated as follows:
Weighted averages are calculated:

$$\overline{x_w} = \sum \hat{w}_i x_i / \sum \hat{w}_i; \quad \overline{y_w} = \sum \hat{w}_i y_i / \sum \hat{w}_i$$

Weighted sums of squares and cross-products are computed:

$$u_w = \sum \hat{w}_i (x_i - \overline{x_w})^2; \quad q_w = \sum \hat{w}_i (y_i - \overline{y_w})^2;$$

$$p_w = \sum \hat{w}_i (x_i - \overline{x_w})(y_i - \overline{y_w})$$

The proportionality factors f_x and f_y are estimated from duplicate measurements:

$$\hat{f}_x^2 = (1/2k) \sum (x_{1i} - x_{2i})^2/[(\overline{x_i} + \overline{y_i})/2]^2$$

$$\hat{f}_y^2 = (1/2k) \sum (y_{1i} - y_{2i})^2/[(\overline{x_i} + \overline{y_i})/2]^2$$

$\bar{x}_i$ and $\bar{y}_i$ as the means of the duplicate measurements. We obtain the following expression:

$$\hat{\lambda} = \hat{f}_x^2/\hat{f}_y^2$$

The slope estimate is calculated:

$$b = [(\lambda q_w - u_w) + \sqrt{[(u_w - \lambda q_w)^2 + 4\lambda p_w^2]}]/2\lambda p_w$$

The intercept is determined:

$$a = \overline{y_w}$$

The usual Deming method is the special case where all weights are equal to 1. Standard errors are obtained by the jackknife method.

The weighted Deming regression analysis is evaluated in reference *11* for the null hypothesis situation. Supplementary evaluations with $\beta = 0.8$ and 1.2 (slopes are usually within this range in methods comparison studies) have confirmed that the procedure also is valid under alternative hypotheses.

A plot of standardized distances from the observed points to the line against the average value $[(\hat{X}_i + \hat{Y}_i)/2]$ is useful for evaluation of linearity and outliers. A practical rejection rule for outliers is three standard deviations of the distribution of standardized distances. A BASIC program that performs the weighted Deming regression analysis is available from the author.

Rank regression analysis (12–14). In the rank regression analysis, in principle, slopes between all possible sets of two points are calculated and ranked. The median expresses a slope estimate. Measurement errors for both methods are taken into account by a symmetry argument, which results in calculation of a shifted median that is the final slope estimate. Confidence intervals and hypothesis testing are established by using traditional rank techniques.

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Laboratory Management

Performance of Deming regression analysis in case of misspecified analytical error ratio in method comparison studies

Kristian Linnet

Application of Deming regression analysis to interpret method comparison data presupposes specification of the squared analytical error ratio (λ), but in cases involving only single measurements by each method, this ratio may be unknown and is often assigned a default value of one. On the basis of simulations, this practice was evaluated in situations with real error ratios deviating from one. Comparisons of two electrolyte methods and two glucose methods were simulated. In the first case, misspecification of λ produced a bias that amounted to two-thirds of the maximum bias of the ordinary least-squares regression method. Standard errors and the results of hypothesis-testing also became misleading. In the second situation, a misspecified error ratio resulted only in a negligible bias. Thus, given a short range of values in relation to the measurement errors, it is important that λ is correctly estimated either from duplicate sets of measurements or, in the case of single measurement sets, specified from quality-control data. However, even with a misspecified error ratio, Deming regression analysis is likely to perform better than least-squares regression analysis.

The comparison of measurements by two analytical methods, for example, x and y, is usually based on a form of regression analysis. The most frequently used approach, ordinary least-squares regression (OLR) analysis is subject to several shortcomings when both measurement sets are subject to random errors, which represents the typical situation. Because the procedure assumes that only the y measurements are associated with random measurement errors, the slope estimate becomes biased, and the testing of hypotheses becomes erroneous *(1-3)*. Therefore, alternative regression procedures are more appropriate to apply in situations with random errors in both x and y measurements. The Deming method, also called the errors-in-variables model or the functional or structural relationship model in the statistical literature, takes measurement errors for both sets of measurements into account and is therefore more generally applicable than OLR *(1-4)*. Application of the Deming method requires specification of the ratio between squared analytical SDs for the two analytical methods. The analytical SDs may be known from quality-control data, and specification of the ratio is then possible. Furthermore, if duplicate sets of measurements are available, as is generally recommended, the ratio may be estimated from the actual data set. However, frequently duplicate data sets are not available, and for a new method, quality control data may be sparse. Therefore, application of the Deming regression analysis may be halted by lack of information concerning the ratio between analytical SDs. By default, one may then choose to set the ratio equal to one and carry out the regression analysis on this assumption. In the present study, I consider the performance of Deming regression analysis when the ratio between squared analytical SDs is set to one in simulated situations that should be realistic in the field of clinical chemistry. The cases correspond to a comparison of electrolyte methods and a comparison of glucose methods. Using this approach, it is possible to evaluate the size of a possible slope bias and the performance of hypothesis-testing in situations with an unknown analytical SD ratio.

Materials and Methods

MODEL OF METHOD COMPARISON SITUATION

The study is based on simulated method comparison situations. A given analytical method measures analyte concentrations with some uncertainty. One may distinguish between the measured value (x_i) and the target value (X_i) of a sample subjected to analysis by a given method. The latter is the average result we would obtain if the given sample was measured an infinite number of

Laboratory of Clinical Biochemistry, Psychiatric University Hospital, DK-8240 Risskov, Denmark.
Address correspondence to: Laboratory of Clinical Biochemistry, Psychiatric University Hospital, Skovagervej 2, DK-8240 Risskov, Denmark. Fax 45 86 17 7009; e-mail linnet@post7.tele.dk.
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times. The measured value is likely to deviate from the target value by some small "random" amount (ϵ or δ). For a given sample measured by two clinical chemistry methods, the following relations exist:

$$x_i = X_i + \epsilon_i$$

$$y_i = Y_i + \sigma_i$$

The dispersions of measured values around the target value is determined by the analytical standard deviation (SD_a) of the method. A linear relationship between the target values of the two methods is assumed:

$$Y_i = \alpha_0 + \beta X_i$$

By correctly assuming that measurement errors are present for both x and y measurements, the Deming regression procedure provides an unbiased estimate of the slope β (see *Appendix*). This is in contrast to the case for OLR analysis. By ignoring measurement errors for x measurements, the latter procedure provides a downward biased slope estimate (see *Appendix*).

To estimate the regression line by the Deming method it is, however, necessary to estimate or assign a value to the ratio between squared analytical standard deviations for the x and y method, $\lambda = SD^2_{ax}/SD^2_{ay}$ (see formula in *Appendix*). λ determines the angle in which to project points onto the line to minimize the sum of squared deviations *(5)* (Fig. 1).

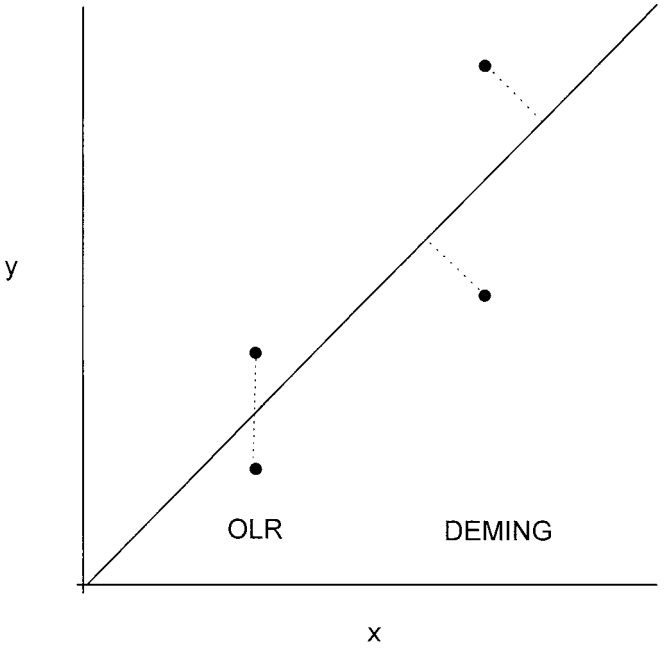

Fig. 1. Comparison of analysis methods.

OLR analysis: projection of measurement sets (x, y) onto the line in the vertical direction so that the sum of squared deviations is minimized; Deming regression analysis: projection of measurement sets (x, y) onto the line at an angle determined by λ so that the sum of squared deviations is minimized. Here λ = 1 and the angle is 90°.

For analytes with values extending over a considerable range, the analytical SD usually increases with the measurement level *(6)*. Often a proportional relationship approximately exists over the major part of the range, which implies that the analytical coefficient of variation (CV_a) is approximately constant. In this situation, we have the relation $\lambda = CV^2_{ax}/CV^2_{ay}$. Deming regression may in this case be carried out either in the simple, unweighted form or in a weighted form in which weights are introduced that are inversely proportional to the squared analytical standard deviation at a given measurement level (see *Appendix*). The latter procedure is the optimal one *(3)*.

SIMULATION PROCEDURE

The performance of regression methods is dependent on the relation between the dispersions of measurement errors and the dispersions of target values. The larger the dispersion of measurement errors is in relation to the dispersion of target values, the larger is the imprecision of the slope estimate. For the ordinary least-squares procedure, the bias of the slope estimate depends on the ratio between the dispersions of x measurements and X target values *(7)*. In clinical chemistry, one observes a wide range of ratios between measurement error and target value dispersions. High ratios occur for compounds that are tightly regulated in the body, e.g., electrolytes, whereas small ratios may occur for substances with a very wide physiological variation, e.g., various hormones whose serum concentrations may span several decades. Intermediate ratios occur for various metabolites such as glucose, urea, and others. In the present study, the focus is on two prototype situations: an "electrolyte-like situation" with a small dispersion of target values and a "metabolite-like case" with a span of target values close to one decade. The performance of the two regression methods was evaluated for various measurement error combinations that should be realistic in clinical chemistry. Random numbers were generated by a computer according to specified distributions. The measurement error distributions were supposed to be gaussian. The regression estimates were computed and subjected to statistical tests as described *(3, 8)*. The computational methods were effected using a modification of the software program CBstat, which is a Windows application for Deming regression analysis developed by the author. Each simulated situation was repeated 5000 times to obtain reliable performance measures. The performance measures were as follows:

(*i*) *Bias of the slope estimate*. The bias is the difference between the true value (β) and the average of estimated slope values for 5000 (*nrun*) simulation runs (b_m). The true value was set to 1 in the simulated situations corresponding to the null hypothesis situation of identity.

(*ii*) *Root mean squared error of the slope estimate*. The root mean squared error (RMSE) is an estimate of the total

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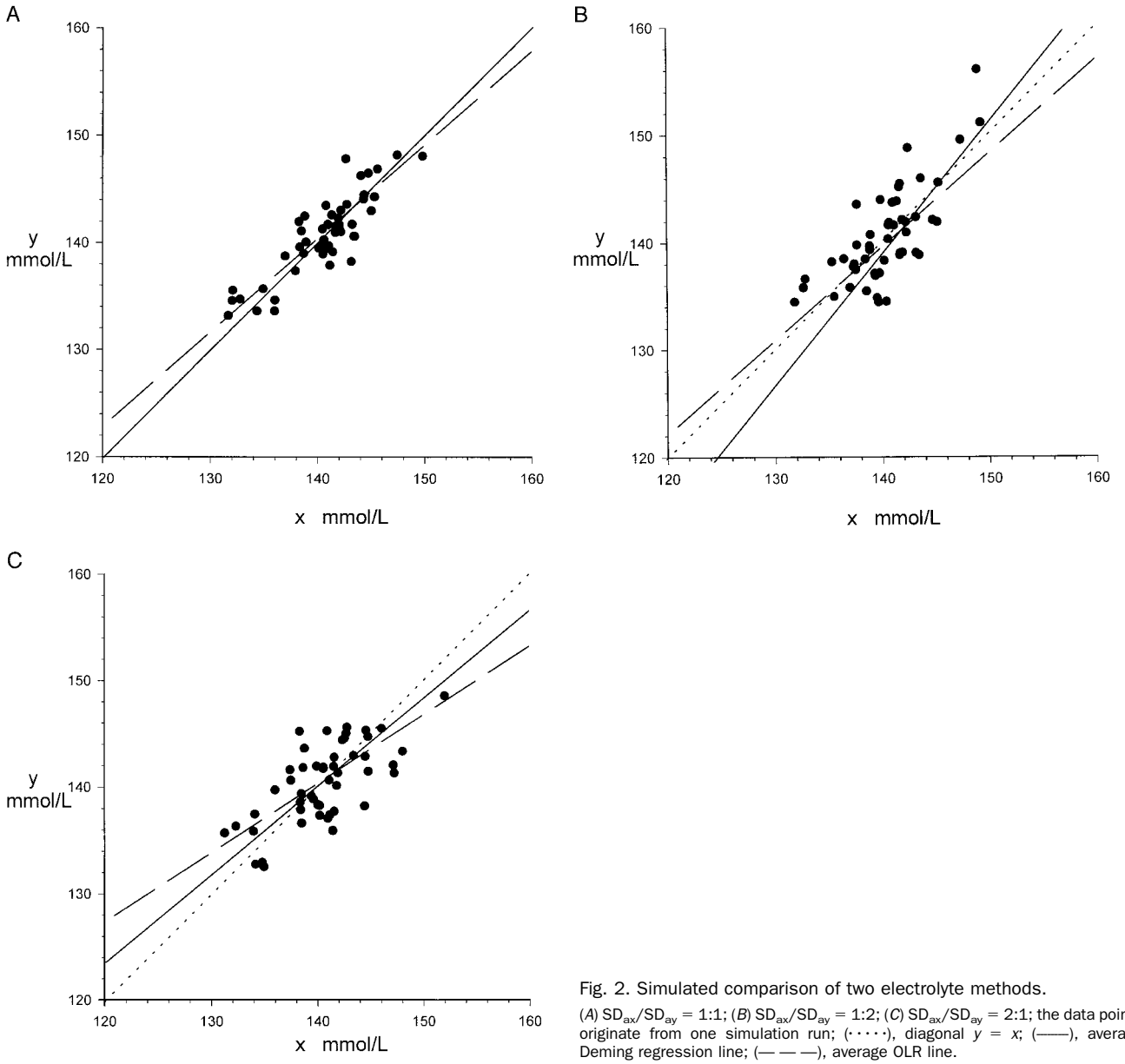

Fig. 2. Simulated comparison of two electrolyte methods.

(*A*) SD_{ax}/SD_{ay} = 1:1; (*B*) SD_{ax}/SD_{ay} = 1:2; (*C*) SD_{ax}/SD_{ay} = 2:1; the data points originate from one simulation run; (·····), diagonal $y = x$; (——), average Deming regression line; (— — —), average OLR line.

error of the slope estimate (b) and includes a systematic part (bias) and a random error part (standard error):

$$RMSE = [\Sigma(b-1)^2/nrun]^{0.5} = [Bias^2 + SE^2]^{0.5}$$

(*iii*) *Real standard error of the slope [SE(b)].* This is the standard error observed in the simulation study, i.e., the standard deviation of the distribution of slope estimates for the 5000 simulation runs.

(*iv*) *Average estimated standard error of the slope [SE(b)].* In each simulation run, a standard error of the slope is estimated as a result of the statistical analysis, so that a t-test of the null hypothesis can be performed. A prerequisite for a correct test is that the estimated standard error, on average, agrees with the real one.

(*v*) *Hypothesis testing.* The performance of hypothesis testing can be evaluated by comparing the observed and expected frequencies of rejection of the null hypothesis on the basis of the t-test for the slope carried out in each simulation run. Under the null hypothesis, one expects 50 rejections out of 1000 trials, when the nominal type I error is set to the usual level of 5%. Thus, if the observed number of rejections is 200, the actual type I error is four times the nominal or expected value, and testing of the null hypothesis is not performed in the correct way.

Results

ELECTROLYTE CASE

The comparison of two methods for the measurement of serum sodium was simulated. The target values were supposed to be gaussian distributed with a mean value of

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Table 1. Regression results for the electrolyte-like case.

	Analytical SD ratio SD_{ax}/SD_{ay}					
	1:1		1:2		2:1	
	Least-squares RA[a]	Deming RA ($\lambda = 1$)	Least-squares RA	Deming RA ($\lambda = 1$)	Least-squares RA	Deming RA ($\lambda = 1$)
Average slope (b_m)[b]	0.880[c]	1.001	0.879[c]	1.236[c]	0.647[c]	0.820[c]
Bias of slope	−12%	0%	−12%	24%	−35%	−18%
RMSE	0.138	0.080	0.163	0.286	0.362	0.207
Real SE(b)	0.068	0.080	0.110	0.161	0.081	0.105
Average estimated SE(b)	0.069	0.080	0.110	0.163	0.081	0.107
Frequency of rejection of null hypothesis (nominal 5%)	41%	5.9%	19%	24%	98%	44%

[a] RA, regression analysis.
[b] The true slope β is equal to 1. Sample size, 50 single measurements for each method. Based on 5000 simulation runs.
[c] Significantly different from 1 ($P < 0.001$).

140.5 mmol/L, corresponding to the mean of the reference interval, stated to be 136–145 mmol/L *(9)*.The SD of the target values was set to 3.8 mmol/L. This corresponds to a range exceeding the reference interval by ~5 mmol/L in each direction, corresponding to the inclusion of some pathological samples. The analytical SDs of the methods were set to 1.405 or 2.81, corresponding to CVs of 1% or 2% at the mean level. For this model, the Pearson product–moment correlation coefficient was 0.88 when the analytical SDs both were 1.405, and 0.75 when one SD was 2.81. It was assumed that the analytical SDs were unknown, and the Deming regression analysis was performed with an assigned SD ratio of one for all cases. OLR analysis was carried out for the sake of comparison. Fig. 2, A-C, and Table 1 refer to SD ratios of 1:1, 1:2, and 2:1 in the simulated examples. Fig. 2A shows that the average Deming regression line coincides with the diagonal as a sign of an unbiased slope estimate for this situation with a correctly specified analytical SD ratio. The OLR procedure has a downward bias of 12% because of the neglect of measurement errors for x. Accordingly, the RMSE of the least-squares method is almost twice the size of the Deming case.

For the situations with analytical SD ratios different from 1, both types of slope estimates become biased (Fig. 2, B and C). The worst case is that for the least-squares method and an analytical CV of 2% for the x measurements (bias, −35%). However, the Deming method also gives slope results with a considerable bias in the situations with a misspecified SD ratio, up to 24% in the example shown here. The bias of the Deming method is positive when SD_{ay} exceeds SD_{ax} and negative when SD_{ay} is smaller than SD_{ax}. In contrast, the bias of the OLR method is always negative and only depends on the relation between x measurement errors and the dispersion of X target values (see *Appendix*).

A more detailed account on the relation between analytical error ratio and bias is displayed in Fig. 3. In Fig. 3A, SD_{ax} is fixed at 1.405 (CV_{ax}, 1%), and SD_{ay} increases from 1.405 to 2.81 (CV_{ay}, 2%). In this situation, the bias of the Deming method gradually increases to a maximum value of +24% as the ratio deviates more and more from the assumed value of one, whereas the bias of the OLR method is constant (−12%). In Fig. 3B, SD_{ay} is kept fixed at 1.405 (CV_{ay}, 1%), and SD_{ax} increases from 1.405 to 2.81 (CV_{ax}, 2%). Now the biases of both procedures increase with increasing SD_{ax} value, so that the maximum biases are observed at a SD_{ay}/SD_{ax} ratio of 0.5 (Fig. 3B). The bias of the Deming procedure increases from zero to a maximum of −18%, whereas the bias of OLR starts at −12% and increases to −35%.

When the null hypothesis has been tested in cases where no difference exists between the target values, the bias has led to the null hypothesis being rejected too frequently. For the OLR method, the frequency ranges from 19% to 98%. In the latter situation, the test will almost always produce a rejected null hypothesis, i.e., the conclusion of the statistical analysis is that there is a systematic difference between the two methods although no real difference exists. With regard to the Deming method, this frequency ranges from 5.9% to 44%.

In the example described above, the target values of the 50 samples were randomly drawn from a gaussian distribution with a mean corresponding to the mean of the reference interval. Therefore, the majority of sample values are located in the middle of the reference interval with relatively few extreme sample values. In method comparison studies, the investigator may choose to deliberately select samples with values in the periphery of the range of interest to obtain a more uniform distribution over the studied interval and thereby increase the precision of estimated regression parameters. To study such a procedure, one may simulate drawing of sample sets from a uniform distribution of target values covering the range of interest (131–150 mmol/L) instead of a gaussian distribution, such as the cases dealt with above. After this change, the Pearson coefficient of correlation increased to 0.94 when both analytical SDs were 1.405 and to 0.87 when one of the analytical SDs was equal to 2.81. For this model, the same general trends are observed, but in a reduced scale.

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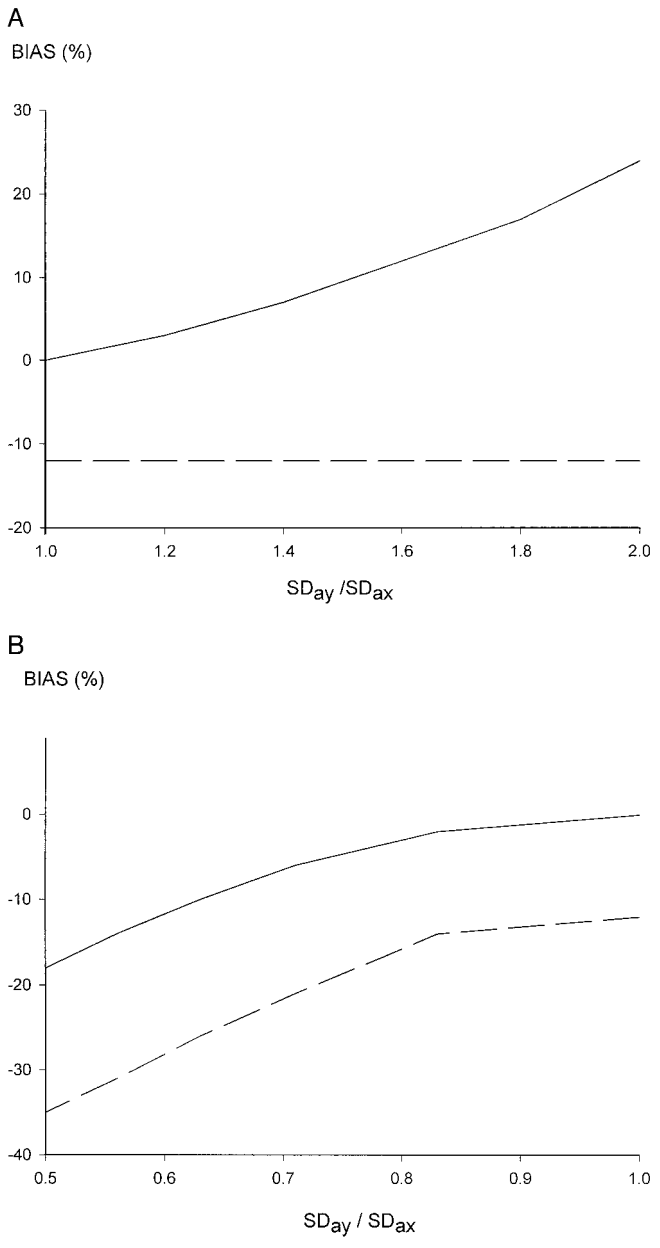

Fig. 3. Bias for OLR analysis and Deming regression analysis as a function of the analytical SD ratio.

(*A*) SD_{ax} is fixed at 1.405 (CV_{ax}, 1%), and SD_{ay} ranges from 1.405 to 2.81 (CV_{ay}, 2%); (*B*) SD_{ay} is fixed at 1.405 (CV_{ay}, 1%), and SD_{ax} ranges from 1.405 to 2.81 (CV_{ax}, 2%).(——), Deming; (— — —), OLR.

The Deming procedure with λ specified to one yields slope biases of +10% and −9% for SD_{ax}/SD_{ay} ratios of 1:2 and 2:1, respectively. Similarly, the slope biases of the OLR procedure are also reduced to about one-half of the values, −6% and −20%, respectively. Thus, by assuring a more even distribution of sample values over a given interval, the bias problems can be reduced but not avoided.

METABOLITE CASE

Many clinical chemical analyses have range ratios in the interval 5–10, e.g., serum glucose determinations. For this analyte, patient samples may typically range from ~2.5 to 20 mmol/L. In a method comparison study, most of the values are likely to be located in the lower half of this interval. Thus, in the simulation model it is supposed that three-quarters of the observations are located in the lower half and one-quarter in the upper half of the interval. The measurement errors were assumed to be proportional to the concentrations, which is a more common situation than that of constant analytical errors for analytes with a considerable range *(6)*. Proportional measurement errors imply that the analytical coefficients of variation, CV_{ax} and CV_{ax}, are constant over the measurement range. Their values were set to 4% and 8%, respectively, so that the ratios of analytical coefficients of variation were 1:1, 1:2, or 2:1 (Table 2). The case with a ratio of 2:1 is shown in Fig. 4. The Pearson coefficient of correlation was 0.99 when both CVs equalled 4% and 0.98 when one CV was 8%. In accordance with the specified model, the weighted form of Deming regression analysis was carried out assuming proportional errors (see *Appendix*). Again, the sample was composed of 50 single observations for each method. All slope estimates obtained by the least-squares regression method are biased, but because of the wider range of target values, the bias is either negligible (0.7%) or small (2.7%). Hypothesis-testing, however, is clearly misleading with type I errors four to six times larger than the nominal one of 5%. This relies partly on the bias, partly on an underestimated standard error.

The weighted Deming method yields an unbiased slope estimate in the case with an analytical CV ratio of 1:1 and biases up to only 0.7% in the other cases. Thus, in the present example, the maximum bias of the weighted Deming procedure amounts to only about one-fourth of the maximum bias of the OLR method and so may be regarded as negligible. Furthermore, estimation of the standard error of the slope, and thus hypothesis-testing, is rather insensitive to a misspecified error ratio. The observed type I error values (5.3–5.5%) are very close to the nominal value of 5%. Thus, although the analytical SD ratio might have been misspecified, hypothesis-testing is reliable in this situation, with a relatively wide range of target values compared with the dispersion of measurement errors.

Discussion

OLR analysis is still the most frequently applied procedure to evaluate method comparison data despite several well-known shortcomings, such as a bias associated with slope estimation, incorrect testing of statistical hypotheses, and low efficiency in cases with proportional errors over one or more decades of values *(3)*. The bias problem may be overcome with the Deming regression procedure, and hypothesis-testing can be done correctly on the basis of this regression procedure if standard errors of slope and intercept are estimated on the basis of modern statistical resampling methods *(8, 10)*. Finally, by applying a weighted modification of the Deming procedure as

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Table 2. Regression results for the metabolite-like case.

	Analytical CV ratio CV_{ax}/CV_{ay}					
	1:1		1:2		2:1	
	Least-squares RA[a]	Weighted Deming RA (λ = 1)	Least-squares RA	Weighted Deming RA (λ = 1)	Least-squares RA	Weighted Deming RA (λ = 1)
Average slope (b_m)[b]	0.993[c]	1.000	0.994[c]	1.007[c]	0.973[c]	0.994[c]
Bias	−0.7%	0%	−0.6%	0.7%	−2.7%	−0.6%
RMSE	0.026	0.018	0.041	0.029	0.047	0.028
Real SE(b)	0.025	0.018	0.040	0.028	0.039	0.027
Average estimated SE(b)	0.017	0.018	0.027	0.029	0.026	0.028
Frequency of rejection of null hypothesis (nominal 5%)	19%	5.3%	19%	5.5%	29%	5.3%

[a] RA, regression analysis.
[b] The true slope β is equal to 1. Sample size, 50 single measurements for each method. Based on 5000 simulation runs.
[c] Significantly different from 1 ($P < 0.001$).

done here for the glucose example, full efficiency may be attained in cases with proportional analytical errors *(8)*. Therefore, application of the Deming procedure is generally preferable to OLR analysis. Specification of the squared analytical SD ratio λ may, however, pose problems. The easiest way to attain a correct λ value is to use duplicate measurements in the method comparison study, allowing for simultaneous estimation of analytical SDs or CVs and so λ. The use of duplicate sets of measurements in method comparison studies is generally recommended *(11)*. However, taking into account that most method comparison evaluations appear to be based on single measurements, one should strive to specify λ correctly. In most cases, quality-control data will be available, and therefore, λ may be specified as the ratio

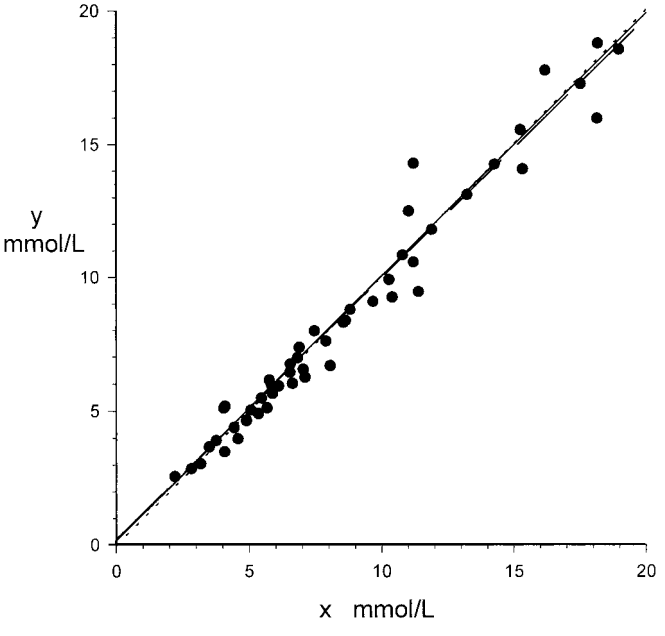

Fig. 4. Simulated comparison of two glucose methods given $CV_{ax}/CV_{ay}=2:1$.

The data points originate from one simulation run. The average regression lines (same symbols as in Fig. 2) almost coincide with the diagonal.

between recorded squared analytical SDs. As shown, misspecification of λ may induce a considerable slope bias for the Deming method in electrolyte-like situations with a short range of data. Hypothesis-testing is also seriously affected. Thus, a correct specification of λ is important when applying the Deming method in situations with a limited range of values. With regard to the metabolite-like case, the bias problem is negligible; also with regard to the testing of hypotheses, the Deming procedure appears to be rather robust towards a misspecified error ratio in these examples.

More generally, when considering the sensitivity of the Deming procedure to a misspecified error ratio in a given situation, one may to some extent be guided by the value of the correlation coefficient. Electrolyte-like cases are characterized by low values for the correlation coefficient, whereas the correlation coefficient is higher in situations with a wider range of values. In cases with a misspecified error ratio, the bias of the Deming method is smaller than the maximum bias observed for OLR analysis. A value of 0.975 for the correlation coefficient has been suggested as the lower limit for acceptable performance of OLR in method comparison studies *(11)*. Thus, according to this point of view, the Deming method may be regarded as relatively insensitive to misspecified error ratios in situations with correlation coefficients exceeding 0.975.

The impact of a misspecified error ratio on the performance of Deming regression analysis has also been considered in the theoretical literature *(12)*. A theoretical evaluation shows that the RMSE of the Deming slope is at a minimum when the error ratio is correctly specified and increases the more the specified ratio deviates from the true ratio. However, for reasonable parameter examples, the RMSE stays lower than that of OLR *(12)*.

Some other regression methods that take measurement errors for both x and y into account apparently do not exhibit the problem with specification of the SD_{ax}/SD_{ay} ratio. In the so-called standardized principal component analysis, the slope is computed in a slightly different way. The procedure actually presupposes that the error ratio is

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related to the slope, that is $(SD_{ax}/SD_{ay})^2 = 1/\beta^2$ *(13)*. Only when this assumption is given does the method provide a slope estimate free of any bias. This procedure is thus not very flexible and, therefore, not as useful as the Deming procedure. Similarly, the rank regression method of Passing and Bablok operates with the same rigid assumption *(14)*. If the relation does not hold true, the slope estimate becomes biased *(3)*.

Appendix

ESTIMATION OF THE DEMING REGRESSION LINE

In situations with constant analytical errors, i.e., analytical SDs that are independent of the measurement level, the unweighted form of Deming regression analysis is appropriate. The procedure relies on computations of sums of squared deviations and cross-products:

$$x_m = \Sigma x_i/N; y_m = \Sigma y_i/N$$

$$u = \Sigma(x_i - x_m)^2; q = \Sigma(y_i - y_m)^2$$

$$p = \Sigma(x_i - x_m)(y_i - y_m)$$

The subscript m refers to the mean of the variable.

In case of duplicate sets of measurements each x_i and y_i represent the mean of individual measurements ($x_i = (x_{1i}+x_{2i})/2$ and $y_i = (y_{1i}+y_{2i})/2$). Analytical standard deviations for methods x and y are estimated as:

$$SD^2_{ax} = (1/2N)\Sigma(x_{2i} - x_{1i})^2 \; SD^2_{ay} = (1/2N)\Sigma(y_{2i} - y_{1i})^2$$

and

$$\lambda = SD^2_{ax}/SD^2_{ay}$$

The Deming regression line is estimated as:

$$b = [(\lambda q - u) + [(u - \lambda q)^2 + 4\lambda p^2]^{0.5}]/2\lambda p$$

$$a = y_m$$

$$Y_{esti} = a + b(x_{esti} - x_m) = a_0 + bX_{esti}; \; a_0 = a - bx_m$$

X_{esti} and Y_{esti} refer to estimated target values.
Standard errors of a_0 and b are estimated on the basis of a resampling principle, the so-called jackknife procedure *(8)*.

In weighted Deming regression analysis, the slope and intercept are estimated analogously, with the modification that weights are introduced *(8)*. The weights (w_i) are inversely proportional to the squared analytical standard deviations at a given concentration. Given a proportional relationship between analytical standard deviations and analyte concentrations and supposing that $\alpha_0 = 0$, we have:

$$w_i = [(X_i + Y_i/2]^{-2}$$

X_i and Y_i are unknown target values, which must be replaced by estimates obtained by an iterative procedure as described *(8)*:

$$w_i = [(X_{esti} + Y_{esti})/2]^{-2}$$

If the proportional relationship does not hold true in the lower part of the analytical range, which often is the case and is indicated by an increasing analytical CV in this region, one may truncate the relationship at a suitable lower limit L, so that $w_i = L^{-2}$ for x and y less than L *(3)*.

Now, weighted averages are computed:

$$x_{wm} = \Sigma w_i x_i/\Sigma w_i; y_{wm} = \Sigma w_i y_i/\Sigma w_i$$

and weighted sums of squares and cross-products:

$$u_w = \Sigma w_i(x_i - x_{wm})^2; q_w = \Sigma w_i(y_i - y_{wm})^2$$

$$p_w = \Sigma w_i(x_i - x_{wm})(y_i - y_{wm})$$

The weighted Deming regression line is estimated as:

$$b = [(\lambda q_w - u_w) + [(u_w - \lambda q_w)^2 + 4\lambda p_w{}^2]^{0.5}]/2\lambda p_w$$

$$a = y_{wm}$$

$$Y_{esti} = a + b(X_{esti} - x_{wm}) = a_0 + bX_{esti}; \; a_0 = a - bx_{wm}$$

λ here refers to CV^2_{ax}/CV^2_{ay}, which in case of single sets of measurements is assigned a value and in case of duplicate sets of measurements is estimated from the data.

ESTIMATION OF THE OLR LINE

The parameters of the OLR line are estimated as:

$$b = p/u$$

and

$$a = y_m$$

$$Y_{esti} = a + b(x_i - x_m) = a_0 + bx_i; a_0 = a - bx_m$$

p and u refer to the sums of cross-products and squared deviations, respectively, as described above.

Standard errors of b and a_0 are calculated as described *(7)*.

The bias of the slope estimate is determined by the relation:

$$\beta_{OLR} = \beta/(1 + SD^2_{ax}/SD^2_X)$$

β_{OLR} is the average slope obtained by OLR analysis; β is the true slope between X and Y target values; and SD_X refers to the dispersion of X target values *(7)*.

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Attachment 3
510(k) Summary

Submitter:	Nonin Medical, Inc.
Contact Person:	Brodie Pedersen Senior Regulatory Engineer Nonin Medical, Inc. 13700 1st Ave. North Plymouth, MN 55441-5443
Phone:	763-553-9968
Fax:	763-553-7807
Date Prepared:	October 31, 2011
Trade Name:	EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series for use with Model 7600 Regional Oximeter System with EQUANOX Technology
Classification Name and Number:	Oximeter Class II, 21 CFR 870.2700
Product Code:	MUD
Predicate Device(s):	Nonin's Model 8004CB Series Oximeter Sensor used with the Model 7600 Equanox Advance Regional Oximeter System is substantially equivalent to the Model 8004CA Oximetry Sensor cleared with the Model 7600 Regional Oximeter System cleared by the FDA in K102715 on 12/17/2010, and the FORE-SIGHT® Oximeter MC-2000 Series Cerebral Oximeter manufactured by CAS Medical Systems Inc. that was cleared by the FDA under K094030 on 12/23/10.

Indications for Use:

Model 8004CB (Adhesive Version)

The 8004CB Single-Patient use, Non-Sterile, Disposable Regional Oximetry Sensor is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. The sensor is for spot-checking and continuous monitoring of neonate, infant, and pediatric patients weighing less than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8004CB sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long term care and mobile environments.

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K113215

Indications for Use continued:

Model 8004CB-NA (Non-Adhesive Version)
The 8004CB-NA Non-Adhesive, Single-Patient use, Non-Sterile, Disposable Regional Oximetry Sensor is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. The sensor is for spot-checking and continuous monitoring of neonate, infant, and pediatric patients weighing less than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8004CB-NA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long term care and mobile environments.

Model 7600 Regional Oximeter System
Nonin's non-invasive Model 7600 4- Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. It is intended for spot-checking or continuous monitoring of adult, or neonate, infant and pediatric patients. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Device Description:

Nonin's® EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series for use with the Model 7600 4-Channel Regional Oximeter System continuously monitors and records the mixed arterial/venous blood oxygen levels (rSO_2) through non-invasive near-infrared spectroscopy of tissue under the sensors.

The 7600 system is comprised of three subsystems; sensor, patient oximetry device (pod) and display unit. The sensor allows light absorption measurements at various wavelengths in the near-infrared spectrum (approximately 700 to 900 nanometers). The sensor is sized appropriately for the patient population.

The sensors plug into the patient oximetry device (pod) which controls the light emitted from the sensor LEDs and measures the light returning via the sensor photodiodes. From these measurements, the 7600PA pod determines specific absorption values and calculates the rSO_2 value. The pod then communicates the rSO_2 readings and other data to the display unit. Up to 4 pods with attached sensors may be used with a single 7600 display unit

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The 7600 display unit displays real-time regional oximetry data. It is a battery-backed, mains-powered device equipped with audio and visual alarm indicators. Real-time data and playback output is accomplished through a Bluetooth transceiver module or serial RS-232 connection.

Technological Characteristics and Performance:

EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series is equivalent in construction to Nonin's previously cleared 8004CA regional oximeter sensor. The performance of the EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series, for use on patient's weighing less than 88pounds (40 kg), accuracy specifications are absolute rSO_2 accuracy (Arms*): 45% to 95% rSO_2 ±5.9%. Based on the measured regional hemoglobin saturation value (rSO_2) of cerebral sensors calibrated to arterial / venous hemoglobin oxygen ($SavO_2$) value, determined from venous and arterial blood samples from 44 subjects ranging in age from 4 days to 10 years. The model used for blood in the brain is 70% venous and 30% arterial. The venous blood was drawn from the right jugular bulb. The accuracy of the sensors in comparison to the blood gas analyzer samples measured over the rSO_2 range of 45 – 95%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Functional and Safety Testing:

Nonin's EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series used with the Model 7600 Regional Oximeter System was developed following the risk management processes defined by ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices. The EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series has successfully undergone laboratory safety and performance testing in accordance with ISO 9919:2005, Medical Electrical Equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use, IEC 60601-1:1995 Medical electrical equipment – part 1: General requirements for safety and IEC 60601-1-2:2007 General requirements for basic safety and essential performance – Collateral standards: Electromagnetic compatibility – requirements and tests.
Evaluation of materials was performed in accordance with ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

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K113215

A prospective controlled multisite study involving a diverse ethnic pediatric population ranging in age from 4 days to 10 years used $SavO_2$ values to simultaneously validate the rSO_2 values measured by the Model 7600 4-Channel Regional Oximeter System with the EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series.

Performance testing and clinical testing were successfully completed in order to ensure that it has appropriate performance, functional features and is substantially equivalent to the predicate device.

Conclusion:

Nonin's EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series used with the Model 7600 Regional Oximeter System is substantially equivalent to the Model 7600 4-Channel Regional Oximeter with Equanox Technology and Bluetooth wireless Technology K102715 cleared 12/17/2010 including regional sensors 8004CA and 8000CA. It is equivalent to the FORE-SIGHT® Oximeter MC-2000 Series Cerebral Oximeter manufactured by CAS Medical Systems Inc. that was cleared by the FDA under K094030 on 12/23/10.

The conclusion drawn is that the revised indications for use and labeling are substantially equivalent to the predicate device and do not raise new questions of safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 14 2012

Nonin Medical, Inc.
c/o Mr. Brodie C. Pedersen
Senior Regulatory Engineer
13700 1st Avenue North
Plymouth, MN 55441

Re: K113215
Trade/Device Name: EQUANOX Advance Neonatal/Pediatric Sensor 8004CB Series for use with Model 7600 Regional Oximeter System with EQUANOX Technology
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: April 10, 2012
Received: April 11, 2012

Dear Mr. Pedersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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1. Indications for Use Statement

510(K) Number: K113215

Device Name:

Nonin Medical, Inc. EQUANOX Advance™ Neonatal/Pediatric Sensor 8004CB Series for use with the Model 7600 4 Channel Regional Oximeter System with Equanox™ Technology

Indications for Use:

Model 8004CB (Adhesive Version)

The 8004CB Single-Patient use, Non-Sterile, Disposable Regional Oximetry Sensor is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. The sensor is for spot-checking and continuous monitoring of neonate, infant, and pediatric patients weighing less than 88 pounds (40 kilograms).. The sensor may be repositioned or replaced with another 8004CB sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long term care and mobile environments.

Model 8004CB-NA (Non-Adhesive Version)

The 8004CB-NA Non-Adhesive, Single-Patient use, Non-Sterile, Disposable Regional Oximetry Sensor is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. The sensor is for spot-checking and continuous monitoring of neonate, infant, and pediatric patients weighing less than 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8004CB-NA sensor without baseline re-establishment. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long term care and mobile environments.

Model 7600 Regional Oximeter System

Nonin's non-invasive Model 7600 4- Channel Regional Oximeter System is intended for use as an absolute real-time adjunct monitor of hemoglobin oxygen saturation of blood underneath the sensor at cerebral and somatic sites. It is intended for spot-checking or continuous monitoring of adult, or neonate, infant and pediatric patients. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K113215

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Development and Validation of a Cerebral Oximeter Capable of Absolute Accuracy

David B. MacLeod, MBBS, FRCA,* Keita Ikeda, PhD,* Charles Vacchiano, PhD, CRNA,†
Aaron Lobbestael, MS,‡ Joyce A. Wahr, MD,§ and Andrew D. Shaw, MBBS, FRCA, FCCM‖

Objective: **Cerebral oximetry may be a valuable monitor, but few validation data are available, and most report the change from baseline rather than absolute accuracy, which may be affected by individuals whose oximetric values are outside the expected range. The authors sought to develop and validate a cerebral oximeter capable of absolute accuracy.**

Design: **An in vivo research study.**

Setting: **A university human physiology laboratory.**

Participants: **Healthy human volunteers were enrolled in calibration and validation studies of 2 cerebral oximetric sensors, the Nonin 8000CA and 8004CA. The 8000CA validation study identified 5 individuals with atypical cerebral oxygenation values; their data were used to design the 8004CA sensor, which subsequently underwent calibration and validation.**

Interventions: **Volunteers were taken through a stepwise hypoxia protocol to a minimum saturation of peripheral oxygen. Arteriovenous saturation (70% jugular bulb venous saturation and 30% arterial saturation) at 6 hypoxic plateaus was used as the reference value for the cerebral oximeter. Absolute accuracy was defined using a combination of the bias and precision of the paired saturations (A_{RMS}).**

Measurements and Main Results: **In the validation study for the 8000CA sensor (n = 9, 106 plateaus), relative accuracy was an A_{RMS} of 2.7, with an absolute accuracy of 8.1, meeting the criteria for a relative (trend) monitor, but not an absolute monitor. In the validation study for the 8004CA sensor (n = 11, 119 plateaus), the A_{RMS} of the 8004CA was 4.1, meeting the prespecified success criterion of <5.0.**

Conclusions: **The Nonin cerebral oximeter using the 8004CA sensor can provide absolute data on regional cerebral saturation compared with arteriovenous saturation, even in subjects previously shown to have values outside the normal population distribution curves.**

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KEY WORDS: cerebral oximetry, cerebral saturation, Bland-Altman analysis, hypoxic protocol, near-infrared spectroscopy

THE INTRODUCTION OF pulse oximetry 30 years ago to monitor the saturation of arterial blood (SaO_2) continuously led to dramatic improvements in patient safety.[1,2] Knowledge of SaO_2, however, provides only part of the clinical picture, because adequate tissue oxygenation depends not only on supply (oxygen delivery, ie, oxygen content of blood and regional blood flow) but also on demand (regional oxygen consumption.) A monitor that continuously and accurately reports the regional oxygen saturation of brain tissue (rSO_2), which is critically susceptible to hypoxia, has been sought for a long time.

The first commercially available cerebral oximeters were accepted as trend monitors, not as absolute monitors. There has been no proven gold standard for determining the absolute or precise level of rSO_2, and, therefore, it was impossible to know whether an oximeter-generated rSO_2 value agreed absolutely with true cerebral saturation. Cerebral oximeters, however, have been accepted as relative or trend monitors, where changes from the baseline of rSO_2 values could accurately reflect the magnitude and direction of changes in cerebral saturation.[3-5] These trend, or relative, monitors have been validated in laboratory settings,[6] and many reports have demonstrated their ability to detect potentially devastating changes in cerebral saturation.[7-9] Two randomized trials have demonstrated the ability of these monitors to improve outcomes after abdominal surgery or cardiac surgery when used to direct interventions to maintain a minimum saturation.[10,11]

Discussion continues on the ability of any monitor to provide absolute measurement, ie, whether the value presented absolutely agrees with the true cerebral tissue oxygen saturation. Part of the issue is that there has not been an accepted "gold standard" against which the accuracy of an oximeter could be tested.[12] Over time, however, laboratory data have accumulated showing that cerebral tissue saturation can be estimated using SaO_2 and jugular bulb venous saturation ($SjvO_2$) in a ratio of 1:3.[13,14]

$$\text{Cerebral arteriovenous saturation } [SavO_2] = (0.25 \times SaO_2) + (0.75 \times SjvO_2)$$

This ratio has been used in clinical studies and in validation studies performed in volunteers.[6]

This study was designed to test the accuracy of a cerebral oximetric system (Equanox Cerebral Oximetry System; Nonin Medical, Inc, Plymouth, MN) in a prospective, single-center, nonrandomized study. During the validation of the Equanox system using the 8000CA sensor, a subject with significantly atypical light scattering and absorbing characteristics was identified. Data from this volunteer and 4 others with unusual light-scattering characteristics were used in the development of a second-generation sensor, the 8004CA, which was validated subsequently.

METHODS

Two separate, sequential, prospective, single-center, nonrandomized investigations to calibrate and validate the accuracy of the 2 oximetric sensors were performed with approval from the medical center institutional review board. Calibration and validation of the 8000CA sensor were completed entirely before initiating the development and calibration and validation studies for the 8004CA sensor. The 2 sensors were evaluated with the same study design and methods.

*From the *Human Pharmacology Laboratory, Department of Anesthesiology, and †School of Nursing, Duke University, Durham, NC; ‡Nonin Medical, Inc, Plymouth, MN; §Department of Anesthesiology, University of Michigan, Ann Arbor, MI; and ‖Department of Anesthesiology, Duke University/Durham VAMC, Durham, NC.*

Funding for this study was provided by Nonin Medical, Inc.

Address reprint requests to David MacLeod, MD, FRCA, Assistant Professor of Anesthesiology Human Pharmacology Laboratory, Department of Anesthesiology, Duke University Medical Center, Durham, NC 27710. E-mail: david.macleod@duke.edu

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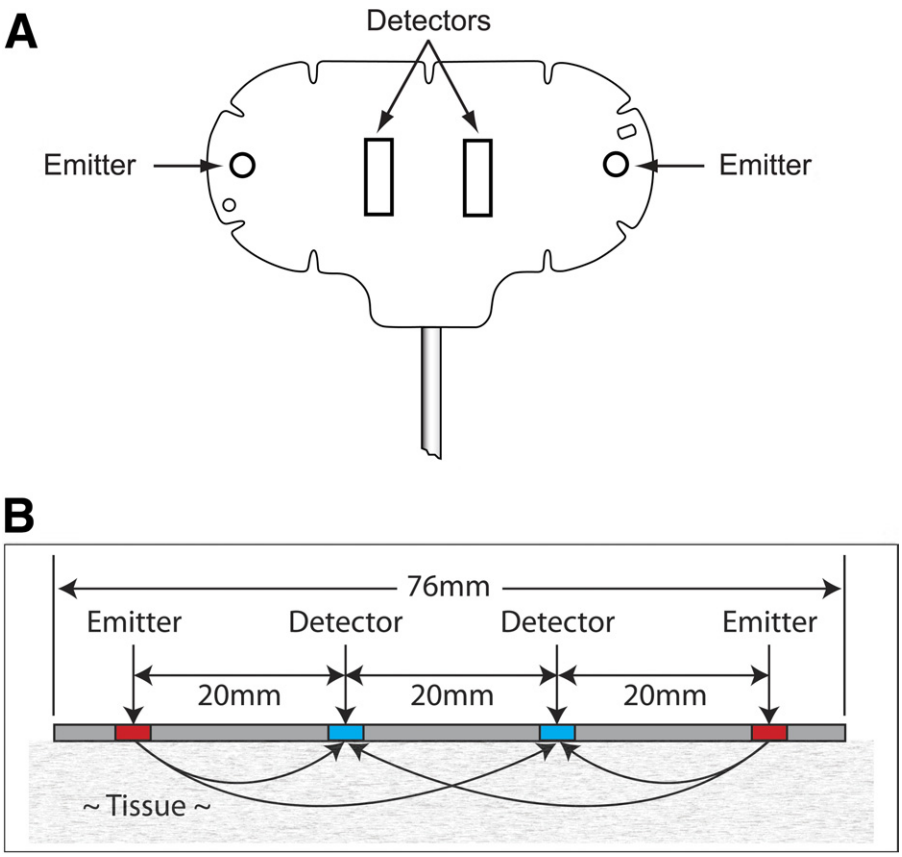

Fig 1. Schematic of the Equanox 8000CA and 8004CA sensors. (A) The Equanox cerebral oxygen saturation monitor (Nonin Medical, Inc, Plymouth, MN) contains 2 light-emitting diodes, each generating 3 or 4 near-infrared spectroscopic wavelengths, and 2 detection sensors, each separated from the next optode by a distance of 20 mm. (B) Measurements from the emitters to the closer detector (20 mm) represent shallow (extracranial) tissue saturation; measurements from emitters to farther detectors (40 mm) represent shallow (extracranial) and deep (intracranial) tissue saturations. (Color version of figure is available online.)

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Normal, healthy volunteers 21-35 years old and with a body mass index ≥18 and ≤30 kg/m^2 who gave written informed consent were enrolled. Subjects were not eligible to be enrolled in a validation study if they had participated previously in the calibration of the same sensor (the calibration was done separately). A completely separate cohort of subjects was enrolled in the validation part of each study. Subjects underwent the hypoxia protocol outlined below. At each study session, 2 anesthesiologists were present; 1 to oversee the safe conduct of the study and be responsible for each subject's safety, the other to oversee the study procedure and data validity.

Device Description

Nonin 8000CA

The initial cerebral oximeter tested was the Nonin Equanox 8000CA (Fig 1). This sensor is based on dual-emitter and dual-detector sensor topology and uses 3 wavelengths in each emitter (730, 810, and 880 nm). Typical oximeters use a single emitter with 2 detectors: 1 detector spaced to capture light from skull and skin only (short path, extracranial saturation), the second detector spaced to capture light from the skin, skull, and brain (long path, extra- and intracranial saturation). Subtracting the extracranial saturation from that of the longer path (intracranial and extracranial saturations) is assumed to isolate intracranial oxygen saturation.[7] However, any difference in the optical properties of the skull and forehead beneath the near versus the far detector will influence the calculated intracranial saturation measurement. The 8000CA sensor has dual emitters and dual detectors, with the long and short paths reversed for each emitter, causing the skull and forehead optical differences associated with each detector to be canceled out.

Nonin 8004CA

During the validation study of the 8000CA sensor, 1 individual was identified with significantly atypical light-scattering characteristics. This individual and 4 others with atypical light-scattering characteristics were used to direct the design of the 8004CA sensor; specifically, an additional wavelength was added to account for tissue-related light absorption and refraction.

Hypoxia Protocol

Enrolled subjects fasted overnight; no sedation or anesthesia was administered. Standard monitors were applied (5-lead electrocardiography, pulse oximetry), and an intravenous catheter and a radial artery catheter were placed. A 5-F catheter (PreSep Central Venous Oximetry Catheter; Edwards Lifesciences, Irvine, CA) was placed in the right or left jugular venous bulb with ultrasound guidance, and its position was confirmed with a lateral skull x-ray. Two Equanox sensors of the same model (8000CA in the first study, 8004CA in the second study) were placed on each side of the forehead for bilateral monitoring. A dedicated facemask and breathing apparatus with a tight seal (RespirAct; Thornhill Research, Inc, Toronto, ON, Canada) were used to induce hypoxia to a predetermined degree and to control precisely the blood carbon dioxide levels despite a variable ventilatory rate. The RespirAct breathing apparatus is a device available for research purposes that uses a prospective, feed-forward, low-gas-flow system to provide precise and independent control of blood carbon dioxide and oxygen levels.[9] End-tidal oxygen and carbon dioxide are monitored and controlled continuously to maintain the target partial pressure of arterial oxygen and end-tidal carbon dioxide.

The hypoxic protocol is depicted in Fig 2. Each plateau lasted 6 minutes, with arterial and venous blood samples collected after a

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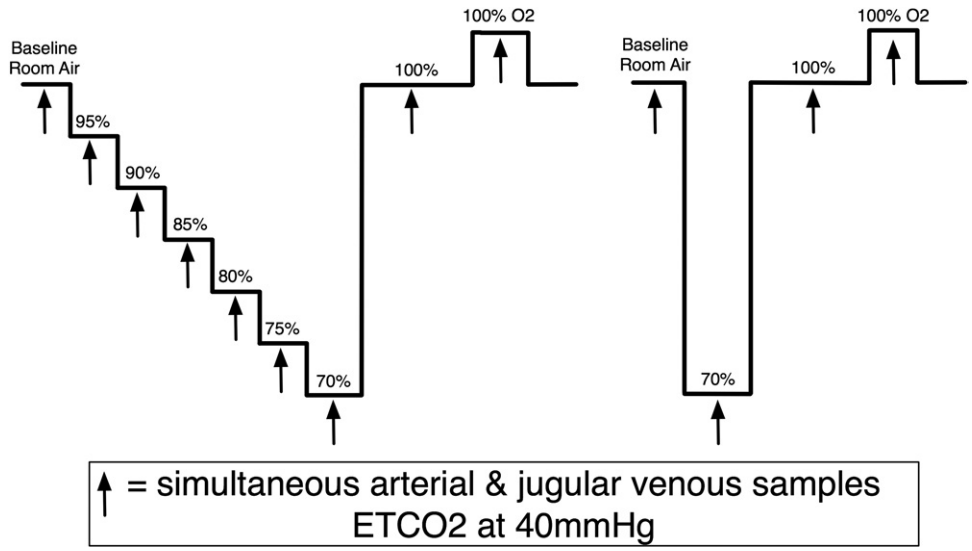

Fig 2. Hypoxia plateau study protocol. The delivered gas mixture was adjusted to decrease the displayed saturation of peripheral oxygen in increments of approximately 5% from baseline to 70%, followed by a rapid return to room air and a saturation of peripheral oxygen of 100%, a subsequent period of breathing 100% oxygen, and a return to room air breathing for 10 minutes. Each steady-state plateau lasted approximately 6 minutes. Then, there was an abrupt decrease in saturation of peripheral oxygen from baseline (95%-100%) to the 70% plateau and immediately returned to baseline (room air), a brief period of breathing 100% oxygen, followed by a rest period of breathing room air for 10 minutes. At all plateaus the breathing mixture was adjusted to target an end-tidal carbon dioxide (ETCO2) of 40 mmHg.

stable arterial saturation was reached. The jugular venous blood sample (2 mL) was withdrawn over a 2-minute period, with arterial samples taken at the beginning and at the end of the jugular draw. Co-oximetry (Gem Premier 4000; Instrumentation Laboratory, Bedford, MA) was used to determine $SjvO_2$ and SaO_2, taken as the average of the 2 arterial samples. The $SavO_2$ was calculated as $(0.7 \times SjvO_2) + (0.3 \times SaO_2)$.[10,11] Cerebral and pulse oximetric data were recorded continuously; blood draws were marked on the laptop data recorder. At completion of the study, all catheters were removed and insertion sites were inspected for hematoma; subjects were contacted by telephone the following day to verify health status.

Calibration

Accuracy was assessed by determining the bias and precision of paired rSO_2 and $SavO_2$ values as defined by Bland-Altman analysis. Bias is a measurement of the systematic "offset" of the test values compared with the reference value, and precision, the standard deviation of the bias, is a measurement of the random error in the test device. To create a single value for the accuracy of the device across the entire range of saturations tested, the square root of the mean square error was used, as dictated by industry standards.[15,16]

$$A_{RMS} = \sqrt{\frac{\sum_{1=1}^{n} (rSO_{2i} - SavO_{2i})^2}{n}}$$

where A_{RMS} incorporates the systematic (ie, bias) and random (ie, variability) components of error, n is the sample size, and rSO_{2i} and $SavO_{2i}$ are the values for the ith subject.

The correct "unit" of measurement for precision, bias, and A_{RMS} is "percentage," because the devices measure the percentage of hemoglobin saturated with oxygen (percentage saturation determined by rSO_2 − percentage saturation determined by $SavO_2$ = bias). However, the authors did not use the percentage sign in reporting precision, bias, and

Table 1. Demographics and Baseline Characteristics of Subjects

	8000CA Sensor		8004CA Sensor	
	Calibration (n = 9)	Validation (n = 9)	Calibration (n = 12)	Validation (n = 11)
Age (y)	25 ± 3	26 ± 5	27 ± 6	25 ± 4
Men	5/9 (56%)	5/9 (56%)	9/12 (75%)	6/11 (54%)
Race/ethnicity				
Asian	1/9 (11%)	1/9 (11%)	0/12 (0%)	0/11 (0%)
African-American	1/9 (11%)	1/9 (11%)	2/12 (17%)	3/11 (27%)
Caucasian	6/9 (67%)	7/9 (78%)	10/12 (83%)	8/11 (73%)
Hispanic	1/9 (11%)	0/9 (0%)	0/12 (0%)	0/11 (0%)
Height (cm)	173.6 ± 10.6	175.8 ± 6.6	175.3 ± 9.0	174.1 ± 9.6
Weight (kg)	71.9 ± 13.6	74.3 ± 13.1	76.9 ± 14.7	70.7 ± 9.7

NOTE. Data are presented as mean ± standard deviation or proportion (percentage).

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Table 2. Summary of Relative Accuracy Data by Sensor and Phase

	8000CA Sensor		8004CA Sensor	
	Calibration	Validation	Calibration	Validation
Statistic*	(n = 9 subjects, 112 data pairs)	(n = 9 subjects, 106 data pairs)	(n = 12 subjects, 100 data pairs)†	(n = 11 subjects, 119 data pairs)
A_{RMS}	2.0 (1.8, 2.3)	2.7 (2.4, 3.2)	2.3 (1.8, 2.8)	1.9 (1.5, 2.9)
Correlation coefficient	0.98 (0.97, 0.99)	0.96 (0.94, 0.97)	0.97 (0.95, 0.98)	0.97 (0.96, 0.98)

Abbreviation: A_{RMS}, absolute accuracy.

*Mean bias and precision are not presented because the mean bias is 0 because the subject-specific mean bias was subtracted from each bias value. Therefore, the precision and A_{RMS} are equivalent.

†Five subjects in the calibration phase of the 8004CA sensor were also in the 8000CA studies.

A_{RMS} to avoid potential confusion that the device has a certain percentage of accuracy or is accurate a certain percentage of the time.

Accuracy of the calibration model was assessed using the pooled A_{RMS}, the mean bias, and precision. The 2-sided 95% accelerated bias-correcting bootstrap confidence interval was calculated for the A_{RMS}, with 2-sided 95% confidence intervals for the mean bias and precision.

Validation

In the validation studies, device-determined rSO_2 values were calculated using the algorithm derived in the calibration phase; the rSO_2 value was compared with the $SavO_2$ value (ie, the reference value) at each observation point for the validation subjects. Only rSO_2 data from the side ipsilateral to the jugular bulb catheter were used.

Accuracy was assessed using bias and precision, as detailed earlier. To determine the relative accuracy, the mean bias for each individual was calculated, and each rSO_2 for that individual was adjusted by the mean bias. The relative accuracy values across all subjects and the range of values then were pooled to determine the relative A_{RMS}. The relative A_{RMS} assessed how closely the device tracked a change in rSO_2 after accounting for the bias associated with a given subject. For absolute accuracy, the absolute rSO_2 value was compared with the absolute $SavO_2$ at each observation point, and the absolute A_{RMS} was determined.

Using data derived in the validation study, the oximeter was considered validated as a relative or trending monitor if the relative A_{RMS} was <5%. If the absolute A_{RMS} was <5%, the device was considered validated as an absolute monitor. This 5% success criterion was based on a comparison with commercially available products. The both-sided 95% accelerated bias-corrected bootstrap confidence intervals were provided for the 2 A_{RMS} statistics to determine whether the null hypothesis could be rejected.

Sample Size Analysis

Assuming that the Equanox would perform as well as current devices (as detailed in their Food and Drug Administration labeling), with an expected bias of 0.13 and a precision of 3.7, a sample of 7 subjects would provide >80% power to detect a difference from a 5% success criterion with approximately 20 plateaus each.

RESULTS

8000CA Calibration and Validation

Twelve subjects gave written informed consent and were enrolled in the 8000CA calibration phase from June 25 to September 12, 2008; 10 subjects gave written and informed consent and were enrolled in the validation phase from October 7 to November 26, 2008. Demographic data are presented in Table 1. Two calibration subjects withdrew consent owing to anxiety, and the data file of 1 subject was corrupted; thus, 9 subjects were included in the calibration analysis. Of the subjects enrolled in the validation phase, the jugular bulb catheter could not be placed in 1 subject; accordingly, 9 subjects were included in the validation analysis. All subjects were healthy nonsmokers 21-34 years old; 20% were non-Caucasians.

8000CA Calibration Study

As presented in Table 2, the relative accuracy of the device in the calibration subjects (n = 9, 112 plateaus) was estimated to be an A_{RMS} of 2.0 and the absolute accuracy was estimated to be an A_{RMS} of 3.1.

8000CA Validation Study

As presented in Table 3, the relative accuracy for the Equanox 8000CA in the validation subjects (n = 9, 106 plateaus) was an A_{RMS} of 2.7, with an absolute accuracy of 8.1. The criterion for relative accuracy was met, but the data for absolute accuracy (8.1) did not meet the success criterion of 5. There was considerable variability among subjects for absolute

Table 3. Summary of Absolute Accuracy Data by Sensor and Phase

	8000CA Sensor		8004CA Sensor	
	Calibration	Validation	Calibration	Validation
Statistic	(n = 9 subjects, 112 data pairs)	(n = 9 subjects, 106 data pairs)	(n = 12 subjects, 100 data pairs)*	(n = 11 subjects, 119 data pairs)
A_{RMS}	3.0 (2.6, 3.5)	8.1 (7.0, 9.6)	5.7 (4.3, 7.5)	4.1 (2.9, 5.3)
Mean bias	0.1 (−0.5, 0.7)	−1.4 (−2.9, 0.2)	−0.3 (−1.4, 0.9)	0.8 (0.0, 1.5)
Precision	3.1 (2.7, 3.5)	8.0 (7.0, 9.2)	5.7 (5.0, 6.6)	4.0 (3.6, 5.0)
Correlation coefficient	0.95 (0.93, 0.96)	0.64 (0.52, 0.74)	0.78 (0.68, 0.84)	0.89 (0.85, 0.92)

Abbreviation: A_{RMS}, absolute accuracy.

*Five subjects in the calibration phase of the 8004CA sensor were also in the 8000CA studies.

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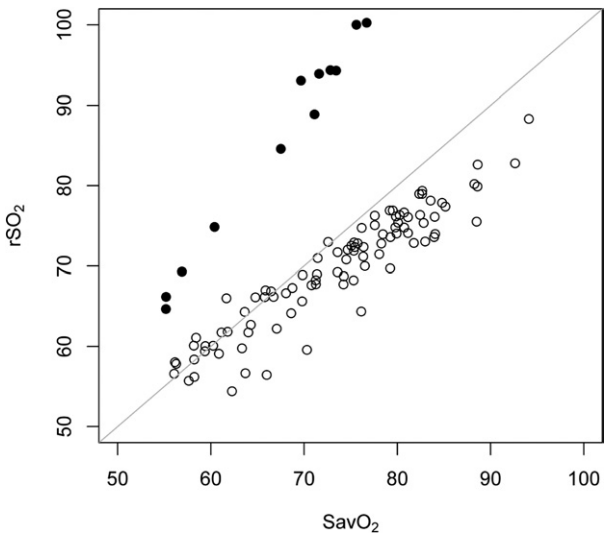

Fig 3. Validation data from the 8000CA study. The regional oxygen saturation of brain tissue (rSO_2) values from the Equanox system are plotted against the arteriovenous saturation ($SavO_2$) calculated from the ipsilateral jugular venous and radial arterial blood samples. A unique subject with significant variation between absolute arteriovenous saturation and regional oxygen saturation of brain tissue values (solid circles).

accuracy, with 1 subject having an absolute A_{RMS} of 18.9. This individual's atypical correlation pattern is shown in Fig 3 (solid circles).

8004CA Calibration and Validation

Thirteen subjects were enrolled and completed the calibration study from September 17 to December 22, 2009, but the data file from 1 was corrupted; 12 subjects with 100 plateaus were included in the calibration analysis. Twelve subjects were enrolled in the validation phase from March 23 to June 22, 2010, but 1 was withdrawn because an arterial line could not be placed; thus, 11 subjects with 119 plateaus were included in the validation analysis.

8004CA Calibration Study

The values for the relative and absolute accuracy of the device within the calibration subjects are listed in Tables 2 and 3 (including the 1 subject from the 8000CA validation study indicated by the solid circles in Fig 3). The absolute accuracy in the calibration population was estimated to be an A_{RMS} of 5.7, with a bias of −0.3 and a precision of 5.7 (Table 2). Individual data pairs are presented in Figs 3 and 4 (open circles).

8004CA Validation Study

The relative accuracy for the validation subjects is presented in Table 2. Three measurements (A_{RMS}, mean bias, and precision) for absolute accuracy in the validation subjects are presented in Table 3. Figure 4A presents the absolute rSO_2 values plotted against the absolute $SavO_2$ values in the validation subjects (solid circles); Figure 4B presents the Bland-Altman data from the validation analysis, where the difference between each pair of $SavO_2$ and rSO_2 values is plotted against the average of the 2 values.

The pooled absolute accuracy in the validation phase was 4.1, meeting the success criterion of <5.0. With this level of accuracy, the correlation between the rSO_2 and $SavO_2$ values was very high, with a correlation of 0.9. This degree of accuracy appeared to be consistent across the range of values (Table 4).

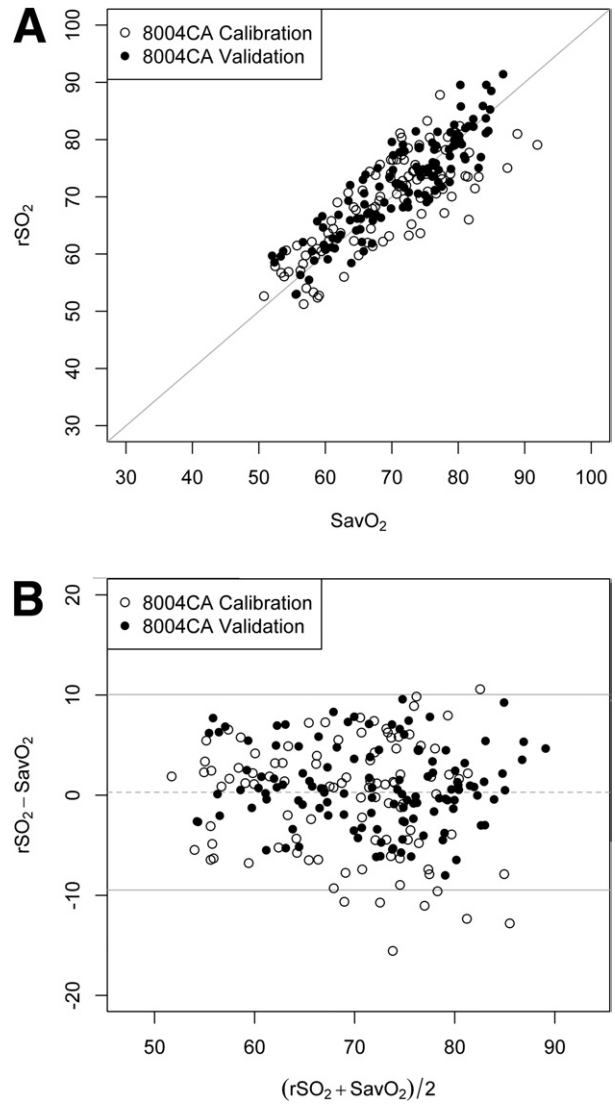

Fig 4. Calibration and validation of the 8004CA sensor. (A) The regional oxygen saturation of brain tissue (rSO_2) values are plotted against the arteriovenous saturation ($SavO_2$) values; open circles represent the paired values from the calibration subjects, including paired data points from the atypical subject shown in Fig 3. The solid circles represent data from subjects enrolled in the validation study. (B) A Bland-Altman plot for absolute accuracy shows where the difference between each regional oxygen saturation of brain tissue value and the corresponding arteriovenous saturation value is determined and plotted against the average of the 2 values. Data pairs from the calibration cohort are the open circles; validation pairs are the solid circles.

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Table 4. Absolute Accuracy of Regional Oxygen Saturation of Brain Tissue for the 8004CA Sensor by Decade of Saturation (Validation Phase Data)

$SavO_2$ Decade	n	A_{RMS}	Mean Bias	Precision	R
≥50%-<60%	15	4.9 (2.5, 6.6)	3.3 (1.2, 5.5)	3.8 (2.7, 5.9)	0.44
≥60%-<70%	34	4.1 (2.5, 5.8)	1.4 (0.0, 2.7)	3.9 (3.1, 5.1)	0.63
≥70%-<80%	49	3.8 (2.6, 4.6)	−0.2 (−1.3, 0.9)	3.8 (3.1, 4.7)	0.41
≥80%-<90%	21	4.1 (1.8, 5.6)	0.2 (−1.7, 2.1)	4.2 (3.1, 5.9)	0.42

NOTE. Data presented as point estimate (lower, upper 95% confidence limit).
Abbreviation: A_{RMS}, absolute accuracy; $SavO_2$, arteriovenous saturation.

DISCUSSION

These data indicate that the 8004CA sensor can provide cerebral saturation values that absolutely agree with $SavO_2$. This sensor, in addition to the standard 3 wavelengths of light to calculate the absorption of light by hemoglobin (oxygenated and deoxygenated), uses a fourth wavelength of light to account for tissue scattering. The 8000CA sensor, which does not include the fourth wavelength, is accurate as a relative monitor and can provide accurate information on the magnitude and direction of change in saturation from baseline.

Every physical substance has a unique "fingerprint" of light absorption. The Beer-Lambert law can be used to calculate the concentration of a substance in a solution, such as oxygenated/deoxygenated hemoglobin in blood, but requires knowledge of the precise distance traveled by the light. This is performed easily in laboratory co-oximeters that use precisely machined cuvettes but is difficult to perform in tissue.[12] Therefore, it was many years after Jöbsis[17] first proposed a tissue oximeter in 1977 that a clinically useful oximeter to determine the concentration of oxygenated hemoglobin in brain tissue (rSO_2) was developed.

The differential form of the modified Beer-Lambert law, in which the change in light attenuation is proportional to the change in the concentration of tissue light-absorbing chromophores (here, oxy- and deoxyhemoglobin), is used to eliminate the need for path length.[18,19] If attenuation changes are measured at ≥2 wavelengths, concentration changes can be calculated, but these calculations are based on 2 assumptions: (1) the absorption of the tissue changes homogenously and (2) the scattering loss is constant.[20,21] A recent report has challenged these assumptions, stating that absorption changes usually are inhomogenous and that each calculated value of tissue saturation is influenced by the change in the concentration of other absorbing substances (crosstalk between chromophores).[20] In addition, the presence of cerebrospinal fluid can affect light absorption in laboratory models.[22] Although the assumptions required for use of the modified Beer-Lambert law permit cerebral oximeters to provide valid rSO_2 values for most individuals,[19] these assumptions can result in monitor-generated values for certain patients that do not agree closely with $SavO_2$ (the patient represented by solid circles in Fig 3) or values that appear to be unreasonable (eg, awake, normal volunteers with rSO_2 values of 30%-40%; data on file at Nonin Medical). In some cases, internal design features censor these "outlier" results such that the monitor provides no rSO_2 value.

Despite these issues, the value of continuous cerebral oximetry is increasingly apparent, including the recognition of catastrophic events,[8,23-25] continuous alerting of changes in cerebral oxygen tension that occur in the presence of normal pressure and arterial saturation,[26] and improving postoperative morbidity and mortality.[11,27] In 2 randomized studies, 1 in cardiac surgical patients and the other in abdominal surgical patients, patients who had rSO_2 monitoring with active display and treatment had fewer and shorter episodes of cerebral desaturation than did control patients with blinded rSO_2 measurement.[10,11] The intraoperative use of cerebral oximetry also has been shown to decrease the risk of stroke in cardiac surgical patients.[27] A recent report has demonstrated that preoperative rSO_2 values correlate with the severity of cardiopulmonary dysfunction, are associated with short- and long-term mortality, and may add to preoperative risk stratification in cardiac surgical patients.[26] The growing body of evidence of the utility of cerebral oximeters has led to the hypothesis that cerebral oximetry can serve as a sensitive measurement of systemic circulatory compromise, even in the face of normal pressure, cardiac output, and arterial saturation.[28]

To date, the only validation study of continuous cerebral oxygen monitoring in adults used a trend monitor rather than an absolute monitor.[6] Validating absolute accuracy has been hampered because there is no established and accepted gold standard for cerebral oximetry and there is no known relation between a particular range of rSO_2 values and cellular status. The closest possible clinical estimate of cerebral tissue saturation uses a ratio of 70% venous blood saturation (jugular bulb) to 30% arterial blood saturation.[13,14] Further research is needed to verify that this ratio of arterial-to-venous blood within the cerebral vault represents actual cerebral tissue saturation and to define the parameters of normal versus abnormal cerebral saturation or what values herald potential cerebral injury.

The demonstration of absolute accuracy in cerebral oximetry has required accounting for differences between individuals in tissue light scattering and absorbance. The reasons proposed for individual variations include the amount of adipose tissue present in the scalp, the amount of cerebral spinal fluid overlying the cortex, and even neuronal activation in the cortex.[29] The present data indicate that the inaccuracy resulting from individual variations in light scattering may be decreased or eliminated through the use of additional wavelengths and/or improved algorithms.

Cerebral oximeters capable of absolute accuracy offer distinct advantages over trend monitors. Although trending accuracy has been shown to be of significant value, it requires a stable and essentially normal baseline to be of real value. As the use of this technology expands beyond elective and scheduled operative cases, the need for absolute accuracy will increase. Circumstances exist, such as emergency surgery, patients ar-

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riving in the emergency department with head injuries, or extracorporeal membrane oxygenation, in which no validated baseline can be obtained. In addition, patients may arrive in the operating room in shock or with cerebral ischemia, in which a "low" first reading would be uninterpretable, unless the monitor can provide absolute accuracy. In a recent report by Heringlake et al,[30] some 5%-6% of cardiac surgical patients appeared to have baseline rSO_2 values <55% even with supplemental oxygen. In these patients, an absolute monitor can remove the question of whether the low value represents a "normal" value for that patient owing to atypical light scattering or absorption or represents true cerebral desaturation. Data derived from absolute monitors can provide consistent results across patients and will begin to inform which absolute physiologic values represent cerebral hypoxia or ischemia.

Limitations

Because of ethical constraints, including the desire to limit the number of individuals subjected to hypoxic conditions, the number of subjects participating in the validation study is small. This limitation is especially true for the evaluation of accuracy across decades (of saturation), as the number of samples within each decade is small. This study is a validation of the inherent accuracy of the monitor and can provide no information on clinical utility.

CONCLUSIONS

The Equanox 8004CA 4-wavelength sensor can provide absolute rSO_2 data accurately. The path to rSO_2 monitors with absolute accuracy has not been short or easy, but achieved by steady stepwise improvements in the understanding of cerebral tissue light scattering and absorption, beginning with first description of the concept by Jöbsis.[17] The next key steps will demonstrate that absolute monitors can influence outcomes positively in this increasingly fragile and vulnerable patient population.

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Measurement of body venous tone

Catherine C.Y. Pang*

Department of Pharmacology and Therapeutics, Faculty of Medicine, University of British Columbia, 2176 Health Sciences Mall, Vancouver, BC, Canada V6T 1Z3

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Abstract

The venous system contains about 70% of the blood volume, and approximately 75% of the venous volume is in the small veins and venules. Veins play an active role in the control of cardiac output (CO) and blood pressure. Drugs that interfere with venous tone have profound effects on CO and blood pressure due to the large venous capacity. Information on body venous tone cannot be obtained from studies using isolated venous preparations and perfused venous beds, which lack modulating cardiovascular reflex mechanisms. In vivo methods used for the assessment of venous function in experimental animals and humans are as follows: the mean circulatory filling pressure (MCFP) method for the determination of body venous tone, constant CO reservoir technique for measuring vascular compliance and unstressed volume, plethysmography or blood pool scintigraphy along with venous occlusion for measuring the volume and compliance of an organ, linear variable differential transformer (LVDT) technique for estimating the diameter of a human dorsal hand vein, intravascular ultrasound (IVUS) imaging technique to monitor the cross sectional area of a large vein, and ultrasonic crystals to estimate the dimension of an organ. These methods are described and critically evaluated to disclose their validity, merits and limitations. © 2001 Elsevier Science Inc. All rights reserved.

Keywords: Venous tone; Vascular compliance; Resistance; MCFP; Constant cardiac output reservoir technique; Plethysmography; LVDT; IVUS; Ultrasound crystal

1. The venous system

It has been estimated that the venous system contains 65–75% of the blood volume, and approximately 75% of which is in the small veins and venules (Milnor, 1990; Rothe, 1983b). Venous blood volume within one peripheral bed, the bat wing, was estimated to be 84% of the total vascular volume (Wiedeman, 1963). Unlike others who computed vascular volume from a fixed tissue, Wiedeman estimated vascular capacity from the inside diameter and length of vessels in the subcutaneous area of the wing of the intact, unanesthetized common brown bat (*Myotis*). The results show that the average lengths of major veins, small veins, venules and postcapillary venules are similar to those of the adjacent arteries, small arteries, arterioles and capillaries, respectively. However, the average diameters of the venous vessels are greater than those of the corresponding arterial vessels. Furthermore, there are more inflowing tributaries that flow into a vein than there are branches of an artery and more inflowing tributaries into a small vein than there are branches of a small artery. Consequently, the total cross-sectional area and volume of veins (2.4×10^5 μm^2, 0.32 mm^3) are much greater than the corresponding values of arteries (1.8×10^4 μm^2, 0.059 mm^3, respectively). Within the venous circulation, the bulk of the volume is in the small veins (30%) and venules (45%). These results show that within a peripheral vascular bed, the venous system accounts for as much as 80% of the total vascular volume, and as much as 75% of the venous volume is within small veins. Venules and small veins are undoubtedly the most important blood reservoir within the circulation.

Veins are composed mainly of collagen, elastin and smooth muscle, with collagen and elastin fibers contributing primarily to passive or viscoelastic properties, and smooth muscle fibers to active tension. In general, smooth muscle cells are more abundant in the superficial veins in the limbs, particularly at sites of the venous valves, than in the deeper veins (Shepherd & Vanhoutte, 1975). The smooth muscle cells in the superficial veins of the extremities function to

* Tel.: +1-604-822-2039; fax: +1-604-822-6012.
E-mail address: ccypang@unixg.ubc.ca (C.C.Y. Pang).

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oppose volume changes associated with alterations in hydrostatic pressure (Shepherd & Vanhoutte, 1975). Changes in the hydrostatic pressure of deeper veins in skeletal muscles are offset by the external pressure exerted by the skeletal muscles.

Valves or valve-like structures are present in most segments of the venous system (Alexander, 1963; Maros, 1981). There are, however, fewer competent valves as one ages (Gottlob & May, 1986). Venous valves are more numerous in deep limb veins than superficial limb veins (Ohhash, Morimoto-Murase, & Kitoh, 1993). In man, the valves are more prominent in the veins of the leg than the arm. The venous valves in the legs ensure unidirectional blood flow, which is assisted by the muscle pump, back to the heart, and prevent reflux with a change of posture from the supine to the standing position. In contrast, valves present in abdominal veins are more rudimentary and readily allow reverse flow (Alexander, 1963).

The splanchnic region (liver, spleen, small and large intestine) is the most important venous bed in the body since it is richly innervated, highly compliant and holds 20–25% of the total blood volume (Rothe, 1983b; Rowell, 1990). In contrast, the skeletal muscle capacitance vessels are sparsely innervated and are not significantly involved in the carotid sinus reflex (Disalvo, Parker, Scott, & Haddy, 1971; Epstein, Beiser, Stampfer, & Braunwald, 1968; Lash & Shoukas, 1991; Lesh & Rothe, 1969; Rothe, 1983a; Samueloff, Browse, & Shepherd, 1966). Cutaneous veins, on the other hand, possess dense sympathetic innervation and are more reactive than deeper skeletal muscle veins to sympathetic activation (Hedwall, Abdel-Sayed, Schmid, & Abboud, 1970; Mellander, 1960; Webb-Peploe & Shepherd, 1968a; Zimmerman, 1966). However, in spite of the dense innervation, the cutaneous veins are primarily involved in thermoregulation (Rothe, 1983a; Rowell, 1983; Shepherd & Vanhoutte, 1975). Changes in sympathetic outflow to the cutaneous veins are often opposite to those of other capacitance vessels (Shepherd & Vanhoutte, 1975; Tkachenko & Chernjavskaja, 1971). In contrast to the cutaneous veins, the cutaneous arterioles of nonacral regions, i.e., cutaneous arterioles in areas other than the hands of humans and paws of other species, participate actively in baroreflex control (Rowell, 1983).

Shoukas and Sagawa (1973) showed that the carotid sinus baroreceptor reflex (baroreflex) controls systemic arterial resistance vessels, as well as capacitance vessels in concert (Brunner, Greene, Frankle, & Shoukas, 1988; Greene & Shoukas, 1986; Haase & Shoukas, 1992; Shoukas, 1982; Shoukas & Sagawa, 1973). The simultaneous constrictions of arterioles to increase total peripheral resistance, and capacitance vessels to increase venous return, augment the increase in blood pressure (Shoukas & Sagawa, 1973). Relative to the arterial resistance vessels, veins are less affected by metabolic factors (Gray, 1971; Lewis & Mellander, 1962; Sharpey-Schafer, Semple, Halls, & Howarth, 1965), but are more affected by the activity of the sympathetic nervous system (Mellander & Lewis, 1963; Tabrizchi & Pang, 1992).

Since the venous system is the primary capacitance region in the body, an alteration of its capacity has a large influence on venous return and cardiac output (CO). Venous tone or venomotor tone should not be confused with venous return, which is the rate of the return of blood to the heart, and is equivalent to CO at a steady state condition. Body venomotor tone is determined by factors that include mean circulatory filling pressure (MCFP), venous compliance, venous resistance and blood volume. CO or venous return, on the other hand, is controlled by cardiac, as well as vascular factors that include arterial and venous resistances, arterial and venous compliances, cardiac contractility, heart rate (HR) and blood volume (Greenway, 1982). Body venous tone is, therefore, an important determinant of CO.

Despite the importance of the venous system in the regulation of blood pressure and CO, there are few studies that evaluate venous function in health and disease conditions and the effects of drugs on venous function. The lack of research in this area is likely due to the technical difficulties associated with venous studies. Information on body venous tone in an intact animal cannot be obtained from in vitro studies using isolated venous preparations or perfused venous beds, which lack neural, hormonal and local modulating mechanisms. In addition, large veins are the principal venous vasculature used in in vitro muscle bath studies, and information obtained may not represent that of small veins and venules, the primary sites of control of venous capacity, compliance and resistance.

Drugs that interfere with body venous tone or reflex control of the venous system have profound effects on haemodynamics and blood pressure. This is exemplified by the well-known observation of postural hypotension following the administrations of drugs that cause venodilatation, e.g., nitrovasodilators (e.g., nitroglycerin) and drugs that block autonomic reflexes (e.g., ganglionic blockers, adrenergic neuron blockers and α-adrenoceptor antagonists). Total body venous tone is best assessed by the determinations of venous compliance (ratio of a change in venous volume to the concurrent change in distending pressure) or venous capacitance function (the entire relationship between contained volume and distending pressure of a segment of the vasculature), venous resistance (which controls the pressure gradient between venules and large veins), and the MCFP (the upstream venous pressure) or pressure gradient of venous return (MCFP – right atrial pressure).

2. Venous capacitance, compliance and resistance, MCFP, and unstressed volume

2.1. Venous capacitance

Vascular capacitance is the relationship between contained volume and the distending pressure of a segment of

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the vasculature and, being a relationship, cannot be described by a single number (Rothe, 1983a, 1993). Vascular capacitance is different from vascular capacity, which was defined by Shoukas and Sagawa (1973) as the amount of blood held by the systemic vascular bed at a specific pressure. Vascular capacity is the sum of unstressed and stressed blood volumes (see later). For both the systemic, as well as the pulmonary bed, the small veins and venules are the primary blood reservoir of the systemic circulation and the primary sites of venous resistance and compliance. Hence, total body venous capacitance should be reflected by the relationship of blood volume and distending pressure at the level of the venules. As a matter of convenience, pressure at the level of the vena cava is often inappropriately used to denote venous pressure. MCFP is a more appropriate measurement of the upstream venous distending pressure, and this is achieved through the measurement of the mean systemic pressure shortly following circulatory arrest and the rapid equilibration of arterial and venous pressures. To determine vascular capacitance, total blood volume must be measured directly and not estimated from a change in blood volume through the transfusion or withdrawal of blood (Rothe, 1993). This is because transcapillary fluid exchange occurs following a change in blood volume, and this alters the circulatory volume.

2.2. Unstressed and stressed blood volumes and capacity

Vascular capacity is the total blood volume contained in the circulation at a specific distending pressure, e.g., the baseline distending pressure (Trippodo, 1981), and is comprised of unstressed and stressed volume. Approximately 60–70% of the total blood volume is haemodynamically inactive and is called the unstressed volume (Greenway & Lautt, 1986). The function of the unstressed volume is to fill the circulatory system to maximum capacity without increasing transmural pressure. The size of unstressed blood volume is determined by the capacity and activity of the smooth muscle of the blood vessels. Due to the muscle's viscoelastic properties (creep or stress relaxation), smooth muscle activity can be altered passively by a change in the inflow pressure or volume, or actively via reflex or neurohumoral-induced vasoconstriction (Numao & Iriuchijima, 1977; Rothe & Gaddis, 1990). Venoconstriction decreases whereas venodilatation increases unstressed volume. Therefore, the venous capacity within a regional bed may be actively reduced by venoconstriction, or passively reduced by a decrease in transmural pressure. To find out if a change in vascular capacity is active, due to venoconstriction, or passive, due to reduced transmural pressure, the upstream venous distending pressure must be measured, but this is technically difficult except for the hepatic bed. Failing to accomplish that, venous blood flow should be measured in order to find out if a change in venous capacity is associated with altered blood flow. The stressed volume, on the other hand, is haemodynamically active. In the absence of a change in total blood volume, a reduction of unstressed volume increases the stressed volume, and this in turn passively increases transmural pressure; the magnitude of the change is a function of the compliance of the vessel.

The splanchnic vascular bed (liver, stomach, spleen and intestine), which normally holds one-third of the total blood volume (Greenway & Lister, 1974), is the most important capacitance bed for the mobilization of blood. In the cat, 64% of the splanchnic blood volume (21% of total blood volume) can be mobilized by direct electrical stimulation of sympathetic nerves (Greenway & Lautt, 1986; Greenway & Lautt, 1989; Greenway & Lister, 1974). This is in contrast to vascular beds in the muscle, skin, adipose tissue, the cardiopulmonary region, heart chambers and the kidneys, which altogether hold 44% of the blood volume, but sympathetic nerve stimulation mobilizes at most 23% of the blood volume from these organs (or 10% of total vascular volume, Greenway & Lautt, 1986).

2.3. Compliance

Compliance (C), as applied to blood vessels, is the ratio of a change in volume (ΔV) to a concomitant change in the transmural distending pressure (ΔP): $C = \Delta V/\Delta P$ (Rothe, 1983a, 1993). It is a measure of the elasticity of a vascular bed. Distensibility, as defined by Rothe (1993), is the fractional change in volume per unit change in pressure ($\Delta V/V_0\Delta P$), where V_0 is the total blood volume. Venous compliance is commonly calculated from the slope of the venous pressure to vascular volume curve and is often normalized by the weight of the animal (and not V_0 as in distensibility, Shoukas & Sagawa, 1971). Since compliance in the systemic circulation is markedly greater than that in the pulmonary circulation, systemic capacitance vessels are the primary blood reservoir for the circulatory system. Indeed, the major change in capacitance in response to a change in CO was found to be in the systemic rather than the pulmonary circulation (Numao & Iriuchijima, 1977).

In the determination of compliance, body temperature needs to be regulated because a fall in body temperature of 6°C was reported to reduce venous compliance by 42% (Shoukas & Brunner, 1980). In studies involving the constant CO reservoir technique, the venous (vascular) volume and transmural pressure curve is often constructed by serial alteration of venous pressure via raising the venous outflow pressure. An increase in outflow pressure reduces outflow and thereby increases venous (vascular) volume. Venous pressure is often measured by inserting a catheter into a large vein, and volume is estimated by the reciprocal change in reservoir volume. Downstream venous pressure (V_p), however, is not an accurate reflection of upstream venous pressure, particularly in conditions of

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high venous resistance. Since small veins and venules are the primary sites of venous compliance, volume and resistance, upstream venous pressure should be measured instead of V_p. As this is technically difficult, venous plateau pressure (VPP) during mechanically induced circulatory arrest (with equilibration of upstream and downstream pressures) should be used to estimate the upstream venous pressure (Deschamps & Magder, 1992). This changes the compliance equation from $C = \Delta V/\Delta P$ to $C = \Delta V/\Delta \mathrm{VPP}$, i.e., from the ratio of ΔV, the regional change in volume for a given change in V_p, to the ratio of ΔV to the difference between VPP before and after a change in V_p (via an elevation of venous outflow pressure). In humans, compliance is commonly estimated by the ratio of a change in blood volume (via an infusion of fluid) to a change in the central venous pressure (CVP). However, a change in blood volume will alter cardiovascular reflex and induce transcapillary fluid shift. Blood volume should, therefore, be directly measured rather than estimated from the reciprocal change in reservoir volume, or the volume of fluid injected into the blood stream.

2.4. Venous compliance versus unstressed volume

It has been shown experimentally that a drug may venoconstrict by reducing either unstressed volume and/or compliance. However, it is unclear if these two variables are independent of each other. Sympathetic activation has been shown to cause a greater decrease in unstressed volume than compliance (Drees & Rothe, 1974; Greene & Shoukas, 1986; Greenway & Lautt, 1986; Rose & Shoukas, 1993; Shoukas, MacAnespie, Brunner, & Watermeier, 1981; Shoukas & Sagawa, 1973). Furthermore, a change in blood volume caused a greater change in unstressed volume than compliance (Drees & Rothe, 1974; Numao & Iriuchijima, 1977; Rothe & Gaddis, 1990). Greenway, Seaman, and Innes (1985) reported that noradrenaline (2 μg/min per kilogram, iv) venoconstricted the hepatic bed of pentobarbital-anesthetized cats by reducing unstressed volume but not compliance. Hepatic blood volume was measured in this study by plethysmography, compliance was calculated from the slope of the hepatic vascular volume–intrahepatic pressure relationship, and unstressed volume was derived from linear extrapolation to 0 mmHg of the blood volume–intrahepatic pressure relationship. Noradrenaline was found to reduce unstressed volume without altering compliance regardless of the method used to alter hepatic volume, i.e., by varying portal venous flow (pumping blood from an extracorporeal reservoir into the portal vein at varying rates, from 0 to 240 ml/min per 100 g liver) or hepatic outflow pressure (raising inferior vena cava pressure in steps from 0 to 9 mmHg). Greenway et al. gave the following explanations for the phenomenon: (1) "hepatic compliance as measured in these experiments is a measure not of the distensibility of the smooth muscle of the venous bed, but of the parenchymal tissue or capsule of the liver" or (2) "venous diameter could decrease due to smooth muscle shortening without a decrease in the distensibility of the wall, if the distensibility is not primarily determined by the contractile elements." More studies are needed to find out the relationship between vessel diameter and compliance of a single vessel and the relationship between unstressed volume and compliance in a constant flow-perfused vascular bed. Until this is resolved, it is unclear if unstressed volume and compliance are truly independent of each other.

Drugs have been shown to affect compliance and unstressed volume in opposite directions, as in the case of the β-adrenoceptor agonist terbutaline, which increased unstressed volume but reduced venous compliance (Lee, Raya, Gay, Olajos, & Goldman, 1987), or the converting enzyme inhibitor captopril (Raya, Gay, Aguirre, & Goldman, 1989) and the vasopressin V_1 receptor antagonist (Raya, Gay, & Goldman, 1990), which reduced unstressed volume and increased compliance. The opposing changes in compliance and unstressed volumes are difficult to comprehend, and these results are often derived from studies that determine compliance from the slope of the venous blood volume–MCFP curve with blood volume altered via haemorrhage and/or transfusion. A change in blood volume would alter cardiovascular reflexes. It needs to be resolved if the concurrently occurring but opposing (venoconstriction, as well as venodilatation) responses are real, or a consequence of the measurement of capacitance function at different levels of vasomotor tone as a result of changes in blood volume.

The method to measure compliance by haemorrhage or blood transfusion was developed by Shoukas and Sagawa (1971). They found that even at a constant CO, a decrease in blood volume (5% of blood volume within 30–45 s) gave compliance values of 2.0 and 2.4 ml/mmHg per kilogram at 10 s and 2 min, respectively, after the completion of haemorrhage in urethane and chloralose-anesthetized dogs. It was also shown by Schafer, D'Almeida, Weisman, and Lautt (1993) in pentobarbital-anesthetized cats that hepatic compliance determined during a reduction of arterial inflow into the liver (2.8 ml/100 g liver per mmHg) is smaller than the apparent compliance ($\Delta V/\Delta P$ relationship) estimated during a slow haemorrhage of 11 ml/kg (4.2 ml/100 g liver per mmHg).

The discrepancy between compliance and the apparent compliance was due to active intrahepatic venoconstriction induced by haemorrhage, which caused a greater decrease in intrahepatic volume per unit change in portal venous pressure (PVP). In the study, the anterior hepatic nerve plexus (along the common hepatic artery) was sectioned to allow nerve stimulation, but the posterior plexus (along the portal vein) was left intact. It is quite possible that the magnitude of active hepatic venoconstriction may have been even greater if the anterior nerve plexus was functional. These results suggest that studies of compliance obtained during haemorrhage have limitations.

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2.5. Mean circulatory filling pressure

Grodins (1959) formulated equations to describe vascular factors that control the systemic circulation [Eqs. (1)–(4)]:

$$Q = (P_a - P_v)/R \quad (1)$$

$$P_a = BV_a/C_a \quad (2)$$

$$P_v = BV_v/C_v \quad (3)$$

$$BV = BV_a + BV_v \quad (4)$$

where Q = CO during steady state; R = systemic resistance; P_a and P_v = arterial and venous pressures, C_a and C_v = arterial and venous compliances, BV_a and BV_v = arterial and venous stressed blood volumes, respectively. By rearranging these four equations, Eqs. (5) and (6) are obtained:

$$P_a = BV/(C_a + C_v) + C_v RQ/(C_a + C_v) \quad (5)$$

$$P_v = BV/(C_a + C_v) - C_a RQ/(C_a + C_v) \quad (6)$$

It is apparent that when the circulation is stopped ($Q = 0$), an equilibrium circulatory pressure can be obtained, whereby $P_a = P_v = BV/(C_a + C_v)$. This equilibrium pressure is synonymous to Guyton's MCFP (Guyton, Polizo, & Armstrong, 1954), and it denotes the upstream venous pressure that drives venous return. MCFP is proportional to total stressed blood volume (as unstressed volume does not contribute to pressure) and is inversely proportional to the overall vascular compliance. Since venous compliance is 30–100 times the magnitude of arterial compliance in various species of animals, MCFP is predominantly and inversely dependent on venous compliance. In an absence of a change in blood volume, an increase in MCFP denotes a reduction in venous compliance, or an increase in venoconstrictor influence.

Experimentally, as well as mathematically, MCFP is the mean vascular pressure that exists after circulatory arrest, and pressure in all parts of the circulation is made to equilibrate. The measurement of MCFP requires stopping the circulation and equilibrating arterial and venous pressures. A change in MCFP reflects a change in the upstream distending pressure, i.e., pressure at the small vein and venule, which are the primary sites of compliance (Rothe, 1993; Tabrizchi & Pang, 1992). MCFP is the best estimate of the upstream pressure that drives blood to the heart (Rothe, 1993). The pressure gradient of venous return (MCFP – right atrial pressure) determines the net driving force of venous return, and (MCFP – right atrial pressure)/CO reflects the resistance to venous return (often referred to as venous resistance).

2.6. Venous resistance

Although venous resistance is lower than arterial resistance, it is an important determinant of venous return due to the low pressure in the venous circulation (Guyton, 1963). An increase in venous resistance reduces flow and increases distending pressure upstream, thereby causing the pooling of blood in the venules; the degree of pooling is dependent on the upstream compliance (Rothe, 1993). The increases of both venous pressure and resistance would favor net capillary filtration (Rothe, 1983a). Similar to arterial resistance, an increase in venous resistance reduces venous pressure downstream. Despite its importance, venous resistance is rarely measured due to technical difficulties associated with the measurements of pressure and flow inside a small vein or venule. Venous resistance is particularly important in the hepatic bed, whereby a pressure gradient of 4–15 mmHg exists between the PVP and CVP. Drugs, such as histamine (Greenway & Oshiro, 1973; Rothe, Flanagan, & Maass-Moreno, 1990) and angiotensin II (Tabrizchi, Lim, & Pang, 1993), have been shown to markedly raise PVP by increasing hepatic venous resistance.

The liver receives a large proportion of CO (approximately 25%) for its size (2.5% of body weight, Greenway & Stark, 1971). This makes it an important blood reservoir (12% of total blood volume, Greenway & Lautt, 1989). The liver has a unique circulation, which allows the concurrent measurements of upstream venous pressure (PVP), hepatic venule (Bohlen, Maass-Moreno, & Rothe, 1991) or hepatic lobar vein (Lautt, Greenway, & Legare, 1987) pressure, distal venous pressure at the central inferior vena cava, liver volume, hepatic arterial flow and portal venous flow. To facilitate the discussion of hepatic resistance, the hepatic blood supply is outlined as follows. Please refer to reviews by Greenway and Lautt (1989), Greenway and Stark (1971) and Lautt and Greenway (1987) for information on the hepatic circulation.

The liver receives flow from the hepatic artery (20–33%) and the portal vein (67–80%). All areas of the liver parenchyma are uniformly perfused by the portal venous and hepatic arterial flow. The portal venous flow receives blood from the spleen (10%), stomach (20%), pancreas (10%) and intestine (60%), and it meets the hepatic artery at the terminal hepatic venule near the hilum of the liver. The existence of a relatively high hepatic venous resistance causes a build-up of PVP upstream. A high venous pressure together with a high venous compliance in the splanchnic bed lead to the pooling of splanchnic blood, and this makes the splanchnic capacitance vessels the most important blood reservoir in the body. Therefore, an acute increase in intrahepatic venous resistance (e.g., following sympathetic activation or the administration of a vasoactive drug, such as angiotensin II or noradrenaline) would cause an increase in PVP, in addition to an increase in arterial pressure. Elevated PVP, in turn, increases splanchnic venous pressure and this passively distends and pools blood in the splanchnic venous beds. However, elevated venous hydrostatic pressure also increases splanchnic capillary filtration, which reduces somewhat the magnitude of splanchnic venous pooling. The pooling of blood in the splanchnic bed also reduces venous return and CO, and this also decreases the impact of the increase in arterial pressure.

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Whereas the importance of hepatic venous resistance in the control of PVP, splanchnic blood volume and splanchnic transcapillary fluid exchange is indisputable, there is confusion as to whether or not the primary site of intrahepatic resistance is proximal or distal to the sinusoidal capillaries, i.e., presinusoidal or postsinusoidal (see review by Greenway & Lautt, 1989 and discussion by Bohlen et al., 1991). An existence of postsinusoidal intrahepatic resistance would increase the significance of the liver as a blood reservoir, due to the resulting high intrahepatic venous pressure and the high hepatic venous compliance. A predominance of postsinusoidal resistance also justifies the use of the PVP to estimate sinusoidal pressure. The major site of vascular resistance has been reported to be postsinusoidal, due to the presence of hepatic sphincters in small hepatic veins within 1–3 cm of the junction of the vena cava and hepatic veins in dogs (Legare & Lautt, 1987), and to the third-order hepatic venous tributaries that have diameters of 1.5–2 mm in cats (Lautt, Greenway, Legare, & Weisman, 1986). Under resting conditions, the portal and sinusoidal vascular resistances were insignificant, since the PVP was similar to the lobar venous pressure (Lautt et al., 1986; Legare & Lautt, 1987). However, both the hepatic venous sphincter and presinusoidal (portal or sinusoidal) vessels were reported to constrict in response to intraportal infusions of noradrenaline or angiotensin II, as well as to hepatic nerve stimulation in both dogs and cats, and to histamine in dogs (Lautt, Greenway, et al., 1987; Lautt & Legare, 1987). The concurrent constrictions of postsinusoidal and presinusoidal vessels led to a larger increase in PVP than lobar venous pressure. With a high dose of noradrenaline (>0.5 μg/kg per minute, intraportal venous infusion), but not a low dose of noradrenaline (>0.5 μg/kg per minute), and with angiotensin II (0.1–0.2 μg/kg per min) as well as hepatic nerve stimulation, the rise in postsinusoidal resistance was greater than presinusoidal resistance in pentobarbital-anesthetized cats (Lautt, Greenway, et al., 1987). Similar observations were made in anesthetized dogs (Lautt & Legare, 1987). In these studies, intrahepatic pressure was monitored by a catheter (that had a sealed tip and two side holes at 3–7 mm from the tip) inserted into the right jugular vein, passed through the heart, into the inferior vena cava and advanced into the hepatic vein proximal to the wedged position (pulled back from the wedged position). It was assumed that because the side holes were away from the wedged position, an artifactually high pressure due to partial obstruction would not occur.

Bohlen et al. (1991) also recorded pressures in the portal vein, hepatic venule and inferior vena cava (abbreviated as P_{pv}, P_{hv} and P_{ivc}, respectively) in order to determine the predominant location of intrahepatic resistance. Using the micropipette servo-null technique, a micropipette was inserted into a hepatic venule at an axis parallel to the long axis of the venule to measure P_{hv}. It was found that P_{hv} in the 10- to 30-μm hepatic venules of anesthetized rats, dogs and rabbits was lower than P_{pv}, but higher than P_{ivc}. In rats and dogs, the pressure gradient from P_{hv} to P_{ivc} was 44% and 31%, respectively, of the total pressure gradient from P_{pv} to P_{ivc}. In both species, portal venous infusion of noradrenaline increased P_{pv} but not P_{hv} or P_{ivc}. This decreased the proportion of the P_{hv} to P_{ivc} gradient in rats and dogs to 19% and 29%, respectively, of the total P_{pv} to P_{ivc} gradient. These results show the existence of portal venous (presinusoidal) as well as hepatic venous (postsinusoidal) intrahepatic resistance sites in rats, dogs as well as rabbits, with a larger contribution of resistance from the presinusoidal than postsinusoidal site, both in the baseline condition, as well as after the administration of noradrenaline.

Maass-Moreno and Rothe (1992) further examined the location of hepatic venous resistance in pentobarbital-anesthetized dogs using double-lumen catheters inserted through the wall of the vena cava into the hepatic vein. The catheters had one lumen opened at the tip and the other at the side at 0.5–1 cm from the tip. They were advanced inside the hepatic vein as far as possible and were then retracted at steps of 0.5 cm. In the baseline condition, P_{pv}, P_{hv} (near the stopping point) and P_{ivc} were 8.3, 7.3 and 3.8 mmHg. As the catheters were pulled out, P_{hv} remained the same until the tips crossed a transition point when pressure decreased suddenly to a level (4.4 mmHg) slightly, but significantly, larger than P_{ivc}. Thus, as each of the catheters moved past the transition point, the P_{hv} to P_{ivc} gradient decreased from about 87% to 13% of the P_{pv} to P_{ivc} gradient. Intraportal infusion of either histamine (4 μg/kg per minute) or noradrenaline (2.6 μg/kg per minute) increased P_{pv} and P_{hv} but not P_{ivc}. However, when both the tip port and the side port were upstream from the transition point, P_{hv} measured at the tip port was greater than P_{hv} at the side port. With the tip port positioned upstream and the side port downstream to the transition point, there was a much greater difference between P_{hv} measured by the two ports, as only P_{hv} upstream increased with the infusions of histamine and noradrenaline. These results show that hepatic venous resistance in anesthetized dogs is primarily presinusoidal under the baseline conditions or following the administration of noradrenaline or histamine. Further studies with the use of catheters with different diameters show that the location of the transition point in the hepatic vein depends largely on the size of the catheter. The transition point for a 2.4-mm OD catheter was 1.4 cm downstream that of a 1.4-mm OD catheter. Anatomical examination of the large hepatic veins shows that the major reduction in diameter of a vein occurs with the appearance of a side branch. The location of the transition point was also always associated with branching and the sudden reduction of the vein diameter. Using a hydraulic model to simulate a catheter entering a hepatic vein and a mathematical model to calculate annular flow between two concentric cylinders, the authors postulated that the presence of a relatively large catheter inside a small vein can increase resistance to flow upstream when the external

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diameter of the catheter exceeded 60% of the internal diameter of the vein. This artifact could occur even when the pressure is measured from a side port of a catheter. These results suggest that the major hepatic resistance to venous flow in the dog occurs upstream to the major (>2 mm ID) hepatic veins.

Presinusoidal or postsinusoidal hepatic venous resistance maintains a higher PVP or a higher intrahepatic venous pressure, respectively, relative to the CVP. Intrahepatic resistance slows splanchnic venous flow and increases splanchnic pressure, thereby allowing adequate capillary exchange of fluids, metabolites and nutrients. Due to its higher pressure and greater compliance than those of the other venous beds, the splanchnic bed is the most important venous blood pool in the body. However, increased CVP can be transmitted back to the portal vein. Mitzner (1974) claimed that in pentobarbital-anesthetized dogs, an effective closing pressure existed in the hepatic sinusoid such that PVP did not change until hepatic outflow pressure was elevated by 3–4 mmHg. It has, however, been shown in both the cat and dog that a rapid rise in CVP passively distends the hepatic venous sphincters such that a percent of the rise in downstream pressure, no matter how small, is partially transmitted upstream (Lautt, Greenway, et al., 1987; Lautt, Legare, & Greenway, 1987). The degree of transmission of pressure across the sphincters increases with the increase in CVP. This was confirmed by a later study, which also showed that hepatic venous resistance is inversely proportional to the distending pressure within the vessel (Greenway & Lautt, 1988). This distensibility allows the splanchnic bed to buffer a large change in CVP by transmitting proportionately more downstream pressure to the upstream compliant splanchnic vessels as CVP increases. This transmission of pressure expands splanchnic blood volume and, thereby, reduces venous return and CVP.

The possible existence of venous sphincters in the hepatic bed to regulate venous resistance is interesting. Morphological studies have supported the existence of sphincter-like regions in large hepatic veins (Child, 1954). Although hepatic venous sphincters have been described in dogs and cats in functional studies (Lautt, Greenway, et al., 1987; Legare & Lautt 1987), their existence in other organs or species of animals has not been documented. Hepatic venous sphincters are believed not to exist in humans (Rowell, 1990).

To measure venous resistance of a particular organ, one must measure blood flow as well as the upstream driving venous pressure, which is at the level of the venules for most organs. This is technically difficult, with the exception of the hepatic bed where the P_{pv} can be used to reflect the driving pressure for the hepatic venous bed. Total body venous resistance is best estimated by: venous resistance V_R=(MCFP − right atrial pressure)/CO, or V_R=(MCFP − CVP)/CO, with MCFP representing the upstream venous pressure at the level of the venules (Wang, Lim, & Pang, 1995).

3. Methods for assessing venous function

Information on body venous tone or capacitance (relationship between transmural pressure and total blood volume) in whole animals with intact cardiovascular reflex systems cannot be obtained from studies using isolated venous preparations and perfused venous beds, which lack intrinsic modulating mechanisms. Several techniques are available for the determination of body venous tone or capacity, all of which, however, have technical limitations. These include the MCFP method for the determination of whole body venous tone or venoconstrictor influence, the constant CO reservoir technique for measuring vascular compliance and capacity, plethysmography in combination with venous occlusion for measuring the volume and compliance of an organ, the linear variable differential transformer (LVDT) technique for estimating the diameter of a human dorsal hand vein, blood pool scintigraphy to measure the intravascular volume of an organ, intravascular ultrasound (IVUS) imaging to monitor the cross-sectional area of a large vein, and ultrasonic crystals to estimate the length or diameter of an organ.

3.1. The MCFP method

The concept of "mean systemic pressure" at zero flow originated from E.H. Weber in 1850 and his paper was cited by Starling (1987). Guyton et al. (1954) produced an equilibrium pressure, which they termed the MCFP, in the circulation of pentobarbital-anesthetized dogs by cardiac arrest (via electrical fibrillation or strong stimulation of both vagi) or sudden occlusion of the pulmonary artery, followed immediately by pumping blood from the aorta (via a cannula inserted via the femoral artery or carotid artery into the aorta) to the external jugular vein. It was found that MCFP readings derived from vagal stimulation were lower than MCFP obtained by electrical fibrillation of the heart, and this discrepancy might have been due to the vasodilator effect of acetylcholine. The equilibrium pressure was not termed "the mean systemic pressure" because it was commonly used to indicate pressure in the peripheral circulation, rather than the entire circulation. At circulatory arrest, the arterial pressure fell rapidly while venous pressure rose. In this early study, venous pressure was measured by a catheter inserted into the right atrium. Within 2–6 s arterial and venous pressures equalized. However, because the pump continued to operate, arterial pressure continued to fall below venous pressure after they crossed each other. MCFP was taken at the point at which arterial pressure and venous pressure crossed. It was possible to obtain as many as 20 reproducible MCFP readings from an animal. Since hypotension would cause reflex sympathetic activation, MCFP readings were taken within 6–10 s after the initiation of circulatory arrest before reflex venoconstriction took place. [Note: It was later shown by Shoukas & Sagawa (1973) that it took approximately 10–15 s for the capaci-

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tance vessels to alter its volume in response to a change in pressure in the isolated carotid sinus in pentobarbital-anesthetized, vagotomized dogs. Interestingly, the time lag for blood pressure (arteriolar smooth muscle) to respond was considerably faster (2–5 s).]

The following MCFP measurements were reported (Guyton et al., 1954). MCFP was around 6 mmHg in pentobarbital-anesthetized dogs, with zero pressure reading measured at the right atrium. Spinal anesthesia reduced MCFP to 5 mmHg, whereas intravenous bolus injection of a high dose of adrenaline increased it to 16 mmHg. The MCFP in spinal-anesthetized dogs infused with sufficient adrenaline to return mean arterial pressure (MAP) to the baseline level was 0–2 mmHg higher than control MCFP before spinal anesthesia. An infusion of Tyrode's solution to raise blood volume to 1.5–1.75 times of baseline caused increases of both MCFP and MAP.

In chloralose–urethane anesthetized dogs, MCFP was around 10 mmHg (Drees & Rothe, 1974). Since arterial pressure in these animals were high (around 140 mmHg), the very high MCFP was likely a consequence of high sympathetic tone typical of anesthetized, surgically stressed animals. MCFP readings between 9 and 10 mmHg were also reported in pentobarbital-anesthetized, open-chest dogs (Hirakawa et al., 1984) and chloralose-anesthetized cats (Bower & O'Donnell, 1991). Drees and Rothe (1974) reported that reproducible values of MCFP, CO, total peripheral resistance and HR could be obtained with repeated MCFP determinations in close succession, as frequently as three times in 5 min.

In practice, arterial and venous pressure do not equilibrate when the circulation is stopped. This has been explained to be due to the presence of a Starling resistor mechanism at the level of the arterioles (Permutt & Riley, 1963). Magder (1990) has reported that in the in vivo perfused hind limbs of anesthetized dogs, the arterial pressure at zero flow is dependent on the initial arterial pressure and is reduced by reactive hyperemia, exercise and treatment with phentolamine (α-adrenoceptor antagonist).

MCFP has been measured in different species of animals including the rat, dog, calf and pig. The following methods were used to stop the circulation: electrically induced ventricular fibrillation, injection of acetylcholine or potassium chloride to stop the heart, pulmonary artery occlusion and the inflation of a balloon implanted in the right atrium.

Samar and Coleman (1978) developed the first method to measure MCFP in conscious rats. The pulmonary artery of anesthetized rats was implanted with a latex balloon located inside a Silastic cuff. Pulmonary arterial flow was stopped by inflating the balloon. The rats were given 10–14 days to recover from open-chest surgery before use. One day prior to the studies, the rats were again anesthetized to allow the insertion of a catheter into the femoral artery, for the measurement of MAP, and into the inferior vena cava via the femoral vein, at a region between the heart and liver, to measure CVP. The injection of water (0.04–0.08 ml) into the balloon simultaneously reduced MAP to about 15 mmHg and increased CVP to a plateau value within 5 s. This method allowed eight or more reproducible measurements of MCFP at intervals of 7 min. Since VPP was about 10 mmHg below the final arterial pressure, MCFP was calculated by adding the influence of the amount of trapped arterial blood as follows: $\mathrm{MCFP} = \mathrm{VPP} + K(\mathrm{FAP} - \mathrm{VPP})$, where K is the ratio of arterial to venous compliance and FAP is the final arterial pressure at circulatory arrest. The arterial to venous compliance ratio was thought to be 1/30 (2.06 and 0.068 ml/mmHg per kilogram for total systemic vascular compliance and arterial compliance, respectively), based on values obtained in pentobarbital-anesthetized, artificially ventilated, open-chest and vagotomized dogs (Shoukas & Sagawa, 1973). The arterial to venous compliance ratio was later found by Samar and Coleman (1979) to be 1/106 in spontaneously hypertensive rats and 1/76 in normotensive Wistar Kyoto rats. MCFP was reported to be 7.6 mmHg in conscious rats in the Samar and Coleman (1978) study.

Yamamoto, Trippodo, Ishise, and Frohlich (1980) developed a simpler method for measuring MCFP in conscious rats. One day prior to the study, catheters were inserted into the carotid artery, the thoracic inferior vena cava and femoral vein of an anesthetized rat for pressure recordings and the administration of drugs. In addition, a latex balloon-tipped catheter was inserted into the right atrium via the right external jugular vein. Circulation was stopped by injecting water (0.3 ml) into the balloon, which caused a simultaneous increase in CVP to a plateau value and a decrease in MAP to 15–25 mmHg within 4–5 s of circulatory arrest, before reflex sympathetic activation occurs (at 11–15 s after the cessation of flow). Spinal cord transection was found to completely inhibit the sondary rise in MCFP. Since plateau CVP at circulatory arrest was 0.2–0.3 mmHg less than MCFP, there was a small amount of trapped arterial blood during circulatory arrest. A correction factor K was experimentally derived by obtaining first, the actual MCFP by equilibrating arterial and venous pressures at circulatory arrest, and then VPP with no blood transfer and finally, calculating K using the Samar and Coleman's (1978) equation: $\mathrm{MCFP} = \mathrm{VPP} + K(\mathrm{FAP} - \mathrm{VPP})$. K was estimated to be 1/60 in conscious rats. The correction factor was later verified by conducting MCFP studies in animals with different blood volumes (following blood transfusion or haemorrhage). In these studies, the MCFP values determined experimentally (with rapid equilibration of pressures via the pumping of 0.26 ml of blood from the arterial to the venous side) were insignificantly different from readings calculated from VPP, FAP and K (at 1/60). Mathematical correction of VPP to obtain MCFP would eliminate the need to equilibrate arterial and venous pressures immediately after circulatory arrest. This method allowed 10 or more reproducible MCFP readings in conscious rats and eliminated open-chest surgery inherent with the Samar and Coleman method. MCFP was found to be 7.9 mmHg in conscious rats in the Yamamoto et al. study.

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We have used the method of Yamamoto et al. to measure MCFP in conscious, unrestrained rats in several studies, but we used balloons made from a relatively noncompliant commercial wrap such as Stretch-Tite (Polyvinyl Films, MA, USA) or Resinite (Borden Chemical, Canada) instead of latex. Such balloons allow a rapid reduction of MAP and the attainment of VPP within 3–4 s after the start of inflation of the atrial balloon under baseline conditions, as well as following the administrations of vasodilator or vasoconstrictor drugs.

Theoretically, there is a difference between the cessation of circulation via cardiac arrest or circulatory arrest. When flow is stopped by cardiac arrest via the injection of acetylcholine or electrical fibrillation, all circulation is stopped. However, when flow is stopped by the inflation of an atrial implanted balloon or the occlusion of the pulmonary artery by an occlusive cuff, the heart continues to beat. The effect of continual cardiac contractile function on MCFP measurements was assessed by Samar and Coleman (1978) and Trippodo (1981). Both concluded that MCFP is indistinguishable from mean systemic pressure measured by the simultaneous occlusions of circulation in the right atrium and thoracic aorta (via the insertion of another balloon-tipped catheter from the right common carotid artery into the aortic arch). Similar measurements between MCFP and mean systemic pressure suggest that there is minimal contribution of pressure from the possible shift of blood from the cardiopulmonary to the systemic circuit.

Although the MCFP technique is perhaps the best available method for the estimation of body venous tone, it is not without limitations. By definition, all pressures in the circulation should be equal to MCFP during circulatory arrest. It has been shown by Gaddis, Rothe, Tunin, Moran, and MacAnespie (1986), in chloralose- or pentobarbital-anesthetized, open-chest dogs with hearts arrested by the injection of acetylcholine, that CVP measured at 7 s after cardiac arrest was equal to PVP in normal and hypervolaemic states, but CVP was lower than PVP in volume-depleted animals (10–20 ml/kg haemorrhage). As well, repeated use of acetylcholine in anesthetized dogs caused pulmonary congestion and atelectasis. When the heart was electrically fibrillated to stop flow, CVP was lower than PVP in normo-, hyper- and hypovolaemic states. In anesthetized pigs, acetylcholine did not consistently stop the heart, therefore, variable arterial pressure plateaus, and arterial to VPP differences were obtained (Ogilvie, Zborowska-Sluis, & Tenaschuk, 1990). When circulation was stopped by the distention of a balloon inserted into the pulmonary artery (via a jugular vein) of chloralose-anesthetized cats, there was equilibration of PVP and CVP at MCFP values above 5 mmHg (Bower & O'Donnell, 1991). It should be noted that baseline MCFP values in these cats were quite high, at around 9–10 mmHg. The lack of equilibration of CVP with PVP also occurred following circulatory arrest in volume-depleted (−10%) or expanded (+10%) urethane-anesthetized rats, but this problem did not occur in normovolaemic rats (Cheng & Rankin, 1992). Furthermore, the lack of equilibration of PVP and CVP in volume-depleted or expanded states persisted in rats pretreated with the ganglionic blocker hexamethonium. Therefore, CVP measured at 7 s following cardiac arrest may not accurately estimate "total body venous tone" as it may not completely include pressure contribution from the splanchnic venous bed. However, even a lack of complete equilibration of PVP and CVP does not invalidate the MCFP concept — the error involved is small and has been estimated by Gaddis et al. to be 0.37 mmHg for each 1-mmHg difference between plateau PVP and CVP.

We have examined the effect of large changes of MAP on the equilibration of CVP and PVP in conscious rats, as well as pentobarbital-anesthetized rats (Tabrizchi, Lim & Pang, 1993). Due to low pressure in the venous circulation, precautions were taken to ensure that the zero references for the venous pressures were correct. In the anesthetized rats, the zero reference for CVP and PVP were taken at the level of the inferior vena cava and the portal vein lines, respectively, where the pressures were measured. The positions of the transducers were verified at autopsy by opening the thoracic cavity and cutting open the right atrium to drain the blood. In the conscious rats, the zero references for CVP and PVP were estimated visually and mathematically corrected at autopsy with each rat raised to roughly the same position as it was in the conscious state. High doses of vasoactive drugs, namely, noradrenaline (1.6 μg/kg), angiotensin II (1.3 μg/kg) and isoproterenol (0.5 μg/kg) were intravenously bolus injected into the rats, and CVP as well as PVP were measured in the baseline condition at the time of peak pressor response to the drugs just prior to, and at approximately 5 s following, circulatory arrest. With the exception of baseline PVP (6.4 ± 0.8 vs. 5.3 ± 0.3 mmHg), baseline readings of MAP (99 ± 2 vs. 89 ± 3 mmHg), HR (375 ± 7 vs. 325 ± 7 beats/min) and CVP (2.1 ± 0.4 vs. 0.8 ± 0.2 mmHg, respectively) in conscious rats were significantly higher than the corresponding values in anesthetized rats. In conscious rats, noradrenaline (+58 ± 3 mmHg, −72 ± 16 beats/min) and angiotensin II (+59 ± 9 mmHg, −58 ± 20 beats/min, respectively) caused a pressor response and reflex bradycardia. Isoproterenol, on the other hand, caused hypotension (−21 ± 3 mmHg) and tachycardia (+106 ± 10 beats/min); the latter was likely mediated via direct activation of β_1-adrenoceptors and hypotension-induced reflex sympathetic activation. Neither noradrenaline nor isoproterenol significantly altered CVP or PVP. Angiotensin II, on the other hand, increased PVP (+2.8 ± 1.3 mmHg) significantly and CVP insignificantly. The angiotensin II-induced increase in PVP was likely due to increased intrahepatic venous resistance. Prior to circulatory arrest, PVP was higher than CVP in the control condition, as well as at peak pressor or depressor response to each of the vasoactive drugs before circulatory arrest; however, the two values were similar during circulatory arrest in the control

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condition, as well as following the injections of noradrenaline, angiotensin II or isoproterenol. In pentobarbital-anesthetized rats, noradrenaline and angiotensin II increased MAP (+58±6, +97±3 mmHg, respectively) and PVP (+3.4±0.3, +9.3±1.1 mmHg, respectively) but did not alter HR or CVP. The lack of hypertension-induced reflex bradycardia is typical of responses in anesthetized rats. Isoproterenol decreased MAP (−38±2 mmHg) and increased HR (+153±11 beats/min), but it did not alter CVP or PVP. Prior to circulatory arrest, PVP was greater than CVP in the baseline condition as well as during peak pressor or depressor response to each of the vasoactive drugs. During circulatory arrest, there was a lack of equilibration of CVP and PVP (7.8±0.3, 10.0±0.4 mmHg, respectively) following the injection of angiotensin II, but adequate CVP and PVP equilibration in the control condition as well as following the injections of noradrenaline or isoproterenol. Therefore, there was adequate equilibration of PVP and CVP at circulatory arrest in conscious rats but a lack of pressure equilibration following circulatory arrest when a high dose of angiotensin II was administered to anesthetized rats. Because angiotensin II also caused a much greater rise in baseline PVP than noradrenaline and isoproterenol, the lack of equilibration was likely related to angiotensin II-induced increase in intrahepatic resistance, as angiotensin II would unlikely increase splanchnic flow. The results show that pentobarbital anesthesia and/or surgery may interfere with the equilibration of PVP and CVP during extreme experimental conditions, such as following an acute injection of a very high dose of angiotensin II that markedly increased intrahepatic resistance.

Venoconstriction can induce a change in compliance and/or unstressed volume. As mentioned previously, unstressed volume is the volume of blood in the vasculature at zero transmural pressure, and stressed volume is the difference between total blood volume and unstressed volume. The MCFP technique has been used to provide information on venous capacitance, the relationship between blood volume and the distending pressure. To accomplish this, compliance is often estimated from the ratio of a change in blood volume (via bleeding or transfusion) to a change in MCFP. The unstressed volume is derived by linear extrapolation to zero MCFP of the blood volume–MCFP relationship (Appleton, Lee, Martin, Olajos, & Goldman, 1986; Chien, Frohlich, MacPhee, & Pegram, 1992; Gay, Wool, Paquin, & Goldman, 1986; Glick, Gehman, & Gascho, 1993). This is based on the assumption that a linear blood volume and transmural pressure relationship can be obtained. The assumption is, however, invalid. An infusion or withdrawal of blood alters capillary pressure and capillary fluid exchange, thereby making the amount of volume altered different from that originally added or removed. Therefore, total blood volume must be measured to obtain the MCFP–vascular volume curve (Rothe, 1993). This is more difficult than measuring the volume of blood or fluid added to or removed from the vasculature. There is indeed evidence that the MCFP–vascular volume curve is not linear at MCFP less than about 4 or 5 mmHg due to transcapillary fluid shifts and viscoelastic creep (Drees & Rothe, 1974; Lee, Lancaster, Gay, Paquin, & Goldman, 1988). Moreover, a change in blood volume, however rapid, will alter cardiovascular reflexes and venomotor activity, thereby changing the values of MCFP, compliance and/or unstressed volume (Drees & Rothe, 1974). Drees and Rothe (1974) evaluated the effect of graded haemorrhage and transfusion at 0.5, 2 and 5 min after the initiation of a volume change in chloralose-anesthetised dogs. The slopes of the MCFP–vascular volume curve or "apparent compliance" were 2.6, 3.5 and 4.2 ml/kg per mmHg, and intercepts at 0 mmHg MCFP (or "extrapolated" unstressed volumes) were −28, −38 and −43 ml/kg at 0.5, 2 and 5 min following the initiation of a volume change. A later study showed that much of the active venoconstrictor influence occurred at 10 s to 5 min following the initiation of haemorrhage (Rothe & Drees, 1976). This complicates and distorts the meaning of stressed/unstressed volumes and compliance as determined by the MCFP technique.

To minimize alterations in cardiovascular reflex activity associated with a change in blood volume, the blood volume–MCFP relationship has been obtained in animals with suppressed autonomic reflex, e.g., after ganglionic blockade (Appleton et al., 1986; Ogilvie & Zborowska-Sluis, 1990) or spinal cord transection (Trippodo, 1981). However, ganglionic blockade does not eliminate the effects of circulating or locally released vasoactive agents, such as angiotensin II, vasopressin or endothelium-derived relaxing and contracting factors whose concentrations may be altered by a change in blood volume or shear stress. In some studies, additional vasomotor tone was added via intravenous infusion of a vasopressor agent, such as adrenaline (Trippodo, 1981). Drees and Rothe (1974) reported that despite ganglionic blockade, compliance and unstressed volumes were both altered by a change in blood volume. In ganglionic-blocked dogs anesthetized with chloralose and urethane, the apparent compliances were 2.2, 2.6 and 3.0 ml/kg per mmHg, and extrapolated unstressed volumes were −17, −25 and −28 ml/kg at 0.5, 2 and 5 min after the initiation of rapid blood volume changes. These results show that volume compensation is not entirely reflexogenic and may involve passive transcapillary fluid shifts, viscoelastic creep or other factors. Inability to obtain reliable readings of compliance and unstressed volume does not invalidate the use of the MCFP technique to estimate a relationship between blood volume and MCFP, as long as blood volume is accurately measured at the time of MCFP readings and not estimated from the volume added to or removed from the animal, and as long as it is realized that the slope of the blood volume–MCFP curve is not the true compliance. However, extrapolation of the curve to zero pressure to obtain unstressed volume may lead to unreliable information (Drees & Rothe, 1974; Trippodo, 1981).

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The MCFP technique has also been used to estimate the pressure gradient to venous return (MCFP – right atrial pressure) and resistance to venous return [(MCFP – right atrial pressure)/CO]. While right atrial pressure can be determined in large animals, technical difficulties do not allow the concurrent measurements of right atrial pressure and MCFP in small animals, such as a rat. Since mean CVP is nearly identical to the mean right atrial pressure (Rothe, 1993), venous resistance (V_R) may be estimated by the equation: V_R=(MCFP – CVP)/CO (Wang et al., 1995). It has been shown in small animals that CVP can be used to estimate right atrial pressure as long as the venous pressure waveform is not obstructed by the presence of intravascular thrombus or extravascular edema (Berg, Lloyd, & Donnerstein, 1992). Although CVP may be obtained from both intrathoracic and intraabdominal sites, readings from the inferior vena cava are more accurate than those from the superior vena cava, as they are less influenced by inspiration movements with spontaneous as well as mechanical ventilation (Berg et al., 1992).

To summarize, the MCFP technique has been used to evaluate the effects of drugs on body venous tone in conscious and anesthetized animals. This method involves briefly stopping the circulation, the equilibration of arterial and venous pressures, and the measurement of CVP at 5–7 s following circulatory arrest. In the absence of a change in blood volume, an elevation in MCFP denotes an increase in venous tone or a reduction in venous compliance. Baseline CVP (without inducing circulatory arrest) is not an index of body venous tone, since CVP is pressure within a large vein and the resultant of a pressure drop at arterioles as well as venules. The use of baseline CVP to reflect body venous tone is analogous to the use of the capillary pressure to reflect arteriolar tone.

The MCFP technique does not permit the measurement of the true unstressed volume or compliance in intact animals, since the determination requires blood volume changes, which would alter cardiovascular reflex. The MCFP technique is, however, the best available method for the determination of venous tone as it requires minimal surgical preparation. When used in conscious rats, reproducible MCFP readings can be obtained, and the animals do not show visual discomfort in response to a brief (5–8 s) cessation of flow. When CO and MCFP are measured concurrently, venous resistance can be calculated.

3.2. The constant CO reservoir technique

The constant CO reservoir technique, also known as the venous return long-circuit technique, has been used to obtain information on venous compliance, venous resistance and unstressed volume. It involves the routing of venous return through an extracorporeal reservoir back to the right atrium, the pulmonary artery, or a systemic artery by a pump that maintains constant CO. A change in reservoir volume is often interpreted as a reciprocal change in unstressed volume. This is only true if there is no appreciable transcapillary fluid exchange or renal fluid loss. Compliance is determined by the ratio of a change in volume to a change in venous pressure through either a temporary elevation of the height of the outflow tube to increase venous pressure, or an increase in the resistance of the venous outflow clamp. Venous pressure is often measured by a catheter inserted into a central vein and is, therefore, representative of only the downstream venous pressure.

The constant CO reservoir technique requires the use of anesthesia and extensive surgery, which affect cardiovascular reflexes and cause the release of vasoactive substances. This technique has been used during cardiopulmonary bypass surgery to concomitantly measure the arterial and venous effects of drugs in humans (e.g., Boer, Ros, Bovill, van Brummelen, & van der Krogt, 1990; Gerson, Allen, Seltzer, Parker, & Markowitz, 1982; Hsu, Hickey, & Forbes, 1979; Hynynen et al., 1989; Minami et al., 1990; Muikku, Hynynen, Salmenperä, & Heinonen, 1992; Pauca & Roy, 1986; Videcoq, Desmonts, Marty, Hazebroucq, & Langlois, 1987). Cardiopulmonary bypass surgery offers a unique opportunity for the assessment of the effects of drugs on the human venous system, but the technique also has limitations. Due to the constraint of time and human experimentation, it is not feasible to obtain full dose–response curves or full equilibration of responses. As there is a continuous increase in arterial pressure and a continuous decrease in reservoir volume with the passage of time (Hynynen et al., 1989; Muikku et al., 1992; Videcoq et al., 1987), a time-control group is essential in the design but is omitted.

Other limitations of cardiopulmonary bypass surgery include the dilution of plasma proteins and haemodilution as a result of priming of the cardiopulmonary bypass circuit, hypothermia and associated reductions in metabolic activity and drug metabolism, exclusion of the lungs from the circulation due to the use of an oxygenator, which may also reduce the metabolism of some drugs (e.g., prostaglandins, 5-hydroxytryptamine), binding of drugs (such as thiopentone and nitroglycerin) and plasma proteins to components of the pulmonary bypass circuit (Levy & Hug, 1988), as well as the redistribution of blood flow in spite of constant CO (Hoka, Arimura, Bosnjak, & Kampine, 1992). Cardiopulmonary bypass surgery also increases the concentration of plasma catecholamines, and the elevations are greater with nonpulsatile than pulsatile perfusion. Minami et al. (1990) reported that at 5 min after the start of bypass, plasma adrenaline and noradrenaline were increased 3.5- and 2.2-fold by nonpulsatile perfusion and 2.6- and 1.6-fold, respectively, by pulsatile perfusion. Between the end of bypass and 2 h after the end of bypass, plasma catecholamine concentrations were the highest: adrenaline and noradrenaline concentrations were increased by 8.5- and 6.7-fold by nonpulsatile flow and 5.9- and 5.8-fold, respectively, by pulsatile flow. MAP and total peripheral resistance were also significantly higher in patients with nonpulsatile (mean of

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61 mmHg and 1055 dyn cm ^{5} s) than pulsatile (mean of 54 mmHg and 899 dyn cm ^{5} s, respectively) perfusion at 20–90 min after the initiation of bypass. Unexpectedly, venous compliance, determined by raising CVP, was higher with nonpulsatile flow (2.4 ml/mmHg per kilogram) than pulsatile flow (1.2 ml/mmHg per kilogram). Reduced venous compliance in patients with pulsatile bypass was associated with less fluid retention. These results suggest that pulsatile perfusion in cardiopulmonary bypass surgery causes less sympathetic activation and fluid retention than the standard nonpulsatile perfusion.

Many of the limitations associated with cardiopulmonary bypass surgery in humans are also applicable to animal studies using the constant CO reservoir technique, and these limitations include: anesthesia, extensive surgery, haemorrhage largely due to the use of heparin, the use of donor blood or a physiological solution containing dextran, haemodilution, contact of blood with tubing and pumps, haemolysis, increased catecholamine release and alteration of blood flow distribution. Greenway (1982) warned that extensive surgery and a change in venous pressure may alter capillary function (and therefore blood volume) and may also produce outflow block in the liver. As well, when a drug alters unstressed vascular volume, it does not imply that the drug has had its effect on the venous system alone, since changes in arterial and venous resistances, HR, cardiac contractility or venous compliance can produce large changes in unstressed volume (Greenway, 1982). Furthermore, extracorporeal circuits can decrease the effects of drugs on CO. In spite of these limitations, the constant CO reservoir technique is the best available method for the estimation of drug effects on stressed and unstressed volumes.

3.3. Plethysmography

Plethysmography has been used to monitor the regional blood volume of a single organ, e.g., an animal's hindquarter, intestinal segment or liver (Åblad & Mellander, 1963; Folkow, Lundgren, & Wallentin, 1963; Greenway et al., 1985; Lewis & Mellander, 1962; Mellander, 1960; Mellander & Johansson, 1968; Patel, Bose, & Greenway, 1981) or a human's limb (Eckstein & Hamilton, 1957; Litter & Wood, 1954; Mason & Braunwald, 1965; Zelis & Mason, 1969). The method involves enclosing an organ or part of an organ in a fluid-filled plethysmograph, which measures the volume by a piston recorder (Mellander, 1960), or a servo-controlled recording device (Zink, Delaive, Mazerall, & Greenway, 1976). A change in the volume of an organ is used to estimate a change in vascular (or venous) volume. Alternatively, blood volume in the organ may be calibrated by a transit time method or a haemoglobin washout method (Greenway, 1987). Blood flow to the organ can be calculated from the initial change in volume per unit time following venous occlusion, or directly measured with a flow probe. In the case of the liver, hepatic volume, portal flow, hepatic flow, PVP, intrahepatic pressure and CVP can be measured (Greenway et al., 1985). In this respect, the liver is unique in that upstream venous pressure (PVP) is easily accessible. A hepatic pressure and volume relationship can be constructed by altering either portal venous flow (by pumping blood into the portal vein at varying rates from an extracorporeal reservoir) or changing outflow hepatic pressure through manipulation of the outflow from the inferior vena cava. These two procedures have been shown to give similar intrahepatic pressure and hepatic blood volume relationships.

In humans, venous plethysmography is confined to the measurement of venous capacitance and arterial resistance in the calf (Breithaupt, Belz, Kempinski, Schicketanz, & Dieterich, 1990; Colardyn & Clement, 1990; Litter & Wood, 1954) or forearm, hand or foot (Colardyn & Clement, 1990; Eckstein & Hamilton, 1957; Mason & Braunwald, 1965; Ogilvie, 1985; Zelis & Mason, 1969). In venous occlusion plethysmography, a limb segment (e.g., forearm) is enclosed in a plethysmograph, and a pneumatic cuff is placed proximal to the site of measurement (e.g., the upper forearm). The cuff is inflated to produce an occlusion pressure lower than the diastolic arterial pressure, typically at 30–50 mmHg, to cause congestion of the venous but not arterial circulation. Another pneumatic cuff may be applied distal to the organ (e.g., the wrist) to eliminate blood flow to the hand during pressure measurements. Venous compliance is calculated by the ratio of the increment in limb volume for a set period (e.g., 2 min) following the inflation of the occlusion cuff to the increment in venous pressure. Pressure–volume curves can also be constructed by inflating the cuff at different pressures, e.g., from 10 to 50 mmHg. Venous pressure may be measured by a catheter inserted into the vein or approximated from the cuff pressure used to induce venous congestion. Cuff occluding pressures above 10 mmHg have been shown to accurately reflect intravenous pressure in normotensive patients (Manyari, Malkinson, Robinson, Smith, & Cooper, 1988). Vascular volume may be estimated with a water-filled plethysmograph (Eckstein & Hamilton, 1957; Litter & Wood, 1954) or a mercury-in-rubber or mercury-in-Silastic strain gauge placed around a limb (Struckmann, Vissing, & Hjortsö, 1992; Zelis & Mason, 1969). Concurrent determinations of capacitance and arterial conductance (blood flow/MAP) or arterial resistance (MAP/blood flow) are also possible when measurements of blood flow and arterial pressure are made. A noninvasive method commonly used to estimate flow involves the evaluation of the initial change in blood volume per unit time (or the initial slope of the blood volume–time curve) during venous occlusion.

Plethysmography is particularly useful for the measurement of vascular volume in the human limbs since the method is predominantly noninvasive. There are, however, limitations to the use of plethysmography. A fluid-filled plethysmograph may compress cutaneous veins. Plethysmography does not directly measure changes in venous

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volume, but rather, the sum of changes of intravascular, as well as extravascular volumes. Since the blood volume of a limb comprises approximately 10% of the total tissue within the limb (Vissing & Nielsen, 1988), a change (or a lack of a change) in the volume of fat, muscle, bone and connective tissue can contribute to (or buffer) the total volume change of the limb (Struckmann et al., 1992). The estimation of vascular volume or venous volume by plethysmography is valid only when capillary filtration is not significantly altered by the occlusive cuff. However, the occlusion of venous outflow by a cuff has been shown to cause transcapillary fluid filtration (Schnizer, Klatt, Baeker, & Rieckert, 1978). Although venous occlusion plethysmography entails the measurement of pressure from a large vein rather than the more compliant small vein or venule, the methodology is valid since it involves the measurement of the venous congestion pressure, which is an estimate of the upstream venous pressure. Both anesthesia and surgery are required in the use of plethysmography to measure volume changes in an internal organ of an experimental animal.

3.4. The LVDT technique

Nachev, Collier, and Robinson (1971) developed a method to estimate the diameter of the dorsal hand vein. In this method, the subject was required to lie supine with the upper arm resting on a sloping support of 30°. A microscope was used to optically measure the change in the size of a dorsal hand vein at a constant congestion pressure of 45 mmHg. The microscope was first focused on a marked dot over the summit of a congested hand vein. Afterwards, the cuff was deflated to allow the vein to collapse. This was followed by adjusting the microscope to bring the dot into focus again, and the distance moved was used to estimate the hand vein diameter. In a later study by the same investigators, vasoactive drugs were infused locally into the vein and the vein size was estimated at 7–15 mm downstream (Collier, Nachev, & Robinson, 1972). The results show that noradrenaline, adrenaline, 5-hydroxytryptamine and angiotensin II caused dose-dependent venoconstriction. Tachyphylaxis, however, developed rapidly to the venoconstrictor effects of high doses of angiotensin II. The constrictor effects of noradrenaline and 5-hydroxytryptamine were blocked by pre-infusions of phentolamine and methysergide, respectively. The venoconstrictor effect of adrenaline was potentiated by propranolol. Isoproterenol, bradykinin, acetylcholine and histamine had no venodilator effects unless the veins were first preconstricted by an infusion of noradrenaline or 5-hydroxytryptamine. The venodilatation effects of isoproterenol and acetylcholine were blocked by prior infusions of propranolol and atropine, respectively. Vasopressin caused neither venoconstriction nor venodilatation.

The LVDT technique, introduced by Aellig (1981), is a simpler method to measure the responsiveness of the human dorsal hand vein to vasoactive drugs. The technique involves the insertion of a butterfly needle into the hand vein for the administration of drugs, resting of the forearm on a support at an angle of 30° from the horizontal to facilitate the emptying of venous blood (to denote maximum constriction) and placement of the LVDT over the hand vein at 10 mm downstream from the needle to monitor vein diameter. A sphygmomanometer cuff is placed on the upper arm to produce maximum venous congestion (maximum relaxation) when the cuff is inflated to 45 mmHg. The difference in readings between venous congestion and emptying is a measure of the diameter of the vein under a particular congestion pressure. The effects of small doses of drugs on venous responses can be assessed in the absence of systemic effects (Aellig, 1994). It has been estimated that the dose required to produce a response in a single vein is about 1000 times less than that required systemically (Robinson, 1978).

The LVDT technique, though simple and relatively noninvasive, is associated with a large degree of intersubject variability when it is used to evaluate the venous effect of vasoactive drugs, e.g., phenylephrine, noradrenaline, angiotensin II (Alradi & Carruthers, 1985; Luthra, Borkowski, & Carruthers, 1991; Martin, Alexieva, & Carruthers, 1986; Vincent, Blaschke, & Hoffman, 1992). In a study involving healthy and diabetic patients, it was estimated that a group size of 140 would be required to detect 20% difference in hand vein diameter between the groups (Blöchl-Daum, Vierhapper, Eichler, & Waldhäusl, 1992), and this is due to the large variance in drug responses. Furthermore, responses of cutaneous veins may not be representative of those of a typical vein, since the cutaneous vein is under thermoregulatory control, and its role is primarily in the control of heat dissipation (Rothe 1983a; Rowell, 1983). In situ studies in pentobarbital-anesthetized dogs show that an elevation of either the core temperature or the local temperature of a hind limb skin flap markedly reduced venous resistance and increased venous compliance (Deschamps & Magder, 1990). Therefore, the precision of LVDT studies requires rigid control of the room temperature in different experiments. In vivo studies in dogs show that local cooling enhances, whereas local warming depresses the cutaneous venomotor response to adrenergic nerve stimulation (Abdel-Sayed, Abboud, & Calvelo, 1970; Webb-Peploe & Shepherd, 1968b). Interestingly, the potentiation of the contractile responses to electrical stimulation, noradrenaline, 5-hydroxytryptamine or adenosine triphosphate by cooling, and the attenuation of the responses by warming, also occurred in vitro in the perfused dog saphenous vein as well as the cutaneous vein (Vanhoutte & Shepherd, 1970). These results suggest that the potentiation of contraction by cooling of cutaneous veins in vivo was likely due to increased reactivity of smooth muscle cells rather than increased neurotransmitter release. This was further substantiated by the in vitro findings of the potentiation by cooling of contractile response in spite of concurrent decreased noradrenaline

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outflow from the isolated saphenous vein strip (Shepherd & Vanhoutte, 1975). Cooling, however, reduced the contractile response of the perfused saphenous vein to barium chloride and potassium chloride, and warming had the opposite effects (Vanhoutte & Shepherd, 1970). Taken together, these findings suggest that cooling enhances excitation–contraction coupling but not the contractile process of venous smooth muscle cells. Warming has the opposite effects.

In addition to room temperature, there are other factors that need to be controlled to increase the precision of measurement of the diameter of a hand vein. The subject needs to be acclimatised, and the body position should be the same for repeated measurements. Since digestion increases splanchnic flow, the time of the day and the time of measurements in relation to meals should also be standardised (Aellig, 1994). Moreover, venous congestion pressure has to be standardized, as it can affect the response to a drug. It has been shown by Abdelmawla, Langley, Szabadi, and Bradshaw (1996) that the diameter of the hand vein is directly related to the congestion pressure. The diameters of the dorsal hand vein at congestion pressures of 20, 30, 45 and 60 mmHg were 0.30, 0.70, 1.05 and 1.20 mm, respectively. Furthermore, potency (ED_{50}) to noradrenaline was inversely related to, but efficacy (E_{max}) to noradrenaline was not affected by, the magnitude of the congestion pressure. ED_{50} to noradrenaline were 3.0 and 8.7 ng/min at congestion pressures of 30 and 45 mmHg, respectively. Therefore, it is not valid to compare the potency of agonists in different studies unless the same venous occlusion pressure has been used. Furthermore, there is little justification for the use of a congestion pressure higher than 45 mmHg in which the drug potency may be reduced thereby requiring the use of a higher drug concentration.

Despite the many limitations, the LVDT method is the simplest and most easily accessible method for the measurement of venous responses in humans. It allows the construction of complete dose–response curves without undue systemic effects.

3.5. Blood pool scintigraphy

Blood pool scintigraphy was originally developed to allow noninvasive assessment of left ventricular function in man. The method involves intravenous injection of a radioactive tracer (^{99m}Tc-labeled human serum albumin) followed by selective recording of images at end-systole and end-diastole using a scintillation camera and an electrocardiogram-triggered gating device. The reproducibility of this technique in the assessment of left ventricular volume and ejection fraction is comparable to that of biplane cineangiocardiography (Schelbert et al., 1975).

Blood pool scintigraphy has been adopted to measure the blood volumes of regional organs in humans and experimental animals. This technique involves the labeling of erythrocytes with ^{99m}Tc-pertechnetate by either in vivo or in vitro means (Callahan, Froelich, McKusick, Leppo, & Strauss, 1982; Pavel, Zimmer, & Patterson, 1977), followed by the measurement of radioactivity of a particular organ with a scintillation detector or a gamma camera, and computer analysis of images (Clements, Strelow, Becker, Vlietstra, & Brown, 1981; Rutlen, Wackers, & Zaret, 1981; Scott-Douglas et al., 1995; Todo, Tanimoto, Yamamoto, & Iwasaki, 1986). The radioactivity detected in a particular organ per unit time is proportional to blood volume, as well as venous capacity, since a large proportion of blood is contained in the capacitance vessels. Venous pressure–blood volume relationship in organs can be constructed to obtain venous compliance or capacitance.

This scintigraphy method is relatively noninvasive and reproducible. Blood volumes measured with blood pool scintigraphy have been shown to correlate well with those estimated by traditional plethysmography (Clements et al., 1981; Rutlen et al., 1981) or the constant CO reservoir technique (Bell & Rutlen, 1990). Blood pool scintigraphy has been used to estimate the venous capacity of organs in humans and animals that include the following: the forearm (Mostbeck & Partsch, 1978; Rutlen et al., 1981; Todo et al., 1986), calf (Rutlen et al., 1981), limbs (Clements et al., 1981; Flamm et al., 1990; Mostbeck & Partsch, 1978; Struckmann et al., 1992) as well as organs inaccessible to traditional plethysmography, such as the brain (Kuikka, Ahonen, Koivula, Kallanranta, & Laitinen, 1977), thorax (Mostbeck & Partsch, 1978), abdomen (Flamm et al., 1990; Froelich, Strauss, Moore, & McKusick, 1988; Mostbeck & Partsch, 1978; Smiseth et al., 1987) and lungs (Bell & Rutlen, 1990; Flamm et al., 1990; Froelich et al., 1988; Okada et al., 1979; Smiseth et al., 1988).

In the human forearm and abdomen, volume–pressure relationships have been obtained to estimate compliance and vascular capacity (Manyari et al., 1988; Manyari, Wang, Cohen, & Tyberg, 1993; Robinson, Manyari, Tyberg, Fick, & Smith, 1989). Vascular pressure–volume relationships of the intestinal bed have also been obtained using the scintigraphy method along with measurements of PVP at three or four different portal pressures (via the inflation of a pneumatic constrictor that was placed around the portal vein) (Scott-Douglas et al., 1995; Semeniuk, Belenkie, & Tyberg, 1998). Repeated curves of human forearm venous pressure–vascular volume obtained by blood pool scintigraphy have been shown to be similar to those obtained by the standard mercury-in-rubber strain-gauge plethysmography (Manyari et al., 1988).

Manyari et al. (1993) assessed the splanchnic venous pressure–vascular volume relationship in humans by elevations of continuous positive airway pressure (CPAP) via a CPAP mask. Increased CPAP, by increasing intrathoracic pressure, opposes right atrial emptying, thereby elevating right atrial pressure, which, in turn, passively increases splanchnic venous distending pressure. The increase of airway pressure from 0 to 12 cm of water was found to increase splanchnic vascular volume by 7%. The pressure–

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vascular volume curves were highly reproducible within and among subjects. This is the first time a pressure–vascular volume relationship is obtained by noninvasive means in the splanchnic vascular bed of humans.

There are several advantages in the use of scintigraphy for the assessment of venous function. As well, scintigraphy allows continuous and relatively noninvasive assessment of intravascular volume for long periods of time. When carried out in conjunction with reference blood sampling, absolute intravascular volume can be obtained (Todo et al., 1986). The technique is easy to use and is sensitive enough to detect small changes in blood volumes associated with exercise (Flamm et al., 1990; Froelich et al., 1988), fluid loading (Scott-Douglas et al., 1995), a change in arterial flow (Scott-Douglas et al., 1995), elevated venous pressure, postural changes (Rutlen et al., 1981), congestive heart failure (Semeniuk et al., 1998; Todo et al., 1986) and drug-induced venodilatation (Semeniuk et al., 1998).

There are several disadvantages to the use of scintigraphy. Accessibility of the technique is low and operating cost is high. For this reason, the studies are normally carried out in humans who are undergoing diagnostic procedures for which the blood pool has been labeled. Correction of background and attenuation of radioactivity are technically complex (Bell & Rutlen, 1990; Manyari et al., 1988; Peters, Neuser, Schaden, & Arndt, 1992; Risöe, Smiseth, Rootwelt, Sire, & Simonsen, 1993; Scott-Douglas et al., 1995). Furthermore, the calculation of absolute blood volume with reference blood sampling of an organ can lead to an error greater than 30%, since organs and blood have dissimilar attenuation (Flamm et al., 1990). Attenuation also differs among individuals who are lean, edematous, or obese. The study of a whole visceral or thoracic organ and the complete exclusion of radioactivity from peripheral organs are difficult due to the partial overlap of some organs (Bell & Rutlen, 1990). As well, red blood cells can be damaged resulting in the loss and subsequent excretion of radioactivity. Movement of an organ and variable background contamination from adjacent tissue may occur during the course of a study. When used in humans, some loss of precision with the measurement of organ radioactivity is unavoidable, since a low amount of radioactivity has to be used (Peters et al., 1992).

3.6. IVUS imaging and ultrasonic crystals

Ultrasound imaging was initially developed as a non-invasive extracorporeal technique to image body organs. The inaccessibility of deep structures led to the development of intracorporeal ultrasound to increase the quality of imaging, and later to intraluminal ultrasound or IVUS to measure the dimensions of cardiac chambers and large vessels. The primary application of IVUS is to reveal the pathology of vascular lesions and provide precise images for guidance and assessment of intervention devices, e.g., the sizing of angioplasty devices (Tobis et al., 1991). The reader should read the review by Cavaye and White (1993) on the IVUS imaging technique.

IVUS has been used to monitor the cross-sectional areas of a large vein and artery of anesthetized rabbits (Schwarzacher, Weidinger, Schemper, & Raberger, 1992) and conscious dogs (Nonaka & Ueno, 1991). In the study by Schwarzacher et al. (1992), an ultrasound catheter was advanced into the abdominal aorta and the inferior vena cava of anesthetized rabbits. The ultrasound transducer was connected to an imaging console, which generated 360° transaxial real-time images that were continuously recorded on videotapes, and evaluated, via a planimetry system, to yield the cross-sectional area of blood vessels. Unfortunately, the size of the IVUS catheter prevents the use of this technology in vessels smaller than the aorta or the inferior vena cava of rabbits. Therefore, the usefulness of the present IVUS methodology in small animals is limited, since small veins and venules are the primary sites of control of venous resistance, compliance and capacity.

Ultrasonic crystals have been used to estimate the changes in the length or diameter of an organ, such as the spleen and the liver (Maass-Moreno & Rothe, 1991; Rutlen, Vengen, & Ilebekk, 1990; Stokland, Thorvaldson, Ilebekk, & Kiil, 1982; Thorvaldson, Stokland, & Ilebekk, 1990). The ultrasonographic technique involves suturing a pair of ultrasonic piezoelectric crystals across two surfaces at the opposite ends of an organ in order to measure the distance between the surfaces. The principle of the methodology involves electrically stimulating the piezoelectric crystal for a brief moment to cause it to vibrate, which causes it to emit a high frequency sound that propagates through the tissue until it hits a receiver on the other side, or is reflected by an interface and returns to the original crystal. The received ultrasound signal causes a vibration of the crystal and generates an appropriate electrical voltage to reflect the distance traveled. Greenway and Rothe (1992) assessed the precision of this technique in the estimation of the dimensions of the spleen and liver relative to the precision obtained by weighing and servo-controlled volume plethysmography, respectively. The crystals were attached with one to four stitches at varied positions over the surface of the spleen and liver. When each crystal was attached by three stitches to the spleen, the crystal tended to lift and buckle when the spleen contracted. When attached by a single stitch, a linear relationship between the thickness and weight was obtained with nerve stimulation of the spleen. In the liver, however, individual thickness measurements using the crystals were not in agreement with those using plethysmography. This was not due to buckling, as even glued crystals had different responses at the same time on the same liver. Average responses from randomly placed crystal pairs were similar to those from plethysmography, but the overall variability was greater for the crystals. The results suggest that the liver does not uniformly alter its shape during active venoconstriction. The authors concluded that the "ultrasonic crystals, when appropriately attached, can reliably monitor

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changes in spleen volume. For the liver, however, the variability in thickness responses at different sites on the same livers is high. Unless a large number of observations are made, the results will be unreliable.'' Clearly, ultrasonic crystals, due to their ease of use, are extremely useful in detecting volume changes in organs provided that the accuracy and precision of the measurements are adequately assessed and precautions are taken to overcome the limitations (Rothe & Maass-Moreno, 1998).

4. Conclusion

Since the venous system contains approximately 70% of the blood volume, an alteration of venous tone affects venous capacity, venous return and CO. Drugs that interfere with venous function cause the pooling of blood in the capacitance vessels and this leads to the reduction of CO and hypotension. Information on body venous tone cannot be obtained from in vitro studies using preparations that are devoid of cardiovascular reflex and neurohumoral influence. Many techniques have been developed to evaluate venous function. The merits and limitations of these techniques must be realized so that selection of appropriate methodologies for the evaluation of venous activity is possible, and meaningful interpretation of the results can be made.

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REVIEW

Non-Invasive Neuroimaging Using Near-Infrared Light

Gary Strangman, David A. Boas, and Jeffrey P. Sutton

This article reviews diffuse optical brain imaging, a technique that employs near-infrared light to non-invasively probe the brain for changes in parameters relating to brain function. We describe the general methodology, including types of measurements and instrumentation (including the tradeoffs inherent in the various instrument components), and the basic theory required to interpret the recorded data. A brief review of diffuse optical applications is included, with an emphasis on research that has been done with psychiatric populations. Finally, we discuss some practical issues and limitations that are relevant when conducting diffuse optical experiments. We find that, while diffuse optics can provide substantial advantages to the psychiatric researcher relative to the alternative brain imaging methods, the method remains substantially underutilized in this field. Biol Psychiatry 2002;52:679–693 *© 2002 Society of Biological Psychiatry*

Key Words: NIRS, non-invasive, functional brain activity, diffuse optical tomography, optical imaging

Introduction

Neuroimaging Methods

Several non- or minimally-invasive neuromonitoring techniques for examining functional brain activity are currently available to the psychiatric researcher and clinician. Historically, electroencephalography (EEG) was the first to appear on the scene, followed by other technologies including positron emission tomography (PET) and single-positron emission computed tomography (SPECT), magnetoencephalography (MEG), and most recently functional magnetic resonance imaging (fMRI). These methods are often categorized in terms of whether they provide direct or indirect information about brain function. Direct methods include MEG, EEG, and event-triggered EEG (also called event related potentials; ERPs), each of which monitors a direct consequence of brain electromagnetic activity. In particular, EEG and ERP record the electrical fields generated by neuronal activity, while MEG records the magnetic fields induced by such activity. PET, SPECT and fMRI, on the other hand, are indirect methods in that they generally monitor hemodynamic changes consequent to brain electrical activity. PET and SPECT brain imaging operate by monitoring the decay of blood-borne radioactive isotopes as they pass through the brain. FMRI, in contrast, detects changes in the local concentration of deoxyhemoglobin via its effect on imposed magnetic fields. While each of these techniques has its own distinct advantages, at present the direct methods tend to have limited spatial resolution, whereas the indirect methods can only detect neuronal activity after it has been filtered by a complex and poorly-understood neurovascular coupling function.

Diffuse Optical Methods

A lesser-known technology for monitoring brain function capitalizes on the absorption and scattering properties of near-infrared light to provide information about brain activity. It was long thought that the scattering of light by tissue made it impossible to recover information from anything but the most superficial layers of tissue (e.g., microscopy). Indeed, most long-standing optical techniques in use in the neurosciences are for superficial tissues only (Villringer and Chance 1997). Some 25 years ago, however, it was discovered that useful information could be obtained from thick tissue samples, including brain monitoring using light applied to and detected from the scalp (Jobsis 1977). This finding spurred the development of diffuse optics as a technique for human brain monitoring. The technique goes variously by the names of near-infrared spectroscopy (NIRS), diffuse optical tomography (or topography; DOT) and/or near-infrared imaging (NIRI). All of the techniques are based on essentially the same concept—shine light onto the scalp, detect it as it exits the head, and use the absorption spectra of the light absorbing molecules (chromophores) present in tissue to interpret the detected light levels as changes in chromophore concentrations.

To compare the spatial and temporal sensitivity of these various brain imaging techniques, we present Figure 1, modeled after a similar figure by (Churchland and Sejnowski 1988). It is clear that MEG and ERPs are strong in temporal sensitivity but relatively weak in terms of

From the Neural Systems Group, Massachusetts General Hospital, Harvard Medical School and Harvard-MIT Division of Health Sciences and Technology (GS, JPS), Charlestown, MA; Athinoula M Martinos Center, Department of Radiology, Massachusetts General Hospital, Harvard Medical School (GS, DAB), Charlestown, MA

Address reprint requests to Gary Strangman, Ph D , Neural Systems Group, 149 13th Street, Room 10018, Charlestown MA 02129

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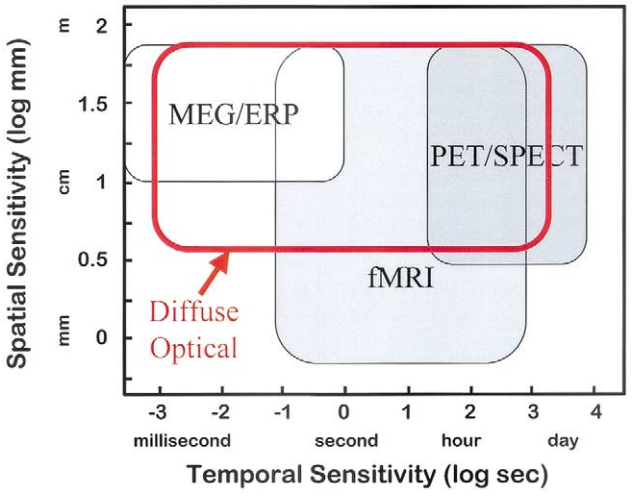

Figure 1. Comparison of the spatial and temporal sensitivities of six non- or minimally-invasive neuroimaging methods.

spatial sensitivity. In contrast, fMRI, PET and SPECT are stronger in spatial sensitivity but weak in terms of temporal resolution. Diffuse optical techniques, in comparison, can provide excellent temporal sensitivity as well as reasonable spatial sensitivity. When multiple colors of light are used, moreover, spectroscopic information about the sampled tissue also becomes available, thereby affording the promise of quantifying the concentrations of the various hemoglobin species-oxyhemoglobin, deoxyhemoglobin, and the sum of these (total hemoglobin, which is proportional to blood volume).

In addition to hemoglobin-based measures of brain activity, diffuse optical techniques also make non-hemoglobin-based measures feasible. For example, by recording data from several wavelengths simultaneously, one can measure other tissue chromophores, including cytochrome oxidase. As a marker of metabolic demands, cytochrome oxidase measurements can provide more direct information about neuronal activity than hemoglobin changes (Heekeren et al 1999; Jobsis et al 1977). There is also evidence to suggest that diffuse optical methods can detect cell swelling that occurs in the 50–200 milliseconds following neuronal firing, which would be an even more direct measure of neuronal activity than the hemodynamic or metabolic markers (Gratton and Fabiani 2001; Steinbrink et al 2000; Stepnoski et al 1991). This type of "fast" signal appears to be significantly smaller than the hemodynamic signals (on the order of a .01% signal change). With sufficiently fast and sensitive electronics, however, such signals could be feasibly recorded by the same equipment as the hemodynamic signals. (The spatial correspondences between these various signals remain to be investigated.) Thus, diffuse optical techniques may be simultaneously capable of providing both indirect and more direct methods of neuronal activity monitoring-complementary sources of information about brain function.

The primary advantages of the optical approach, however, lie in areas not explicitly represented by Figure 1. In particular, the instrumentation—which is completely non-invasive—can be made portable, unobtrusive, low-cost, low-power, and can even be made robust to motion artifacts (e.g., Totaro et al 1998). For the psychiatric researcher, these additional strengths can bring otherwise previously unthinkable projects into the realm of possibility. For example, with proper fiber coupling, extensive movement can be tolerated, opening up the possibility of studying infants, small children, patients with severe movement disorders, or other highly animated subjects, without sedation. The portability and near-zero run-time cost of the instrument affords bedside (or home) monitoring for extended periods, which could be useful for monitoring the effects of slowly acting drugs, or slowly evolving pathologies. And, the fact that near infrared light is non-ionizing means that there is no limit to the number of scans one can undergo.

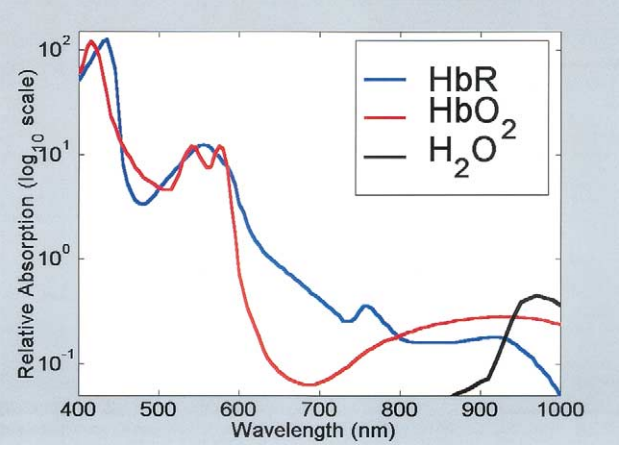

Figure 2. Absorption factors for the primary light absorbers (chromophores) in biological tissue in the near-infrared wavelength range (HbR, deoxyhemoglobin, HbO_2, oxyhemoglobin). The relatively low absorption factors between roughly 650 and 950 nm provide an "optical window" in tissue through which one is able to see changes in oxy- and deoxyhemoglobin deep within tissue, including the head.

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The "Optical Window"

Diffuse optical recordings depend on two critical characteristics of the electromagnetic spectrum as it interacts with biological tissue. First, while biological tissue is relatively opaque to visible light, it is not totally opaque, as demonstrated by a simple experiment. Darken a room, shine a flashlight through your hand and notice that the white light from the flashlight exits with a red hue, indicating that the tissue least absorbs the redder wavelengths. Near-infrared (NIR) light—from approximately 650–950 nm—is even more weakly absorbed by tissue than the red wavelengths (Figure 2). As a result, this range of wavelengths is often called an "optical window" into biological tissue. This property allows light of these wavelengths to penetrate several centimeters through tissue and still be detected.

The second critical characteristic of NIR light as it interacts with biological tissue is also apparent in Figure 2. The two dominant chromophores for the NIR wavelength range just happen to be two biologically relevant markers for brain activity: oxyhemoglobin (HbO_2) and deoxyhemoglobin (HbR). Thus, NIR wavelengths pass relatively easily through tissue, and their absorption can provide information relevant to brain function.

Having described what makes the technique possible, we next discuss the methodology details, including the types of measurements one can make, the nature of diffuse optical monitoring equipment, and the basic underlying theory necessary for data interpretation. We will then review brain research applications of diffuse optical techniques—with an emphasis on psychiatric patient groups—and will finally discuss the practical issues presently faced by optical researchers.

Methods and Materials

Types of Diffuse Optical Measurements

The amplitude of the recorded signal in a diffuse optical measurement is determined by two factors: (i) absorption of light by the tissue, and (ii) light scattering within the tissue. An increase in either factor results in a decrease in detected light levels, and a corresponding decrease in signal. The goal of diffuse optical measurements is to detect such changes and, in some cases, determine whether the change was due to a change in absorption or scattering by the tissue under investigation. As mentioned, absorption changes are predominantly driven by changes in hemoglobin concentrations. When a diffuse optical probe is placed on the head, the observed hemoglobin changes reflect underlying brain activity (Kleinschmidt et al 1996; Villringer et al 1997). Scattering changes, in contrast, have a less clear relevance to the psychiatric researcher in large part because the sources of scattering changes within the head are only partly understood. For example, scattering may be higher in regions with dense fiber tracts (differences thereby being observable across subjects or evolving over time). However, the importance of scattering changes to normal and diseased brain activity and baseline states remains to be investigated in detail. Presently, most optical brain monitoring experiments simply assume scattering remains essentially constant during the experiment and that all observed signal fluctuations are due to changes in absorption.

Three main categories of diffuse optical measurements have been developed: time domain, frequency domain and continuous wave measurements (Table 1). Time domain, or time-resolved, systems introduce into tissue extremely short (picosecond) incident pulses of light, which are broadened and attenuated by the various tissue layers (e.g., skin, skull, cerebrospinal fluid and brain). A time domain system detects the temporal distribution of photons as they leave the tissue, and the shape of this distribution provides information about tissue absorption and scattering. In frequency domain systems, the light source shines continuously but is amplitude-modulated at frequencies on the order of tens to hundreds of megahertz. Information about the absorption and scattering properties of tissue are obtained by recording the amplitude decay and phase shift (delay) of the detected signal with respect to the incident signal (Chance et al 1998). In continuous-wave (CW) systems, light sources emit light continuously, like frequency domain systems, but at constant amplitude, or modulated at frequencies not higher than a few tens of kilohertz (which provides stray-light rejection). CW systems measure only the amplitude decay of the incident light.

Each of these techniques has intrinsic advantages and drawbacks, the characteristics of which are outlined in Table 1. The choice of measurement mode is basically determined by the type of information one needs to collect. For the psychiatric researcher interested in monitoring brain function changes over time, a frequency domain or continuous wave instrument would typically be sufficient; the added spatial specificity of time domain instruments and the ability to separate absorption and scattering effects is not clearly necessary for such measurements.

Point Measurements vs. Imaging

Each of the three instrument types can in theory be deployed in either point measurement or imaging configurations. Fundamentally, the difference between a point-measurement instrument and an imaging instrument lies merely in the number and geometrical arrangement of sources and detectors. In particular, a point-measurement

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Table 1. Characteristics of the Three Main Types of Diffuse Optical Measurements

Measurement Type	Advantages	Disadvantages	Example Uses	References
Time domain	Spatial resolution Penetration depth Most accurate separation of absorption and scattering	Sampling rate Instrument size/weight Stabilization/cooling Cost	Imaging cerebral oxygenation and hemorrhage in neonates, breast imaging	(Benaron and Stevenson 1993; Chance et al 1988; Hebden et al 1997)
Frequency domain	Sampling rate Relatively accurate separation of absorption and scattering	Penetration depth	Cerebral and muscle oximetry, breast imaging	(Franceschini et al 2000; Gratton et al 1997; Jiang et al 1995; Pogue and Patterson 1994)
Continuous wave	Sampling rate Instrument size, weight and simplicity Cost	Penetration depth Difficult to separate absorption and scattering	Finger pulse oximeter Functional brain experiments (as per fMRI)	(Nioka et al 1997; Schmitz et al 2000; Siegel et al 1999)

fMRI, functional magnetic resonance imaging

instrument requires only one source location and one or more detector locations. In contrast, a true imaging instrument requires that each detector be able to detect light from two or more source locations.

Consider first the spectroscopy (NIRS), or point measurement, instrument (Figure 3A). As seen in Figure 2, the two dominant absorbers in tissue for the NIR wavelength range are HbO_2 and HbR. Because the absorption coefficients of these two species are always roughly the same order of magnitude in the NIR range, any measurement at a single wavelength will be significantly affected by changes in the concentration of either of the two species, confounding the interpretation of any single measurement. However, as alluded to earlier, simultaneous measurements made at two wavelengths can be used to separate the two types of changes, resulting in simultaneously acquired concentration changes for both HbO_2 and HbR. A NIRS instrument for brain recordings will therefore emit light at two (or more) wavelengths through a source optical fiber into the head, and measure the exiting light for *each* wavelength at a detector location some distance away. Three or more wavelengths can be used either to (i) improve the measures of HbO_2 and HbR, or (ii) extract changes in other, less-absorbing species such as water, and/or cytochrome oxidase (Heekeren et al 1999; Matcher et al 1994). All of this can be accomplished with just one (multi-color) source location and one detector location.

An imaging instrument, in contrast, requires multiple source and detector locations arranged in such a way so as to provide overlapping measurement sensitivities (Figure 3B). The overlapping measurements can be mathematically combined, in a self-consistent way, to generate a spatial image of changes in remitted light over time beneath the probe (Arridge 1999; Arridge and Schweiger 1997). If data from multiple colors are simultaneously gathered at every detector location, spectroscopic images (images of both HbO_2 and HbR) can be generated.

Instrumentation Components

To evaluate the appropriateness of optical instrumentation for a given application requires some understanding of the components that comprise such an instrument. Any diffuse optical instrument will require, at a minimum, three

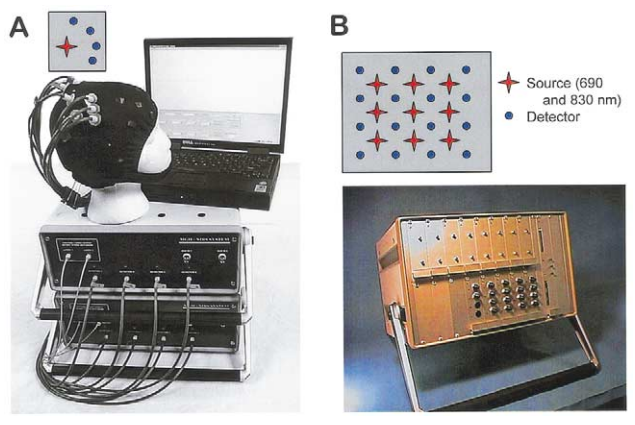

Figure 3. Two example continuous-wave optical instruments. (**A**) An example NIRS experimental setup, including 2 instruments, optical fibers for conducting light to and from the head, and a recording computer. Each instrument provides two light colors (690 and 830 nm) and four avalanche photodiode detectors, affording four separate spectroscopic point-measurements. (**B**) An example DOT instrument, consisting of sixteen detectors (top two rows of connectors), and eighteen laser sources (bottom four rows of connectors). Sources are modular, but typically consist of nine 690 nm lasers and nine 830 nm laser diodes. With an appropriate geometrical arrangement of sources and detectors (top), image reconstruction becomes possible. NIRS, near–infrared spectroscopy; DOT, diffuse optical tomography.

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Table 2. Types of Light Sources Used in Diffuse Optical Measurements

Source Type	Power Range	Available Colors	Comments
Filtered white light (e.g. tungsten lamp with NIR filter)	Low (<5 mW)	Flexible and variable color resolution	Better color resolution means less power per color
Light emitting diodes (LEDs)	Low to Medium (<1 to 30 mW)	30 nm band surrounding nominal color	Inexpensive
Laser diodes (e.g. in a laser pointer)	Low to High (<1 to >500 mW)	Discrete colors (±1 nm) Limited color choices	More expensive

NIR, near-infrared; LEDs, light emitting diodes

primary components: a NIR light source, a detector, and electronics for the two. The ideal light source provides multiple discrete NIR wavelengths each at relatively high, tunable power—a type of light source that does not presently exist. Instead, one of three types of light sources is typically used to provide sufficient NIR light for diffuse optical monitoring of brain, as shown in Table 2. Generally speaking, the source tradeoffs depend on two factors: the need for discrete wavelengths and the need for more power. Power is important because detected signals are typically on the order of 10 pW for a source-detector separation of 4 cm, or a loss of 7–9 orders of magnitude in light power. Increasing power can help compensate for this loss, within the safe exposure limits (see Safety Considerations, below).

Detectors form the next critical component of a diffuse optical instrument. Fundamentally, the detection of the extremely low light levels leaving the head requires sensitive detectors, and the four broad classes of optical detectors that are presently in use are outlined in Table 3. The choice of detector is dependent on the particulars of the application. In neuroimaging, as with optical imaging of deep tissue in general, highly sensitive detectors are essential and speed is often highly valued. This suggests the use of PMTs or APDs, respectively. (Though SPDs have been used effectively and are better for use in applications requiring a wide range of incident flux.) Where many wavelengths are desired, CCDs are often used in conjunction with a white light source. The remitted light can be dispersed by a prism onto the CCD, which allows the simultaneous detection of many wavelengths and easily varied spectral resolution.

The final component in a diffuse optical device is the electronic hardware. While the details of the electronics will be of minimal importance to the psychiatric researcher, an understanding of what the electronics must achieve is useful for instrument evaluation. Any given detector is sensitive to all wavelengths of light, and there usually are many source colors and/or source locations to be monitored by any given detector. The electronics must therefore be engineered to allow separation of the various colors and locations. This is achieved in multiple ways. With a CCD camera, separation is achieved spatially, by dispersing light colors across the surface of the detector. The other detectors require modulating and/or multiplexing the sources and then decoding the detector signal so that the colors and locations can be monitored without generating so-called "cross-talk" interference with one another, whereby light from one source is actually interpreted as coming from another source. Minimizing cross-talk can be achieved by time-sharing sources (turn only one on at a time), or various multiplexing schemes (I-Q modulation (Siegel et al 1999); or frequency modulation or time-division multiplexing (Boas et al 2002)). Generally speaking, the electronic needs for an optical instrument are minimal and could easily be loaded onto a single digital signal-processing chip. The overall instrument size, therefore, is determined predominantly by the size of the detectors plus the light sources, as well as the power supply required to stably drive the sources and electronics.

Table 3. Types of Detectors Used in Diffuse Optical Measurements

Detector Type	Speed	Sensitivity	Dynamic Range	Example Application
Silicon photodiodes (SPDs)	Medium (up to 10 kHz)	Low	High (~100 dB)	Multi-use instrument where light levels span many orders of magnitude
Avalanche photodiodes (APDs)	Fast (>100 MHz)	High	Medium (~60 dB)	Adult human measurements
Photomultiplier tubes (PMTs)	Fast (>100 MHz)	Very high below 820 nm, then drops rapidly	Medium (~60 dB)	Adult human measurements
Charge-coupled devices (CCDs)	Slow (up to 1 kHz)	Variable	Up to 60 dB	Simultaneous detection of many wavelengths (e.g., from tungsten lamp)

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There are a wide variety of instruments currently in use, both commercial (Colier et al 1997; Cope and Delpy 1988; Franceschini et al 2000; Gomersall et al 1998; Kawaguchi et al 2001; Quaresima et al 2000) and custom-built (Grosenick et al 1999; Konishi et al 2000; Ntziachristos et al 1999; Pogue et al 1997; Schmitz et al 2000; Siegel et al 1999) reflecting the possible tradeoffs when engineering such instruments. The tradeoffs can be made in all three areas just discussed: detectors, light sources, and instrument electronics. The detector choice largely determines the instrument sensitivity, maximum sampling rate and dynamic range. The type of light source determines the amount of spectroscopic data and, in part, the penetration depth (based on the power available). Light modulation/demodulation schemes determine the number of colors and locations that can simultaneously be "seen" by a detector, and they also affect the maximum possible sampling rate for each instrument. The remaining post-detector recording electronics ultimately determine the instrumentation bandwidth, sample rate, total number of samples, the options for post-recording filtering and processing, and occasionally the instrument's dynamic range. All existing instruments handle these tradeoffs differently. Again, for research questions involving changes in functional brain activation within and across subjects (including patient populations), an instrument using APD photodetectors and emitting at least 2–4 colors of light per source location would typically be sufficient. The required number of sources and detectors—and hence the nature of the electronics—is determined by the spatial nature of the question at hand (few needed for hemispheric comparisons, and many for more precise spatial localization).

Safety Considerations

Whenever considering the use of a novel, in-vivo monitoring technology, the issue of safety must be addressed. Unlike MEG and EEG which are passive recording techniques, diffuse optical techniques—like MRI and PET—operate by depositing energy into the subject and recording changes in that energy when remitted. For diffuse optical recordings, safety considerations revolve around maximum safe exposure durations and power densities for near-infrared light, which are defined by the American National Standards Institute (2000). NIR light is non-ionizing (unlike, for example, ultraviolet and shorter light wavelengths), so the primary concern has been with tissue heating. For brain monitoring, heating is most relevant for the skin of the scalp, as the vast majority (>95%) of the NIR power is deposited in this layer. The exact limit depends on many factors, including the wavelength, coherence (lasers vs. other light sources), duration and area of exposure, but the power required for diffuse optical measurements—even for relatively large source-detector separations (and hence 7–9 orders of magnitude in total signal loss)—remains well below the level where tissue damage from heating might occur (Ito et al 2000). That limit, the maximum permissible exposure for skin (assuming incoherent light and continuous illumination), ranges from .2 W/cm^2 at 630 nm to .4 W/cm^2 at 850 nm. The limits are substantially lower for eye exposure, particularly for coherent sources, and hence caution must always be exercised with respect to inadvertent eye exposure to the light sources. At present, there is little information on the direct effects of NIR light on brain tissue. On the positive side, there is evidence that the NIR wavelength range can provide therapeutic benefits via photodynamic therapy (Schmidt et al 1996) and can even promote wound healing (Whelan et al 2001), though the mechanism by which this latter effect occurs is still under investigation.

Basic Theory

Modified Beer-Lambert Law (MBLL)

To quantify changes in concentrations of absorbing species, a model of light diffusing through tissue is required. A traditional approximation to the full photon migration theory is called the modified Beer-Lambert Law (MBLL), which is an empirical description of optical attenuation in a highly scattering medium (Cope et al 1987). A change in the concentration of an absorbing species causes the detected light intensity to change and, according to the MBLL, the concentration change is proportional to the logarithm of the detected light intensity during the change divided by the light intensity before the change. The proportionality constant is comprised of two, simple conceptual pieces: (1) a measure of the path length the scattered light actually traveled through the tissue (decomposed as the source-detector separation times a quantity called the differential pathlength factor), and (2) the extinction coefficient of the absorbing species. The source-detector separation is easily measured along the surface of the head, and the extinction coefficient for a given species can be looked up in tables. The differential pathlength factor is either measured (with a time-domain or frequency domain instrument) or it is estimated (for a continuous wave measurement).

As already mentioned, in order to determine the contribution of multiple chromophores (e.g., oxy- and deoxyhemoglobin), we must take measurements at one or more wavelengths per chromophore to be resolved. For example, by measuring the change in light intensity at two wavelengths, and using the known extinction coefficients of oxyhemoglobin (ε_{HbO_2}) and deoxyhemoglobin (ε_{HbR}) at those wavelengths (from Figure 2), one can then sepa-

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rately determine the concentration changes of oxyhemoglobin and deoxyhemoglobin by solving the two equations with two unknowns for Δ[HbR] and Δ[HbO_2]. This approach can be generalized to more than two wavelengths (Cope et al 1991).

Beyond MBLL

The MBLL method provides a reasonable first approximation to calculating concentration changes. However, this model is dependent on knowledge about the precise spatial location and extent of any change in [HbR] and/or [HbO_2] relative to the location of the source and detector (Boas et al 2001). Without such knowledge, a simplifying assumption is typically made wherein any concentration changes are assumed to be uniform throughout the entire sampling region (Cope and Delpy 1988; Cope et al 1991). For measurements in settings such as functional brain activity, this assumption is violated. In an adult human, the scalp and skull range from approximately 1 to 2 cm thick, depending on the subject and the region on the head (Figure 4). Moreover, a lack of significant findings in these layers from whole-head functional MRI scanning suggest that these layers generally exhibit little or no change in hemodynamic variables during task performance. Thus, the region of hemoglobin change will typically be focal relative to the entire sampling region for a given source-detector pair. The consequences of violating the global-change assumption are only beginning to be characterized (Uludag et al 2002). Thus far, however, the validity of the technique has tested favorably against several other monitoring modalities (Kleinschmidt et al 1996; Terborg et al 2000; Villringer et al 1997) and theoretical studies suggest that any resulting errors can be limited to less than 10% (Strangman et al., unpublished). One way to further reduce such focal-change errors is to use an imaging instrument and associated image reconstruction algorithms. Imaging, by definition, accounts for the focal nature of changes by replacing the MBLL with reconstruction algorithms that find a self-consistent spatial "explanation" for the observed multiple overlapping measurements. This will be discussed further in Image Reconstruction, below.

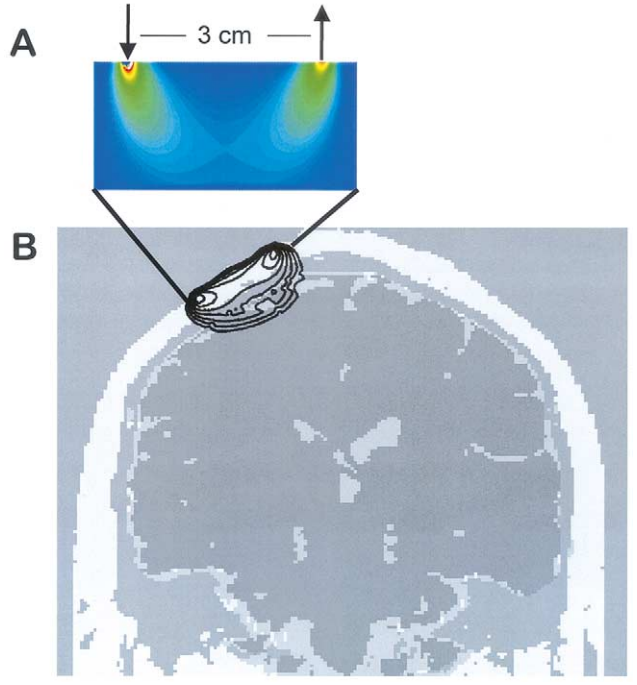

Figure 4. (**A**) An example sensitivity plot for light traveling in a homogeneous, highly scattering medium for a continuous-wave or frequency-domain measurement. Arrows indicate the location of a source (left) and detector (right), and colors indicate the number of detected photons that reached any given point in the homogeneous medium. White, reds and yellows indicate the highest numbers (and hence the highest sensitivities), blues and purples indicate progressively lower sensitivities. (**B**) A similar plot for light traveling through the head of an example subject. Contour lines appear every half-order of magnitude and end at the sensitivity limit of our NIRS instrument. Anatomical MRI scans were performed and segmented into 1 mm voxels labeled as air, scalp, skull, CSF or brain. Simulations of light propagation through both media were performed in 3D—using different optical properties for each tissue type—to determine the spatial distribution of light flux through the head based on the source-detector positioning shown. NIRS, near–infrared spectroscopy; MRI, magnetic resonance spectroscopy; CSF, cerebral spinal fluid.

Neuromonitoring Applications

Physiology

An example time series from a CW NIRS instrument appears in Figure 5, obtained from probe located over position C3 in the International 10/20 system (approximately over left primary motor cortex) on a subject sitting upright, quietly resting with eyes open. The high-frequency oscillations correspond to the cardiac cycle, whereas the low frequency oscillations likely correspond to Mayer wave oscillations (Obrig et al 2000). Simple measures such as these can provide useful physiological information, but for functional monitoring such baseline signals can confound data interpretation. With sufficient temporal resolution, as is available in the data in Figure 5, it becomes possible to model and remove some such physiological changes (e.g., heart rate), resulting in a cleaner signal and substantially increased signal-to-noise ratio for functional changes (Gratton and Corballis 1995).

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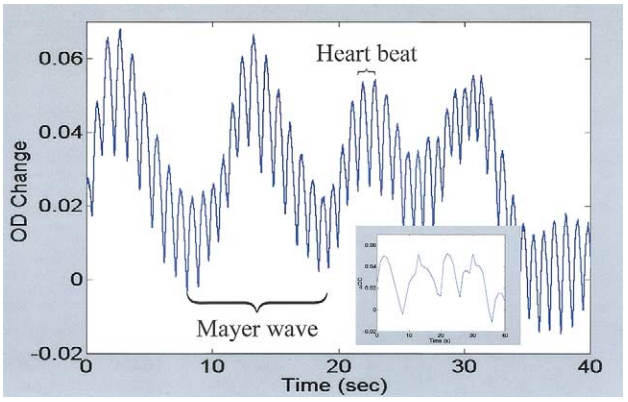

Figure 5. Optical density change [$OD = -\log(I_{final}/I_{baseline})$, where I is the measured light intensity] recorded from position C3 (i.e., over primary motor cortex) in a seated subject during quiet rest. Several physiological oscillations are evident including the cardiac cycle and Mayer waves. Inset shows the same signal sampled at 1 Hz, illustrating the loss of information that can occur with slower sampling, as is the case with fMRI. The relatively high speed of optical instruments allows more complete interpretation of collected data, which can in turn increase the signal-to-noise ratio for changes due to functional brain activity. fMRI, functional magnetic resonance imaging.

The inset in Figure 5 shows the same signal when sampled at 1 Hz—a typical recording rate for fMRI—wherein there is insufficient information for such modeling, making signal interpretation for this subsampled signal more difficult than with the higher sampling rate. Fast recordings not only improve temporal signals, but they can also enhance spatial localization by detecting the temporal properties of structures (e.g., localizing an artery by looking for pulsations in the signal; Barbour et al 2001). Slow physiological changes—ones that evolve on a time-scale similar to that of the hemodynamic response to brain activation (such as Mayer waves)—must be reduced or eliminated by other techniques, such as the use of event related experimental paradigms (Rosen et al 1998).

Basic Research

In the functional brain imaging arena, diffuse optical techniques are not as widespread as other methods, but they have been applied in a variety of fields in both basic and clinical neuroscience and neuroimaging. Figure 6 shows example responses recorded in a simple motor task, as compared to the simultaneously acquired, spatially co-registered fMRI signal from primary motor cortex in a human volunteer. To summarize the procedure: after consent to a protocol approved by the Massachusetts General Hospital review board, we fitted a subject with a continuous-wave diffuse optical apparatus (Figure 3A), positioned over the left sensorimotor area. The subject was then positioned for scanning in a Siemens Sonata 1.5T scanner, and anatomical SPGR images were collected to enable the identification of fiducial markers near the fiber tips. This allowed post-scanning co-localization of the optical probes in the MR imaging space. The subject performed eight 16 sec blocks of a right-hand tapping task (onsets indicated by vertical bars in Figure 6), interleaved with 16 sec periods of rest. Statistical maps of the fMRI were used to select activated voxels near the surface of the cortex, four of which were averaged to produce the fMRI timeseries in the figure. Once the optical fibers were identified in the MR imaging space, we selected the source-detector pair closest to the identified region of fMR activation, converted the data to HbO_2 and HbR concentrations, and plotted the results. The decrease in [HbR] mirrors the observed increase in the blood-oxygenation level dependent fMRI signal, with good correspondence between the two recording modalities. The inset shows the signal obtained from a source-detector pair several cm from the activated region.

The diffuse optical results for this motor task are typical of brain activation, and hence similar findings have been

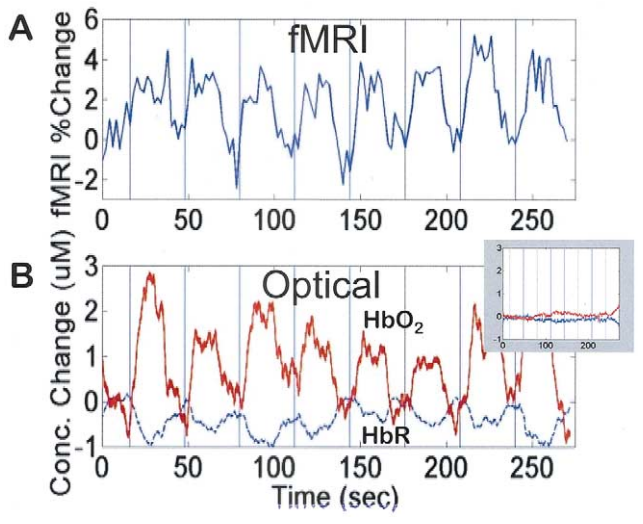

Figure 6. Raw time courses for a single run of a simple motor task, consisting of eight 16 sec periods of finger tapping alternating with 16 sec periods of rest. Vertical bars indicate onset of motor activity. (**A**) fMRI time course for left primary motor cortex during right finger tapping, averaged over four significantly activated voxels. (**B**) Changes in [HbO_2] and [HbR] as determined from the source-detector pair closest to the fMRI activation. Inset shows control HbR and HbO_2 timecourses from a measurement several centimeters away from the activated region (same y-axis scaling). fMRI, functional magnetic resonance imaging.

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demonstrated in the visual system (Villringer et al 1993; Wobst et al 2001), the somatosensory system (Beese et al 1998; Obrig et al 1996; Steinbrink et al 2000), the auditory system (Sakatani et al 1999a; Sato et al 1999), and with language stimuli (Sato et al 1999; Watanabe et al 1998) and other cognitive tasks (Hoshi and Tamura 1993; LaBar et al 1999; Villringer et al 1994). In general, these studies find spatially localized increases in [HbO_2] and corresponding decreases in [HbR] in response to functional challenge, with onsets around 2 sec following task onset and times-to-peak in the 5–9 sec range. All such findings are as expected from fMRI studies. Moreover, the particular brain regions exhibiting such changes are typically concordant with the findings from other neuroimaging modalities, at least in those cases where similar paradigms have been investigated. Interestingly, the HbR changes appear to be somewhat more spatially localized than the HbO_2 changes (Hirth et al 1996), although the reason for this is still under investigation.

The potential basic research questions that remain and can be addressed with diffuse optical techniques are numerous. One possibility is to examine hemodynamic responses as a function of task or disease—not only in terms of amplitude and onset times, but also the relative contributions by HbO_2 and HbR, and the timing relationships between these hemodynamic components. Some initial steps in this direction specifically for psychiatric populations are mentioned in the following section. Another possibility is the investigation of spatial distributions of activity (and how such distributions evolve over time) as a function of task, subject population or even, in a more clinical setting, as a function of treatment for a given disease. In general, a research question for which one of the other brain monitoring modalities might be considered, particularly if it involves more superficial cortical regions, will likely be amenable to diffuse optical techniques.

Clinical Applications

One of the first clinical applications of diffuse optical techniques for functional brain monitoring was the investigation of fetal, neonatal and infant cerebral oxygenation and functional activation. This population was of interest because other neuroimaging methods were (and are) not feasible given the high activity level of such subjects. In this domain, the diffuse optical approach has helped uncover developmental alterations in the cerebral hemodynamic response to auditory and visual stimulation (Meek et al 1998; Zaramella et al 2001), has helped characterize changes in cerebral perfusion as a function of surgical events such as bypass and reperfusion (Kurth et al 1995), and has provided measures of fetal brain oxygen supply during labor (Aldrich et al 1995) and post birth-asphyxia (van Bel et al 1993). In another major effort, several groups are working towards employing diffuse optics in monitoring adults with ischaemic and hemorrhagic stroke, although this effort is still in its early stages (Kirkpatrick et al 1998; McKinley et al 1996; Stankovic et al 1999; Stankovic et al 2000; Vernieri et al 1999; Wolf et al 1997).

Relatively few psychiatric applications of diffuse optical techniques have thus far been reported. Hock and colleagues have examined Alzheimer's patients during verbal fluency and other cognitive tasks, finding decreases in HbO_2 and total hemoglobin ($HbT = HbO_2 + HbR$) relative to baseline in the parietal lobe (Hock et al 1996; Hock et al 1997). Both young and elderly controls demonstrate increases in both parameters in the same region, supporting the idea that Alzheimer's may result in damage to the parietal lobe itself, or to regions with significant inputs to the parietal lobe. Two groups have looked at schizophrenia patients. The first found unusual, "dysregulated" patterns of HbO_2 and HbR change—i.e., increases in HbO_2 were not necessarily paralleled by decreases in HbR, and vice versa—in frontal regions of schizophrenic patients as compared to healthy subjects during a mirror drawing task (Okada et al 1994). The second group showed that the typical pattern of right-lateralized activation during a continuous performance test was absent in schizophrenic patients (Fallgatter and Strik 2000). A third psychiatric population, namely depressed patients, have also been examined with diffuse optical techniques, finding reduced frontal activation during a verbal fluency test relative to controls (Matsuo et al 2000), and atypical lateralization of frontal activation responses (more strongly favoring the non-dominant hemisphere) during a mirror drawing test (Okada et al 1996).

In addition to cognitive studies, evaluations of the hemodynamic response have also been completed during deep brain stimulation in Parkinson's patients (Murata et al 2000; Sakatani et al 1999b), during induced seizures in patients with intractable epilepsy (Watanabe et al 2000), and during magnetic brain stimulation for the treatment of depression (Eschweiler et al 2000). For the Parkinson's patients, frontally recorded oxygenation varied dramatically depending on the rate and location of stimulation. The study of epilepsy patients suggested that NIRS could be a useful non-invasive probe for localizing seizure foci. And, in the case of magnetic brain stimulation for depression, NIRS-derived total hemoglobin concentrations actually predicted the patient's response to treatment.

Clearly, such work only begins to address questions about the nature of functional circuit disruption in psychiatric populations. It does, however, suggest that (i) diffuse optical techniques are sufficiently sensitive to detect such

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changes, and (ii) that the information provided about both HbR and HbO_2—unavailable from other brain imaging methods—may be important in certain psychiatric disorders. The discovery of substantial "dysregulation" of hemodynamic parameters in patient populations is likely to become important in the interpretation of other psychiatric brain imaging data. Moreover, it would appear that diffuse optical techniques have considerable potential not only in characterization and ongoing evaluation of psychiatric diseases, but also in diagnosis and outcomes prediction.

The fact that relatively few such papers have appeared—certainly in comparison to PET and fMRI studies—and the broad applicability of the technique across populations and research questions, suggests that psychiatric research is still wide open for the application of diffuse optical techniques. As just one example, there has been surprisingly little cortical activation testing of patient groups with motor dysfunction—e.g., Huntington's, obsessive compulsive, and Parkinson's patients—for which diffuse optical methods are particularly well suited. Other opportunities await the proper combination of research interest, study population and instrument selection.

Current Issues

The advantages that diffuse optical techniques can provide brain researchers are substantial. These include portability, unobtrusiveness and low cost. As with any technique, however, these advantages come with some limitations, and so we consider here the issues that need to be considered when designing diffuse optics experiments.

Non-invasive Spatial Localization

As with EEG, MEG and PET, diffuse optical methods cannot provide anatomical images or other direct measures of anatomy—at least not of the sort people have come to expect with the availability of MRI. To afford between-subject comparisons for functional brain changes in a diffuse optical setting, therefore, an extrinsic frame of reference is required. With over 50 years of experience, EEG researchers have developed an external-referential system—the International 10-20 system—which provides 21 standardized electrode placement positions (Harner and Sannit 1974), and has been expanded to dense sensor grids of 256 detectors (Suarez et al 2000). While such a system is technically only self-consistent, efforts have been made to determine the location of various major anatomical landmarks relative to the standard 10-20 system locations (Homan et al 1987; Steinmetz et al 1989). Between-subject variability is still substantial, but such references can be of considerable help in orienting the optical researcher by standardizing placement positions and easing the challenge of communicating to others the placements on the surface of an irregularly shaped object such as the head. Again, precise positioning is only important for situations where functional changes are confined to known, small regions of the brain, which (arguably) tends to be less true for many psychiatric diseases.

Another aspect of localization in optical studies arises from fiber placement. A single ("point") measurement with optical techniques is slightly more complicated than, for example, an EEG electrode placement, because an optical measurement requires two fibers (a source and detector); an EEG point measurement requires only a single electrode location. An example sensitivity profile of a source-detector pair on an adult human head appeared in Figure 4. Each contour corresponds to the absorption of half an order of magnitude in light levels. One can therefore see that the sensitivity to changes in brain tissue will be maximal below and between the source and detector. As an approximate rule of thumb—for frequency domain and continuous wave measurements—the depth of maximum brain sensitivity is approximately half the source-detector separation distance. Thus, for a source-detector separation of 3 cm, the region of maximum brain sensitivity will be found between the source and detector fiber tip locations, and roughly 1.5 cm below the surface of the scalp, though banana-shaped region of sensitivity extends both above and below this depth. The maximum overall sensitivity, as evident in Figure 4, is actually at each fiber tip. It is typically assumed, however, that the scalp and skull produce little or no change in hemoglobin concentrations, which implies that observed changes localize to brain tissue (Firbank et al 1998). The sensitivity pattern for time domain measurements, on the other hand, is variable, affording deeper sensitivities by selectively rejecting light that travels exclusively through these superficial tissue layers.

Regardless of the measurement type, however, the fact that tissue strongly scatters light means spatial resolution decreases with depth. Localizing activation to the amygdala, for example, is not feasible, and cingulate cortex would be difficult (see also the discussion on penetration depth in the following section). Superficial cortex, including (but not limited to) dorsolateral prefrontal cortex, superior parietal cortex, and language and primary sensorimotor areas, on the other hand, are all within detectable limits of the current diffuse optical tools.

Coupling, Light Levels, and Penetration Depth

Another challenge for optical methods can be achieving good, stable optical contact and sufficient light levels

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detected from the subject. Several issues affect coupling: hair (absorption and instability), hair follicles (follicles strongly absorb near infrared wavelengths), skin color or variations (darker skin regions are typically more absorbing of NIR wavelengths), and general fiber stability against the head (a function of rigidity, strain relief, torque and subject comfort). Such variables make a generalized solution to the coupling problem challenging for in vivo diffuse optics experiments. Many solutions have been implemented for holding the optical fibers—with a goal of rigidity, plus flexibility with respect to head shape. A few examples include: fibers inserted through modified motorcycle helmets, thermoplastic molded to the contours of each subject's head, spring-loaded fibers attached to semi-rigid plastic forms, and fibers embedded in neoprene rubber forms. New and improved coupling methods are continuously being developed.

Once fibers are relatively stable, and properly coupled to the head (i.e., no extra-cranial light leakage from source to detector), the remaining determinants of detected light levels are tissue optical properties and instrument properties. Instrument properties, including the instrument speed/sensitivity tradeoffs, were discussed earlier. As for subjects, since both hair and hair follicles are strongly absorbing at the wavelengths of interest, hair-free portions of the head (or subjects with thinner or lighter colored hair) usually provide improved signal strength and penetration depth for optical recordings. It is nevertheless possible to record through the hair with many instruments. The thickness of the subject's scalp and skull are also relevant to monitoring brain function, as thicker scalps and skulls will both absorb more light and will require larger separations to achieve sensitivity to brain chromophores. The parameters vary not only between subjects, but also around the head within a given subject, and are unknowns unless an MRI scan is available. Geometrical factors (e.g., source-detector separations, whether sources and detectors point towards or away from one another, etc.) are additional signal-level determinants, but work is underway to help quantify these effects.

While there are clearly a substantial number of factors contributing to signal detection, it is important to remember that penetration depth is fundamentally a function of contrast. A very large change (e.g., a hemorrhage) in the thalamus of an adult human may be detectable by a diffuse optical instrument, though with poor spatial resolution. In comparison, a small change—as found with functional activation—may only be detectable 1–2 cm below the surface of the cortex. As mentioned, while penetration depth increases with source-detector separation, current diffuse optical instruments can only detect light with maximum source-detector separations of up to 5 or 6 cm on an adult head. This contrasts with an infant head, where light may well be detectable when transmitted straight through from one side of the head to the other, due to a thinner skull, smaller head, less hair and smaller follicles.

In sum, there is an abundance of factors that can influence signal levels aside from the instrumentation hardware. The practical consequence of these factors is straightforward: some initial trial and error is typically required to maximize signal quality for a given combination of instrument, study population, and probed brain area. In general, these factors affect healthy and patient populations equally and in many cases, such empirical work has already been completed (e.g., the initial work discussed under Neuromonitoring Applications, above). In our experience, the signals from diffuse optical recordings are inadequate in fewer than 10% of volunteers.

Absolute Quantification of Hemoglobin Species

Presently, most non-invasive diffuse optical brain measurements are capable of only detecting changes, much like blood oxygenation level dependent fMRI. Removing an optical probe and replacing it, even if placed in the "exact" same position on the head, will inevitably result in different coupling efficiencies between the fibers and the head. As a result, *absolute* oxy- and deoxyhemoglobin concentration measurements taken on separate days cannot yet be reliably compared. This would preclude studies where, for example, it is necessary to compare baseline oxygenation states during the temporal evolution of a disease state. The use of relative measures, however, can go a long way (as shown by the extensive application of fMRI and non-catheterized PET studies); for example, functional modulation (i.e., *changes* from baseline) can be monitored and compared over the evolution of a disease. Moreover, the diffuse optical method retains the potential for providing such absolute measures (see below).

Image Reconstruction

Imaging provides one potential—though as yet not fully realized—solution to the absolute quantification problem. By recording from many source-detector pairs simultaneously, (i) the coupling efficiencies can be accounted for, and (ii) the overlapping measurements can be combined to generate self-consistent measurements across regions in a way that is impossible with point measurements. The resulting image therefore provides more accurate, absolute and quantitative measures of hemoglobin concentrations. The present limitation for this procedure is the theory of image reconstruction. In the case of brain imaging, the activation regions and optical probes are both distributed in three dimensions, with non-uniformly varying incidence orientations of the probes. Moreover, the tissues consist of highly non-uniform, undulating layers of optically distinct

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types. Image reconstruction investigations generally concentrate on reconstructions from either flat or circular, semi-infinite, uniform media (Arridge and Schweiger 1997; Paulsen and Jiang 1995; Pogue et al 1999), although a few more complicated geometries have been considered (Schweiger and Arridge 1999). Present research is beginning to focus on algorithms that can generate 3D images from measurements made on a curved, layered structure such as the head (Bluestone et al 2001). The advances hold great promise for using optical methods to detect functionally localized activity in the brain, and to eventually provide absolute measures of HbR and HbO_2 concentrations, thereby allowing comparison of single measurements across days or even years.

Summary and Conclusions

Diffuse optical methods have several advantages over existing technologies for brain monitoring, including excellent temporal resolution coupled to reasonable spatial resolution, spectroscopic information for hemodynamic events, portability, unobtrusiveness, and the ability to be achieved by low-power and low-cost instruments that are robust to motion artifacts. The technology is also completely non-invasive, unlike PET and SPECT. For the psychiatric researcher, these strengths facilitate the investigation of several difficult populations such as infants, small children, and patients with claustrophobia and severe movement disorders. The portability and low runtime cost of the instrument affords bedside or home telemetry and monitoring for extended periods of time. This in turn can be useful for monitoring the time course of pathologies and associated behaviors, as well as the effects of various interventions, including drugs. Tradeoffs include difficulty with precise anatomical localization with respect to the brain (as with all other non-invasive technologies except MRI), and relatively poor penetration and localization in depth. For investigations of cortical activation, however, and especially when referenced to an external landmark system (e.g., the international 10/20 system), diffuse optical methods can provide opportunities unavailable with any other existing technology.

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