U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K130709 - 977 pages
COMPANY:	SOTERA WIRELESS, INC (SOTEWIRE)
PRODUCT:	MONITOR,PHYSIOLOGICAL,PATIENT(WITHOUT ARRHYTHMIA DETECTION OR ALARMS) (MWI)
SUMMARY:	Product: VISI MOBILE MONITORING SYSTEM
DATE REQUESTED:	May 11, 2015
DATE PRINTED:	May 11, 2015
Note:	Printed

5 510(K) SUMMARY

Date prepared	June 11, 2013
Name	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.373.4841; F. 858.427.4639
Contact person	Eben Gordon Senior Director, Regulatory
Trade name	ViSi Mobile Monitoring System
Common name	Vital signs monitor
Regulation Name	Cardiac Monitor Including Cardiotachometer and Rate Alarm
Classification number	21 CFR 870.2300
Product code	MWI, DRT, DXN, DQA, FLL
Regulatory class	II
Predicate devices	ViSi Mobile Monitoring System; K112478 (Clearance: 3/27/2012) CNAP Monitor 500i, 500at; K082599 (Clearance: 10/17/2008)
Description	The ViSi Mobile Monitoring System is a lightweight, body-worn vital signs monitor featuring a high resolution, full color touch screen display, with visual and audible alarms and alerts. The ViSi Mobile Monitor is designed to continuously non-invasively measure ECG, heart rate, SpO2, blood pressure, pulse rate, respiration rate, and temperature. The ECG, SpO2, and Respiration waveforms are viewable on demand. The ViSi Mobile Monitoring System is capable of one-time and continuous NIBP measurements.
Indications for use	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult (18 years or older) patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments. Continuous non-invasive blood pressure (cNIBP) testing has not been conducted on ambulatory patients.
Summary of substantial equivalence	The ViSi System has the following similarities and differences with the indicated predicate devices:

OCT 07 2013

- Intended use – The ViSi System has the same vital sign monitoring intended use as the ViSi System and CNAP Monitors. The cNIBP measurement of the ViSi System is the same as the CNAP Monitor.

- Device Performance – The modified ViSi System with intermittent NIBP MAP and cNIBP measurements have been clinically validated to meet the same performance requirements (mean error ≤ ± 5 mmHg; standard deviation ≤ 8 mmHg) as outlined in the consensus standards for automated non-invasive blood pressure monitors.

- Technology – The ViSi System is unchanged from it predicate submission except for the display of intermittent NIBP MAP readings and the continuous non-invasive blood pressure (cNIBP) measurements.

  The intermittent NIBP MAP measurement is based on the same technology as is currently in the cleared ViSi System and is equivalent to the CNAP Monitor. The ViSi's MAP measurement has been validated by comparison to an intra-arterial reference and meets the performance requirements of ISO 81060-2.

  The ViSi's cNIBP measurement has a different principle of operation from that of the CNAP Monitor predicate device. Both methods are similar in that pressure is determined on a beat-to –beat basis and are joint solutions employing automatic calibration to NIBP measurements.

  The question of effectiveness of the cNIBP measurement has been addressed by the clinical performance validation to the requirements of ISO 81060-2, an equivalent consensus standard to which the CNAP Monitor meets (i.e. AAMI/ANSI SP10).

The safety and effectiveness of the design elements implemented into the ViSi System have been confirmed by their compliance to the prevailing standards. The ViSi System has demonstrated compliance with the following consensus standards: IEC 60601-1-8, IEC 80601-2-30, IEC 62304, ISO 81060-2, and IEC 62366.

General Safety and Effectiveness Concerns – The instructions for use for the ViSi System contains the necessary cautions and warnings to provide for safe and effective use of the device.

The ViSi System has successfully undergone functional testing to demonstrate equivalence to the predicate devices. The following quality assurance measures were applied to the device: Risk analysis, Requirements review, Code inspections, Verification and validation, Bench testing, and Clinical performance testing.

The ViSi System have been tested and found to comply with recognized performance standards for medical devices. The results of all the testing demonstrate that the ViSi System is safe, effective, complies with the appropriate medical device standards, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 7, 2013

Sotera Wireless, Inc.
Attn: Mr. Eben Gordon
Sr. Director, Regulatory Affairs
9444 Waples St., Suite 280
San Diego, CA 92121

Re: K130709
Trade/Device Name: Visi Mobile Monitoring System, Model 92-10010
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (Two)
Product Code: MWI, DRT, DXN, DQA and FLL
Dated: September 30, 2013
Received: October 1, 2013

Dear Mr. Gordon:

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 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,

Owen P. Faris -S

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

Enclosure

4 INDICATIONS FOR USE

510(k) Number (if known): _K130709_____

Device Name: _____ViSi Mobile Monitoring System _____

Indications for Use:

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult (18 years or older) patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Continuous non-invasive blood pressure (cNIBP) testing has not been conducted on ambulatory patients.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.10.07
15:13:05 -04'00'

Page _1_ of _1__

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

October 7, 2013

Sotera Wireless, Inc.
Attn: Mr. Eben Gordon
Sr. Director, Regulatory Affairs
9444 Waples St., Suite 280
San Diego, CA 92121

Re: K130709
Trade/Device Name: Visi Mobile Monitoring System, Model 92-10010
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (Two)
Product Code: MWI, DRT, DXN, DQA and FLL
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Sincerely yours,

Owen P. Faris -S

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

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K130709

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Charles Ho Digitally signed by Charles Ho DN: cn=Charles Ho, o=CDRH, ou=FDA, email=Charles.ho@fda.hhs.gov, c=US Date: 2013.10.07 11:35:27 -04'00'
Branch Chief Sign-Off	Linda J. Ricci -S 2013.10.07 12:43:46 -04'00'
Division Sign-Off	Digitally signed by Owen P. Faris -S Date: 2013.10.07 15:15:59 -04'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format

4 INDICATIONS FOR USE

510(k) Number (if known): _K130709_____

Device Name: _____ViSi Mobile Monitoring System _____

Indications for Use:

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Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.10.07 15:13:05 -04'00'

Page _1_ of _1__

K130709

Sotera WIRELESS

WWW.SOTERAWIRELESS.COM

FDA CDRH DMC
MAR 19 2013
Received

March 18, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: 510(k) No. – K130709
Replacement eCopy
ViSi Mobile Monitoring System

Dear Sir or Madam:

Attached please find a "Replacement eCopy" as requested in your" eCopy Hold Letter" dated March 18, 2013. The eCopy is an exact duplicate of the paper copy.

Submitter	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.427.4620; F. 858.427.4639
Common name	Vital signs monitor
Trade name	ViSi Mobile Monitoring System
Class	II
Classification name	Cardiac monitor (including cardiotachometer and rate alarm)
Classification regulation	870.2300
Product code	MWI, DRT, DXN, DQA and FLL
Panel	Cardiovascular
Reason for submission	Addition of cNIBP measurement and MAP (NIBP)
Design and Use	Prescription, non-invasive, non-sterile, software containing
Clinical information	Included in submission

The ViSi Mobile Monitoring System is substantially equivalent to the ViSi Mobile Monitoring System (K112478) and the CNAP Monitor 500i (K082599). The ViSi System Mobile System has equivalent intended use, design, and performance specifications to the predicate devices. While the principle of operation for cNIBP differs from the predicate device, clinical testing demonstrated equivalent performance.

Sotera considers our intent to market this device as confidential information and requests that it be treated as such by FDA pursuant to 21 CFR 807.95.

07

The User Fee for this submission has been deposited per regulations, and the User Fee Cover Sheet is attached with the Payment Identification Number (b)(4) [redacted]

If you have any questions or require additional information, please contact me at eben.gordon@soterawireless.com, by telephone at 858.373.4841, or via facsimile at 858.427.4639.

Thank you in advance for your consideration of our application.

Sincerely,
SOTERA WIRELESS, INC.

Eben Gordon

Eben Gordon
Senior Director, Regulatory
Official Correspondent

K130709

Sotera WIRELESS

WWW.SOTERAWIRELESS.COM

March 13, 2013

FDA CDRH DMC
MAR 15 2013
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: 510(k) Notification – Traditional 510(k)
ViSi Mobile Monitoring System

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, Sotera Wireless, Inc. is submitting a notification of its intent to market its ViSi Mobile Monitoring System. The modifications to the previously cleared ViSi Mobile Monitoring System (K112478) are:

1. The addition of the Continuous Non-invasive Blood Pressure (cNIBP) measurement; and
2. The addition of Mean Arterial Pressure (MAP) to the Non-Invasive Blood Pressure (NIBP) measurement.

Enclosed are two (2) copies of a Traditional 510(k) to request marketing clearance for the ViSi Mobile Monitoring System. One of the copies is an eCopy. The eCopy is an exact duplicate of the paper copy.

Submitter	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.427.4620; F. 858.427.4639
Common name	Vital signs monitor
Trade name	ViSi Mobile Monitoring System
Class	II
Classification name	Cardiac monitor (including cardiotachometer and rate alarm)
Classification regulation	870.2300
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Thank you in advance for your consideration of our application.

Sincerely,
SOTERA WIRELESS, INC.

Eben Gordon

Eben Gordon
Senior Director, Regulatory
Official Correspondent

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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) SOTERA WIRELESS, INC 9444 Waples St. Suite 280 San Diego CA 92121 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4831	2. CONTACT NAME Eben Gordon 2.1 E-MAIL ADDRESS eben.gordon@soterawireless.com 2.2 TELEPHONE NUMBER (include Area code) 858-373 4841 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 858-427 4639

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/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 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: SBD135086

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/cdrh/mdufma 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

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

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

[ ] 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 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] 05-Dec-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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 OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
3/13/2013	(b)(4)	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ 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: Sotera Wireless	Establishment Registration Number *(if known)*: 3009673645		
Division Name *(if applicable)*	Phone Number *(including area code)*: 858.373.4841		
Street Address: 9444 Waples St.	FAX Number *(including area code)*: 858.427.4639		
City: San Diego	State / Province: California	ZIP/Postal Code: 92121	Country: USA
Contact Name: Eben Gordon			
Contact Title: Director, Regulatory Affairs	Contact E-mail Address: eben.gordon@soterawireless.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 Graphics (301) 443-6740 EF

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)*

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ 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
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	MWI	2	DXN	3	DRT	4	DQA
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	K112478	1	ViSi Mobile Monitoring System	1	Sotera Wireless, Inc.
2	K082599	2	CNAP Monitor 5001, 500at	2	CNSystem Medizintechnik Ag
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

Non-invasive Blood Pressure Monitor

	Trade or Proprietary or Model Name for This Device		Model Number
1	ViSi Mobile Monitoring System	1	92-10010
2		2	
3		3	
4		4	
5		5	

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

1 K112478	2 K122278	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] 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
DRT	21 CFR 870.1130	[ ] Class I [x] Class II
Classification Panel: Cardiovascular devices		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities, including general medical-surgical floors, intermediate care floors, and emergency departments

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 3009673645	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name: Sotera Wireless, Inc.		Establishment Registration Number: 3009673645		
Division Name *(if applicable)*		Phone Number *(including area code)*: 858.373.4841		
Street Address: 9444 Waples St.		FAX Number *(including area code)*: 858.427.4639		
City: San Diego		State / Province: California	ZIP Code: 92121	Country: USA
Contact Name: Eben Gordon	Contact Title: Director, Regulatory Affairs		Contact E-mail Address: eben.gordon@soterawireless.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	

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	62304	IEC	Medical device software - Software life cycle processes		01/01/2006
2	60601-1-8	IEC	Medical electrical equipment – Part 1-8: General Requirements – Collateral Standard: General requirements, tests and guidance for alarm systems	Ed. 2	01/01/2006
3	62366	IEC	Medical devices -- Application of usability engineering to medical devices		01/01/2007
4	80601-2-30	IEC	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers		01/01/2009
5	81060-2	ISO	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type		01/01/2009
6					
7					

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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March 13, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: 510(k) Notification – Traditional 510(k)
ViSi Mobile Monitoring System

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, Sotera Wireless, Inc. is submitting a notification of its intent to market its ViSi Mobile Monitoring System. The modifications to the previously cleared ViSi Mobile Monitoring System (K112478) are:

1. The addition of the Continuous Non-invasive Blood Pressure (cNIBP) measurement; and
2. The addition of Mean Arterial Pressure (MAP) to the Non-Invasive Blood Pressure (NIBP) measurement.

Enclosed are two (2) copies of a Traditional 510(k) to request marketing clearance for the ViSi Mobile Monitoring System. One of the copies is an eCopy. The eCopy is an exact duplicate of the paper copy.

Submitter	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.427.4620; F. 858.427.4639
Common name	Vital signs monitor
Trade name	ViSi Mobile Monitoring System
Class	II
Classification name	Cardiac monitor (including cardiotachometer and rate alarm)
Classification regulation	870.2300
Product code	MWI, DRT, DXN, DQA and FLL
Panel	Cardiovascular
Reason for submission	Addition of cNIBP measurement and MAP (NIBP)
Design and Use	Prescription, non-invasive, non-sterile, software containing
Clinical information	Included in submission

The ViSi Mobile Monitoring System is substantially equivalent to the ViSi Mobile Monitoring System (K112478) and the CNAP Monitor 500i (K082599). The ViSi System Mobile System has equivalent intended use, design, and performance specifications to the predicate devices. While the principle of

operation for cNIBP differs from the predicate device, clinical testing demonstrated equivalent performance.

Sotera considers our intent to market this device as confidential information and requests that it be treated as such by FDA pursuant to 21 CFR 807.95.

The User Fee for this submission has been deposited per regulations, and the User Fee Cover Sheet is attached with the Payment Identification Number (b)(4) [redacted].

If you have any questions or require additional information, please contact me at eben.gordon@soterawireless.com, by telephone at 858.373.4841, or via facsimile at 858.427.4639.

Thank you in advance for your consideration of our application.

Sincerely,
SOTERA WIRELESS, INC.

Eben Gordon

Eben Gordon
Senior Director, Regulatory
Official Correspondent

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4 INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: _____ ViSi Mobile Monitoring System _____

Indications for Use:

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

5 510(K) SUMMARY

Date prepared	March 13, 2013
Name	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.373.4841; F. 858.427.4639
Contact person	Eben Gordon Senior Director, Regulatory
Trade name	ViSi Mobile Monitoring System
Common name	Vital signs monitor
Regulation Name	Cardiac Monitor Including Cardiotachometer and Rate Alarm
Classification number	21 CFR 870.2300
Product code	MWI, DRT, DXN, DQA, FLL
Regulatory class	II
Predicate devices	ViSi Mobile Monitoring System; K112478 (Clearance: 3/27/2012) CNAP Monitor 500i, 500at; K082599 (Clearance: 10/17/2008)
Description	The ViSi Mobile Monitoring System is a lightweight, body-worn vital signs monitor featuring a high resolution, full color touch screen display, with visual and audible alarms and alerts. The ViSi Mobile Monitor is designed to continuously non-invasively measure ECG, heart rate, SpO2, blood pressure, pulse rate, respiration rate, and temperature. The ECG, SpO2, and Respiration waveforms are viewable on demand. The ViSi Mobile Monitoring System is capable of one-time and continuous NIBP measurements.
Indications for use	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.
Summary of substantial equivalence	The ViSi System has the following similarities and differences with the indicated predicate devices: • Intended use – The ViSi System has the same vital sign monitoring intended use as the ViSi System and CNAP Monitors. The cNIBP measurement of the ViSi System is the same as the CNAP Monitor.

- Device Performance – The modified ViSi System with intermittent NIBP MAP and cNIBP measurements have been clinically validated to meet the same performance requirements (mean error ≤ ± 5 mmHg; standard deviation ≤ 8 mmHg) as outlined in the consensus standards for automated non-invasive blood pressure monitors.

- Technology – The ViSi System is unchanged from it predicate submission except for the display of intermittent NIBP MAP readings and the continuous non-invasive blood pressure (cNIBP) measurements.

  The intermittent NIBP MAP measurement is based on the same technology as is currently in the cleared ViSi System and is equivalent to the CNAP Monitor. The ViSi's MAP measurement has been validated by comparison to an intra-arterial reference and meets the performance requirements of ISO 81060-2.

  The ViSi's cNIBP measurement has a different principle of operation from that of the CNAP Monitor predicate device. Both methods are similar in that pressure is determined on a beat-to –beat basis and are joint solutions employing automatic calibration to NIBP measurements.

  The question of effectiveness of the cNIBP measurement has been addressed by the clinical performance validation to the requirements of ISO 81060-2, an equivalent consensus standard to which the CNAP Monitor meets (i.e. AAMI/ANSI SP10).

The safety and effectiveness of the design elements implemented into the ViSi System have been confirmed by their compliance to the prevailing standards. The ViSi System has demonstrated compliance with the following consensus standards: IEC 60601-1-8, IEC 80601-2-30, IEC 62304, ISO 81060-2, and IEC 62366.

General Safety and Effectiveness Concerns – The instructions for use for the ViSi System contains the necessary cautions and warnings to provide for safe and effective use of the device.

The ViSi System has successfully undergone functional testing to demonstrate equivalence to the predicate devices. The following quality assurance measures were applied to the device: Risk analysis, Requirements review, Code inspections, Verification and validation, Bench testing, and Clinical performance testing.

The ViSi System have been tested and found to comply with recognized performance standards for medical devices. The results of all the testing demonstrate that the ViSi System is safe, effective, complies with the appropriate medical device standards, and is substantially equivalent to the predicate devices.

6 PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

In my capacity as Senior Director of Regulatory Affairs for Sotera Wireless, Inc., I certify that, to the best of my knowledge, all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted.

_____
(Signature)

__Eben Gordon_____
(Typed name)

March 13, 2013
_____
(Date)

_____

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

7 CLASS III SUMMARY AND CERTIFICATION

This section does not apply since equivalence to a Class III device is not being claimed.

8 FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

Clinical testing was performed to validate the ViSi Mobile Monitoring System's performance. Please refer to **Exhibit 1** for the completed FDA-3454 Certification: Financial Interests and Arrangements of Clinical Investigators.

9 DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

Design and development activities for the ViSi System were guided by compliance to the relevant standards and guidance documents. Not applicable requirements, deviations, etc. are identified in the completed Standards Data Report for 510(k)s form, FDA 3654, provided in **Exhibit 2,** for which compliance is claimed. Compliance to the following standards is hereby claimed:

1. IEC 62304:2006 Medical device software - Software life cycle processes
2. IEC 60601-1-8:2006 Medical electrical equipment – Part 1-8: General Requirements – Collateral Standard: General requirements, tests and guidance for alarm systems
3. IEC 62366:2007 Medical devices -- Application of usability engineering to medical devices
4. IEC 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
5. ISO 81060-2:2009 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type

I attest that the above declaration is truthful and accurate.

Eben Gordon
Senior Director, Regulatory

10 EXECUTIVE SUMMARY

The cleared (K112478) ViSi Mobile Monitoring System ("ViSi System") is a multi-parameter vital signs monitor that continuously measures and displays a patient's core vital signs including ECG (three or five wire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments

The ViSi System consists of:

- The wrist-worn Monitor as the "hub" for data display and alarm processing.
- The reusable Chest Sensor measures 3-wire or 5-wire ECG, heart rate, respiration, and skin temperature.
- The reusable Thumb Sensor measures SpO2 and pulse rate.
- The Cuff Module provides standard, cuff-based NIBP measurements.
- The Patient Kit contains disposable monitoring accessories for each individual patient. The kit contains a disposable blood pressure cuff, Thumb Cradle, Wrist Cradle, Cable Securement, and ECG electrodes.

The ViSi System has been modified to enable:

1. The measurement and display of Continuous Non-invasive Blood Pressure (cNIBP); and
2. The display of Mean Arterial Pressure (MAP) for the Non-Invasive Blood Pressure (NIBP) measurement.

The proposed Indications for Use shall read (changed language is underlined):

"The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), <u>continuous non-invasive blood pressure (cNIBP</u>), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments."

Table 10c outlines the differences and similarities between the modified ViSi System and the predicate devices:

Table 10c: Device comparison table

Device	ViSi System (TBD)	ViSi System Predicate device (K112478)	CNAP Monitor 500i, 500at Predicate device (K082599)
Manufacturer	Sotera Wireless	Sotera Wireless	CNSystem Medizintechnik Ag
Intended Use	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP),non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.	The CNAP Monitor is indicated for the monitoring of non-invasive continuous blood pressure and pulse rate in hospitals, clinical institutions, medical practices and outpatient settings. The device displays the blood pressure waveform and generates trends, beat-to-beat analysis numeric and alarms for the parameters blood pressure and pulse rate. The CNAP Monitor 500 is to be used for adults and pediatric patients from the age of 4 years and is to be operated by physicians and other medical professional staff.
Parameters monitored	Same as ViSi System (Predicate device) plus continuous non-invasive blood pressure (cNIBP)	Electrocardiogram (ECG), respiration rate, blood oxygen saturation (SpO2), non-invasive blood pressure (NIBP), pulse rate, heart rate, temperature	Non-invasive blood pressure, pulse rate
cNIBP Calibra-tion interval	With each NIBP measurement	Does not measure cNIBP	With each NIBP measurement
Patient population	Same as ViSi System (Predicate)	Adults	Adults and pediatric patients (> 4 years)
NIBP Technology	Same as ViSi System (Predicate)	NIBP measurement uses an oscillometric technique in the upper arm.	NIBP measurement uses an oscillometric technique in the upper arm.
cNIBP Technology	Continuous non-invasive beat-to-beat blood pressure measurement based on principles of pulse wave velocity	Does not measure cNIBP	Continuous non-invasive beat-to-beat blood pressure measurement (Peñáz principle)
cNIBP Calibration	Joint solution - Automatic calibration to NIBP	Does not measure cNIBP	Joint solution - Automatic calibration to NIBP
Monitor Connectivity	Same as ViSi System (Predicate)	Standalone	Standalone
BP Standards Compliance	ISO 81060-2/ IEC 80601-2-30	ISO 81060-2/ IEC 80601-2-30	ANSI/AAMI SP10/ IEC 60601-2-30
cNIBP Measurement range	SYS: 60 - 240 mmHg DIA: 40 - 160 mmHg MAP 50 - 185 mmHg	Does not measure cNIBP	SYS: 40 - 250 mmHg DIA: 30 - 210 mmHg MAP 35 - 230 mmHg
cNIBP Accuracy	≤ ± 5 mmHg; Std. Dev. ≤8 mmHg	Does not measure cNIBP	± 5 mmHg

Device	ViSi System (TBD)	ViSi System Predicate device (K112478)	CNAP Monitor 500i, 500at Predicate device (K082599)
NIBP Measurement method	Same as ViSi System (Predicate)	Oscillometric	Oscillometric
NIBP Measurement range	SYS: 60 - 240 mmHg DIA: 40 - 160 mmHg MAP: 50 - 185 mmHg	SYS: 60 - 240 mmHg DIA: 40 - 160 mmHg	SYS: 40 - 250 mmHg DIA: 30 - 210 mmHg MAP 35 - 230 mmHg
NIBP Accuracy	Same as ViSi System (Predicate)	± 5 mmHg, Std. Dev. ≤ 8 mmHg	± 5 mmHg
ECG Heart rate accuracy	Same as ViSi System (Predicate)	±3 beats/min. or 3% whichever is greater	Does not measure ECG
Respiration accuracy	Same as ViSi System (Predicate)	± 3 Breaths/min. or ± 10% whichever is greater	Does not measure respiration
SpO2 Accuracy	Same as ViSi System (Predicate)	Non Motion ± 2% (70 – 100%)	Does not measure respiration
Pulse rate accuracy	Same as ViSi System (Predicate)	±3 beats/min. (no motion) (Pleth)	Not specified
Temperature measured	Same as ViSi System (Predicate)	Skin	Does not measure temperature

The cNIBP measurement is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed.

The cNIBP measurement is achieved through software modification. While the principle of operation for cNIBP differs from the predicate device, clinical testing based on ISO 81060-2: *Non-invasive Sphygmomanometers – Part 2: Clinical validation of automated measurement type* demonstrated equivalent performance to the predicate and meeting the standard's mean error and standard deviation requirement (≤ ±5 mmHg and ≤ 8 mmHg, respectively). The clinical validation study was conducted using an invasive blood pressure monitor as a reference. The study results and ISO specifications are presented in **Table 10a.**

Table 10a: cNIBP Clinical Study, Performance Accuracy Results

Parameter	ISO 81060-2 Specification	Systolic (mmHg)	Diastolic (mmHg)	MAP (mmHg)	Conclusion
Mean Error	≤ ±5.0	-2.05	-1.71	-0.72	**Pass**
Standard Deviation	≤ 8.0	6.07	3.58	3.82	**Pass**

The NIBP software algorithm has not been modified with the introduction of the MAP measurement. The industry-standard technique of oscillometry is used for non-invasively measuring systolic blood pressure, diastolic blood pressure, and mean arterial pressure (MAP). The ViSi System acquires its NIBP measurement on cuff inflation. As the pressure applied to the cuff increases, the pulsatile amplitudes increase between diastolic pressure and mean pressure, and then decrease between mean pressure and systolic pressure. The ViSi System's NIBP algorithm identifies the pulse with the maximum amplitude

and calculates pulse amplitudes for the surrounding pulses. The pulse amplitudes and corresponding applied cuff pressures are then fit to a mathematical model.

In the initial 510(k) submission (K112478), the ViSi System's intermittent NIBP automated blood pressure measurement was validated using a non-invasive (auscultatory) reference sphygmomanometer according to ISO 81060-2. In this submission, the clinical validation study of the intermittent blood pressure measurement was conducted by comparison to an intra-arterial reference to demonstrate accuracy for systolic, diastolic, and mean arterial pressure (MAP) readings. The supportive data met ISO 81060-2, section 6.2 requirements. The NIBP study results and ISO specifications are presented in **Table 10b.**

Table 10b: NIBP Clinical Study, Performance Accuracy Results

Parameter	**ISO 81060-2 Specification**	**Systolic (mmHg)**	**Diastolic (mmHg)**	**MAP (mmHg)**	**Conclusion**
Mean Error	≤ ±5.0	-1.65	-.1.49	-0.91	**Pass**
Standard Deviation	≤ 8.0	5.01	3.22	2.04	**Pass**

In addition, compliance to non-clinical performance and safety requirements specified in the following consensus standards was verified demonstrating the device modification for cNIBP meets benchmark requirements:

- IEC 62304:2006 Medical device software - Software life cycle processes
- IEC 60601-1-8:2006 Medical electrical equipment – Part 1-8: General Requirements – Collateral Standard: General requirements, tests and guidance for alarm systems
- IEC 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
- ISO 81060-2:2009 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
- IEC 62366:2007 Medical devices -- Application of usability engineering to medical devices

The Human Factors study conducted with fifteen clinical participants validated that the cNIBP feature of the ViSi System was implemented in a manner that strongly suggests there will be minimal potential for use error. Use related errors and use associated risks have been minimized and safe and effective use of the ViSi System can be reasonably assured.

Risk Management is an essential element of the design and development process of the ViSi System. The assessment of the impact of the modification of the ViSi System was based on the principles of ISO 14971:2007, *Medical devices – Application of risk management to medical devices*. Based on the Risk Analysis, verification and validation activities were identified and acceptance criteria applied. The residual risk for each of the hazards identified is lower than the risk acceptability criteria specified in the risk management plan. The report concluded that the risk management process was implemented correctly and that the overall residual risk associated with the modified ViSi System is acceptable.

The ViSi System has the following similarities and differences with the indicated predicate devices:

- Intended use – The ViSi System has the same vital sign monitoring intended use as the ViSi System and CNAP Monitors. The cNIBP measurement of the ViSi System is the same as the CNAP Monitor.

  The ViSi System, similar to the predicate devices, is intended to be used by licensed practitioners in a healthcare environment.

- Device Performance – The modified ViSi System with intermittent NIBP MAP and cNIBP measurements have been clinically validated to meet the same performance requirements (mean error ≤ ± 5 mmHg; standard deviation ≤ 8 mmHg) as outlined in the consensus standards for automated non-invasive blood pressure monitors.

  Since ISO 81060-2 is intended for intermittent automated measurements, the standard was adapted to apply to the ViSi System's cNIBP measurement. The ViSi System cNIBP and the CNAP monitors both met adapted versions of the prevailing relevant consensus standards (ISO 81060-2 and AAMI/ANSI SP10, respectively).

- Technology – The ViSi System is unchanged from it predicate submission except for the display of intermittent NIBP MAP readings and the continuous non-invasive blood pressure (cNIBP) measurements.

  The intermittent NIBP MAP measurement is based on the same technology as is currently in the cleared ViSi System and is equivalent to the CNAP Monitor. The ViSi's MAP measurement has been validated by comparison to an intra-arterial reference and meets the performance requirements of ISO 81060-2.

  The ViSi's cNIBP measurement has a different principle of operation from that of the CNAP Monitor predicate device (blood pressure relationship to pulse wave velocity Vs. Peñáz principle). Both methods are similar in that pressure is determined on a beat-to –beat basis and are joint solutions employing automatic calibration to NIBP measurements.

  The question of effectiveness of the cNIBP measurement has been addressed by the clinical performance validation to the requirements of ISO 81060-2.

- Safety – The hazards analysis has shown that there are no residual risks for the patient or operator. In addition, the ViSi System software cannot cause injury to the patient or operator. The ViSi System is featured with alarm and alerts that monitor physiological parameters and device functions. Since the ViSi System is not classified as life supporting, the implemented preventive measures ensure the safe application of the device.

The ViSi System with intermittent MAP and cNIBP measurement has been verified and clinically validated to meet the requirements of the recognized consensus standards. The results demonstrate that the ViSi System is safe, effective, compliant with relevant standards, and is substantially equivalent to the predicate devices.

11 Device Description

The previously cleared (K112478) ViSi Mobile Monitoring System ("ViSi System") has been modified to enable continuous non-invasive blood pressure (cNIBP) measurement. The cNIBP measurement is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every 3 seconds.

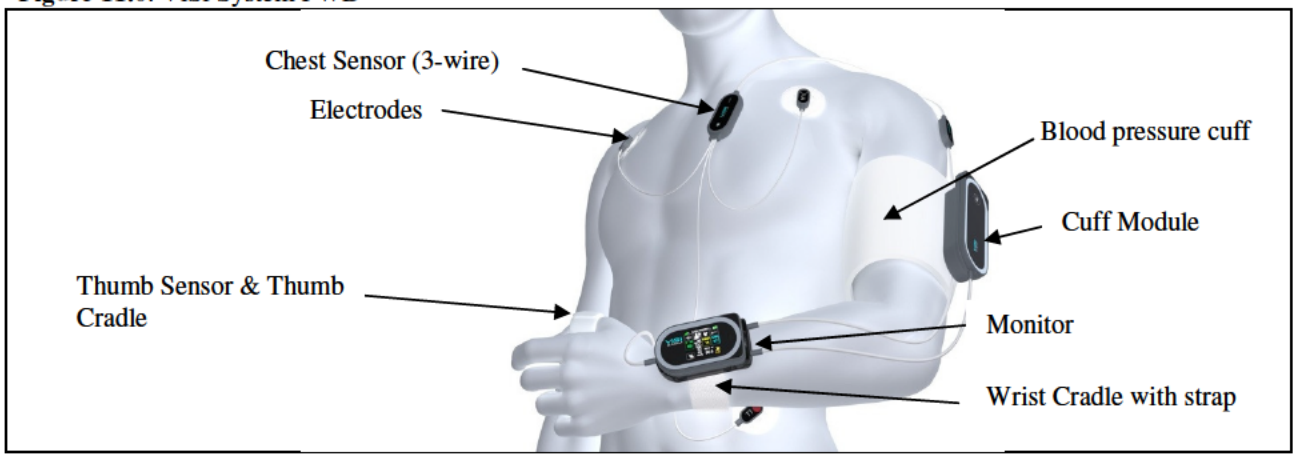
Other than the addition of cNIBP measurement, the ViSi System's intended use is unchanged. It is a multi-parameter vital signs monitor that continuously measures and displays a patient's core vital signs including ECG (three or five wire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature.

The cNIBP measurement is achieved through the software modifications; there is no additional or modified hardware required for the cNIBP measurement. The ViSi System continues to work as a "distributed digital body-worn system" consisting of:

- The wrist-worn Monitor as the "hub" for data and alarm processing.
- The reusable Chest Sensor measures 3-wire or 5-wire ECG, heart rate, respiration, and skin temperature.
- The reusable Thumb Sensor measures SpO2 and pulse rate.
- The Cuff Module provides standard, cuff-based NIBP measurements. The Cuff Module latches onto a disposable cuff and is controlled via digital communication with the wrist Monitor.
- The Patient Kit contains disposable monitoring accessories for each individual patient including: a blood pressure cuff, Thumb Cradle, Wrist Cradle, Cable Securement, and ECG electrodes.

Figure 11.0 below depicts the ViSi Patient Worn Device ("PWD"):

Figure 11.0: ViSi System PWD



The PWD is a fully functional monitoring device which operates independently (standalone).

Detailed Description

Note: the PWD is the same device as previously cleared in K112478.

ViSi Monitor – this compact device is worn on the patient's wrist. The Monitor is held in place by the Wrist Cradle. The battery powered Monitor can be removed for charging. The Monitor has a touch screen interface to access the different displays and monitoring functions (**Figure 11.1**).

Figure 11.1: ViSi Monitor display (left); cNIBP reading in red (right)

The ViSi Monitor houses core processing functions and the node of the CAN Bus, which communicates data to the display, including both numeric and waveform physiological data, trend data, alarm status, patient identifiers, and system status and control information. The Monitor has proprietary receptacles into which cables from the Chest Sensor, Cuff Module, and Thumb Sensor can be inserted.

Wrist Cradle – this component is attached to the wrist by a Velcro strap and holds the Monitor in place on the wrist.

Thumb Sensor - this component is a non-invasive optical sensor. When a patient's heart beats and pushes arterial blood into the thumb, these emitters detect the light absorption characteristics of hemoglobin and give an indication of oxygen saturation in this tissue.

Thumb Cradle - this component is attached to the base of the thumb by a Velcro strap. The Thumb Sensor is fitted into the Thumb Cradle prior to attachment to the thumb.

Cuff Module – this component measures blood pressure. The Cuff Module inflates the Cuff, measures subsequent pressure pulses, and then deflates the Cuff when its measurements are completed. The Cuff Module contains its own internal battery and pneumatic elements for this inflation and deflation.

Chest Sensor - this component measures ECG, heart rate, respiration rate, and skin temperature using either three or five wires. The trunk cable contains 2 microcontrollers, both STM32s. One processor is used for acquiring and analyzing raw ECG waveforms, calculating heart rate, and acquiring accelerometer motion data. A second processor located on the cable will be used solely for acquiring accelerometer motion data. The Chest Sensor has a cable for connection to the Monitor.

Cuff **-** this accessory is an off–the–shelf Welch Allyn (Skaneateles Falls, New York) FlexiPort Blood Pressure cuff which has been cleared (K070060) for such use.

Electrodes - Off-the-shelf electrodes Red Dot, Radiolucent Monitoring Electrodes manufactured by 3M Health Care (St. Paul, Minnesota) are provided in the Patient Kit. The electrodes are 510(k) cleared (K930312) for this use.

Cable Securements – these adhesive pads are provided in the Patient Kit to secure the Chest Sensor and cable to the body of the patient.

Battery Charger – the charger can charge up to 8 Monitors and/or Cuff Modules simultaneously. The charging station is designed so that either a Monitor or a Cuff Module can be installed in any bay.

11.1 Intended Use/Contraindications

Intended Use

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Contraindications

The contraindications have not changed and are the same as reported in K112478.

11.2 Device Photographs

The ViSi System has not changed with the modification to add cNIBP measurement capability. The following photographs (**Figures 11.2.a and 11.2b**) are the same as presented in K112478.

 Monitor 92-10010	 Cuff Module 92-10011	 Patient Kit 94-10067
 Thumb Sensor 93-10020	 Chest Sensor 93-10012	 Charger 92-10023

Figure 11.2.a: ViSi System components

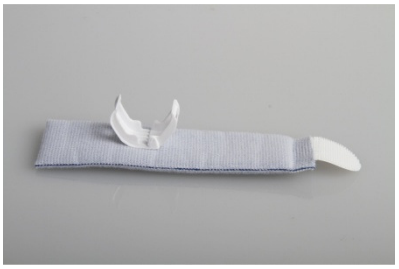
 Patient Kit	 Wrist Cradle	 Thumb Cradle
 Cable Securement	 Disposable Cuff	 ECG Electrode

Figure 11.2.b: ViSi Mobile Patient Kit Contents

11.3 Product specifications

The ViSi System NIBP and cNIBP specification meets the requirements of the consensus standard, ISO 81060-2.

Continuous Non-invasive Blood Pressure (cNIBP)

Systolic Range	60 - 240 mmHg
Diastolic Range	40 - 160 mmHg
Mean Arterial Pressure (MAP)	50 - 185 mmHg
Accuracy - Mean Error	≤ ± 5 mmHg
Accuracy - Standard Deviation	≤8 mmHg

Non-invasive Blood Pressure (NIBP)

Systolic Range	60 - 240 mmHg
Diastolic Range	40 - 160 mmHg
Mean Arterial Pressure (MAP)	50 - 185 mmHg
Accuracy - Mean Error	≤ ± 5 mmHg
Accuracy - Standard Deviation	≤8 mmHg

11.4 Principles of Operation

11.4.1 Algorithm Summary

Pulse Wave Velocity and Blood Pressure

(b)(4)

[redacted]

(b)(4)

[redacted]

[1] Geddes LA, Voelz MH, Babbs CF, Bourland JD, Tacker WA. Pulse transit time as an indicator of arterial blood pressure. *Psychophysiology* 18: 71-74, 1981. (**Exhibit 18)**

[2] Hughes DJ, Babbs CF, Geddes LA, Bourland JD. Measurements of Young's Modulus of Elasticity of the Canine Aorta with Ultrasound. *Ultrasonic Imaging* 1: 356-367, 1979. (**Exhibit 18)**

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

11.5 Risk Management

Risk Management is an essential element of the design and development process of the ViSi System. The broad approach to identify, evaluate, and mitigate risks used in the design and develop of the ViSi System was based on the principles of ISO 14971:2007, *Medical devices – Application of risk management to medical devices*. Planned risk management activities were specified at the onset of the development project.

Risk analysis included the identification of characteristics, including those related to use and reasonably foreseeable misuse that could affect the safety of the ViSi System. Hazards were identified, risks estimated and evaluated. The report of the evaluation, *ViSi System Risk /Hazard Analysis - cNIBP Module*, 0-000959, Rev. A, (**Exhibit 3**) is part of the ViSi System risk management file.

Based on the criteria specified in the risk management plan, Sotera determined whether the initial risk was acceptable or whether additional control measures were needed to mitigate the risk to an acceptable level. Risks were mitigated through the use of design choices that eliminated hazards, protective measures incorporated into the device (to reduce the probability of occurrence), and the use of appropriate safety information such as warnings and instructions for use.

The implementation of risk control measures was verified and documented in *Summary Risk Management Report, ViSi, cNIBP*, R-000340-001, Rev. A **(Exhibit 4).** The verification was organized in two steps.

All verification/ test results were recorded in the risk management file. The effectiveness of the risk control measures was verified and the results recorded in the risk management file.

A summary of the results of the risk management process is also included in the risk management report. The residual risk for each of the hazards identified is lower than the risk acceptability criteria specified in the risk management plan. The report concluded that the risk management process was implemented correctly, and that the overall residual risk associated with this device is acceptable. In summary:

- All identified risks have been documented.
- Any new hazardous situations introduced by implementation of risk reduction measures have been documented and evaluated.
- Individual risks posed by the device are acceptable using the maximum tolerable risk index value in the risk management report.
- All identified risk reduction measures have been referenced or documented as design inputs for the ViSi System.
- All risk reduction measures have been verified and implemented.
- The assessment of residual risks is acceptable.

In conclusion, with a reasonable assurance of device safety; the ViSi System with cNIBP is acceptable for release and marketing.

11.6 Patient Contacting Materials

The patient contacting materials for the ViSi System are unaffected by this submission. The patient contacting materials are the same as is indicated in K112478.

11.7 Packaging

The packaging materials are not changed from the previously cleared (K112478) packaging.

11.8 Models Designators

The model numbers are the same as the previously cleared (K112478) model numbers.

Model No.	Description
92-10010	ViSi Mobile Monitor
92-10011	ViSi Mobile Cuff Module
93-10012	ViSi Mobile Chest Sensor (5-wire ECG, AAMI color code)
93-10014	ViSi Mobile Chest Sensor (3-wire ECG, AAMI color code)
93-10016	ViSi Mobile Chest Sensor (5-wire ECG, IEC color code)
93-10018	ViSi Mobile Chest Sensor (3-wire ECG, IEC color code)
93-10020	ViSi Mobile Thumb Sensor
94-10066	ViSi Mobile Patient Kit (Single-use, adult, S)

Model No.	Description
94-10067	ViSi Mobile Patient Kit (Single-use, adult, M)
94-10070	ViSi Mobile Patient Kit (Single-use, adult, M+)
94-10068	ViSi Mobile Patient Kit (Single-use, adult, L)
94-10069	ViSi Mobile Patient Kit (Single-use, adult, L+)

11.9 Accessories/Components

Model No.	Description
92-10023	ViSi Charger

12 SUBSTANTIAL EQUIVALENCE DISCUSSION

The predicate devices used for the direct comparison of and the determination of substantial equivalence to the ViSi Mobile Monitoring System are:

- ViSi Mobile Monitoring System; K112478 (Clearance: 3/27/2012)
- CNAP Monitor 500i, 500at; K082599 (Clearance: 10/17/2008)

Direct comparisons between the ViSi System and predicate devices are provided in **Table 12.**

Table 12: Substantial Equivalence Comparison Table

Device	ViSi System (TBD)	ViSi System Predicate device (K112478)	CNAP Monitor 500i, 500at Predicate device (K082599)
Manufacturer	Sotera Wireless	Sotera Wireless	CNSystem Medizintechnik Ag
Intended Use	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate (RESP), heart rate (HR), non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.	The CNAP Monitor is indicated for the monitoring of non-invasive continuous blood pressure and pulse rate in hospitals, clinical institutions, medical practices and outpatient settings. The device displays the blood pressure waveform and generates trends, beat-to-beat analysis numeric and alarms for the parameters blood pressure and pulse rate. The CNAP Monitor 500 is to be used for adults and pediatric patients from the age of 4 years abs is to be operated by physicians and other medical professional staff.
Parameters monitored and displayed	Same as ViSi System (Predicate) plus continuous non-invasive blood pressure (cNIBP)	Electrocardiogram (ECG), respiration rate, blood oxygen saturation (SpO2), non-invasive blood pressure (NIBP), pulse rate, heart rate, temperature	Non-invasive blood pressure, pulse rate
cNIBP Parameter displayed	Beat-to-beat numerics	Does not measure cNIBP	Beat-to-beat numerics, waveforms
cNIBP calibration interval	With each NIBP measurement	Does not measure cNIBP	With each NIBP measurement
Patient population	Same as ViSi System (Predicate device)	Adults	Adults and pediatric patients (> 4 years)
Environment of Use	Same as ViSi System (Predicate device)	Hospital-based facility including emergency departments, general medical-surgical and intermediate care floors.	Hospitals, clinical institutions, medical practices and outpatient settings
NIBP Technology	Continuous non-invasive beat-to-beat blood pressure measurement based on principles of pulse wave velocity	Non-invasive blood pressure measurement uses an oscillometric technique in the upper arm.	Non-invasive blood pressure measurement uses an oscillometric technique in the upper arm.
cNIBP Technology	Pressure dependent pulse wave velocity	Does not measure cNIBP	Continuous non-invasive beat-to-beat blood pressure measurement (Penaz method) using double finger cuffs.
cNIBP Calibration	Joint solution - Automatic calibration to NIBP	Does not measure cNIBP	Joint solution - Automatic calibration to NIBP
Monitor Connectivity	Same as ViSi System (Predicate device)	Standalone	Standalone
Monitor	Same as ViSi System (Predicate device)	Patient Monitor	Pole mounted
Display	Same as ViSi System (Predicate device)	Internal LCD Display	Internal LCD Display
Power Source	Same as ViSi System (Predicate device)	Battery	Battery, AC Mains
Operating System	Same as ViSi System (Predicate device)	Green Hill's µ-velOSity RTO	Not known
EMC Compliance	Same as ViSi System (Predicate device)	IEC 60601-1-2	IEC 60601-1-2
Product Safety	Same as ViSi System (Predicate device)	IEC 60601-1	IEC 60601-1
cNIBP Alarm Setting	Same as ViSi System (Predicate device)	Preset, automatic	Preset, automatic, settable

Device	ViSi System (TBD)	ViSi System Predicate device (K112478)	CNAP Monitor 500i, 500at Predicate device (K082599)
Alarm Annunciation (visual & audio)	Same as ViSi System (Predicate device)	Monitor	Monitor
EMC Compliance	Same as ViSi System (Predicate device)	IEC 60601-1-2	IEC 60601-1-2
Product Safety	Same as ViSi System (Predicate device)	IEC 60601-1	IEC 60601-1
BP Standards Compliance	ISO 81060-2/ IEC 80601-2-30	ISO 81060-2/ IEC 80601-2-30	ANSI/AAMI SP10/ IEC 60601-2-30
cNIBP Measurement range	SYS: 60 - 240 mmHg DIA: 40 - 160 mmHg MAP 50 - 185 mmHg	Does not measure cNIBP	SYS: 40 - 250 mmHg DIA: 30 - 210 mmHg MAP 35 - 230 mmHg
cNIBP Accuracy	± 5 mmHg, Std. Dev. ≤ 8 mmHg	Does not measure cNIBP	± 5 mmHg
cNIBP Resolution	Same as ViSi System (Predicate device)	1 mmHg	1 mmHg
NIBP Measurement method	Same as ViSi System (Predicate device)	Oscillometric	Oscillometric
NIBP Measurement range	SYS: 60 - 240 mmHg DIA: 40 - 160 mmHg MAP 50 - 185 mmHg	SYS: 60 - 240 mmHg DIA: 40 - 160 mmHg	SYS: 40 - 250 mmHg DIA: 30 - 210 mmHg MAP 35 - 230 mmHg
NIBP Accuracy	Same as ViSi System (Predicate device)	± 5 mmHg, Std. Dev. ≤ 8 mmHg	± 5 mmHg
NIBP Pulse rate range	Same as ViSi System (Predicate device)	30 - 240 beats/min.	40 - 200 beats/min. (pulse rate)
NIBP Pulse rate accuracy	Same as ViSi System (Predicate device)	±3 beats/min. or ±3% whichever is greater	Not specified
ECG Leads	Same as ViSi System (Predicate device)	3-wire: II 5-wire: I, II, III, AVL, AVR, AVF, V	Does not measure ECG
ECG Heart rate range	Same as ViSi System (Predicate device)	30 - 240 beats/min.	Does not measure ECG
ECG Heart rate accuracy	Same as ViSi System (Predicate device)	±3 beats/min. or 3% whichever is greater	Does not measure ECG
Respiration Range	Same as ViSi System (Predicate device)	3 – 50 breaths/min.	Does not measure respiration
Respiration accuracy	Same as ViSi System (Predicate device)	± 3 Breaths/min. or ± 10% whichever is greater	Does not measure respiration
SpO2 display range	Same as ViSi System (Predicate device)	49 – 100%	Does not measure respiration
SpO2 Accuracy	Same as ViSi System (Predicate device)	Non Motion ± 2% (70 – 100%)	Does not measure respiration
Pulse rate range	Same as ViSi System (Predicate device)	0 - 240 beats/min. (Pleth)	20 - 200 beats/min.
Pulse rate accuracy	Same as ViSi System (Predicate device)	±3 beats/min. (no motion) (Pleth)	Not specified
Temperature measured	Same as ViSi System (Predicate device)	Skin	Does not measure temperature
Temperature range	Same as ViSi System (Predicate device)	0 - 50°C	Does not measure temperature
Temperature accuracy	Same as ViSi System (Predicate device)	± 0.1 °C (36.0 - 39.9 °C); ± 0.2 °C	Does not measure temperature

Device	ViSi System (TBD)	ViSi System Predicate device (K112478)	CNAP Monitor 500i, 500at Predicate device (K082599)
Temperature (Operating)	Same as ViSi System (Predicate device)	0 - 50°C	10 - 40°C
Humidity (Operating)	Same as ViSi System (Predicate device)	15 – 95% non-condensing	30 – 85% non-condensing
Pressure (Operating)	Same as ViSi System (Predicate device)	106 kPa – 70 kPa	106 kPa – 65 kPa

Substantial Equivalence Discussion

The cNIBP measurement is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed.

The cNIBP measurement is achieved through software modification. While the principle of operation for cNIBP differs from the predicate device, clinical testing based on ISO 81060-2: *Non-invasive Sphygmomanometers – Part 2: Clinical validation of automated measurement type* demonstrated equivalent performance to the predicate and meeting the standard's mean error and standard deviation requirement (≤ ±5 mmHg and ≤ 8 mmHg, respectively). The clinical validation study was conducted using an invasive blood pressure monitoring equipment as a reference. The study results and ISO specifications are presented in **Table 10a.**

Table 10a: cNIBP Clinical Study, Performance Accuracy Results

Parameter	**ISO 81060-2 Specification**	**Systolic (mmHg)**	**Diastolic (mmHg)**	**MAP (mmHg)**	**Conclusion**
Mean Error	≤ ±5.0	-2.05	-1.71	0.72	**Pass**
Standard Deviation	≤ 8.0	6.07	3.58	3.82	**Pass**

The NIBP software algorithm has not been modified with the introduction of the MAP measurement. The industry-standard technique of oscillometry is used for non-invasively measuring systolic blood pressure, diastolic blood pressure, and mean arterial pressure (MAP). The ViSi System acquires its NIBP measurement on cuff inflation. As the pressure applied to the cuff increases, the pulsatile amplitudes increase between diastolic pressure and mean pressure, and then decrease between mean pressure and systolic pressure. The ViSi System's NIBP algorithm identifies the pulse with the maximum amplitude and calculates pulse amplitudes for the surrounding pulses. The pulse amplitudes and corresponding applied cuff pressures are then fit to a mathematical model.

In the initial 510(k) submission (K112478), the ViSi System's intermittent NIBP automated blood pressure measurement was validated using a non-invasive (auscultatory) reference sphygmomanometer according to ISO 81060-2. In this submission, the clinical validation study of the intermittent blood pressure measurement was conducted by comparison to an intra-arterial reference to demonstrate accuracy for systolic, diastolic, and mean arterial pressure (MAP) readings. The supportive data met ISO 81060-2, section 6.2 requirements. The NIBP study results and ISO specifications are presented in **Table 10b.**

Table 10b: NIBP Clinical Study, Performance Accuracy Results

Parameter	**ISO 81060-2 Specification**	**Systolic (mmHg)**	**Diastolic (mmHg)**	**MAP (mmHg)**	**Conclusion**
Mean Error	≤ ±5.0	-1.65	-1.49	-0.91	**Pass**
Standard Deviation	≤ 8.0	5.01	3.22	2.04	**Pass**

In addition, compliance to non-clinical performance and safety requirements specified in the following consensus standards was verified demonstrating the device modification for cNIBP meets benchmark requirements:

- IEC 62304:2006 Medical device software - Software life cycle processes
- IEC 60601-1-8:2006 Medical electrical equipment – Part 1-8: General Requirements – Collateral Standard: General requirements, tests and guidance for alarm systems
- IEC 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
- ISO 81060-2:2009 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
- IEC 62366:2007 Medical devices -- Application of usability engineering to medical devices

The Human Factors study conducted with fifteen clinical participants validated that the cNIBP feature of the ViSi System was implemented in a manner that strongly suggests there will be minimal potential for use error. Use related errors and use associated risks have been minimized and safe and effective use of the ViSi System can be reasonably assured.

Risk Management is an essential element of the design and development process of the ViSi System. The broad approach to assess the impact of the modification of the ViSi System was based on the principles of ISO 14971:2007, *Medical devices – Application of risk management to medical devices*. Based on the Risk Analysis, the verification and validation activities were identified and acceptance criteria applied. The residual risk for each of the hazards identified is lower than the risk acceptability criteria specified in the risk management plan. The report concluded that the risk management process was implemented correctly and that the overall residual risk associated with the modified ViSi System is acceptable.

The ViSi System has the following similarities and differences with the indicated predicate devices:

- Intended use – The ViSi System predicate (K112478) monitors all the same vital signs as the pending ViSi System except for cNIBP. The CNAP Monitor 500 (K082599) monitors non-invasive continuous blood pressure and pulse rate. Considered together, these intended uses are the same as the proposed ViSi System with cNIBP.

  The ViSi System, similar to the predicate devices, is intended to be used by licensed practitioners in a healthcare environment.

- Device Performance – The modified ViSi System with intermittent NIBP MAP and cNIBP measurements have been clinically validated to meet the same performance requirements (mean error ≤ ± 5 mmHg; standard deviation ≤ 8 mmHg) as outlined in the consensus standards for automated non-invasive blood pressure monitors. The intermittent ViSi System NIBP MAP measurement was validated to ISO 81060-2 without deviation from the standard.

  Since ISO 81060-2 is intended for intermittent automated measurements, and the cNIBP derives calibration from a cuff-based non-invasive blood pressure measurement, the standard was adapted to apply to the ViSi System's cNIBP measurement. The ViSi System cNIBP and the CNAP

Monitor both met adapted versions of the prevailing relevant consensus standards (ISO 81060-2 and AAMI/ANSI SP10, respectively).

- Technology – The ViSi System is unchanged from it predicate submission except for the display of intermittent NIBP MAP readings and the continuous non-invasive blood pressure (cNIBP) measurements.

  The intermittent NIBP MAP measurement is based on the same technology as is currently in the cleared ViSi System and is equivalent to the CNAP Monitor. The ViSi System's MAP measurement has been validated by comparison to an intra-arterial reference and meets the performance requirements of ISO 81060-2.

  The ViSi System's cNIBP measurement has a different principle of operation from that of the CNAP Monitor predicate device (blood pressure measurements related to pulse wave velocity Vs. Peñáz principle). Both methods are similar in that pressure is determined on a beat-to–beat basis and are joint solutions employing automatic calibration to NIBP measurements.

  The question of effectiveness of the cNIBP measurement has been addressed by the clinical performance validation to the requirements of ISO 81060-2.

- Safety – The hazards analysis has shown that there are no residual risks for the patient or operator. In addition, the ViSi System software cannot cause injury to the patient or operator. The ViSi System is featured with alarm and alerts that monitor physiological parameters and device functions. Since the ViSi System is not classified as life supporting, the implemented preventive measures ensure the safe application of the device.

The ViSi System with intermittent MAP and cNIBP measurement has been verified and clinically validated to meet the requirements of the recognized consensus standards. The results demonstrate that the ViSi System is safe, effective, compliant with relevant standards, and is substantially equivalent to the predicate devices.

13 LABELING

13.1 Proposed Device ViSi Mobile Monitoring System – cNIBP

The operation of the continuous non-invasive blood pressure feature is described in section 5.2.8 (page 79) of ViSi Mobile Monitoring System User Manual (**Exhibit 5**). Other changes to the ViSi Mobile Monitoring System User Manual resulting from the addition of cNIBP are highlighted in yellow on pages 19, 39, 41, 47, 67, 79 -81, 86, 89, 103, 125-128, and 146.

13.2 Predicate Device - ViSi Mobile Monitoring System (K112478)

The ViSi Mobile Monitoring System User Manual provided in **Exhibit 5** is the predicate device labeling with modifications from the original text highlighted in yellow.

13.3 Predicate device –CNAP Monitor 500 (K082599)

CNAP Monitor 500 Operator's Manual is provided in **Exhibit 6.**

14 STERILIZATION, SHELF LIFE, & CLEANING

14.1 Sterilization

The ViSi System and components are provided non-sterile and do not require sterilization prior to use.

14.2 Shelf-Life

The new hardware components are re-usable and shelf-life does not apply.

14.3 Cleaning and disinfection

The hardware components are the same as presented in K112478. There have been no changes to the recommended cleaning and disinfection procedures.

15 BIOCOMPATIBILITY

The patient contacting materials have not been changed with this application. The biocompatibility information provided with the previous submission (K112478) remains applicable.

16 SOFTWARE

16.1 Level of Concern

The software level of concern for the ViSi System is Major since the device is intended to sound alarms for clinical events that include life threatening conditions. The software level of concern is unchanged from the previous FDA clearance.

16.2 Software Description

The software implementation of the continuous blood pressure measurement in the ViSi System has been designed according to the requirements outlined in *Vital Signs: cNIBP System Requirements Specification*, 0-000994, Rev. A (**Exhibit 8**). The software is implemented in "C" programming language, compiled and executed using the Green Hills µ-velOSity operating system, and run on the ST microprocessors on the PWD.

16.3 Software Hazard Analysis

Software hazards analysis was performed and the results documented in *ViSi System Risk /Hazard Analysis - cNIBP Module,* 0-000959, Rev. A **(Exhibit 3).** The table below identifies pre-mitigation hazards that were determined to unacceptable due to wrong or harmful interventions based on incorrect blood pressure readings. The measures recommended to mitigate these risks are.

Potential causes	Mitigation description
Incorrect calibration as a result of incorrect NIBP measurement due to:	
Calibration algorithm error	Use of default calibration curve: Evaluation of calibration using change in PAT, goodness of fit, number of PAT values; Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold
Algorithm issues due to:	
Inaccurate fiducial point, PPG, ECG	Outlier rejection; Use of averaging
Incorrect beat picking	Testing against accepted beat databases
Inaccurate pleth readings	PAT measurement qualifications and rejection criteria

Risk Mitigation tags were s assigned to risk mitigations and added to the SRS document. These requirements were tested as part of the overall software verification and validation. Post-mitigation, all software hazards identified were determined to meet the Company's risk management policy of acceptable risks. The residual software risks are summarized in *Software Risk Management Report, ViSi, cNIBP*, R-000339-001 (**Exhibit 19**). The software risks identified also serves as an input into the *Summary Risk Management Report, ViSi, cNIBP*, R-000340-001, Rev. A (see section 11.5, Risk Management). to provide a conclusion regarding the overall safety of the ViSi cNIBP device.

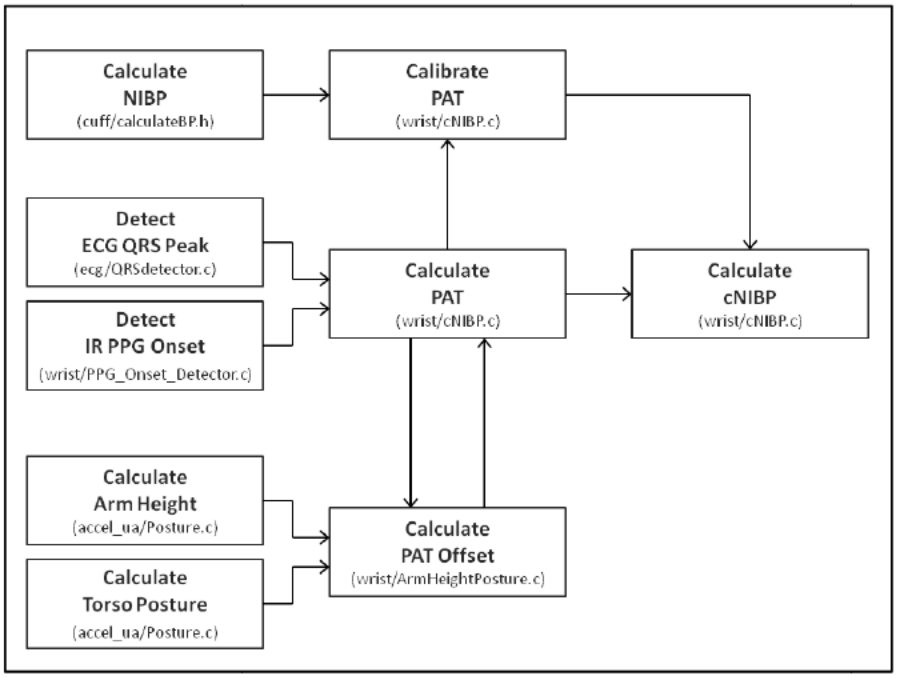
16.4 Software Requirements Specification (SRS)

The requirements for the software -- which include functional, performance, interface, and design -- have been identified and used as input for cNIBP software design. These input requirements are documented in *Vital Signs: cNIBP System Requirements Specification*, 0-000994, Rev. A (**Exhibit 8**).

16.5 Architecture Design Chart

A block diagram showing the l t onships of the maj c c t vare are included in *S t g t NIBP*, 0-000996, Rev. A (**Exhibit 7).**

cNIBP Architectural Design Chart



16.6 n p c on (SDS)

The detailed i t ti software requirements is described in *S r ign Specification, cNIBP*, 0-000996, Rev. A (**x 7).**

16.7 Traceability Analysis

A traceability analysis linking prod s e lt i d in *Software d ti , NIBP, 1c*, R-000333-001, Rev. A, Appendices A d B. Report R-000333-001 is provided in **x 9.**

16.8 ironment Description

The framework of lifecycle process d in e i s a k e f safe design and maintenance of the ViSi System sof s t e n NSI/AAMI/IEC 62304:2006; *M d l i re – Software life cycle processes.*

The Software Development Life Cy C t el t the ViSi System software. The V-Model life cycle n o , c e lassic Waterfall o e . is i the Company's procedure, SOP-011, Rev. B, *are Development Life Cycle.*

The Design Input Phase started with a review of the system specifications, system-level hazards and system-level architectural design, and ends with the derived software requirements. Output from the phase included Software Requirements Specification (SRS) and Software Validation Plan.

The Design Phase is intended to ensure that the preliminary and detailed software designs satisfy the requirements and constraints specified in the SRS. The Design Phase output included the Software Design Specification (SDS), System Hazards Analysis, and Software Verification Plan.

The implementation phase is where coding and debugging occurred. With the Life Cycle Model (V-model), once coding is complete, the path of execution continues up the right side of the V where the Software V&V plans developed previously were utilized.

16.9 Verification and Validation Documentation

Software Verification

Software verification employed a white box test based approach that verified the design of critical lower level features, including any features designed and implemented as mitigations of identified risks and hazards. Integration testing was performed with the goal of identifying any issues stemming from interoperability of the core processors, and the communication and interaction between the system's modules. To the extent that they could not be tested with black-box functional testing methodology, the software requirements were included in software verification testing. All other software requirements fell within the scope of software validation testing.

Code and design reviews were held throughout the design process. Software Verification Test (SVT) protocols were developed and executed. The results are summarized *in Software Verification Report, ViSi System, cNIBP*, R-000332-001, Rev. A (**Exhibit 10**).

Software Validation

Planned Software Validation activities were performed according to Sotera procedure which followed a scenario-based approach that links intended use objectives with software requirements.

The design input documents and associated risk/hazard analysis documents listed below were reviewed as part of Software Validation to ensure correctness, consistency, and completeness. Any defects discovered during the validation would have resulted in an anomaly report. Validation test cases were created with specific test objective, unique test case identifiers, and required test steps. *Software Validation Summary Report, ViSi, cNIBP, 1c,* R-000333-001, Rev. A (**Exhibit 9),** summarizes test results and findings. The requirements traceability matrix (RTM) is provided in the validation report.

A result that deviates from the expected result stated in the test case is defined as an anomaly. Test incidents that are judged failures (due to anomalies) are recorded and tracked to resolution.

The pass/fail criteria for the validation activities listed in the R-000333-001 software validation report. The ViSi System software validation activities were completed successfully.

16.10 Revision Level History

A history of software revisions generated during the course of product development beginning with design verification is summarized in **Table 16.10.** The current software release is 253.5.1.

Table 16.10: Software revisions

Software release	Summary of changes
253.4.0	Implementation of all cNIBP features as documented in 0-000994 (SRS, UI, H1, 1c)
253.4.1	cNIBP features complete; Bug fixes listed in JIRA up to this date including CNIBP-23, CNIBP-17, CNIBP-19
253.5.0	cNIBP Algorithm updates - Ratio of systolic to MAP limited [1.2,1.8]; Minimized number of PATs necessary to compute cNIBP numeric increasing speed of acquisition; cNIBP is removed if we fail to acquire calibration PAT. No spinner is displayed after inflation. PPG - Fixed PPG sequence number mismatch crash; Motion algorithm reverted to styles used in trials; SpO2 rounded to nearest integer instead of floored; JIRA fixes cNIBP-32, cNIBP-30, cNIBP-29, cNIBP-18, cNIBP-17
253.5.1	Fixed software anomalies cNIBP-34, cNIBP-38, cNIBP-37 - Recalibration for cNIBP

16.11 Software Revision Control Procedures

All changes to software items are coordinated and controlled by the Software Configuration Management. An off-the-shelf software configuration management tool, Subversion, maintains and logs all changes. Only individuals authorized by Engineering can access this log, either to read it or write to it. Backup of the Subversion repositories is done automatically.

The release of software is controlled by the Software Configuration Management. Master copies of code and documentation are maintained in Subversion. In addition to a Version Description Document, the release documentation includes the following, as appropriate:

- Changes since previous delivery
- Dependencies between versions of configuration items
- Dependencies on particular hardware or software platforms
- Build Instructions
- Installation instructions for this delivery
- Production Release

Baselines are stored and retrievable from the off-the-shelf software configuration management tool, Subversion Version Control system.

Whenever a formal baseline for a software revision is established, it is accompanied with a Version Description Document (VDD), as a means of documenting configuration status accounting. These documents are submitted to Document Control for release prior to the start of formal verification and

validation processes. The VDD contains basic elements necessary to build the correct executable image reliably and consistently.

Following formal baseline establishment, each software modification is approved and tracked. Software Configuration Management ensures that all changes to the software are implemented and/or released in a controlled manner.

16.12 Unresolved Anomalies

JIRA software is used to record and track software anomalies (aka 'bugs') and other software issues during development of the ViSi System. Software anomalies have been entered into the JIRA database, updated, and closed as issues are addressed. **Table16.12** summarizes the software anomalies remain in cNIBP software version 253.5.1

Table 16.12: Software revisions

Severity	Category	No. Unresolved
5	Catastrophic - Directly causes or contributes to death or serious injury.	0
4	Critical - Indirectly causes or contributes to death or serious injury.	0
3	Moderate - Causes or contributes to non-serious injury.	0
2	Minor - No injury or damage to health. Customer satisfaction issue.	2
1	Negligible - No injury or damage to health. Not noticeable or minor customer satisfaction issue.	14

Sixteen non-serious software anomalies remain. **Exhibit 11**, ViSi cNIBP Software Anomalies – Version 253.5.1, provides a detailed explanation of each remaining JIRA issue and the assessment of patient risk. The sixteen anomalies will be resolved before final software and commercial release.

17 ELECTRICAL SAFETY, EMC

17.1 Electrical Safety

The ViSi System components: ViSi Monitor, Cuff Module, Chest Sensors, and Thumb Sensor are the same as previously submitted and cleared in K112478. In this earlier submission, the ViSi System passed the widely accepted benchmark for medical electrical equipment, IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for safety* (2nd edition). Accordingly, these test results are not being resubmitted since the initial results remain valid.

17.2 Electromagnetic Compatibility

As stated in §17.1, the ViSi System components are the same as previously submitted and cleared in K112478. In this earlier submission, the ViSi System passed the industry standard criteria of electromagnetic compatibility, IEC 60601-1-2:2007, *Medical Electrical Equipment – Part 1-2: General Requirements for safety – Collateral standard: Electromagnetic – Requirements and tests*. Accordingly, these test results are not being resubmitted since the initial results remain valid.

18 PERFORMANCE TESTING - BENCH

Verification testing was performed on the ViSi System to verify functionality and conformance to IEC 80601-2-30 requirements. Since no hardware changes were required for the implementation of cNIBP and NIBP MAP, not all sections of the standard required repeating. An assessment was made for each section in the standard and the results of the assessment documented in the final report. The required testing to verify compliance to the standard is outlined in test protocol *Design Verification, EN 1060-1, EN 1060-3, IEC 80601-2-30 Compliance*, 0-001002, Rev, A (**Exhibit 12**). The results are reported in *ViSi System, 1C (cNIBP) Design Verification Report - EN 1060-1, EN 1060-3, IEC 80601-2-30 Compliance,* R-000310, Rev. A (**Exhibit 13**). **Table 18** (below) summarizes the tests and results of testing performed to verify compliance to IEC 80601-2-30.

Table 18: Verification test summary

Test description	Specification	Results	Conclusion
201.12.1.101 – Measuring and display ranges	Alarm & no reading above/ below rated range	Alarms, "+++", "----"	Pass
201.12.1.102 – Limits of the error of the manometer from environmental conditions @ 10 -40 °C	≤ ±3 mmHg	≤ ±1 mmHg	Pass
201.12.1.103 – Nominal blood pressure indication range	Dia: 40-130 mmHg Sys: 60-230 mmHg	Dia: 40-160 mmHg Sys: 60-240 mmHg	Pass
201.12.1.107 – Limits of the change in error of the blood pressure determination	< ±3 mmHg	≤ ±2 mmHg	Pass
201.12.3.101 – Alarm systems	Med. alarm for low and high BP	Alarms at low and high BP	Pass

Successful verification testing activities establish the conformance to IEC 80601-2-30.

19 PERFORMANCE TESTING - CLINICAL

In vivo validation of the ViSi System's non-invasive blood pressure accuracy was conducted in a prospective study titled: *Accuracy Study of Noninvasive Continuous Blood Pressure in Comparison to Invasive Radial Arterial Blood Pressure: ISO Accuracy Validation Protocol PR-2012-048.*

The two objectives of the study were:

1. Demonstrate the ability of the ViSi System cNIBP feature to continuously measure blood pressure over a 4 hour period of time as compared to an Invasive Arterial Reference (blood pressure ranges and methods as described in ISO 81060-2).
2. Determine the accuracy of the ViSi System Non-Invasive Automated Blood Pressure monitor in adult subjects by comparison to an invasive reference pressure transducer as described in ISO 81060-2.

The study was conducted October 23 – December 7, 2012, at Clinimark Laboratory (Louisville, Colorado). After Institutional Review Board (IRB) approval, 16 adult volunteer subjects were enrolled. Patients ranged in age from 19 - 48, had arm circumferences between 21 - 38 cm, systolic blood pressures between 90 - 193 mmHg, and diastolic blood pressure between 49 - 120 mmHg.

19.1 Continuous Non-Invasive Blood Pressure Accuracy (cNIBP)

This study determined the accuracy of the ViSi System's continuous blood pressure measurements in adult subjects by comparing results to those achieved with a reference invasive arterial pressure transducer. The study was conducted in accordance with ISO 81060-2: *Non-invasive Sphygmomanometers – Part 2: Clinical validation of automated measurement type* and ISO 14155: *Clinical investigation of medical devices for human subjects – Good clinical practice*.

An arterial catheter was placed in the volunteer test subjects and invasive Reference arterial blood pressures were measured per the ISO standard. All demographics called for in the ISO standard were met by this subject population; including the required blood pressure ranges as measured by invasive arterial Reference. The goal was to measure invasive blood pressure through the arterial catheter for a period of up to 4 hours to validate the accuracy of the Continuous Non-Invasive Blood Pressure (cNIBP) feature over that same 4 hour period.

Reference radial arterial blood pressure values were measured directly using a Biopac Data Acquisition System with a Biopac TSD104A Blood Pressure Transducer connected to an 'Argon Medical Devices Single Pressure Transducer'. This device does not apply averaging or smoothing. The Reference arterial blood pressure system was calibrated against a mercury manometer. After placement of the arterial catheter, dynamic testing was used to verify that the dynamic resonant frequency response was greater than 16 Hz using methods described by Gardner (ISO 81060-2, Section 6.2.1). Blood pressure values were determined for comparison using the same algorithms in both Reference arterial signal and the device-under-test. Reference radial arterial blood pressure values were determined by following the ISO 81060-2 standard as outlined in section 6.2.4.

During the 4 hour study period (actual: mean 3.7, minimum 2.6, maximum 4.0), continuous readings were recorded from the arterial reference (excluding trips to the bathroom and periods of transducer re-level). Reference systolic, diastolic and mean blood pressure values were determined for each cardiac cycle over

the entire study period. Every 3 seconds during the entire study period, the cNIBP device-under-test calculated the numeric values (systolic, diastolic, and mean) from all cardiac cycles in the previous 60 seconds. These data were paired with invasive Reference arterial data for which mean and limits of variation were calculated in the same way as specified in ISO 81060-2. The study results and ISO specifications are presented in **Table 19.1.**

Table 19.1: cNIBP Clinical Study, Performance Accuracy Results

N = 54,166	**ISO 81060-2 Specification**	**Systolic (mmHg)**	**Diastolic (mmHg)**	**MAP (mmHg)**	**Conclusion**
Mean Error	≤ ±5.0	-2.05	-1.71	-0.72	**Pass**
Standard Deviation	≤ 8.0	6.07	3.58	3.82	**Pass**

The results of this study are reported in: *Accuracy Study of ViSi Noninvasive Blood Pressure Cuff System with ViSi Continuous Noninvasive Blood Pressure Feature in Comparison to Invasive Arterial Blood Pressure,* TR2012048, Rev. 7 (**Exhibit 14**).

The number of subjects, age distribution, gender distribution, limb size distribution, and subject blood pressure distribution met ISO 81060-2 requirements. Separate data and Bland-Altman plots for systolic, diastolic, and mean pressures are provided in the study report. Charts displaying reference systolic and diastolic measurement distributions, arm circumference, and age distribution are presented in the referenced study report. Finally, a line listing for all patients is provided.

The clinical study adhered to the test subject requirements and acceptance criteria specified in ISO 81060-2. The results presented in *Accuracy Study of the ViSi Noninvasive Blood Pressure Cuff System with the ViSi Continuous Noninvasive Blood Pressure Feature in Comparison to Invasive Arterial Blood Pressure* demonstrate that the ViSi System's cNIBP meets the accuracy performance requirements for automated sphygmomanometers.

19.2 Non-Invasive Blood Pressure Accuracy (NIBP)

The NIBP feature of the ViSi System was cleared originally on March 22, 2012 (K112478). The ViSi System was clinically validated using a non-invasive (auscultatory) reference sphygmomanometer which does not allow for the reporting mean blood pressure. In order to report mean blood pressure, the NIBP study was repeated using an intra-arterial reference standard for comparison according to ISO 81060-2.

During the 4 hour study period, 10 paired blood pressure readings were measured for each volunteer subject resulting in 162 data pairs. Reference arterial blood pressure values for each ViSi NIBP measurement were determined by following the ISO 81060-2 as outlined in section 6.2.4. These readings were used to validate accuracy of the NIBP device-under-test with 5 cuffs.

The acceptance criteria used in the study were derived from ISO 81060-2 (Section 5.2.4.1.2, Data Analysis). Data from the ViSi Non-Invasive Blood Pressure cuff system with 5 cuffs was within the accuracy requirements of the ISO 81060-2. Results of the data analysis are presented in **Table 19.2.**

Table 19.2: NIBP Clinical Study, Performance Accuracy Results

N = 162	**ISO 81060-2 Specification**	**Systolic (mmHg)**	**Diastolic (mmHg)**	**MAP (mmHg)**	**Conclusion**
Mean Error	≤ ±5.0	-1.65	-1.49	-0.91	**Pass**
Standard Deviation	≤ 8.0	5.01	3.22	2.04	**Pass**

The results of this study are also reported in: *Accuracy Study of ViSi Noninvasive Blood Pressure Cuff System with ViSi Continuous Noninvasive Blood Pressure Feature in Comparison to Invasive Arterial Blood Pressure,* TR2012048, Rev. 7 (**Exhibit 14**). The study protocol, *Accuracy Study of Noninvasive Continuous Blood Pressure in Comparison to Invasive Radial Arterial Blood Pressure: ISO Accuracy Validation Protocol*, PR-2012-048, is included in the study report as Appendix G.

The results of the blood pressure accuracy evaluation demonstrate that the ViSi System with five adult cuff sizes (small adult 10, adult 11, adult long 12, large adult 12, large adult long 12L) meets the [Invasive arterial comparison method] requirements for *Same Arm Simultaneous Method (Dual Observer) in Comparison to a Mercury Reference Sphygmomanometer.*]

The number of subjects, age distribution, gender distribution, limb size distribution, and subject blood pressure distribution met ISO 81060-2 requirements. Separate data and Bland-Altman plots for systolic, MAP, and diastolic pressures are provided in the study report. Charts displaying reference systolic, MAP, and diastolic measurement distributions, blood pressure and cuff size distributions are presented in the referenced study report. Finally, a line listing for all patients is provided with the range of the variation.

The clinical study adhered to the test subject requirements and acceptance criteria specified in ISO 81060-2. The results presented in *Accuracy Study of the ViSi Noninvasive Blood Pressure Cuff System with the ViSi Continuous Noninvasive Blood Pressure Feature in Comparison to Invasive Arterial Blood Pressure* demonstrate that the ViSi System's NIBP meets the accuracy performance requirements for automated sphygmomanometers.

20 HUMAN FACTORS

20.1 Human Factors Engineering

Human factors activities were conducted in support of the ViSi System development in accordance with the principles of IEC 62366, *Medical devices- Applications of usability engineering to medical devices*. The process involved the identification of both anticipated and unanticipated use-related hazards (derived through formative evaluations) and the determination of how such hazards might occur. Strategies were developed and applied to mitigate or control use-related hazards. Finally safe and effective device use was demonstrated through human factors validation testing.

As input to the Use Error Analysis, a review of use errors with other monitoring systems was conducted. Use errors made with other commercially available monitors were considered as candidate use errors for the ViSi System. Sources of information about use errors with other monitoring systems included the FDA's Adverse Event Report Database (MAUDE) and FDA device recalls.

The Use Error analysis was evaluated for the likelihood of usability or safety problems given the design of the device-user interface. The analysis included consideration for use errors with other monitoring devices, reasonably foreseeable misuse, characteristics of the device use environment, user capabilities, limits, and predispositions, and established human factors principles for good design. Risks identified during the Use Error Analysis are incorporated into the Risk Management Report.

In the prior submission (K112478), Summative Usability (Human Factors) testing was conducted to demonstrate that the intended users of the ViSi System's patient worn device could safely and effectively perform critical tasks for the intended uses in the expected environment. The validation involved clinicians who performed common and safety-related operations with production equivalent ViSi Systems in a simulated environment.

Twenty (20) registered nurses were presented with a series of written questions and physical tasks designed to evaluate the usability of the PWD. Proctors administered the test in a one-on-one setting with one test proctor and one clinical user.

The required percentage of clinical participants answered each question correctly and completed each task correctly in the allotted time. The PWD was shown to be safe and effective when used by the intended clinical user. ViSi System PWD passed this Summative Usability (Human Factors) study. The study report, R-000067, *Human Factors Summative Validation, ViSi Mobile Monitoring System, H1,* was provided to the FDA in the previous 510(k) submission.

cNIBP

The study protocol, *ViSi System Human Factors, cNIBP Feature*, 0-001000, Rev. A (**Exhibit 15**) required clinical users to answer to written questions and complete scenarios designed to evaluate clinical usability of the cNIBP feature.

Fifteen (15) clinical users were provided with the ViSi System and all appropriate user documentation. They were asked to review the appropriate documentation after which the Proctor asked the clinical user to answer a set of questions and complete tasks using the device.

The Proctor observed the clinical user, recording the time to complete each task and score accuracy of task completion during the test.

ViSi System cNIBP Human Factors Study, R-000326, Rev. A (**Exhibit 16),** reported the results of the study. Each question was answered correctly by the required percentage of clinical participants and each task was completed correctly in the allotted time by each clinician.

Clinical Participant #5 missed Task #4 which required the user to perform a calibration by depressing the cNIBP button. Since there is a delay in the enabling of the button, the user became confused and began depressing other buttons. While confusing, the user error does not result in a hazard to the patient. After the button became enabled, the clinician performed the calibration successfully.

The Human Factors study with fifteen clinical participants validated that the cNIBP feature of the ViSi System was implemented in a manner that strongly suggests there will be minimal potential for use error. Use related errors and use associated risks have been minimized and safe and effective use of the ViSi System can be reasonably assured.

21 CERTIFICATE OF COMPLIANCE WITH CLINICALTRIALS.GOV

The Certificate of Compliance with Clinicaltrials.gov is provided in **Exhibit 17.**

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: August 31, 2012

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 checkbox.

☒ (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		
	Arthur Cabrera, MD, Anesthesiologist	David Ransom, MD, Principal Investigator
	Dena Raley, Chief Technical Offier	Paul Batchelder, Chief Science Officer
	Anne Fedor, RN	

☐ (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
Eben Gordon	Sr. Director, Regulatory Affairs
FIRM/ORGANIZATION Sotera Wireless, Inc.	
SIGNATURE Eben Gordon	DATE *(mm/dd/yyyy)* 02/17/2013

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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]

IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes. (Software/Informatics)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
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], www fda gov/cdrh/stdsprog html

[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 www fda gov/cdrh/guidance html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes. (Software/Informatics)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Sections 1-6	Scope, Norm Ref, Terms, General Req., SW Dev. Process, SW Maintenance	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7-9	SW risk management, SW Configuration process, SW problem resolution	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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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]

IEC 60601-1-8 Ed. 2:2006-10, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performa

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], www fda gov/cdrh/stdsprog html

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

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[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 www fda gov/cdrh/guidance html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-8 Ed. 2:2006-10, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performa

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2,3,4,5,6	Scope, Norm Ref, Terms, Gen. Requirements, ME Equipment, Alarm Systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62366:2007, Medical devices - Application of usability engineering to medical devices. (General)

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?	☒	☐
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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: _____

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[2] Authority [21 U S C 360d], www fda gov/cdrh/stdsprog html

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 62366:2007, Medical devices - Application of usability engineering to medical devices. (General)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4,5,6,7	Scope, Norm Ref, Terms, Principles, Usability, Accompanying document, Trai	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EC 80601-2-30:2009, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performanc

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#3-78	
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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Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EC 80601-2-30:2009, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performanc

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201, 202	Scope, Norm Ref, Terms, Gen. Requirements, Classificaiton, ME Equipment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

ISO 81060-2:2009, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#3-81	
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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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: Non-Invasive Blood Pressure (NIBP) Monitor Guidance

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 81060-2:2009, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1,2,3,4,5,6,7	Scope, Norm Ref, Terms, Gen. Requirements, Val. with Aus,, Val. with Inv.	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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DESCRIPTION

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ViSi System Risk /Hazard Analysis - cNIBP Module

Document No.: 0-000959	Revision: A
CO #: 01799	Release Date: 31 JAN 2013

Product Description	This Hazards Analysis applies to the optional cNIBP feature of the ViSi Mobile Monitoring System
Scope	This Hazards Analysis applies to the cNIBP feature only of the ViSi Mobile Monitoring System. It includes system-level and software risks. There are no hardware changes made from the already released ViSi Mobile product. The remaining aspects of the ViSi System are addressed in Hazard Analysis 0-000020, and 0-000082

Risk Management Team

Name	Title	Role
S. Tsadok	Prin Eng, Pt Safety and Clinical Performance	Risk Management Team Leader
E. Gordon	Sr. Director, Regulatory Affairs	Risk Management Team member
C. DiBattista	Mgr, Application Design	Risk Management Team member
J. Welch	VP, RA/QA/ Clinical Engineering	Risk Management Team member
D. McCombie	Dir, Science	Risk Management Team member
D. Walker	Mgr, Embedded SW Engineering	Risk Management Team member
J. Moon	CTO	Risk Management Team member

Revision History

Author	Revision	Date	Description
S. Tsadok	A	1/31/2013	Initial release

Hazard Category **cNIBP**

Entry D	Hazard	Potential Harm	Applies To	Potential Cause	Intial Severity	Intial Probability	Intial Risk Eval.	Mitigation Description	RM D	Residual Severity	Residual Probability	Residual Risk Eval.	Notes/Comments
10	Wrong / harmful intervention based on incorrect BP reading	1) delay in treatment 2) incorrect treatment	P	Incorrect calibration as a result of incorrect N BP measurement due to:									
				- incorrect cuff size	3	2	A	Provide mutliple cuff sizes	02000	3	2	A	MMEA - FU
				- incorrect cuff placement	3	3	A	Labeling / training	02001	3	2	A	MMEA - FU
				- calibration algorithm error	3	4	I	Use of default calibration curves	02002	3	1	BA	SW: requires verification of algorithmic calculations
								Evaluation of calibration using change in PAT, goodness of fit, number of PAT values	02003				SW: requires verification of algorithmic calculations
								Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold	02004				MMEA - FU
								Clinical/pivotal trials	01075				Pivotal trials
				- motion artifact	3	4	I	Labeling / training to keep patient still	02005	3	2	A	MMEA - FU
								PPG noise tracking	02006				SW: requires verification of algorithmic calculations
			P	Incorrect PAT due to:									
				- Change in PEP, VTT due to change in load caused by:									
				- change in medication	3	4	I	labeling to recalibrate with changes in care	02007	3	3	A	MMEA - FU
				- change in cardiovascular blood volume	3	4	I	labeling to recalibrate with changes in patient condition	02008	3	3	A	MMEA - FU
				- change in body position / posture	3	4	I	Measure and correct for torso and arm posture changes	02009	3	2	A	SW: requires verification test
				- change of PEP, VTT due to change in contractility due to changes in medication	3	4	I	labeling to recalibrate with changes in care	02007	3	3	A	MMEA - FU
								Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold	02004				MMEA - FU, requires verification test
			P	Algorithm issues due to:									
				- inaccurate fiducial point, PPG, ECG	3	4	I	Outlier rejection	02010	3	2	A	SW: requires verification test
								Use of averaging	02011				SW: requires verification test
				- bad ECG lead placement	3	4	I	Labeling training on correct electrode placement	02012	3	3	A	MMEA - FU
				- poor skin to electrode conductivity	3	4	I	PAT measurement qualifications and rejection criteria	02013	3	2	A	SW: requires verification test
				- motion	3	4	I	Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold	02004	3	3	A	MMEA - FU
				- difficulties with the patient's waveform morphology	3	4	I	Clinical evalution of algorithm per ISO 9919	01075	3	2	A	clinical pivotal trials report
				- incorrect beat picking	3	4	I	Testing against accepted beat databases	02014	3	2	A	SW: requires verification test
				- inaccurate pleth readings	3	4	I	PAT measurement qualifications and rejection criteria	02013	3	2	A	SW: requires verification test
				- incorrect arm position or change in arm position relative to heart	3	4	I	Measure and correct for torso and arm posture changes	02009	3	2	A	SW: requires verification test
								Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold	02004				MMEA - FU

Mitigation								
RM ID	Summary Description	Description	Type	Device(s)	H/W	S/W	Process	Labeling
00000	None required	No mitigation is necessary						
01075	cNIBP clinical validation	Validate cNIBP accuracy clinically against change in NIBP baseline.	PROD	System				
02000	NIBP calibraton measurement	Provide mutliple cuff sizes	PROD	NIBP	X			
02001	NIBP calibraton measurement	Labeling / training	INFO	System				X
02002	NIBP calibraton measurement	Use of default calibration curves	PROD	WT		X		
02003	NIBP calibraton measurement	Evaluation of calibration using change in PAT, goodness of fit, number of PAT values	PROD	WT		X		
02004	NIBP calibraton measurement	Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in he cNIBP that exceeds a threshold	PROD	WT		X		X
02005	NIBP calibraton measurement	Labeling / training to keep patient still	INFO	System				X
02006	NIBP calibraton measurement	PPG noise tracking	PROD	WT		X		
02007	PAT calculation	labeling to recalibrate with changes in care	INFO	System				X
02008	PAT calculation	labeling to recalibrate with changes in patient condition	INFO	System				X
02009	PAT calculation	Measure and correct for torso and arm posture changes	PROD	WT		X		
02010	cNIBP algorithm	Outlier rejection	PROD	WT		X		
02011	cNIBP algorithm	Use of averaging	PROD	WT		X		
02012	cNIBP algorithm	Labeling, training on correct electrode placement	INFO	System				X
02013	cNIBP algorithm	PAT measurement qualifications and rejection criteria	PROD	WT		X		
02014	cNIBP algorithm	Testing against accepted beat databases	PROC	ECG			X	

Risk Evaluation Lookup Table		Severity				
		1	2	3	4	5
Probability	1	BA	BA	BA	A	A
	2	BA	BA	A	A	I
	3	BA	A	A	I	I
	4	A	A	I	I	I
	5	A	A	I	I	I

BA Broadly acceptable
A As low as reasonably practicable
I Intolerable

"Applies to" codes

P Patient
U User
B Bystander
S Service
F Facility
E Environment

Severity

0	None	No health impact, no limitation
1	Nuisance	No health impact. Awkward use. Limitation.
2	Minor	Short term discomfort, minor injury with low or no impact on activities of daily living
3	Serious	Small injury requiring minor medical intervention (cuts, bruises, etc.)
4	Critical	Injury requiring immediate medical attention. Result in failure to rescue. Damage to property/environment exceeding $1,000,000
5	Catastrophic	Direct permanent serious injury, disability, death, damage to property/environment exceeding $10,000,000

Probability

0	Never	Will never occur during the expected service life
1	Remote	Extremely rare occurrance during the expected service life
2	Seldom	Not likely to occur during the expected service life
3	Sometimes	Possible to occur during expected service life
4	Likely	Probable to occur several times during the expected service life
5	Definite	Will occur during the expected service life

Document Type:		SW RISK MANAGEMENT REPORT			
Owner:	Engineering	CO #:	01864	Release Date:	13 March 13
Document Control Approval:					

1.0 PURPOSE

1.1 This report summarizes the results of system risk management activities and, together with the results of the Software Risk Management Report, provides a conclusion regarding the safety of the cNIBP release.

2.0 SCOPE

2.1 This report applies to the cNIBP release of the ViSi Mobile as a body-worn system.

2.2 The risk management activities centered around the risks identified in the SW and System Hazards Analyses and MMEA for the cNIBP project as implemented on the ViSi Mobile body-worn system.

2.3 This report references the Risk Management Report of the original commercial release of the ViSi Mobile system.

3.0 EXECUTIVE SUMMARY

3.1 Risk Management activities were conducted in accordance with SOP-010.

3.2 The hazard analysis and risk assessment for the cNIBP additions of the System components to the standalone ViSi Monitor.

3.3 The identified risks were mitigated by design, training, and labeling. All required mitigations were tested. There were 16 issues identified during software testing. Two are considered Minor, and 14 Negligible. All are within the Acceptable patient safety categories ALAP and BA (see SOP_010).

3.4 Based on the risk analysis conducted and documented in SW Risk Management Report R-000339-001, the ViSi Mobile System is concluded to be safe for its intended use.

4.0 REFERENCES

4.1 Internal

4.1.1 0-000868 (H1, Design Input Requirements Release 1c)

4.1.2 0-000959 (H1, System Hazard Analysis, 1c cNIBP)

4.1.3 0-000019, Rev. H – MMEA, H1

4.1.4 SOP-010, Rev. D – Product Risk Management

4.1.5 R-000326 Report, Human Factors Summative Usability Validation, 1c cNIBP

4.1.6 R-000340 Report, Software Risk Management, 1c cNIBP

4.2 External

4.2.1 ISO 14971: 2007

5.0 RISK MANAGEMENT ACTIVITIES

5.1 All SW Risk Management activities for this report were covered in the SW Risk Management Report R-000339-001.

5.2 The MMEA mitigations were tested as part of the human factors validation covered in report R-000326

6.0 RESULTS FROM HUMAN FACTORS REPORT

6.1 The Human Factors and Usability Reports (R-000326) show that the cNIBP design is safe and effective when used by the intended clinical user.

7.0 CONCLUSION

7.1 Based on the level of risk associated with the known remaining issues, the 1c cNIBP ViSi Mobile system is concluded to be safe for its intended use.

User Manual

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Information for servicing the ViSi Mobile Monitoring Systems is contained in the ViSi Mobile Monitoring System Technical Manual, Reference#: 95-10059 (hardcopy) / 95-10062 (CD). For additional information or assistance, please contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

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Information for servicing the ViSi Mobile Monitoring Systems is contained in the ViSi Mobile Monitoring System Technical Manual, Part Number: 6-000147. For additional information or assistance, please contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

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- Notes -

1. Preface

1.1 Introduction

This User Manual is intended to provide information for the proper operation of the Sotera Wireless ViSi Mobile Monitoring System™. A formal knowledge of patient monitoring and an understanding of the features and functions of the system are prerequisites for its proper use. This manual is written for trained clinicians. Although this manual describes guidelines for optimizing monitoring techniques, clinicians using this system should be trained to take and interpret patient vital signs. Automatic vital signs monitoring is an adjunct to clinical assessment; good clinical judgment should always prevail.

Do not operate the ViSi Mobile Monitoring System before reading these instructions.

1.2 Warnings, Cautions and Notes

Please read and adhere to all warnings, cautions and notes listed here and in the associated sections throughout this manual.

1.2.1 Definitions

Warning statements alert the user to conditions or practices that could result in injury to a person, or serious adverse events associated with the use or misuse of the ViSi Mobile Monitoring System.

Caution statements alert the user to conditions or practices that could result in problems with the ViSi Mobile Monitoring System associated with its use or misuse.

Note: Note statements provide supplemental information to the user.

Warnings

Intended Use

Do not use the ViSi Mobile Monitoring System outside the intended use described in this manual. Doing so can result in a delay in or inappropriate therapy.

Do not use the ViSi Mobile Monitoring System in neonatal or pediatric patients under the age of 12 years since the System has not been tested for these patient groups. *See page 119.*

Do not use the ViSi Mobile Monitor as a primary hypoxia diagnostic tool.

Safety

Do not use the ViSi Mobile Monitor in an MRI suite or a hyperbaric chamber.

The ViSi Mobile Monitoring System has not been tested in the presence of electro-surgical devices.

Avoid electrosurgery burns at the ECG monitoring sites by ensuring the electrosurgery-return circuit is connected properly.

Monitoring may be temporarily interrupted during the use of electrocautery in the vicinity of/or on a patient being monitored with a ViSi Mobile Monitoring System. Observe the patient closely while electrocautery is in use.

To ensure patient safety, use only components and accessories recommended or supplied by Sotera Wireless, Inc. *See 2.1Introduction on page 21* for a list of permitted components and accessories. Accessories must always be used in accordance with your facility's policies and the manufacturer's recommendations.

Use only the AC adapter recommended for the ViSi Mobile Charger. Use of other AC adapters may result in damage to the unit.

There may be a possible hazard caused by the summation of leakage currents when several items of equipment are interconnected.

The ViSi Mobile Monitoring System has not been tested in the presence of flammable anesthetics or other flammable agents in combination with air, nitrous oxide, or oxygen-enriched environments.

Route the patient cabling to avoid the possibility of patient entanglement or strangulation.

To ensure patient safety, the conductive parts of the ECG electrodes, including connectors and other patient-applied components, should not contact other conductive parts, or earth ground, at any time. *See page 55.*

Never connect the ViSi Mobile Chest Sensor Cable directly to the AC power outlet. *See page 55.*

Warnings

Never connect the ViSi Mobile Cuff Module directly to an AC power outlet. To recharge the battery, disconnect the Cuff Module from the patient, and then place it in the ViSi Mobile Charger. *See page 83.*

To prevent possible cross-contamination, properly clean and disinfect all reusable components between patients. *See pages 83 and 107.*

The ViSi Mobile Monitor should never be used to measure the NIBP of one patient while the Monitor is simultaneously connected to another patient. *See page 73.*

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is undergoing cardio-pulmonary bypass. *See page 73.*

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is being treated with an intra-aortic balloon pump or left ventricular assist device. *See page 73.*

Periodically observe the patient's arm for signs of impaired circulation, which may be a result of measurements made too frequently. Loosen or remove the ViSi Mobile Disposable Cuff if signs and/or symptoms of prolonged impaired circulation are evident. *See page 73.*

Never place the ViSi Mobile Monitor or the ViSi Mobile Cuff Module into the ViSi Mobile Charger while connected to a patient. *See page 83.*

Never connect the ViSi Mobile Monitor directly to an AC power outlet. To recharge the battery, disconnect the Monitor from the patient, and then place it in the ViSi Mobile Charger. *See page 83*

Do not clean the ViSi Mobile Monitor with detergents while worn by the patient. *See page 107.*

Do not place the ViSi Mobile Monitoring System on or over an implanted programmable medical device.

Disposable Patient Kit

All components of the ViSi Mobile Patient Kit are for single patient use only. To avoid possible cross contamination, do not reuse any of the items from the Patient Kit on a patient other than the original patient. Dispose of the ViSi Mobile Patient Kit items after use per your facility's policy. *See pages 23 and 50.*

All disposable components of the ViSi Mobile Monitoring System are for single patient use only. To avoid possible cross contamination, do not reuse any disposable items on a patient other than the original patient. *See page 62.*

Warnings

Patient Monitoring

Do not connect more than one ViSi Mobile Monitor to a patient.

Do not connect more than one patient to a single ViSi Mobile Monitor.

Patient Monitoring

The ViSi Mobile Monitor, Thumb Sensor, Cuff Module, and the Chest Sensor Cable must all be connected to the same arm for the System to function correctly. *See pages 50 and 52.*

The Wrist Strap should securely hold the ViSi Mobile Wrist Cradle in place without impairing circulation. Immediately loosen the Wrist Strap if the patient complains of pain, tingling, or numbness in the affected hand or wrist. *See page 51.*

Only use the ViSi Mobile Chest Sensor Cable provided by Sotera Wireless, Inc. for the ViSi Mobile Monitoring System. The Chest Sensor Cable is designed to provide defibrillation protection as indicated in the Specifications section of this manual. ViSi Mobile is designed to be compatible with the use of external defibrillators. *See pages 50 and 55.*

Only use the ViSi Mobile Thumb Sensor provided by Sotera Wireless, Inc. with the ViSi Mobile Monitoring System. *See page 50.*

The ViSi Mobile Thumb Sensor is intended for use on the patient's thumb only. Do not apply the Thumb Sensor to the patient's fingers. *See page 53.*

Inspect patient's skin at sensor site every 8 hours. If skin surface has been compromised, reposition the ViSi Mobile Thumb Sensor or move the Thumb Sensor to the patient's other thumb. *See page 54.*

The Thumb Strap should securely hold the ViSi Mobile Thumb Sensor in place without impairing circulation. Immediately loosen the Thumb Strap if the patient complains of pain, tingling, or numbness in the affected thumb. *See page 54.*

Only Sotera Wireless, Inc. supplied ViSi Mobile Thumb Sensors should be used. Using non-approved Thumb Sensors may result in inaccurate SpO2 readings. *See page 54.*

Before monitoring a new patient, ensure all the sensors have been removed and that monitoring was stopped using the Stop Monitoring procedure. *Se e 5.2.9Stop Monitoring on page 82.*

To prevent settings from being inadvertently changed, lock the ViSi Mobile Monitor screen (if enabled) as soon as tasks are completed. *See page 64.*

Warnings

Vital Signs

If a vital signs measurement is questionable, retake the measurement. If the result is still questionable, use a different method of measurement.

Chest Sensor Cable: ECG, Respiration, Temperature (Skin)

Use all of the same type of ECG electrodes on the patient. Mixing ECG electrode types can adversely affect ECG monitoring. *See page 55.*

If ECG electrodes need to be replaced, use all of the same type of ECG electrode on the patient. Mixing ECG electrode types can adversely affect ECG monitoring. *See page 101.*

Avoid placing the ViSi Mobile Cable Securement and ECG electrodes over areas of abrasions, irritation, or other sensitive areas. If possible, remove, reposition, and replace ECG electrodes and Cable Securement if the patient complains of pain/itching at the sites. *See page 58.*

The ViSi Mobile Monitor does not provide automated arrhythmia analysis. As a result, certain arrhythmias may cause the Monitor to display inaccurate heart rates. If frequent arrhythmias are suspected, their presence should be confirmed by another method, such as a 12-lead ECG or Holter monitoring. *See page 64.*

The ViSi Mobile Monitor does not have automated ST segment analysis, therefore, if a change in the ST segment of the ECG waveform is suspected, it should be confirmed by another method, such as a 12-lead ECG. *See page 64.*

Pacemaker signals can differ among pacemakers, ICDs, or CRT devices. The Association for the Advancement of Medical Instrumentation (AAMI) cautions: “In some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms”. All pacemaker patients should be kept under close or constant observation. *See page 50.*

External pacemakers or other external electrical stimulators may cause the ViSi Mobile Monitor to produce erroneous results. *See page 50.*

RESP (chest wall motion) can continue in the absence of ventilation (obstructed airway). Do not rely on the RESP alone to determine adequacy of ventilation. Other vital signs, such as HR and SpO_2, should be assessed as well. *See pages 38 and 64.*

TEMP monitoring with the ViSi Mobile Monitoring System is intended for trending purposes only and is not intended to replace core temperature monitoring. Before making clinical decisions based on the skin temperature measurement, verify the measurement using another clinically acceptable method of core temperature measurement. *See pages 38 and 64.*

Warnings

Impedance pneumography for the determination of respiration (RESP) is not recommended for use in the presence of mechanically induced, high frequency ventilation. *See page 64.*

Cuff Module / NIBP

ViSi Mobile Disposable Cuffs are for single patient use only. To avoid possible cross contamination, do not reuse a Cuff on a patient other than the original patient. *See page 60.*

The ViSi Mobile Disposable Cuff should be snug enough to support the Cuff Module while not impairing circulation when deflated. *See pages 60, 73 and 77.*

Avoid applying the ViSi Mobile Disposable Cuff over a wound as this can cause further injury. *See page 60.*

Avoid applying the ViSi Mobile Disposable Cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury to the patient. *See page 60.*

Take care in the application of the ViSi Mobile Disposable Cuff when applying the Cuff to an arm on the same side of a mastectomy. *See page 61.*

ViSi Mobile NIBP measurements have not been clinically tested in the presence of actual or ventricular arrhythmias. Use alternative BP methods if these arrythmias are present. *See page 61.*

Inflate the ViSi Mobile Disposable Cuff only after proper application to the patient's limb. *See page 61.*

If you are uncertain of the reliability of an NIBP measurement, repeat the measurement. If the reading is still suspect, use another method to measure the blood pressure. *See page 73.*

SpO_2

Oxygen saturation measurements using SpO_2 are dependent on proper sensor placement, exposure to ambient light conditions, and general patient conditions. Before making clinical decisions based on SpO_2 measurements, verify the measurement using another clinically acceptable method, such as arterial blood gas analysis. *See pages 38 and 64.*

High ambient light condition, including direct sunlight, may interfere with the performance of the ViSi Mobile Thumb Sensor. *See page 38.*

Low perfusion, electro-surgical devices, dysfunctional haemoglobin, the presence of certain dyes and inappropriate positioning of the ViSi Mobile Thumb Sensor may result in erroneous measurements. *See page 38.*

Warnings

Alarms / Alerts

A responsible clinician must be within audible range of the assigned patient wearing the ViSi Mobile Monitor at all times. *See page 85*.

When alarms are turned OFF, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarm limits are set to OFF. *See page 85.*

When alarms are paused, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarms are paused. *See page 88.*

Once new alarm limits are confirmed, they cannot be changed back to the original pre-set limits. Once Auto Set is selected, review the newly calculated alarm limits carefully before deciding to confirm or cancel the new alarm limits. *See page 89.*

Line isolation monitor transients may resemble actual cardiac waveforms and inhibit heart rate alarms. Ensure correct electrode placement and cable arrangement to minimize line isolation monitor transients. *See page 94.*

To avoid possible hearing damage, do not place your ear too close to the ViSi Mobile Monitor that is alarming audibly. *See page 95.*

When the ViSi Mobile Monitor alarms or alerts, check the patient first to confirm that there is no immediate danger to the patient. *See page 96.*

User Maintenance

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the ViSi Mobile Monitoring System components appropriately before disposing of them in accordance with your country's laws for equipment containing electrical and electronic parts. *See page 110.*

Cautions

Intended Use

Federal (U.S.A.) law restricts the ViSi Mobile Monitoring System to the sale, distribution, or use by, or on the order of a licensed medical practitioner.

The effectiveness of the ViSi Mobile Monitoring System's blood pressure monitoring has not been established in pregnant, including pre-eclamptic, patients.

Safety

The ViSi Mobile Monitoring System has not been tested in the presence of flammable anesthetics or other flammable agents in combination with air, nitrous oxide, or oxygen-enriched environments.

Do not use a ViSi Mobile Monitor, its components, or accessories that appear damaged. Inspect all reusable components for damage before each use.

Do not attempt to connect any patient worn component, ViSi Chest Sensor Cable or ViSi Mobile Cuff Module to an electrical outlet of any kind.

A component that has been dropped or severely abused should be checked by qualified service personnel before use on a patient.

The ViSi Mobile Monitoring System is not intended for home use.

Do not use the ViSi Mobile Monitoring System to monitor a patient in a wet environment, such as a shower.

Explosion Hazard. Do not use in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide. *See page 30.*

Use care when using automatic cuff inflation for prolonged periods on unconscious or semi-conscious patients since the patient may not be able to alert the clinician to any pain he/she may be experiencing. Pressing the "Stop NIBP" button interrupts the NIBP measurement and deflates the cuff. *See page 77.*

Consult your BioMed department or vendors for assistance in identifying EMC compliance status of other medical devices when using the ViSi Mobile Monitoring System. *See page 137.*

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment. *See page 137.*

Cautions

Service / Maintenance

If the ViSi Mobile Monitor detects an unrecoverable problem, an error message containing the error number is displayed. Remove the Monitor from use and report the error to Sotera Wireless, Inc.

When the ViSi Mobile Monitor is in the Charger and a charging alert occurs, remove the Monitor from service. *See page 32.*

General maintenance of the ViSi Mobile Monitoring System should be conducted at the prescribed intervals. *See 7.User Maintenance on page 107.*

The ViSi Mobile Monitoring System components should only be serviced by Sotera Wireless, Inc. technicians or authorized service providers. *See page 107.*

Equipment / Components

If the ViSi Mobile Monitor is to be stored for an extended period of time, it is recommended the Monitor be stored with the Shipping Plug inserted to reduce the battery discharge. The ViSi Mobile Monitor must always have the Shipping Plug inserted when shipped by a common carrier to comply with Federal Regulations regarding electromagnetic emissions. *See page 22.*

When inserting the ViSi Mobile Monitor into the Wrist Cradle, ensure proper alignment: flat end to flat end and the round end is pointing down towards the wrist. *See pages 25 and 52.*

Selection of the correct ViSi Mobile Disposable Cuff size is necessary to ensure accurate NIBP measurements. A Cuff that is too small can result in a falsely high NIBP measurement. A Cuff that is too large can result in a falsely low NIBP measurement. *See page 47.*

To avoid damage from dropping the ViSi Mobile Monitor, ensure that the Wrist Strap is snugly wrapped around the wrist. *See page 52.*

To avoid damage from dropping the ViSi Mobile Monitor, make sure that the Monitor is securely snapped into the ViSi Mobile Wrist Cradle. *See page 52.*

The ViSi Mobile Monitoring System does not support printing capability. *See page 64*.

The performance of the automated sphygmomanometer may be affected by extremes of temperature, humidity and altitude. *See page 74.*

The ViSi Mobile Monitor may not perform to specification if stored or shipped outside the specified temperature range. *See page 136.*

The ViSi Mobile Monitor may be temporarily interrupted by UHF RFID Systems (860-960MHz). *See page 140.*

Cautions

Cleaning / Disinfecting

Do not clean the ViSi Mobile Monitor while it is plugged into the ViSi Mobile Charger. *See page 107.*

Do not clean the ViSi Mobile Cuff Module while it is plugged into the ViSi Mobile Charger. *See page 108.*

Do not apply liquid to the ViSi Mobile Cuff Module. To clean, use a damp cloth. *See page 108.*

Ensure the sensor connector contacts are thoroughly dried to prevent possible malfunction. *See page 108.*

Thumb sensors which are saturated with fluid should be allowed to air dry thoroughly before re-use. *See page 108.*

Do not use abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components. *See page 109.*

Use only recommended cleaning / disinfecting agents to prevent damage to the device and components. *See page 109.*

Do not autoclave the ViSi Mobile Monitor, its components, or accessories. *See page 109.*

Do not use excessive amounts of liquid when cleaning the ViSi Mobile Chest Sensor Cable or the ViSi Mobile Thumb Sensor. *See page 109.*

After patient use, the disposables from the ViSi Patient Kit may contain bio-hazard materials. *See page 110.*

When the ViSi Mobile Cuff Module is connected to the other ViSi Mobile Components, the entire system has an ingress protection rating of IPX0. *See page 133.*

Notes

Note: Figures in this manual are provided for reference purposes only. Screens may differ based on the monitorin g device configuration , licen ses available, paramete rs se lected and patient configuration of the ViSi Mobile Monitoring System.

1.3 Description

The ViSi Mobile Monitoring System is a patient worn, portable, battery operated, stand-alone physiological monitoring device indicated for the monitoring of ECG (3 lead-wire or 5 lead-wire), Heart Rate (HR), Pulse Rate (PR), Respiration (RESP), Non-Invasive Blood Pressure (NIBP), Pulse Oximetry (SpO_2), and Skin Temperature (TEMP). The Monitor measures and displays patient vital signs, and generates alarms and alerts.

The industry-standard technique of oscillometry is used for non-invasively taking single measurements of the systolic and diastolic blood pressure (NIBP) as well as pulse rate. The method is based on the observation of oscillations in the sphygmomanometer cuff pressure that are caused by the oscillations of blood flow, i.e., the pulse in the patient's upper arm. It uses a sphygmomanometer cuff like the auscultatory method, but with an electronic pressure sensor (transducer) to observe cuff pressure oscillations, electronics to automatically interpret them, and automatic inflation and deflation of the Cuff. The Cuff Module measures on inflation. The measurement is realized by a Cuff, to which the Cuff Module is attached (pneumatic connection). The electric connection to the Monitor is established through a cable that connects to its upper side.

1.3.1 Intended Use

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 lead-wire), respiration rate (RESP), heart rate (HR), non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including general medical-surgical floors, intermediate-care floors, and emergency departments.

1.3.2 Contraindications

- Impedance pneumography for the determination of Respiration Rate (RESP) is not recommended for use in the presence of mechanically induced high frequency ventilation.
- The ViSi Mobile Monitoring System has not been tested for use on neonatal or pediatric patients under the age of 12 years.
- Do not use the same ViSi Mobile Monitor System to measure the NIBP of one patient while it is connected simultaneously to another patient.
- Do not use the ViSi Mobile Monitor on a patient with an Intra-Aortic Balloon Pump (IABP), or a Left Ventricular Assist Device (LVAD). The Monitor requires an unperturbed arterial pulse waveform for non-invasive blood pressure calculations. IABP and LVAD perturb the arterial pulse waveform.
- Do not use the ViSi Mobile Monitor System on a patient on cardio-pulmonary bypass.
- Do not use the ViSi Mobile Cuff Module on a patient's arm where the use of a blood pressure cuff is contraindicated.
- Do not use the ViSi Mobile Monitoring System in an MRI Suite.
- The effectiveness of the ViSi Mobile Monitoring System's blood pressure monitoring has not been established in the presence of any dysrhythmias.

- Notes -

2. General Description

2.1 Introduction

The ViSi Mobile Monitoring System is a lightweight portable patient vital signs monitor featuring a high resolution, full color display touchscreen with visual and audible alarms and alerts.

The System comprises the ViSi Mobile Monitor, Thumb Sensor, Chest Sensor Cable (either 3 lead-wire or 5 lead-wire), Cuff Module, Charger and Patient Kit.

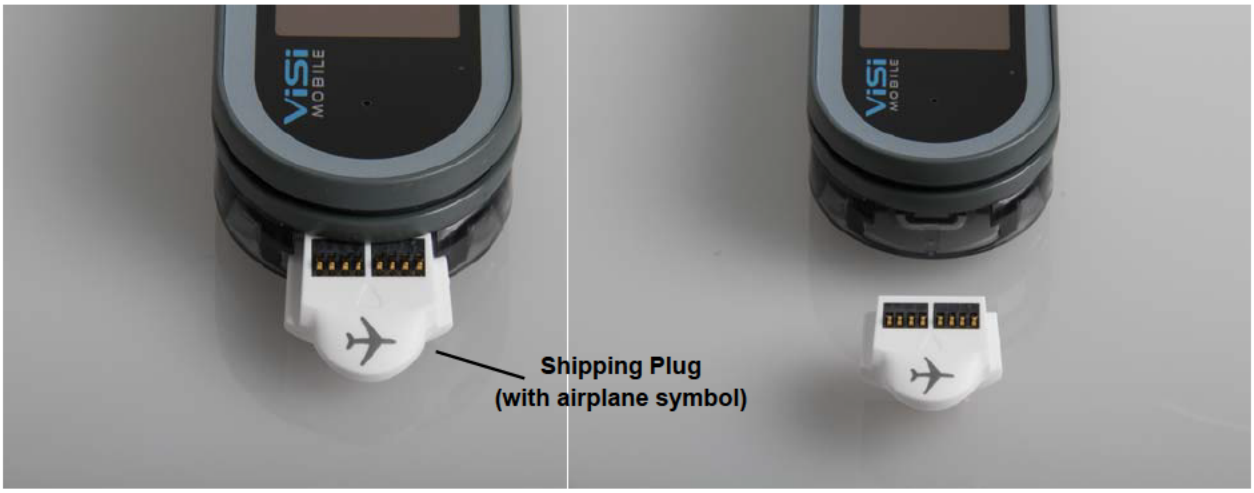
Powered by a rechargeable battery lasting at least 12 hours, the Monitor weighs approximately 125 grams. For ease of use, the Monitor features three interchangeable plug-in sites for the Chest Sensor Cable and Cuff Module.

2.2 Unpacking

Remove the Monitor and associated components from the shipping cartons and examine them for signs of shipping damage. Save all packing materials, invoice, and bill of lading. These may be required to process a claim with the carrier. Check all materials against the packing list. Contact the Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area for prompt assistance in resolving shipping problems.

2.2.1 Removing and Inserting the Shipping Plug

All Monitors are shipped in the Wrist Cradle with a Shipping Plug (airplane symbol) inserted. This Plug is found in the Thumb Sensor connector of the Monitor. The Shipping Plug's only function is to completely power off the Monitor. Reinserting the Plug into a Monitor powers down the Monitor in a controlled fashion, and allows internal operations to be completed before completely powering off.



To remove the Shipping Plug

Grasp the tip of the Plug that extends out from the Wrist Cradle and pull firmly outward.

The contact points are disconnected. The Monitor begins a power up phase and the initial information screen appears.

To insert the Shipping Plug

Ensure that the ViSi Mobile Monitor is properly seated in the Wrist Cradle, the Plug is oriented with the connector contacts facing upwards, and push in firmly.

The power down process begins. The power down cycle is complete once the screen goes blank and the green LED indicator has stopped blinking

If the ViSi Mobile Monitor is to be stored for an extended period of time, it is recommended the Monitor be stored with the Shipping Plug inserted to reduce the battery discharge. The ViSi Mobile Monitor must always have the Shipping Plug inserted when shipped on a common carrier to comply with Federal Regulations regarding electromagnetic emission.

2.3 System Components

2.3.1 ViSi Mobile Patient Kit

The Patient Kit contains the disposable components of the system. The Patient Kit components are for single patient use only. The Patient Kits are available in three Adult sizes: Small, Medium, and Large. Choose the Patient Kit that contains the Cuff size best suited for the patient. Cuff sizes follow standard range of arm circumference. *See 4.2.5Selecting the ViSi Mobile Patient Kit on page 47.*

All components of the ViSi Mobile Patient Kit are for single patient use only. To avoid possible cross contamination, do not reuse any of the items from the Patient Kit on a patient other than the original patient. Dispose of the ViSi Mobile Patient Kit items after use per your facility's policy.

ViSi Mobile Patient Kit Contents	
Equipment	**Quantity**
ViSi Mobile Disposable Cuff (with pneumatic connector)	1
ECG Electrode	6
ViSi Mobile Wrist Cradle	1
ViSi Mobile Thumb Cradle	1
ViSi Mobile Setup Guide	1
ViSi Mobile Cable Securement	2

ViSi Mobile Disposable Cuff

The Cuff is available in small, medium and large adult sizes (*see 4.2.5Selecting the ViSi Mobile Patient Kit on page 47*). The Cuff is used to take a NIBP measurement once the Cuff Module is plugged in. *See ViSi Mobile Cuff Module on page 28*.

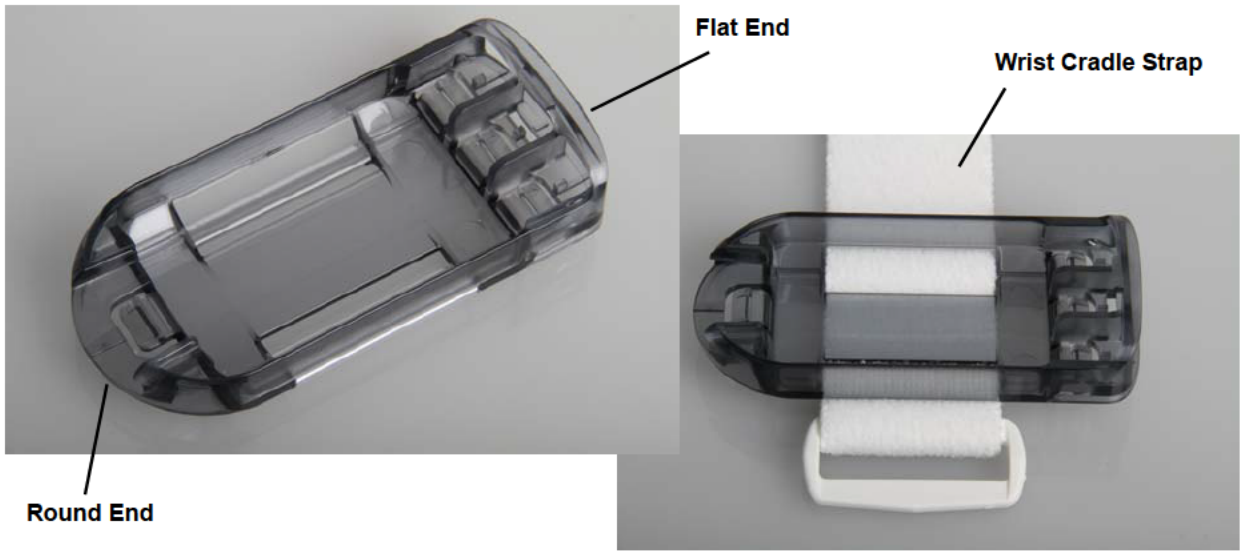
Note: Only cuffs designed for use with the ViSi Mobile Cuff Module may be used.

ECG Electrode

ECG Electrodes are adhesive pads with conductive gel that are connected to the ECG lead-wires of the Chest Sensor Cable to display the ECG waveform and detect the HR. Use only snap-on type electrodes.

ViSi Mobile Wrist Cradle

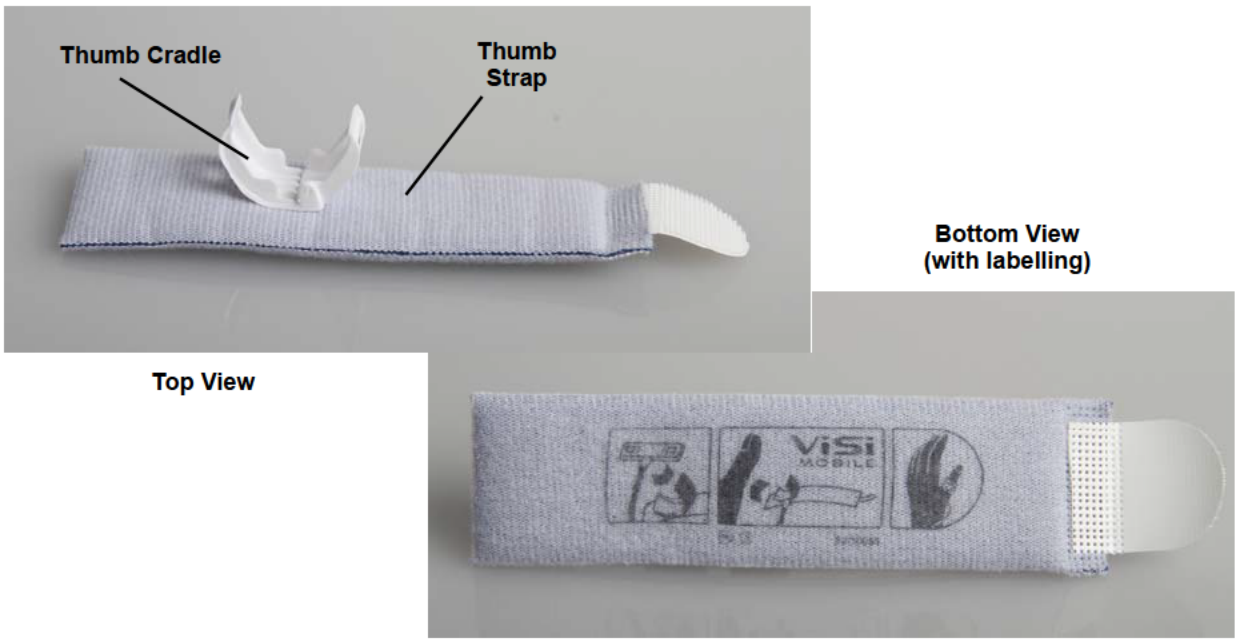
The Wrist Cradle holds the Monitor and provides the electrical connectors for the sensors. The Wrist Cradle is held in place on the patient's wrist with a strap. The Wrist Cradle Strap is available in small, medium and large adult sizes.



When inserting the ViSi Mobile Monitor into the Wrist Cradle, ensure proper alignment: flat end to flat end and the round end is pointing towards the wrist.

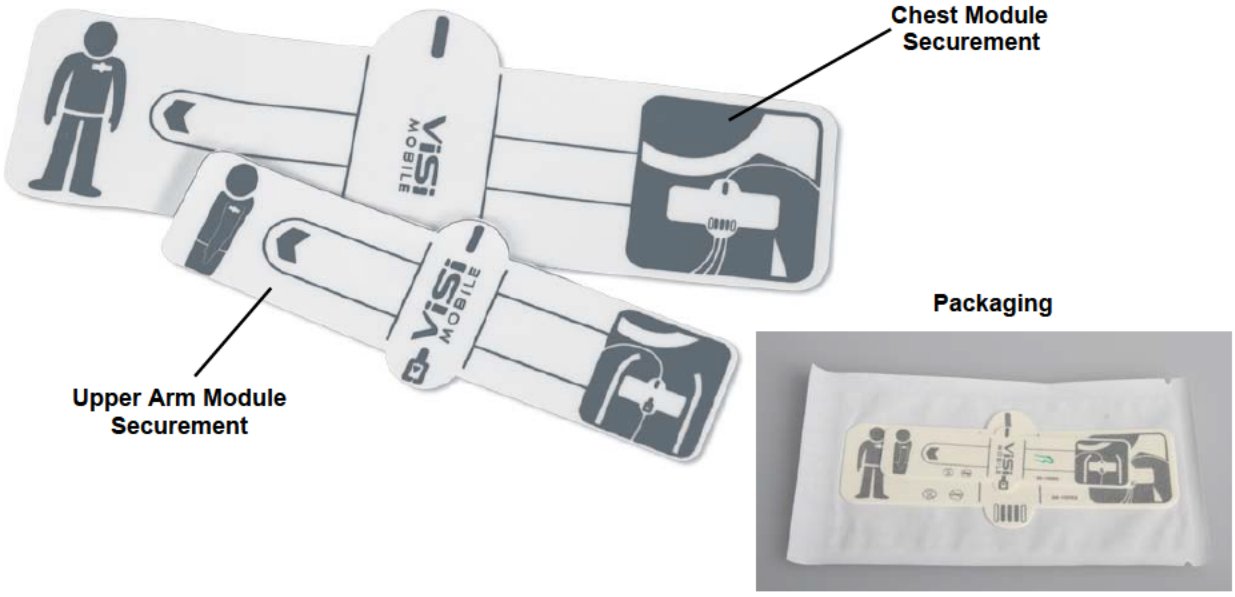
ViSi Mobile Thumb Cradle

The Thumb Cradle holds the Thumb Sensor and secures it to the base of the thumb.



ViSi Mobile Cable Securement

There is one large and one small Cable Securement in the Patient Kit. The large Cable Securement secures the Chest Module of the Chest Sensor Cable to the patient's torso. The small Cable Securement secures the Upper Arm Module of the Chest Sensor Cable to the upper arm. *See ViSi Mobile Chest Sensor Cable on page 29.*



2.3.2 ViSi Mobile Monitor

The Monitor is a compact and lightweight device that is worn on the patient's wrist. The Monitor is held in place by the Wrist Cradle, which allows sensors to be connected. The Monitor can be removed from the Wrist Cradle in order to charge, or swap for another Monitor. The Monitor uses a touchscreen user interface to access the displays and monitoring functions.

Note: The power indicator shows the level of Monitor's battery charge by flashing green (the battery has at least 2 hours of monitoring time left), yellow (the battery is low with less than 2 hours of monitoring time left), and red (the battery is critically low with less than 30 minutes of monitoring time left).

2.3.3 ViSi Mobile Thumb Sensor (SpO_2)

The Thumb Sensor is applied to the patient's thumb with the sensor and sensor cradle facing the patient's palm. The Thumb Sensor is plugged into the rounded end of the Wrist Cradle with the connector contacts facing upwards.

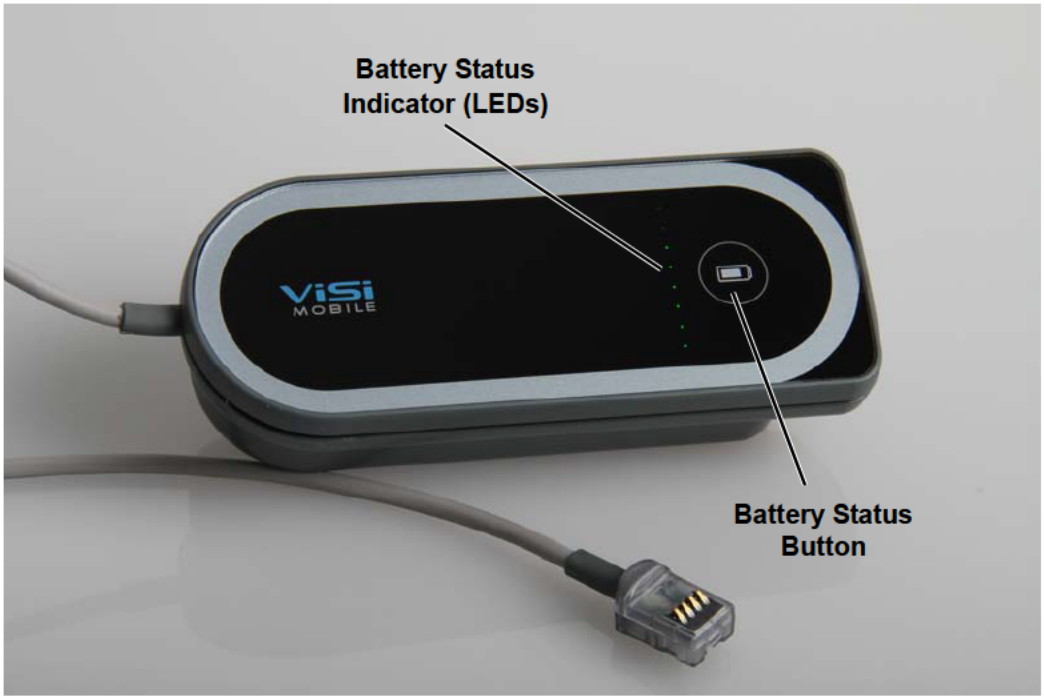
Insert with connector contacts facing upwards

Note: The Thumb Sensor locks the ViSi Mobile Monitor into the Wrist Cradle and must be unplugged to remove the Monitor from the Wrist Cradle.

Note: A Locking Plug should be used to lock the Monitor into the Wrist Cradle if the Thumb Sensor is not used. Locking Plugs may be ordered separately from Sotera Wireless.

2.3.4 ViSi Mobile Cuff Module

The Cuff Module is used to take NIBP measurements. The Cuff Module plugs into any one of the connectors on the flat end of the Wrist Cradle.



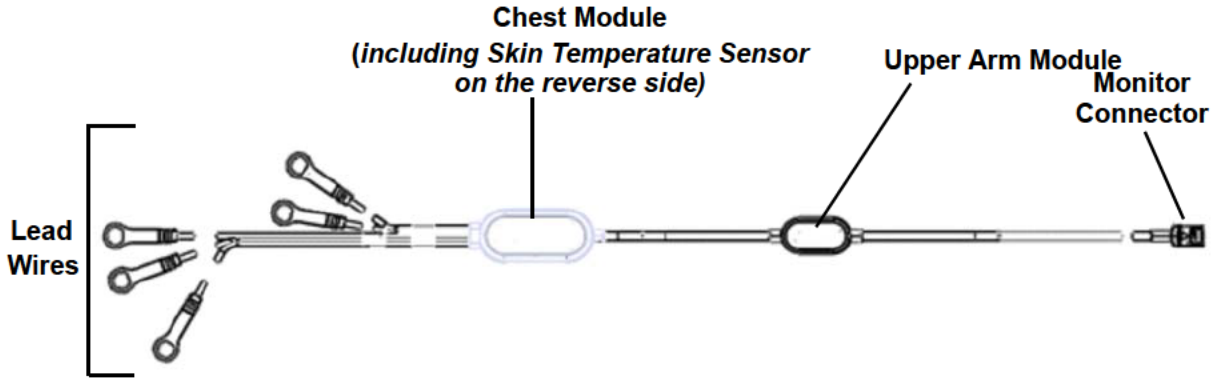
Note: When the battery status button is pressed, the battery status indicator shows the level of the Cuff Module's battery charge. Green lights indicate the battery has a minimum of 11% charge. More green lights indicate a greater charge level. A yellow light indicates the battery charge is less than 10%. A red light indicates there is less than 4% battery charge.

Note: When a calibration check is required, return the Cuff Module to the Bio Med. It is recommended a calibration check is performed ever year.

2.3.5 ViSi Mobile Chest Sensor Cable

The Chest Sensor Cable is either a 3 lead-wire or 5 lead-wire and plugs into any one of the connectors on the flat end of the Wrist Cradle. *See Applying the ViSi Mobile Chest Sensor Cable and ECG Electrodes on page 55 for recommended Chest Sensor Cable placement.*

The ViSi Mobile Chest Sensor Cable is designed to be fully compatible with external defibrillators. No additional precautions are required.



Chest Sensor Cable
5 Lead

Front View
(Place this side away from the patient's skin)

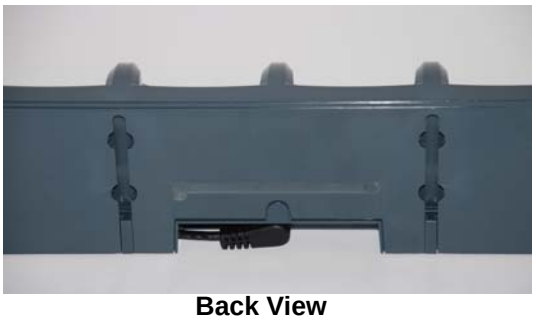
Chest Sensor Cable
3 Lead

2.3.6 ViSi Mobile Charger

The Charger is used to charge both Monitors and Cuff Modules, providing eight charging docks for simultaneously charging multiple units.

The Charger consists of a desktop/wall mount charger, power supply and power cable.

Front View



Back View

To set up the Charger

1. Connect the power cable to the back side of the desktop/wall mount charger.
2. Plug into the AC power outlet.

   The light on the front of the Charger will display green when the Charger is connected to the AC power outlet.

   The Charger will beep once when it is connected to the AC power outlet.

Note: When connected to the AC power outlet, if a fault with the ViSi Mobile Charger is detected, the Charger will audibly beep every second.

Explosion Hazard. Do not use in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.

2.3.7 Charging the ViSi Mobile Monitor and Cuff Module

The ViSi Mobile Charger provided by Sotera Wireless, Inc. is the required Charger for both the Monitor and the Cuff Module. The Charger is capable of charging up to eight of any combination of Monitors and Cuff Modules. To charge either the Monitor or the Cuff Module place the flat end into one of the slots with the front facing outwards.

Note: The ViSi Mobile Charger is to be used for ViSi Mobile components only.

Note: ViSi Mobile Monitors and Cuff Modules contain sealed batteries that are not replaceable by the user. If a Monitor or Cuff Module has a battery issue, contact the Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.

The LED on the Charger is used to indicate the charging status of devices that are currently inserted:

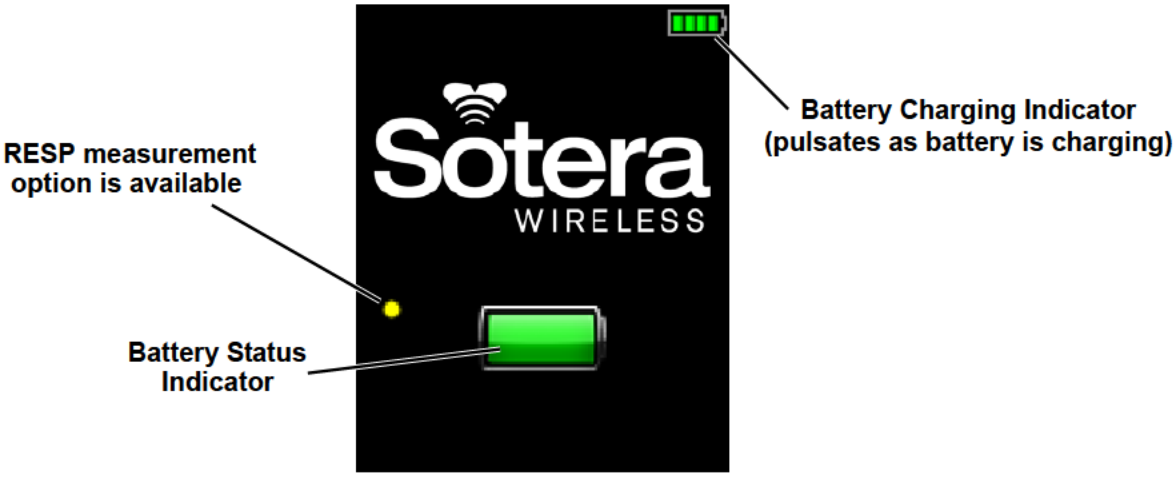
LED Color	Charging Status
Steady Green	Everything is normal: • No devices in the Charger. • All devices are charging normally or are fully charged.
Flashing Green / Yellow	At least one device in the Charger is in battery recovery mode with the device not talking to the Charger.
Steady Yellow	At least one device in the Charger is not being charged due to a fault with the device. The other devices are charging.
Steady Red	Charger fault. No devices are charging, the Charger has shutdown.

To charge a Monitor

Insert the Monitor that you want to charge into one of the Charger docks.

When the ViSi Mobile Monitor is in the Charger and a charging alert occurs, remove the Monitor from service.

The Charge Status screen will be displayed briefly. The Monitor's battery status indicator (in the top right hand of the screen) stops pulsating when the battery is fully charged



Note: When the yellow dot is displayed on the screen, it indicates the Monitor will measure RESP when a Chest Sensor is connected to a patient. RESP is not available as part of the default set of vital sign measurements and must be purchased separately.

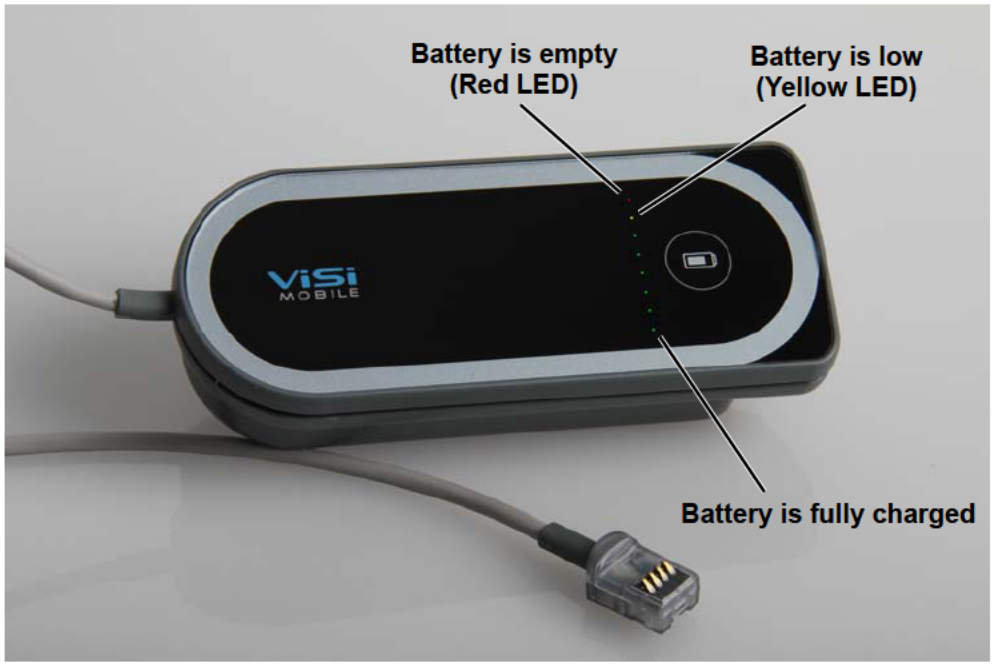
Note: If the screen is blank, touch the screen to activate the display and show the battery charge status.

The power indicator will blink while the Monitor is charging: green indicates there is enough charge to monitor a patient for at least two hours; yellow indicates the battery charge is low (less than two hours of monitoring); and red indicates the battery charge is critically low (less than 30 minutes of monitoring).

To charge a Cuff Module

Insert the Cuff Module that you want to charge into one of the Charger docks.

One of the charging indicator lights will blink while the Cuff Module is charging.



When one of the green charging indicators is flashing, the battery in the Cuff Module is charging. The position of the green charging indicator represents the level of charge. When the charge indicator furthest away from the red charging indicator is flashing, the Cuff Module is fully charged.

When the yellow charging indicator is flashing, the battery in the Cuff Module is low. No more than a couple of cuff inflations are possible.

When the red charging indicator is flashing, the battery in the Cuff Module is empty. No cuff inflations are possible.

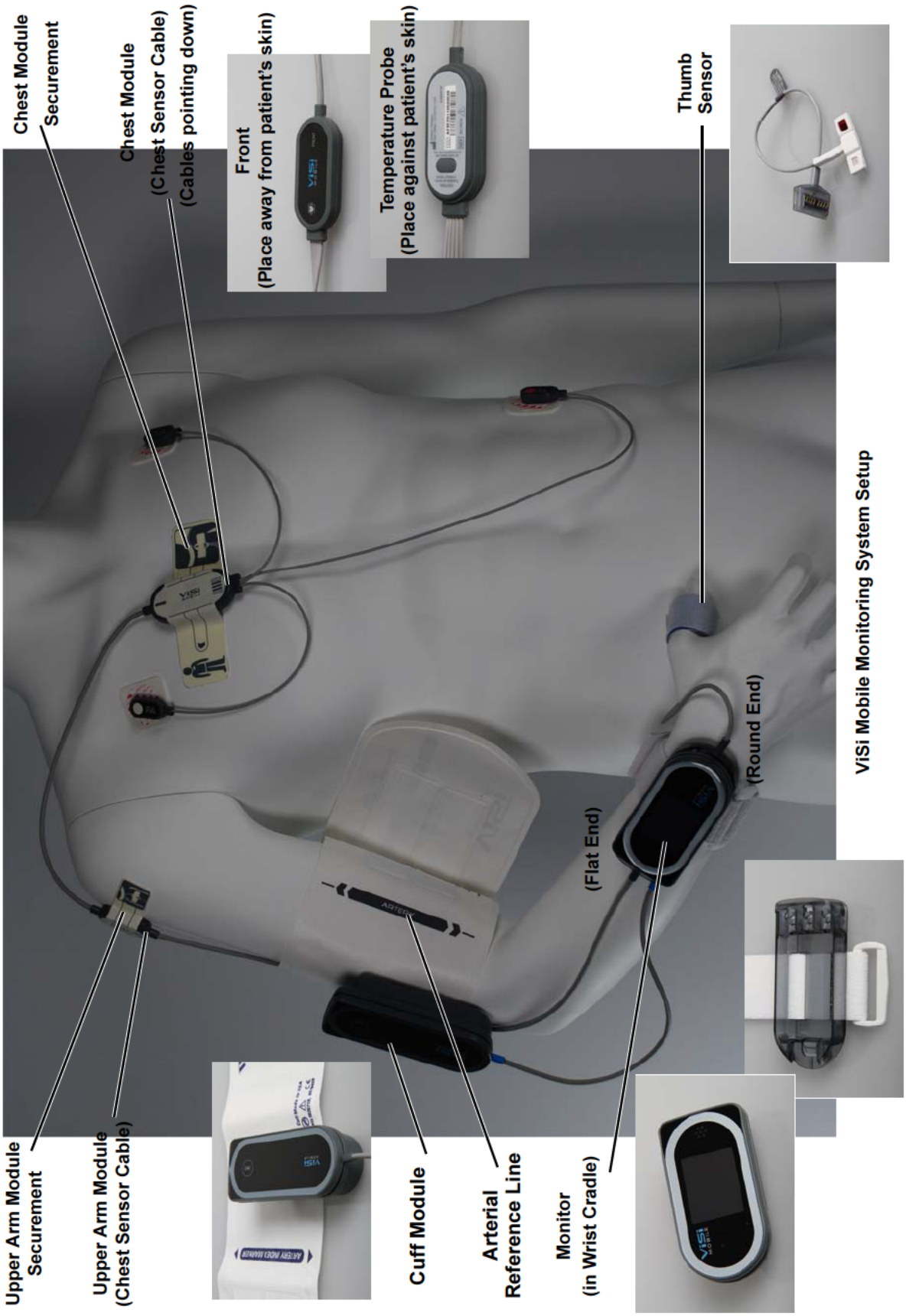
- Notes -

3. Clinical Features

3.1 Introduction

The ViSi Mobile Monitor is completely body-worn and designed to continuously measure ECG/HR, SpO_2, PR, RESP, and TEMP. The ECG, SpO_2, and RESP waveforms are viewable on demand. NIBP can be measured as a one-time measurement, or it can be measured automatically at predefined intervals.

The Chest Sensor Cable measures the ECG/HR, RESP, and TEMP. The illustration on the next page shows a 3 lead-wire placement.



ViSi Mobile Monitoring System Setup

3.2 Key Features

- Battery life > 12 hours
- Full charge reached after approximately 2 hours of charging
- Chest Sensor Cable options: 3 lead-wire and 5 lead-wire (HR and ECG waveforms)
- RESP (measurement and waveform)
- SpO_2% (measurement and waveform)
- TEMP ($^oC/^oF$) (Skin Temperature measurement)
- NIBP (single measurement and automatic measurements at predefined cycles)
- Touchscreen display
- Alarms and Alerts generated with visual and audible indication on the Monitor
- Self Test

3.3 Overview of Clinical Features

The ViSi Mobile Monitoring System is a lightweight portable patient vital signs monitor featuring a high resolution, full color display with visual and audible alarms and alerts. The ViSi Mobile Monitor is completely body-worn and designed to continuously measure ECG/HR, SpO_2, PR, RESP, and TEMP. ECG, SpO_2, and RESP waveforms are viewable on demand. NIBP can be measured as a one-time measurement, or it can be measured automatically at programmed intervals.

The Monitor is powered by a rechargeable battery. For ease of use, the Monitor features interchangeable plug-in sites for the ViSi Mobile Chest Sensor Cable and ViSi Mobile Cuff Module. The Chest Sensor Cable measures the ECG/HR (with a 3 lead-wire or 5 lead-wire), RESP, and TEMP.

3.3.1 ECG Monitoring and Heart Rate (HR) Monitoring

With the 3 lead-wire Chest Sensor Cable, the Monitor continuously monitors Lead II.

With the 5 lead-wire Chest Sensor Cable, the Monitor continuously monitors seven ECG lead views simultaneously, Leads I, II, III, aVR, aVL, aVF, and a V lead. The ECG waveform can be displayed one lead at a time.

The ability to monitor multiple leads simultaneously improves beat detection to determine the HR and minimizes false detections as a result of muscle artifact.

3.3.2 Respiration Rate (RESP) Monitoring

RESP is determined by measuring the AC impedance between the RA and LL ECG electrodes. Chest wall motion, rise and fall, associated with inspiration and expiration is automatically detected when the RA and LL leads are placed in the standard Lead II configuration on the chest, or in the MCL configuration.

RESP is determined from the frequency of the respiration (chest wall motion). The respiration channel can detect the absence of RESP.

RESP (chest wall motion) can continue in the absence of ventilation (obstructed airway). Do not rely on the RESP alone to determine adequacy of ventilation; other vital signs such as HR and SpO_2 should be assessed as well.

Note: Respiration rate monitoring is an optional feature that requires an additional license key.

3.3.3 Skin Temperature (TEMP) Monitoring

TEMP is continuously measured skin surface temperature as measured by the probe located on the underside of the Chest Module. The probe must be placed directly in contact with the patient's skin. TEMP can be displayed in °C or °F. *See To apply the Chest Sensor Cable on page 58.*

Note: Skin temperature may not be the same as core body temperature or temperature measured from oral or tympanic methods.

Note: Skin temperatur e r epresentative of skin surface temperatur e will take appr oximately 6 minutes from the time the Chest Module is applied.

TEMP monitoring with the ViSi Mobile Monitoring System is intended for trending purposes only and is not intended to replace core temperature monitoring. Before implementing therapy based on the skin temperature measurement, verify the measurement using another clinically acceptable method of core temperature measurement.

3.3.4 Pulse Oximetry (SpO_2 and Pulse Rate) Monitoring

The Pulse Oximetry channel non-invasively continuously measures the functional oxygen saturation of the hemoglobin in arterial blood using the transmittance across the base of the thumb. A pulsatile arterial source at the base of the thumb is required to measure the SpO_2.

In the absence of a HR source from an ECG, the Pulse Rate (PR) can be measured and displayed from the SpO_2 channel.

Oxygen saturation measurements using SpO_2 are dependent on proper sensor placement, exposure to ambient light conditions, and general patient conditions. Before making clinical decisions based on SpO_2 measurements, verify the measurement using another clinically acceptable method, such as arterial blood gas analysis.

High ambient light condition, including direct sunlight, may interfere with the performance of the ViSi Mobile Thumb Sensor.

Low perfusion, electro-surgical devices, dysfunctional haemoglobin, the presence of certain dyes and inappropriate positioning of the ViSi Mobile Thumb Sensor may result in erroneous measurements.

3.3.5 NIBP Monitoring

The ViSi Mobile Cuff Module is intended for measuring arterial blood pressure (systolic and diastolic) using a Cuff. Measurements may be initiated manually (one at a time), or automatically at selectable predefined intervals of 5, 10, 15, 30, 60, 90 and 120 minutes.

The accuracy of NIBP measurements is influenced by several factors:

- Correct cuff size
- Correct cuff placement on the arm
- The position of the upper arm in relation to the heart at the time of the measurement
- Motion artifacts

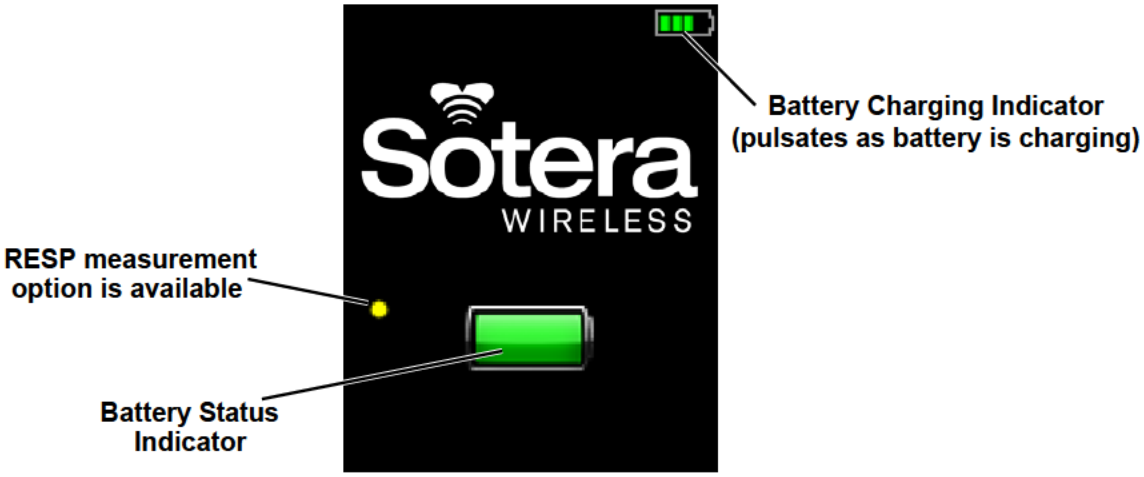
Note: To measure continuous non-invasive blood pressure (cNIBP), the Cuff Module is only required for the initial inflation to calibrate the Pulse Arrival Time (PAT).

3.4 Display Screens

This section describes various screens displayed on the ViSi Mobile Monitor. Each screen is accessed by interacting with the touchscreen display.

3.4.1 Battery Charge Screen

The **Battery Charge** screen displays the battery status while the Monitor is charging in the Charger.



Note: When the yellow dot is displayed on the screen, it indicates the Monitor will measure RESP when a Chest Sensor is connected to a patient. RESP is not available as part of the default set of vital sign measurements and must be purchased separately.

3.4.2 Hibernation Screen

The **Hibernation** screen (blank screen) is the default when no monitoring is currently in progress.

The **Hibernation** screen conserves battery power under the following conditions:

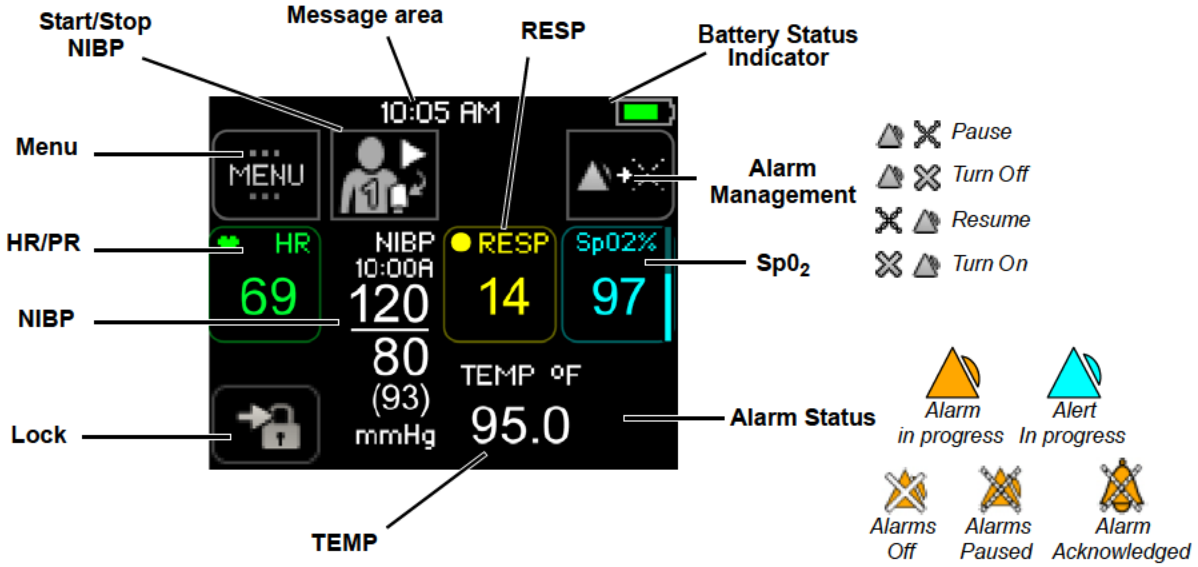
- The Shipping Plug is not plugged into the Monitor
- The Monitor is not in the Charger
- No sensors are connected to the Monitor

Note: When in Hibernation, the power indicator blinks approximately every 9 seconds. The power indicator color is reflective of the battery status: "Green" indicates there is sufficient battery charge for at least two hours of monitoring; "Yellow" indicates the battery charge is depleted and there is less than 2 hours of monitoring available; and "Red" indicates the battery charge is depleted and there is less than 30 minutes of monitoring available. When the power indicator stops blinking, the battery charge is empty.

Note: Connecting a sensor to the Monitor displays the Vital Sign screen. There will be a brief delay before the Vital Sign screen is displayed to allow the Monitor's self test to complete.

3.4.3 Vital Signs Screen

The **Vital Signs** screen is the default screen that displays automatically (on initial setup) when sensors are placed on the patient and connected to the Monitor.



Use the **Vital Signs** screen to:

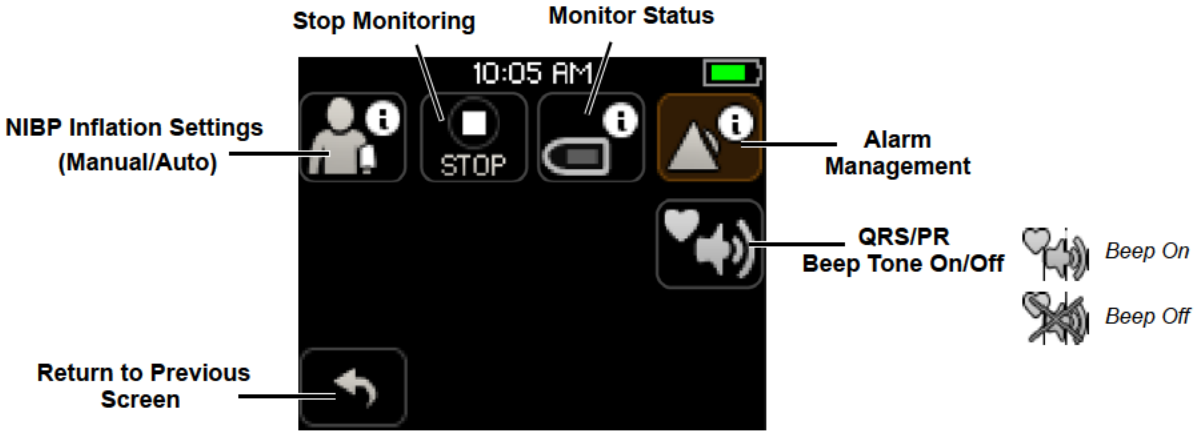
- View current vital sign measurements
- Vital Signs Measurement: Access the waveforms *(see page 68)*
- Alarm Status: View alarm status
- Battery Status Indicator: View the battery status
- Menu: Access the Menu screen *(see page 42)*
- Start/Stop NIBP: Start and stop manual NIBP measurement *(see page 73)*
- Alarm Management: Pause alarms/alerts *(see page 88)*
- Alarm Management: Acknowledge (silence) alarms/alerts *(see page 97)*
- Lock: Lock the Monitor to prevent unauthorized access

Note: A respiration measurement will not be displayed until 60 seconds has elapsed since the time the ECG leads were connected to the patient and 6 breaths have been identified.

Note: Systolic, diastolic and MAP measurements will be displayed in red when measuring NIBP continuously (cNIBP).

3.4.4 Menu Screen

Touch **Menu** on the **Vital Sign** screen to view the **Menu** screen.

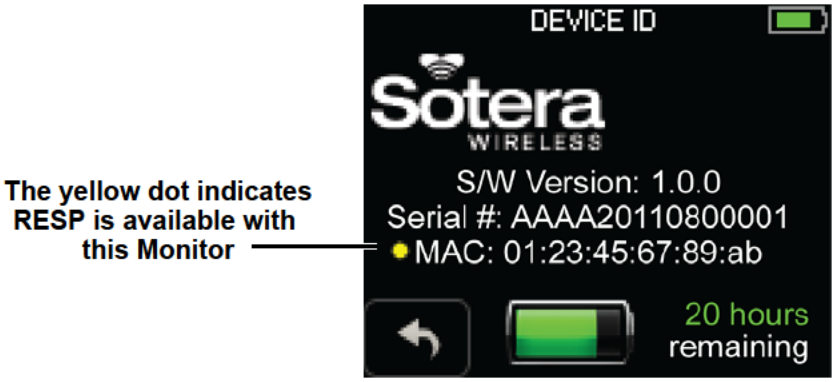


Use the **Menu** screen to:

- Change the NIBP measurements from Manual to Auto and set auto inflation interval *(see page 77)*
- Stop monitoring *(see page 82)*
- View Monitor status *(see page 42)*
- View and change the alarm limits settings *(see page 89)*
- Silence or enable the HR / PR beep tone

3.4.5 Monitor Status Screen

Touch **Monitor Status** on the **Menu** screen to access the **Monitor Status** screen.



Use the **Monitor Status** screen to:

- View the battery status

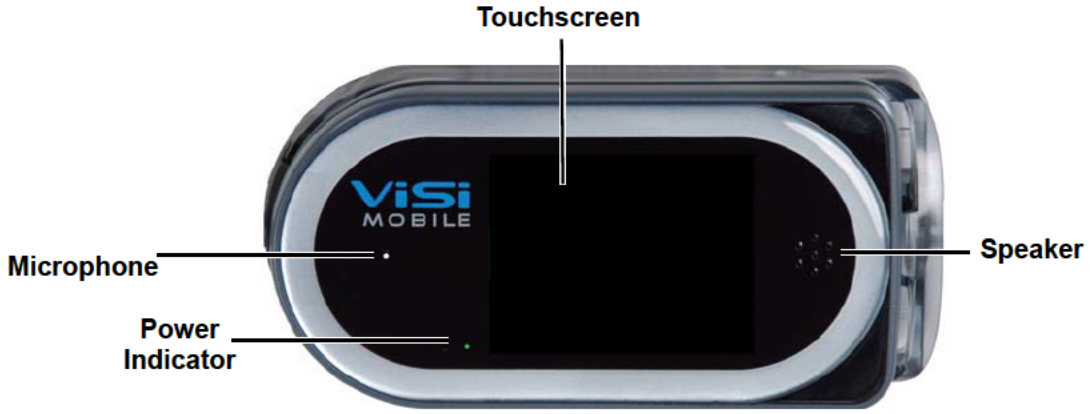
- View the version of Monitor's software
- View the Monitor's serial number
- View the Monitor's MAC address
- View features that are available, such as RESP

3.4.6 Quiet Monitoring Screen

The **Quiet Monitoring** screen (blank screen) is the default when sensors are connected both to the Monitor and the patient and no user interaction has occurred for a predefined period of time. Continuous monitoring is in progress during this time.

Note: After a predefined period of no direct interaction with the Monitor, the Monitor locks automatically and enters Quiet Monitoring.

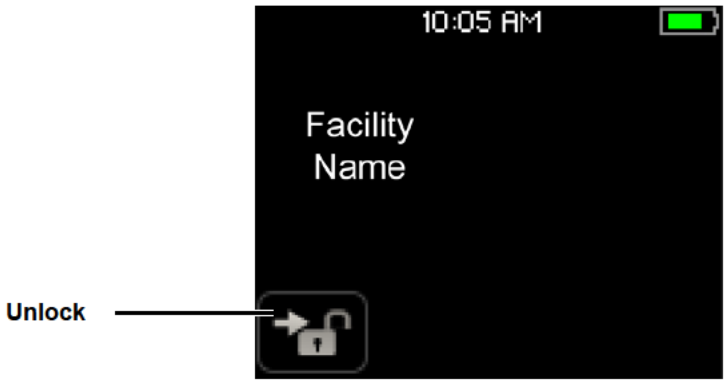
The **Quiet Monitoring** Screen conserves battery power and minimizes patient disturbance. Vital signs alarms and alerts remain active. Touching the screen continuously for 2 seconds resumes the Monitor's display with the **Patient View** screen.



Note: When in Quiet Monitoring, the power indicator blinks approximately every 3 seconds. The power indicator color is reflective of the battery status: "Green" indicates there is sufficient battery charge for at least two hours of monitoring; "Yellow" indicates the battery charge is depleted and there is less than 2 hours of monitoring available; and "Red" indicates the battery charge is depleted and there is less than 30 minutes of monitoring available. When the power indicator stops blinking, the battery charge is empty.

3.4.7 Patient View Screen

The **Patient View** screen appears whenever the touchscreen is touched continuously for 2 seconds during **Quiet Monitoring**.



Use the **Patient View** screen to:

- View the current time
- View battery charge level
- Unlock the Monitor

4. Operation

4.1 Introduction

The ViSi Mobile Monitoring System is a sophisticated multi-parameter vital signs monitor. In order to optimize the user of ViSi, please adhere to the following instructions related to patient set-up, initiating monitoring and the removal of the System.

4.2 Preparing for a New Patient

In order to set up the complete ViSi Mobile Monitoring System, you will need the following components:

- ViSi Mobile Patient Kit (select size)
- ViSi Mobile Monitor
- ViSi Mobile Cuff Module
- ViSi Mobile Thumb Sensor
- ViSi Mobile Chest Sensor Cable (3 lead-wire or 5 lead-wire configuration)

Note: Skin preparation equipment (skin preparation pads, scissors and/or razor as needed) not included.

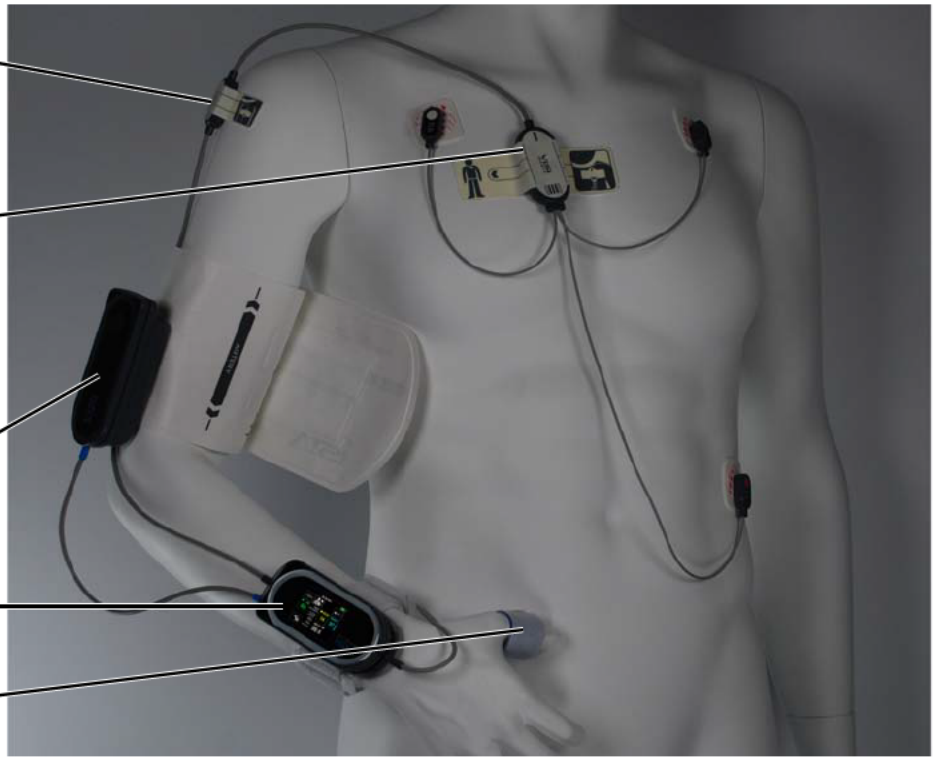
4.2.1 Inspecting the Equipment and Accessories

Before starting patient monitoring, you should visually inspect the ViSi Mobile Monitoring System components:

1. For each component, examine the exteriors for cleanliness and general physical conditions. Ensure the housings are not cracked or broken, that everything is present, there are no spilled liquids and no signs of abuse.
2. Inspect all component cables for damage. Check their strain relief for general condition. Ensure there are no breaks in the insulation. If any cables show signs of damage, do not use.
3. Inspect all disposable accessories (Wrist Cradle, Cuff, Thumb Strap, Securements, etc). If any show signs of damage or pre-use, do not use.

4.2.2 Applying Sensors

Applying the sensors is simple and may be done in any order. At the completion of the setup, the components of the ViSi Mobile Monitoring System will be connected to the patient as shown in the diagram below.



Whenever a sensor is connected to the Monitor, a self-test of that sensor is initiated automatically to verify the sensor is in good working order. If the sensor and Monitor speaker are in good working order, you will hear a double beep. This process takes a few seconds, after which monitoring of the selected vital sign commences as soon as the sensor is connected to the patient.

The double beep is also a validation that the Monitor speaker is in good working order and that audio tones associated with alarms will be annunciated accordingly.

Alarm limits are set automatically according to default settings. *See 6.Alarms and Alerts on page 85.*

Successful vital signs monitoring is dependent on several factors:

- Determining the vital signs to be monitored
- Selecting a Monitor and Cuff Module that are adequately charged for maximum duration of uninterrupted monitoring
- Selecting the 3 lead-wire or 5 lead-wire Chest Sensor Cable
- Selecting the appropriately sized Cuff (from the Patient Kit)
- Preparing the skin for ECG electrode placement
- Correctly applying all sensors used for monitoring

Note: The battery in the Monitor will deplete at a faster rate when sensors are connected to the Monitor, even when monitoring has not been started.

Note: The Chest Module includes a body surface temperature probe. To ensure proper function, place the temperature sensor on the body with the Chest Module "Front" label facing forward (away from the patient's skin).

4.2.3 Selecting Vital Signs to Monitor

The following vital signs may be monitored:

- ECG (one or seven simultaneous leads, using the 3 lead-wire or 5 lead-wire Chest Sensor Cable respectively)
  - ↳ HR (from the ECG)
  - ↳ RESP (optional)
  - ↳ TEMP (Skin Temperature)
- SpO_2
  - ↳ PR (from the Thumb Sensor)
- NIBP
  - ↳ SYS
  - ↳ DIA
  - ↳ MAP
  - ↳ PR (from NIBP)

4.2.4 Selecting the ViSi Mobile Chest Sensor Cable

The Chest Sensor Cable provides the sensors to monitor the ECG, HR, RESP (optional), and TEMP.

Note: The skin surface temperature probe is on the underside of the Chest Module. It must be placed on the skin surface in order to properly measure skin surface temperature.

Select the Chest Sensor Cable that best suits the monitoring needs of your patient:

- The 3 lead-wire Chest Sensor Cable monitors Lead II, or the MCL configuration.
- The 5 lead-wire Chest Sensor Cable monitors seven leads of ECG simultaneously in lead configurations I, II, III, aVR, aVL, aVF, and a V lead. The specific V lead depends on the placement of the V electrode.

4.2.5 Selecting the ViSi Mobile Patient Kit

The System's disposable components, including the Cuff are contained in the Patient Kit. The Patient Kits are designated as S, M, and L based on the Cuff size.

Selection of the correct ViSi Mobile Disposable Cuff size is necessary to ensure accurate NIBP measurements. A Cuff that is too small can result in a falsely high NIBP measurement. A Cuff that is too large can result in a falsely low NIBP measurement.

Cuff / Patient Kit Size	Arm Circumference (cm)
Adult S	20 – 26
Adult M	25 – 34
Adult L	32 – 43

4.2.6 Checking the Battery Charge of the ViSi Mobile Monitor and Cuff Module

Before you start to monitor your patient with the System, you will need to select both a Monitor and a Cuff Module that are adequately charged for maximum duration of uninterrupted monitoring.

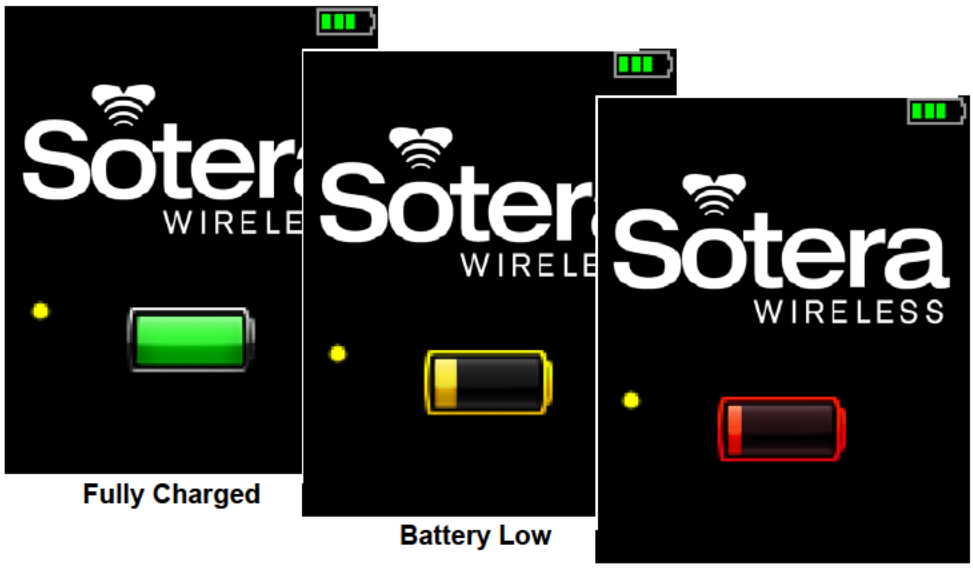
To check the battery charge of the Monitor

1. Turn on the display by touching the screen while the Monitor is in the Charger.
2. Verify that the large battery icon in the center of the screen is green.

A full green battery symbol indicates that the battery is fully charged. A partially green battery symbol indicates the degree to which the battery is charged. The full monitoring period will not be achieved unless the battery is fully charged

A yellow battery symbol indicates the battery is low with less than 2 hours of monitoring time left.

A red battery symbol indicates the battery is critically low with less than 30 minutes of monitoring time left.



Fully Charged

Battery Low

Battery Critically Low

To check the battery charge of the Cuff Module

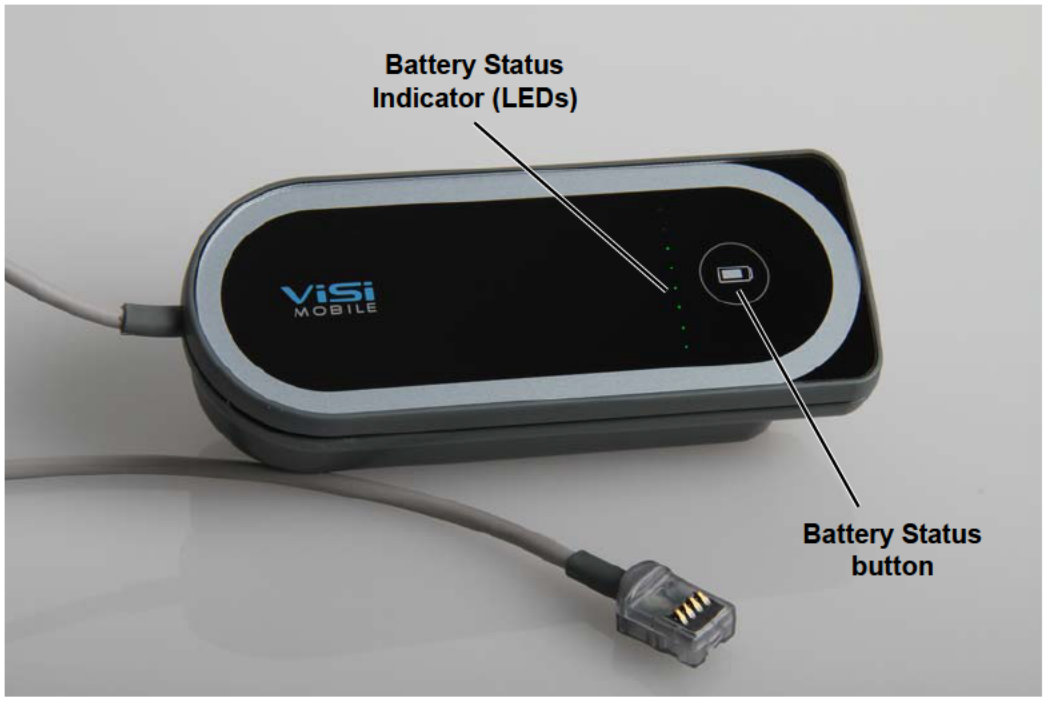
Press **Battery Status** button on the front of the Cuff Module.

There is a row of eight colored lights on the front surface of the Cuff Module.

Illuminated green lights indicate that the level of the battery charge is adequate for at least several NIBP measurements. When six illuminated green lights are visible on the Cuff Module, the Module is fully charged.

When the yellow light is illuminated, the battery charge is low. At least one NIBP measurement is possible.

When the red light is illuminated, the battery charge is too low for any further NIBP measurements.



4.3 Applying ViSi Mobile Monitoring System / Initiate Monitoring

The ViSi Mobile Monitor may be used to monitor one vital sign, such as SpO_2, or multiple vital signs simultaneously. Apply the appropriate sensor for each vital sign to be monitored, as described below. Start by selecting the appropriately sized Patient Kit (S, M, L).

The Monitor's ECG channel is capable of monitoring patients with an Implanted Pacemaker (PM), Implantable Cardioverter-Defibrillator (ICD), or Cardiac Resynchronization Therapy (CRT) device. A vertical dashed line before the *P* wave (atrial pace), and before the *QRS* (ventricular pace) indicate paced events. In the case of biventricular pacing (CRT), two vertical dashed lines occur before the QRS.

Note: Stimulus pulses from a pacemaker, as indicated by the vertical dashed lines, are not counted as heartbeats, as de fined by the pacer pulse r ejection specification. *See 9.Specifications on page 119.*

Pacemaker signals can differ among pacemakers, ICDs, or CRT devices. The Association for the Advancement of Medical Instrumentation (AAMI) cautions: "In some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms". All pacemaker patients should be kept under close or constant observation.

External pacemakers or other external electrical stimulators may cause the ViSi Mobile Monitor to produce erroneous results.

Only use the ViSi Mobile Chest Sensor Cable provided by Sotera Wireless, Inc. with the ViSi Mobile Monitoring System. The Chest Sensor Cable is designed to provide defibrillation protection as indicated in the *Specifications* section of this manual. ViSi Mobile is designed to be compatible with the use of external defibrillators.

Only use the ViSi Mobile Thumb Sensor provided by Sotera Wireless, Inc. with the ViSi Mobile Monitoring System.

All components of the ViSi Mobile Patient Kit are for single patient use only. To avoid possible cross contamination, do not reuse any of the items from the Patient Kit on a patient other than the original patient. Dispose of the ViSi Mobile Patient Kit items after use per your facility's policy.

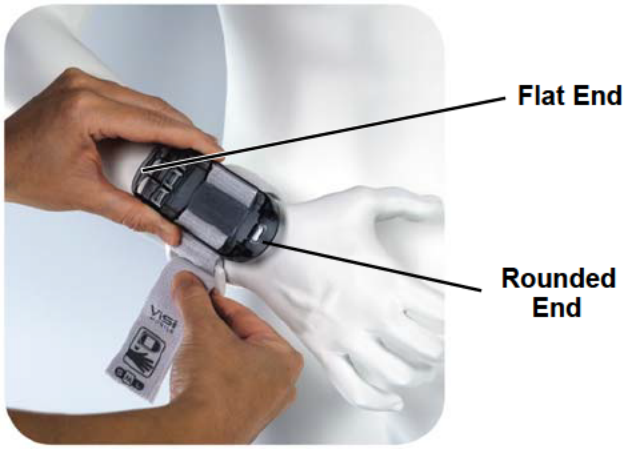
The ViSi Mobile Monitor, Thumb Sensor, Cuff Module, and the Chest Sensor Cable must all be connected to the same arm for the System to function correctly.

4.3.1 Applying the ViSi Mobile Wrist Cradle

If there are no contraindications, for patient comfort, apply the Wrist Cradle to the patient's wrist (either left or right).

To apply the Wrist Cradle

1. Remove the Wrist Cradle from the Patient Kit.
2. Orient the Wrist Cradle with the flat end pointed towards the elbow, slide the patient's hand through the Wrist Strap and position the cradle on the top side of the wrist.
3. Pull snugly and secure.

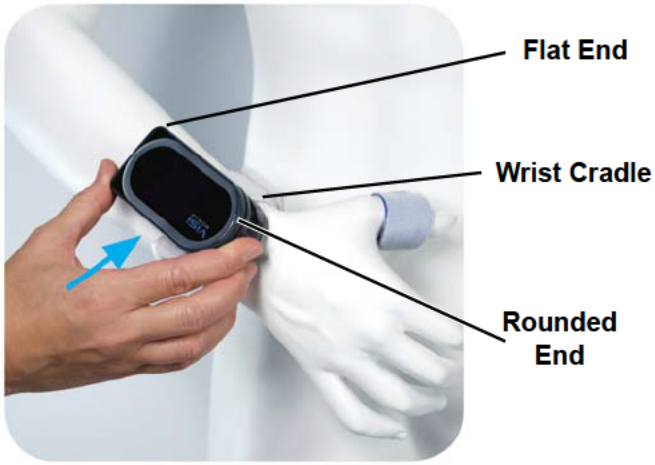


The Wrist Strap should securely hold the ViSi Mobile Wrist Cradle in place without impairing circulation. Immediately loosen the Wrist Strap if the patient complains of pain, tingling, or numbness in the affected hand or wrist.

4. Placing the flat end in first, insert the Monitor into the Wrist Cradle and push down.

   When the Monitor is pushed down all the way, you will hear a "clicking" sound.

Note: The Monitor is not completely secur ed within the W rist Cradle un til the Thu mb Sensor or Locking Plug is inserted into the connector on the rounded end of the Monitor.



When inserting the ViSi Mobile Monitor into the Wrist Cradle, ensure proper alignment: flat end to flat end and the round end is pointing down towards the wrist.

To avoid damage from dropping the ViSi Mobile Monitor, ensure that the Wrist Strap is snugly wrapped around the wrist.

To avoid damage from dropping the ViSi Mobile Monitor, make sure that the Monitor is securely snapped into the ViSi Mobile Wrist Cradle.

5. If you are not performing SpO_2 monitoring, secure the Monitor to the cradle by inserting a Locking Plug into the opening on the rounded end of the Monitor.

Locking Plug

4.3.2 Applying Sensors

The ViSi Mobile Monitor, Thumb Sensor, Cuff Module, and the Chest Sensor Cable must all be connected to the same arm for the System to function correctly.

Vital signs monitoring starts automatically as soon as a sensor is connected to the Monitor and attached to the patient. When performing a patient setup, the alarms pause automatically, allowing you to complete the setup before the alarms are turned on.

Sensors are designed to securely plug into the Monitor so that they cannot fall out unintentionally.

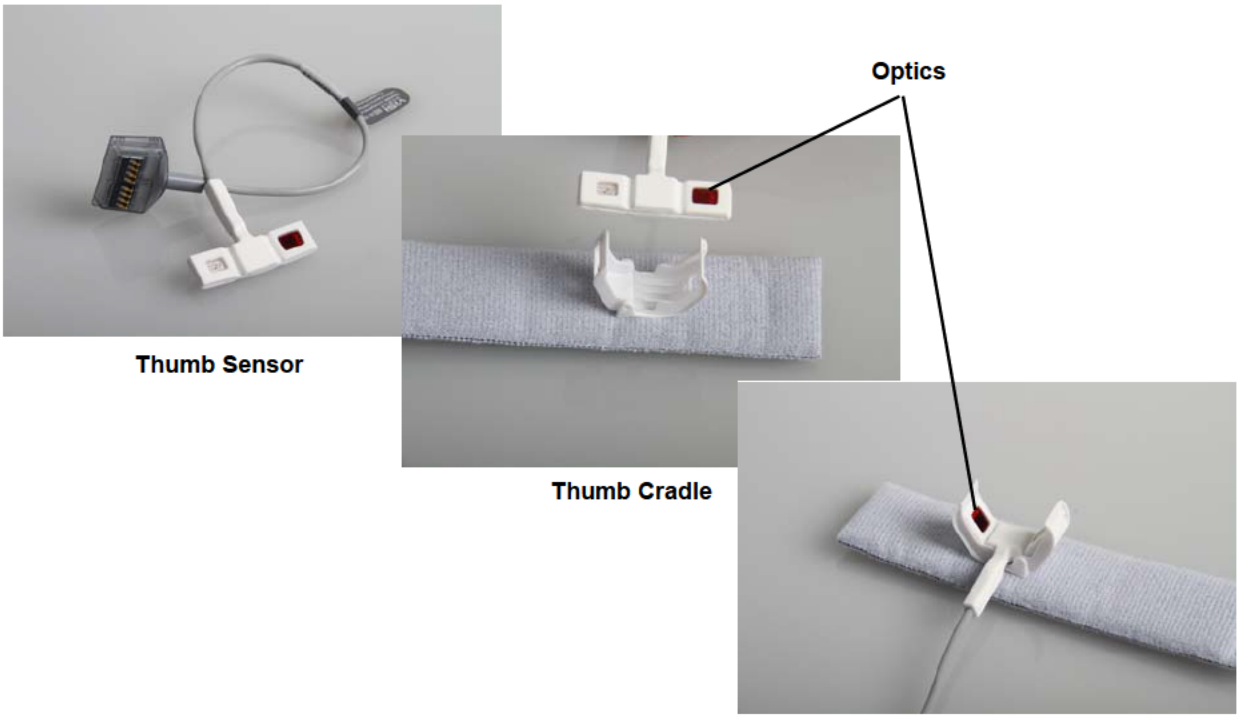
You should hear a double-beep sound when a sensor is inserted correctly.

4.3.3 Applying the ViSi Mobile Thumb Sensor

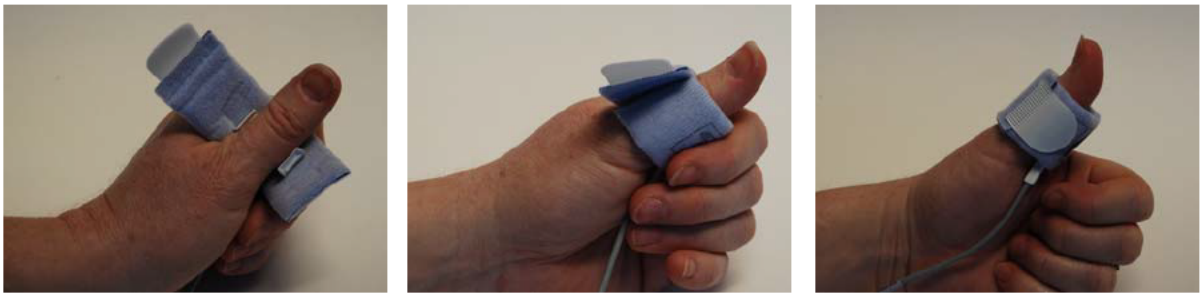
The ViSi Mobile Thumb Sensor is intended for use on the patient's thumb only. Do not apply the Thumb Sensor to the patient's fingers.

To apply the Thumb Sensor

1. Remove the Thumb Cradle from the Patient Kit.
2. Insert the Thumb Sensor into the Thumb Cradle such that the sensor optics are pointing away from the Thumb Cradle.



3. Place the Thumb Sensor at the base of the thumb and secure it with the Thumb Strap.



The Thumb Cradle is designed to hold the Thumb Sensor in place securely without impairing circulation.

Ensure that the ViSi Mobile Thumb Sensor is securely fastened. A Thumb Sensor that is wrapped too tight or too loose can adversely affect SpO_2 measurement.

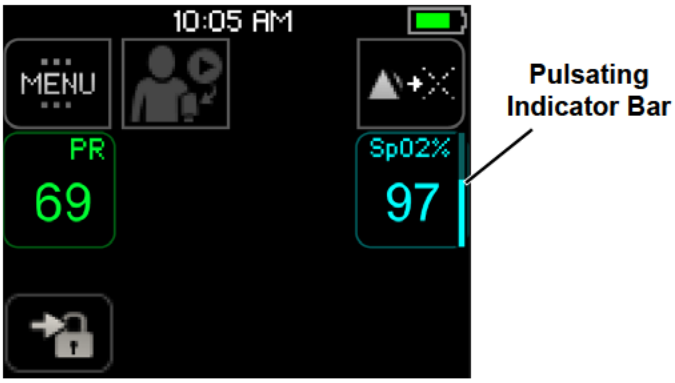
Inspect patient's skin at sensor site every 8 hours. If skin surface has been compromised, reposition the ViSi Mobile Thumb Sensor or move the Thumb Sensor to the patient's other thumb.

4. Check the patient's thumb for good color and circulation to ensure that the Thumb Sensor has not restricted circulation.

The Thumb Strap should securely hold the ViSi Mobile Thumb Sensor in place without impairing circulation. Immediately loosen the Thumb Strap if the patient complains of pain, tingling, or numbness in the affected thumb.

5. Connect the Thumb Sensor into the connector on the rounded end of the Monitor with the connector contacts facing upwards.

   The monitoring of SpO_2 and the PR starts after a few seconds. Alarm limits are set automatically according to predefined settings. See 6.Alarms and Alerts on page 85.



6. While palpating the pulse in the wrist of the arm opposite the Monitor, watch the pulsating indicator bar to the right of the SpO_2 numeric and ensure that the bar fluctuates with the pulse.

   The pulsating indicator bar confirms signal adequacy by moving up and down in sync with the detection of pulsating blood flow. Use the pulsating indicator bar to confirm the Thumb Sensor is optimally placed. It may take several seconds for the signal to stabilize.

   The indicated PR should match the palpated pulse rate. PR is replaced with HR when measuring ECG and SpO_2 simultaneously.

Note: If sensing of the SpO_2 or the PR is erratic, loosen the Thumb Strap from the thumb and reposition the Thumb Sensor until a stable SpO_2 and PR are obtained. Re-secure the Thumb Sensor with the Thumb Strap.

Only Sotera Wireless, Inc. supplied ViSi Mobile Thumb Sensors should be used. Using non-approved Thumb Sensors may result in inaccurate SpO2 readings.

4.3.4 Applying the ViSi Mobile Chest Sensor Cable and ECG Electrodes

Use all of the same type of high quality ECG electrodes on the patient. Mixing ECG electrode types can adversely affect ECG monitoring.

To ensure patient safety, the conductive parts of the ECG electrodes, including connectors and other patient-applied components, should not contact other conductive parts, or earth ground, at any time.

Only use the ViSi Mobile Chest Sensor Cable provided by Sotera Wireless, Inc. with the ViSi Mobile Monitoring System. The Chest Sensor Cable is designed to provide defibrillation protection as indicated in the *Specifications* section of this manual. ViSi Mobile is designed to be compatible with the use of external defibrillators.

Never connect the ViSi Mobile Chest Sensor Cable directly to the AC power outlet.

Skin Preparation

Skin preparation and ECG electrode placement directly impact the quality of the ECG signal and HR determinations. The following steps are recommended for skin preparation:

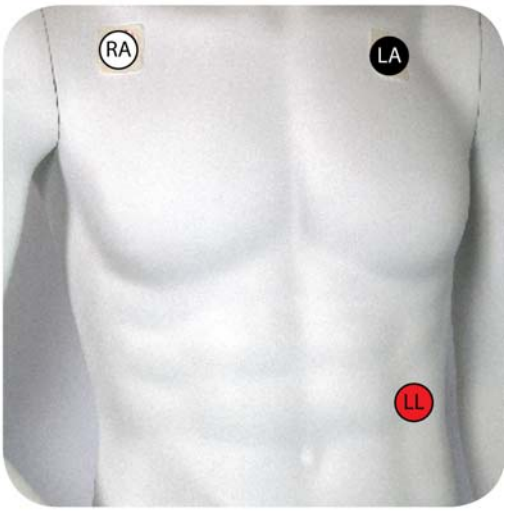
- Select ECG electrode sites on the patient's chest
  - ↳ Choose sites that are flat, avoiding fatty areas and major muscles.
  - ↳ For patient comfort, avoid placing ECG electrodes where lying on the side will put pressure on the ECG electrode.
  - ↳ Sites just below the middle of the clavicles are good locations for the RA and LA ECG electrodes.
- If needed, shave or clip hair in approximately a 1.5 to 2-inch diameter area for each ECG electrode site.
  - ↳ Also, for patient comfort, shave or clip hair from the areas where the Chest Sensor Cable and upper arm sensor are secured.
- Thoroughly clean the sites to remove excess skin oils, skin cells, and residue from the ECG electrode sites.
  - ↳ You may use isopropyl alcohol prep pads or another skin preparation pad, or soap and water.
  - ↳ Gently rub the site dry with a dry gauze pad or other dry pad.

Note: To avoid skin irritation, avoid areas that appear damaged; remove ECG electrodes if the patient complains of pain/itching; replace ECG electrodes per the electrode manufacturer's instructions and place on different sites.

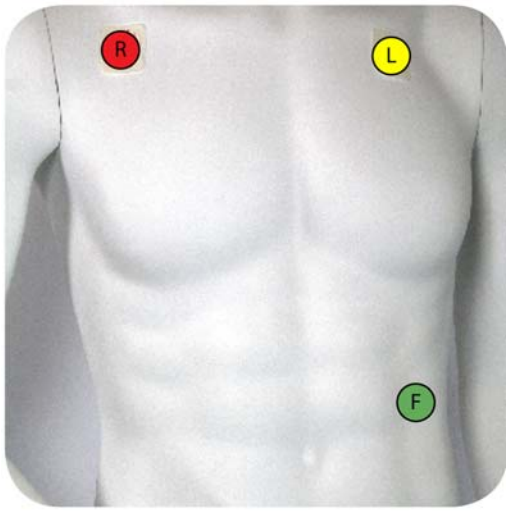
Note: Only use snap-on type electrodes.

3 lead-wire and ECG Electrode Placement

With the 3 lead-wire Chest Sensor Cable, the ECG channel provides Lead II only. The ECG electrode placement shown in the diagram below is recommended for Lead II monitoring



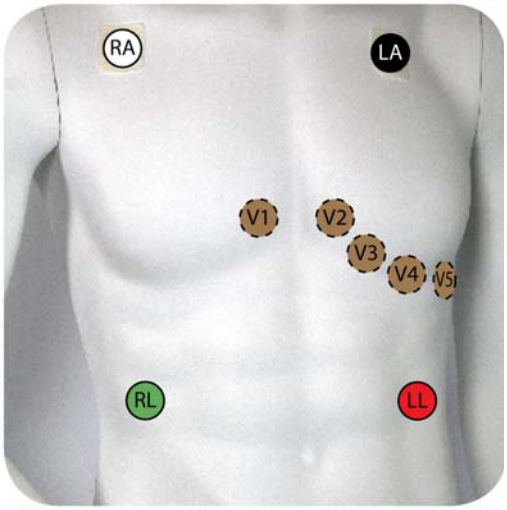
Lead Wire Color Code - U.S. (AAMI)
RA - White
LA - Black
LL - Red

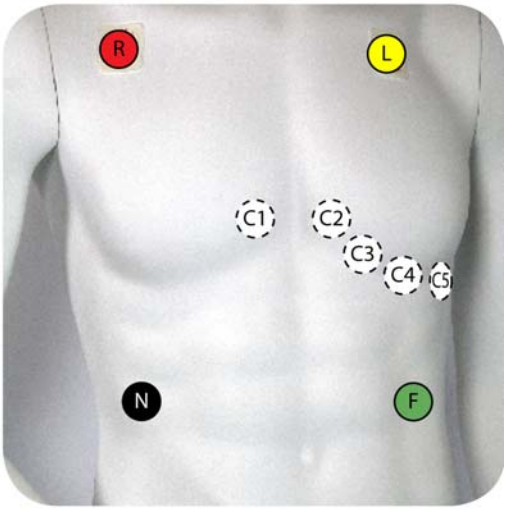


Lead Wire Color Code - International (IEC)
R - Red
L - Yellow
F - Green

5 lead-wire and ECG Electrode Placement

With the 5 lead-wire Chest Sensor Cable, the ECG channel is capable of monitoring seven leads simultaneously (Lead I, II, III, aVR, aVL, aVF, and a V lead). The ability to monitor multiple leads simultaneously improves beat detection to determine the HR and minimizes false detections as a result of artifact. The ECG electrode placement shown in the diagram below is recommended.





Lead Wire Color Code - U.S. (AAMI)
RA - White
LA - Black
LL - Red
V - Brown
RL - Green

Lead Wire Color Code - International (IEC)
R - Red
L - Yellow
F - Green
C - White
N - Black

V1	4th intercostal space (just right of sternum)
V2	4th intercostal space (just left of sternum)
V3	Midway between V2 and V4
V4	Mid clavicular line, 5th intercostal space
V5	Anterior axillary line, between V4 and V6
V6	Mid axillary line, horizontal with V4

Note: Place the V lead in the position appr opriate to your monitoring r equirements: V1, V2, V3, V4, V5 or V6.

Note: The ECG waveform can be displayed one lead at a time on the ViSi Mobile Monitor.

To apply the Chest Sensor Cable

Avoid placing the ViSi Mobile Cable Securement and ECG electrodes over areas of abrasions, irritation, or other sensitive areas. If possible, remove, reposition, and replace ECG electrodes and Cable Securement if the patient complains of pain/itching at the sites.

1. Remove the ECG electrodes from the Patient Kit.
2. Apply the ECG electrodes to the prepared sites on the chest as shown.
3. Remove the large Cable Securement from the Patient Kit.
4. Secure the Chest Module of the Chest Sensor Cable between the sternum and the shoulder (same side as the Monitor) using the large Cable Securement.

Note: The Chest Sensor Cable should be oriented vertically. Do not orient the sensor more than 45 degrees to the left or right.

Note: Ensure the "Front", "ViSi Mobile" and "Defibrillation" labels on the Chest Module of the Chest Sensor Cable are facing outwards away from the patient's skin.

Note: Ensure the "barcode" label and the Temperature sensor on the Chest Module of the Chest Sensor Cable are placed inwards directly against the patient's skin.

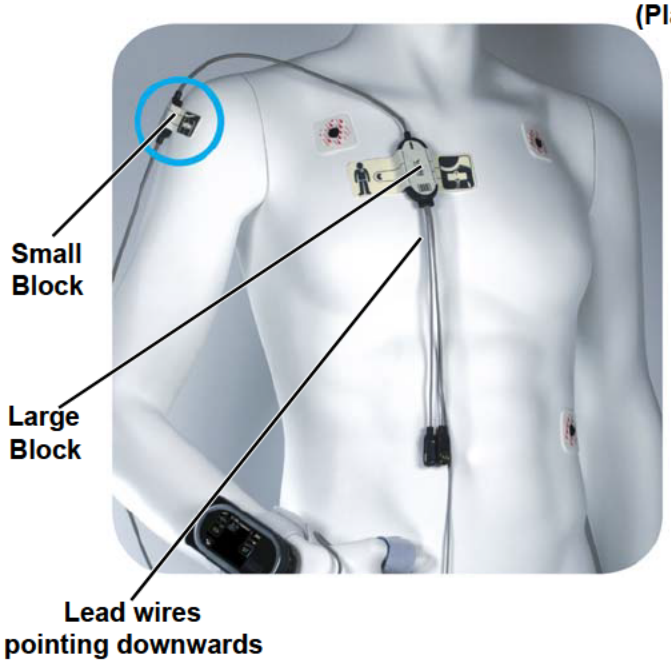
Note: For patient comfort, shave or clip the hair in the areas where the Cable Securement come in contact with the chest.

5. Apply the lead wires from the Chest Sensor Cable to the ECG electrodes.

Note: For patient comfort lead wires may be attached to ECG electrodes prior to applying the electrodes to the patient's chest.

6. Remove the small Cable Securement from the Patient Kit.

7. Secure the Upper Arm Module of the Chest Sensor Cable on the outside of the upper arm using the small Cable Securement.



Chest Module (front view)
(Place this side away from the patient's skin)

Chest Module (rear view)
(Place this side against patient's skin

Note: The default ECG configuration is Lead II.

8. Plug the Chest Sensor Cable into any of the three ports on the flat end of the Monitor with the connector contacts facing upwards.

Note: Monitoring of ECG, HR, RESP (optional), and TEMP starts automatically. Alarm limits are set automatically according to predefined settings.

Note: Only attach one ViSi Mobile Chest Sensor Cable to the patient and ViSi Mobile Monitor.

Insert with connectors contacts facing upwards

9. While palpating the pulse in the wrist of the arm opposite the Monitor, watch the beating heart symbol at the top left of the HR numeric to ensure that it fluctuates with the patient's heart beat.

   The heart symbol beats with the pulse to confirm that the sensor is optimally placed. It may take several seconds for the signal to stabilize.

- The indicated HR should match the palpated pulse rate.
- If the indicated HR is erratic or doesn't match the palpated pulse rate, check to make sure that the ECG electrodes and lead wires are secure.

Note: In rare circumstances, the ECG electrodes may need to be placed in different locations to improve the ECG signal.

10. While observing the patient, count the respiration rate and compare it to the **RESP** rate on the Monitor. It may take several seconds for the signal to stabilize.
    - The indicated RESP should match the observed rate.
    - If the indicated RESP is erratic or doesn't match the observed rate, check to make sure that the ECG electrodes and lead wires are secure.

Note: The Temperature sensor takes several minutes to reach a stable temperature reading.

4.3.5 Applying the ViSi Mobile Cuff Module and Disposable Cuff

ViSi Mobile Disposable Cuffs are for single patient use only. To avoid possible cross contamination, do not reuse a Cuff on a patient other than the original patient.

To apply the Cuff Module

1. Remove the Cuff from the Patient Kit.
2. Squeeze as much air out of the Cuff as possible.
3. Ensure that the patient is resting so that the upper arm muscles are relaxed. The level of the middle of the Cuff, while the arm is at rest, should be approximately at heart level.
4. Wrap the Cuff around the upper part of the same arm to which the Monitor is attached.
    - Align the bottom part of the Cuff approximately 1" above the antecubital fossa.
    - Align the artery marker on the Cuff with the brachial artery.
    - The connector for the Cuff Module should be to the outside of the arm, away from the body.
    - Have the patient remain still to avoid the introduction of unnecessary motion artifact.

Note: The ViSi Mobile Disposable Cuff is designed to be used on the same arm with the other ViSi Mobile sensors. It may temporarily cause the loss of function of other devices (not ViSi Mobile) simultaneously used on the same limb.

Note: Only attach one ViSi Mobile Cuff Module to the ViSi Mobile Monitor.

The ViSi Mobile Disposable Cuff should be snug enough to support the Cuff Module while not impairing circulation when deflated.

Avoid applying the ViSi Mobile Disposable Cuff over a wound as this can cause further injury.

Avoid applying the ViSi Mobile Disposable Cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury to the patient.

Take care in the application of the ViSi Mobile Disposable Cuff when applying the Cuff to an arm on the same side of a mastectomy.

ViSi Mobile arterial measurements have not been clinically tested in the presence of actual or ventricular arrhythmias. Use alternative BP methods if these arrythmias are present.

5. Connect the Cuff Module securely to the Cuff with the cable in the direction of the Monitor.

Inflate the ViSi Mobile Disposable Cuff only after proper application to the patient's limb.

6. Plug the Cuff Module into any of the open ports on the flat end of the Monitor with the connector contacts facing upwards.

Insert with connector contacts facing upwards

The Start symbol on the NIBP Start button blinks, prompting you to start a Cuff inflation. See Taking a NIBP Measurement on page 73 for instructions on how to take a NIBP measurement.

4.4 Removing ViSi Mobile Monitoring System

All disposable components of the ViSi Mobile Monitoring System are for single patient use only. To avoid possible cross contamination, do not reuse any disposable items on a patient other than the original patient.

To remove Cuff and Cuff Module

1. Disconnect the Cuff Module from the Monitor: Grasp the Cuff Module cable near the plug and, while holding the Monitor still, pull out the plug.
2. Unwrap the Cuff from the arm.
3. If the patient will no longer be monitored:
   - Disconnect the Cuff Module from the Cuff.
   - Dispose of the Cuff according to your facility's policy.

To remove the Chest Sensor Cable

1. Disconnect the Chest Sensor Cable from the Monitor: Grasp the Chest Sensor Cable cable near the plug and, while holding the Monitor still, pull out the plug.
2. Remove the Cable Securements from the patient's chest and arm and dispose of them according to your facility's policy.
3. To prevent placing stress on the lead wires, grasp each lead wire near the connection to the ECG electrodes. Pull the lead wires from the ECG electrodes.
4. Carefully remove the ECG electrodes from the patient and dispose of them according to your facility's policy.

To remove the Thumb Sensor

1. Disconnect the Thumb Sensor from the Monitor: Grasp the Thumb Sensor cable near the plug and, while holding the Monitor still, pull out the plug.
2. Remove the Thumb Sensor from the patient.
3. Holding the ends of the Thumb Sensor between your thumb and index finger, gently bend the Thumb Sensor backwards until it releases from the Thumb Cradle.
4. If the patient will no longer be monitored, dispose of the Thumb Cradle and Thumb Strap according to your facility's policy.

To remove the Wrist Cradle and Monitor

1. For ease of removal of the Wrist Cradle and Monitor, ensure all sensors are disconnected from the Monitor.
2. Remove the Monitor from the Wrist Cradle.
3. Unwrap the Wrist Strap from the patient's wrist and remove the Wrist Cradle from the patient's wrist.
4. If the patient will no longer be monitored, dispose of the Wrist Cradle and Wrist Strap according to your facility's policy.

Clean the reusable components of the System: Monitor, Chest Sensor Cable, Thumb Sensor, and Cuff Module, in accordance with your facility's procedures and the cleaning recommendations in this manual. *See 7.User Maintenance on page 107.*

5. Patient Monitoring

5.1 Introduction

The ability to monitor patients with a patient-worn ViSi Mobile Monitoring System opens up many opportunities to assess vital signs during all phases and activities involved in a patient's recovery process.

5.2 Monitoring the Patient

RESP (chest wall motion) can continue in the absence of ventilation (obstructed airway). Do not rely on the RESP alone to determine adequacy of ventilation. Other vital signs, such as HR and SpO_2, should be assessed as well.

Impedance pneumography for the determination of respiration (RESP) is not recommended for use in the presence of mechanically induced, high frequency ventilation.

The ViSi Mobile Monitor does not provide automated arrhythmia analysis. As a result, certain arrhythmias may cause the Monitor to display inaccurate heart rates. If frequent arrhythmias are suspected, their presence should be confirmed by another method, such as a 12-lead ECG or Holter monitoring.

The ViSi Mobile Monitor does not have automated ST segment analysis, therefore, if a change in the ST segment of the ECG waveform is suspected, it should be confirmed by another method, such as a 12-lead ECG.

Oxygen saturation measurements using SpO_2 are dependent on proper sensor placement and general patient conditions. Before making clinical decisions based on SpO_2 measurements, verify the measurement using another clinically acceptable method, such as an arterial blood gas analysis.

TEMP monitoring with the ViSi Mobile Monitoring System is intended for trending purposes only and is not intended to replace core temperature monitoring. Before making clinical decisions based on the skin temperature measurement, verify the measurement using another clinically acceptable method of temperature measurement.

To prevent settings from being inadvertently changed, lock the ViSi Mobile Monitor screen (if enabled) as soon as tasks are completed.

The ViSi Mobile Monitoring System does not support printing capability.

5.2.1 Unlocking the Monitor

If your System is configured to require authorization to view the **Vital Signs** screen, you must first unlock the Monitor by entering a PIN code. If you do not have a PIN code, please see your system administrator.

If your System is not configured to require authorization, the **Enter Pin Code** screen does not appear.

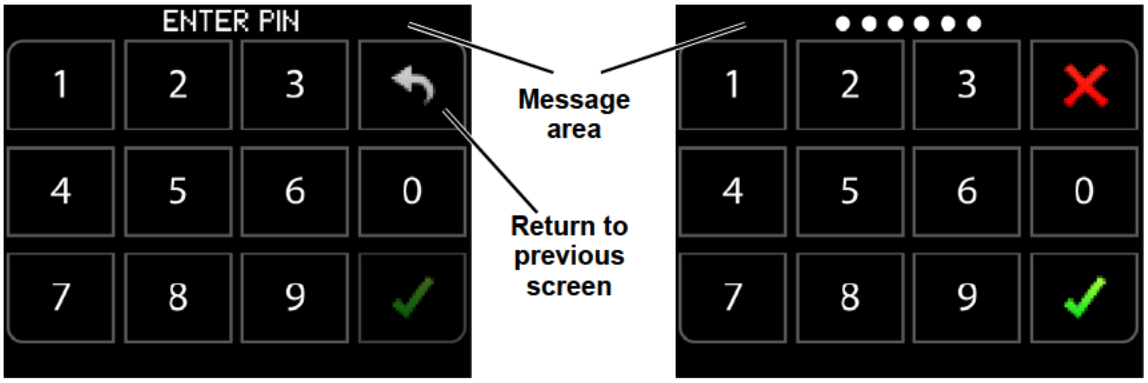
To unlock the Monitor

1. With one finger, touch the Monitor's screen for two seconds to activate the Monitor's display.

   The Patient View screen appears.

2. Touch **Unlock** in the lower left corner of the screen.

   The Enter PIN Code screen appears.



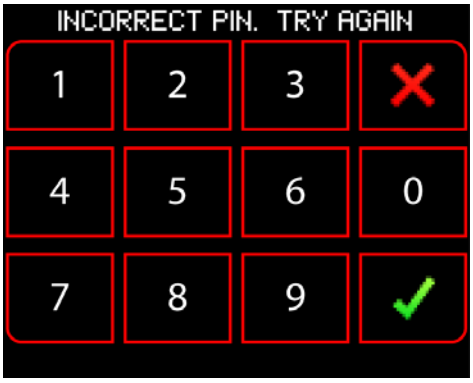
3. Enter PIN code on the PIN code pad.

   As PIN digits are entered, a white dot appears in the message area for each digit entered and the Return to Previous Screen button changes to a Cancel button.

4. Touch **Confirm** to enter the PIN code and confirm authorization.

If you touch the Confirm button the system navigates to the Vital Signs screen (when a valid PIN code has been entered). If you touch the Cancel button, the entered PIN code is cleared and the Return to Previous Screen button appears allowing to return to the Patient View screen.

Note: When an invalid PIN code is entered, the outline of the PIN code buttons will flash red and the entered PIN code is cleared.



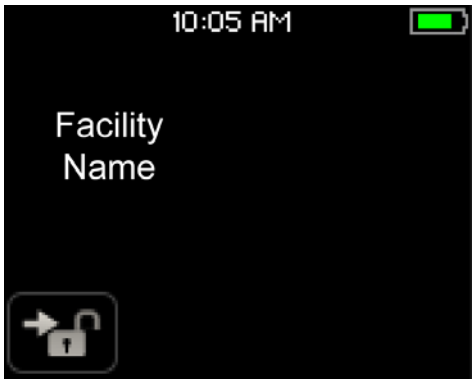
5.2.2 Locking the Monitor

When you have finished working with the Monitor, you should lock the Monitor to prevent the patient from accidentally accessing clinical settings.

To lock the Monitor

1. When you are finished interacting with the patient and the Monitor, touch **Lock**.

   The Vital Signs screen is locked to prevent settings from being inadvertently changed. The Patient View screen appears.



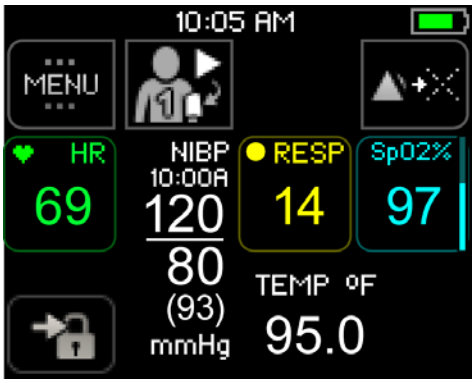
5.2.3 Viewing Vital Signs

Vital signs monitoring, with alarms, starts as soon as a sensor is connected to the patient and plugged into the Monitor. When there has been no interaction with the Monitor for a period of time, the display goes into **Quiet Monitoring**.

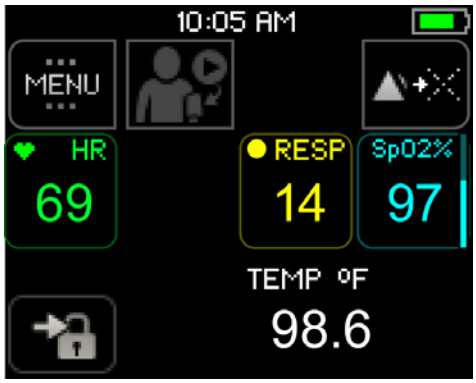
To view vital signs

1. With one finger, touch the Monitor screen for two seconds to activate the display.
2. Enter your PIN code if required. *See To unlock the Monitor on page 65.*

   The Vital Signs screen appears and displays all currently monitored vital signs.



Cuff Module connected



Cuff Module not connected

Note: If the Cuff Module is not connected and NIBP is not being measured continuously (cNIBP), the Start NIBP button is disabled and the NIBP numeric display area is blank.

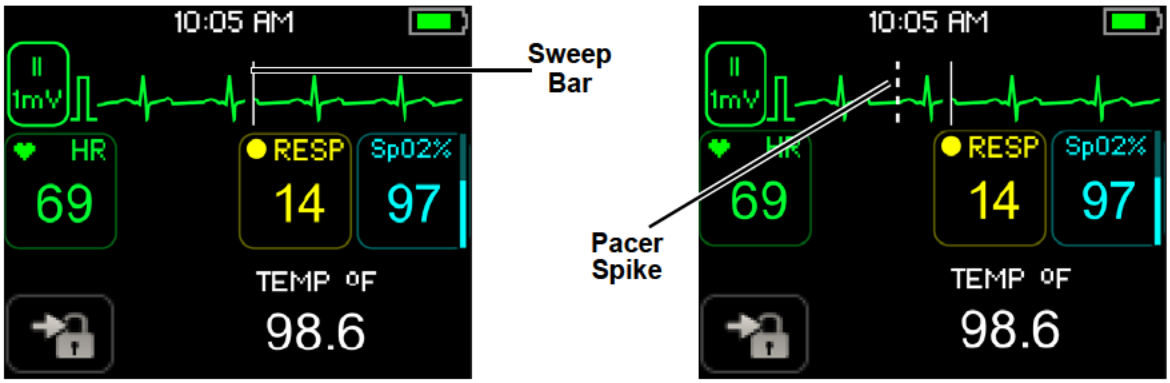
Note: If the Cuff Module is not connected and NIBP is being measured continuously (cNIBP), the Calibrate cNIBP button is disabled. The NIBP measurements will continue to be displayed.

Note: Systolic, diastolic and MAP measurements will be displayed in red when measuring NIBP continuously (cNIBP).

Note: The vital sign measurements are refreshed every 3 seconds.

5.2.4 Viewing Waveforms Associated with Vital Signs

Waveforms move across the display from left to right. A *sweep bar* erases the oldest waveform and replaces it with the newest waveform as it moves from left to right.



The speed of the waveform display (sweep speed) is scaled to 25 mm/sec for ECG and SpO_2 waveforms.

The sweep speed of the RESP waveform display is scaled to 6.25 mm/sec. The RESP frequency is less than the ECG or SpO_2. The slower sweep speed for the RESP waveform compensates for the lower frequency of activity in order to display several RESP cycles on the display.

Note: The NIBP measurement does not have a waveform.

To view the ECG waveforms

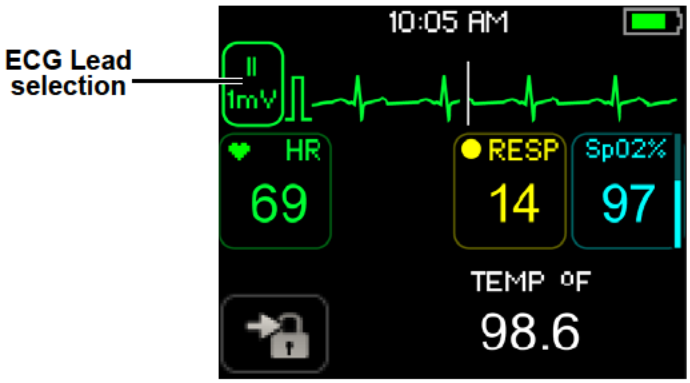
Depending on which Chest Sensor Cable is connected (3 lead-wire or 5 lead-wire), several views (leads) of the ECG waveform may be available for view.

Note: It is recommended that you step through the available ECG waveform leads to confirm the ECG setup is correct.

Note: When using a 3 lead-wire Chest Sensor Cable, only a Lead II waveform is available.

Note: There is no pacer detection with a 3 lead-wire Chest Sensor Cable.

1. Touch the **HR** numeric.

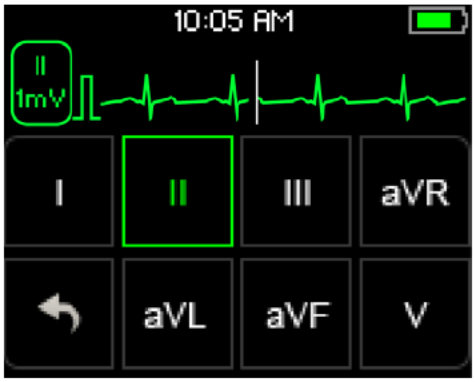


The top third of the display is replaced with the ECG waveform. The displayed lead is indicated to the left of the waveform. The square wave indicates the standard calibration of the ECG waveform.

To view other leads with the 5 lead-wire Chest Sensor Cable

1. Touch **ECG Lead Selection** or the **waveform**.

   The lower part of the display is replaced with Lead Selection buttons.



2. Select the lead corresponding to the waveform that you want to view.

   All available leads can be viewed one at time from this view.

Note: Selecting different leads to view has no affect on monitoring. All available leads are monitored simultaneously and continuously. The lead selection affects only the display.

3. Touch **Return to Previous Screen** to exit this view.

   The display returns to the previous view of the ECG waveform and vital signs.

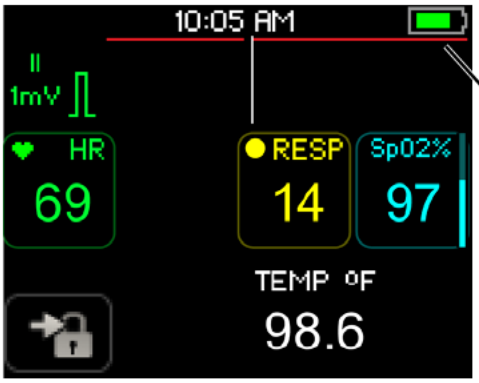
4. To return to the main **Vital Signs** screen, touch the **HR** numeric.

   The ECG waveform is no longer displayed.

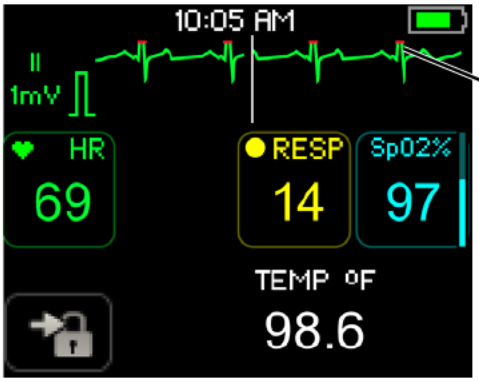
Note: When you touch a vital sign, its corresponding waveform is displayed, even if another waveform is currently displayed.

Input Overload / Dynamic Range

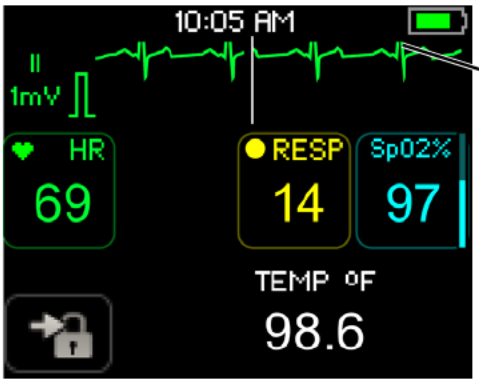
The ViSi Mobile Monitor display indicates an input overload condition (i.e. the input dynamic range of the amplifier associated with the displayed ECG lead has been exceeded) by displaying the trace in red at the top (or bottom) of the ECG waveform display area.



Amplifier is overloaded due to an input that exceeds the positive limit of the dynamic range on a continuous basis



Positive limit of the dynamic range is being exceeded only at the peaks of the QRS complex of the ECG waveform

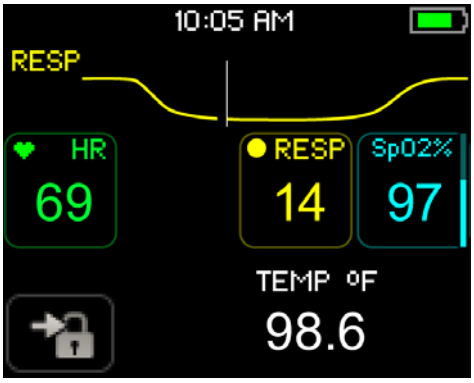


Dynamic range of the ECG amplifier has not been exceeded, but in which the peaks of the QRS complex of the ECG waveform extend beyond the upper edge of the display area

To view the RESP waveform

1. Touch the **RESP** numeric.

   The top third of the display is replaced with the RESP waveform.



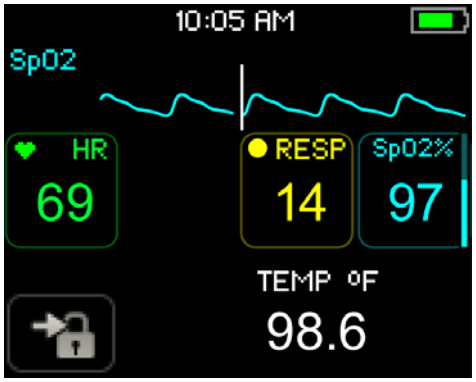
2. To return to the main **Vital Signs** screen, touch the **RESP** numeric.

   The RESP waveform is no longer displayed.

To view the SpO_2 waveform

1. Touch the **SpO_2** numeric.

   The top third of the display is replaced with the SpO_2 waveform.

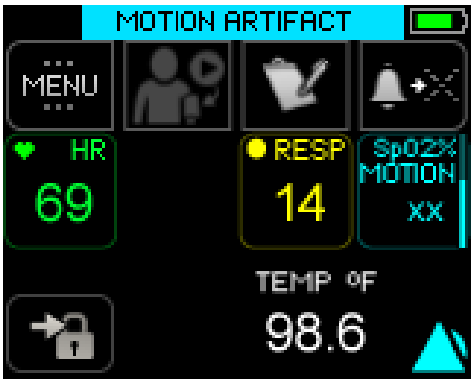


2. To return to the main **Vital Signs** screen, touch the **SpO_2** numeric.

   The SpO_2 waveform is no longer displayed.

5.2.5 Motion Artifact

If a vital sign cannot be measured due to a motion artifact, the word “MOTION” displays below the vital sign name, and “xx” is displayed in place of the numeric(s).



5.2.6 Taking a NIBP Measurement

The industry-standard technique of oscillometry is used for non-invasively measuring systolic blood pressure (SBP) and diastolic blood pressure (DBP). The method is based on the measurement of oscillations through the occluding cuff which is placed on the patient's upper arm during an NIBP measurement. The pulsatile oscillations are measured using a pressure transducer, and then digitized using a microprocessor. The NIBP algorithm uses the digitized oscillations and applied cuff pressure as input to an empirical model to calculate SBP and DBP.

Blood pressure measurements can be affected by the patient's position and/or physiological condition:

- The cuff should be at the same level as the patient's heart.
- NIBP are not reliable indicators for patients with arterial or frequent premature ventricular beats.
- Improper cuff size or application may lead to inaccurate readings.

This section describes how to take a single NIBP measurement and how to initiate automatic NIBP measurements at various intervals. For patient comfort, when the NIBP is set to manual, remove the Cuff and the Cuff Module from the patient's arm. Once removed, disconnect the Cuff Module from the Monitor between measurements. Store the Cuff and Cuff Module in a convenient location.

The ViSi Mobile Monitor should never be used to measure the NIBP of one patient while the Monitor is simultaneously connected to another patient.

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is undergoing cardio-pulmonary bypass.

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is being treated with an intra-aortic balloon pump or left ventricular assist device.

Periodically observe the patient's arm for signs of impaired circulation, which may be a result of measurements made too frequently. Loosen or remove the ViSi Mobile Disposable Cuff if signs and/or symptoms of prolonged impaired circulation are evident.

If you are uncertain of the reliability of an NIBP measurement, repeat the measurement. If the reading is still suspect, use another method to measure the blood pressure.

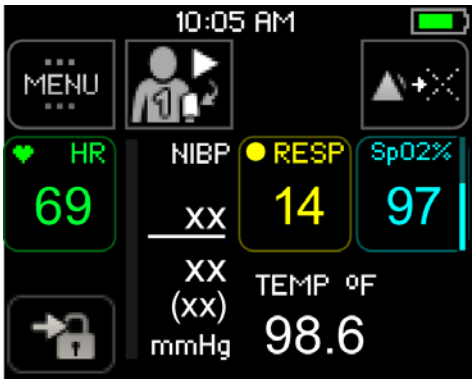
The ViSi Mobile Disposable Cuff should be snug enough to support the Cuff Module while not impairing circulation when deflated.

Note: The ViSi Mobile Cuff Module cannot be used with the auscultatory method of measuring NIBP.

To take a single NIBP measurement

1. Apply the Cuff and Cuff Module. *See Applying the ViSi Mobile Cuff Module and Disposable Cuff on page 60.*

   After the Cuff Module has been connected to the Monitor, the NIBP vital sign numerics (Systolic and Diastolic) display as "xx", indicating no measurement has been taken.



2. Touch **Start NIBP** to start a measurement.

   After a few seconds to zero and calibrate the barometric pressure, the Cuff begins inflating.

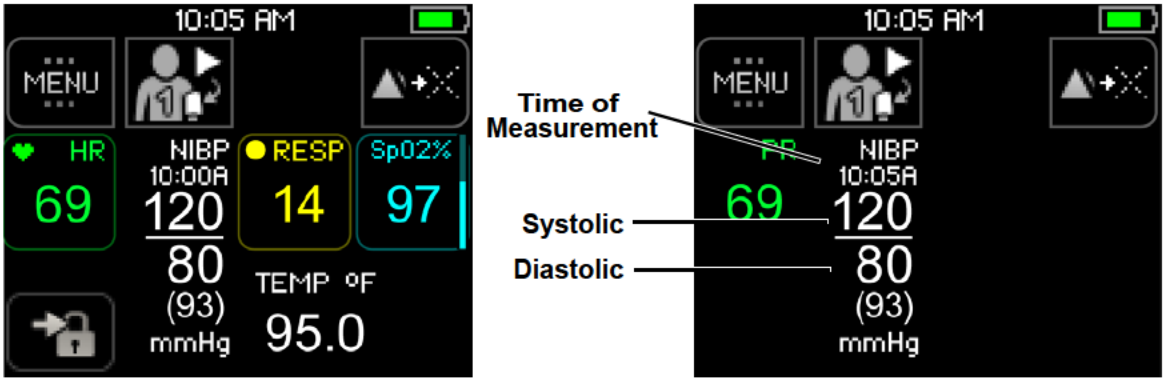
   An inflation pressure indicator bar, located to the left of the NIBP numerics, increases/decreases in height as the pressure increases/decreases in the Cuff. The actual cuff pressure is displayed under the NIBP label.

   Once the Cuff begins to inflate, the Start NIBP button changes to Stop NIBP.

Note: If unexpected readings are encountered, confirm the correct application of the ViSi Mobile Disposable Cuff (*see page 60*). If unexpected readings persist, have maintenance performed as described in the Technical Reference Manual.

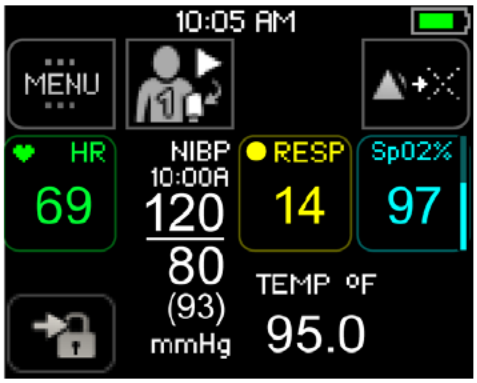
The performance of the automated sphygmomanometer may be affected by extremes of temperature, humidity and altitude. *See "Specifications" on page 119.*

Upon completion of a successful measurement, the Systolic and Diastolic measurements are displayed in white. The time of the measurement is displayed below the NIBP label. If there is no other heart rate/pulse rate source (i.e. Thumb Sensor or Chest Sensor Cable are not connected to the Monitor), then a one-time PR from the NIBP measurement is displayed next to the NIBP measurement for 30 seconds.

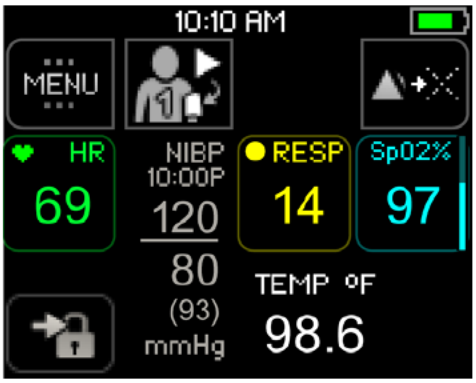


Note: If the NIBP measurement was unsuccessful, the Cuff Module automatically retries to measure the blood pressure. A maximum of 3 attempts will be made. If the failure is due to a cuff leak or cuff occlusion, there is no retry and the LEAK or OCCL message appears on the screen directly below the NIBP label.

NIBP numerics fade and shrink in size after 30 seconds to indicate that the reading is not recent.



Current Reading

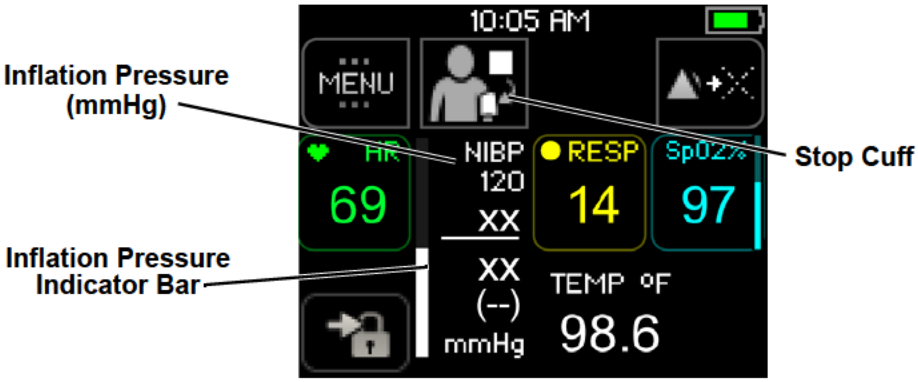


Older Reading
Note that the numerics for the older reading are faded and shrunk in size

NIBP measurements that are older than 30 minutes are no longer displayed.

To stop an NIBP measurement

An NIBP measurement currently in progress may be stopped at any time.



Touch **Stop NIBP** to stop the cuff inflation and NIBP measurement.

The cuff will deflate.

5.2.7 Initiating Automatic NIBP Measurements

When frequent NIBP measurements are required, the Monitor can be set up to automatically take a blood pressure measurement every 5, 10, 15, 30, 60, 90 or 120 minutes.

To initiate automatic NIBP measurements

1. Apply the Cuff and Cuff Module.
   See Applying the ViSi Mobile Cuff Module and Disposable Cuff on page 60.

The ViSi Mobile Disposable Cuff should be snug enough to support the Cuff Module, while not impairing circulation when deflated.

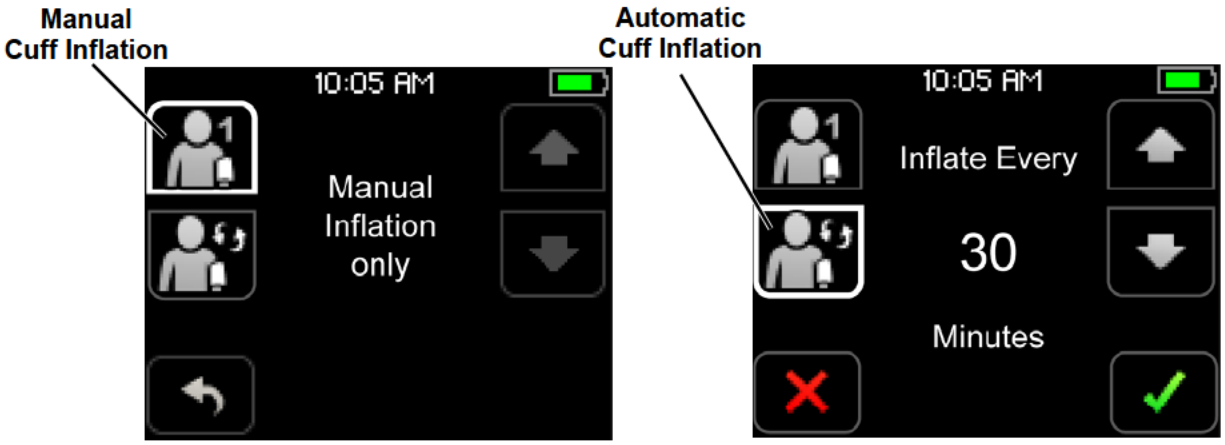
Use care when using automatic cuff inflation for prolonged periods on unconscious or semi-conscious patients since the patient may not be able to alert the clinician to any pain he/she may be experiencing. Pressing the "Stop NIBP" button interrupts the NIBP measurement and deflates the cuff.

2. Set the **NIBP mode** to **Automatic**.

   a. Touch **Menu** on the **Vital Signs** screen to display the **Menu** screen.

   The Menu screen appears.

   b. Touch **NIBP Settings** to display the **Cuff Management** screen.
   The Cuff Management screen appears.



   c. Touch **Automatic Cuff Inflation**.
   d. Touch the **Up** or **Down** arrow to increase or decrease the time interval.

e. Touch **Confirm** to confirm the new settings.
- or -

Touch **Cancel** to return to the **Menu** screen.

Once you have touched Confirm, an automatic NIBP measurement is taken immediately, and again at the set interval. The Automatic setting is saved and the system returns to the Vital Signs screen. If you touch Cancel, the system discards the changed settings and returns to the Menu screen.

Note: As long as the NIBP Module is plugged in, a manual NIBP measurement can be initiated at any time. If the timing of the manual measurement overlaps with the automatic measurement interval, then that automatic measurement is skipped; otherwise the automatic measurement occurs as scheduled.

Note: Touching the "Stop NIBP" button on the Vital Signs screen interrupts any NIBP measurement cycle presently in progress. The next automatic measurement will occur as scheduled.

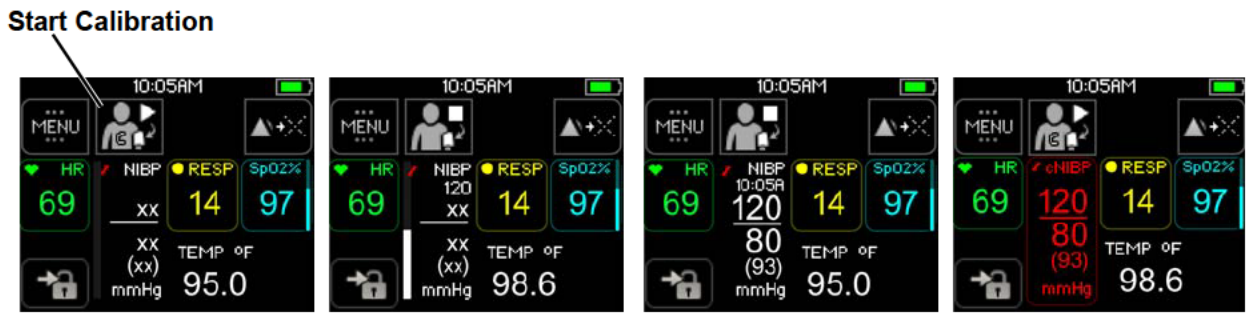
5.2.8 Continuous NIBP Monitoring

Sotera's continuous blood pressure monitor (cNIBP) is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed based on averaging PAT calculations from the previous 30 seconds and updating the display every three seconds. The ViSi Mobile Monitor is able to continuously measure NIBP without further cuff inflations.

The accuracy of cNIBP is dependent on the initial cuff calibration. Use good clinical practice to confirm cNIBP accuracy before initiating or treating a patient.

Note: Continuous NIBP monitoring is an optional feature that requires an additional license key.

To calibrate cNIBP



Chest Sensor, Thumb Sensor and Cuff Module connected | NIBP Reading In Progress | Spot-Check Reading | cNIBP Calibrated

1. Connect the ViSi Mobile Chest Sensor, Thumb Sensor and Cuff Module and navigate to the **Vitals Signs** screen.

   The Start Cuff button *will change to the Calibrate cNIBP button.*

2. Touch **Calibrate cNIBP** on the **Vital Signs** screen.

   The Cuff will start to infl ate, indicating the calib ration process has started. After a single NIBP measurement has been t aken, t he V iSi Mobile Monitor will calibrate cNIB P. The NIBP measurement will be displayed in white during the calibration process.

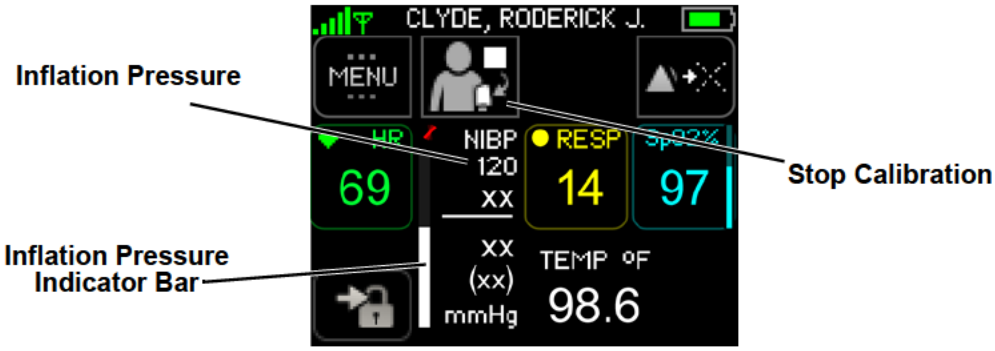
Once cNIBP has been calibrated, Systolic, Diastolic and MAP measurements will be displayed in red. The displayed measurement will be refreshed every 3 seconds.

Note: The calibration process will take approximately 1 to 2 minutes to complete.

Note: If the first calibration is not successful, a second calibration attempt will automatically occur. A failure to calibrate will be indicated by a "Calibration Failed" alert and the Cuff will inflate for again.

To stop the cNIBP calibration

A cNIBP calibration currently in progress may be stopped at any time.



Touch **Stop NIBP** to stop the cuff inflation and NIBP measurement.

The cuff will deflate.

To recalibrate cNIBP

To manually recalibrate cNIBP, following the steps outlined in section *To calibrate cNIBP on page 79*.

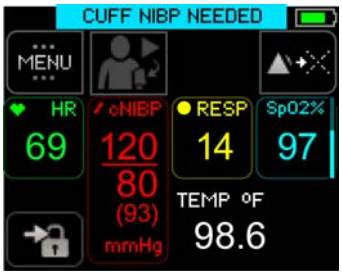
There are several reasons why cNIBP will require recalibration:

- A vasoactive drug is administered to the patient.
- Any of the cNIBP measurements exceed the upper or lower alarm limits.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 15mmHg for a normotensive patient over a period longer than 60 seconds.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 20mmHg when in a hypertensive range (systolic above 190mmHg or diastolic above 140mmHg) over a period longer than 60 seconds.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 10mmHg when in a hypotensive range (systolic below 90mmHg or diastolic below 60mmHg) over a period longer than 60 seconds.

- An unexpected interruption of monitoring occurred, such as all sensors being disconnected. If the interruption is less than 30 seconds, no recalibration is required. *See section All Sensors Disconnected on page 84.*

Note: When a recalibration event is detected and the Cuff Module is connected, the ViSi Mobile Monitor will automatically recalibrate cNIBP.

Note: When a recalibration event is detected and the Cuff Module is not connected, the ViSi Mobile Monitor will display the Cuff NIBP Needed alert. Connect the Cuff Module and recalibrate manually.



You should manually recalibrate cNIBP after any drug administration.

5.2.9 Stop Monitoring

Stop monitoring when ALL vital signs monitoring is no longer required.

To stop monitoring

1. With one finger, touch the Monitor screen for two seconds to activate the display.

   The Patient View screen appears.

2. Enter your PIN code if required. *(See To unlock the Monitor on page 65.)*

   The Vital Signs screen appears.

3. Touch **MENU**.

   The Menu screen appears.

4. Touch **STOP**.

   The Stop Monitoring screen appears.

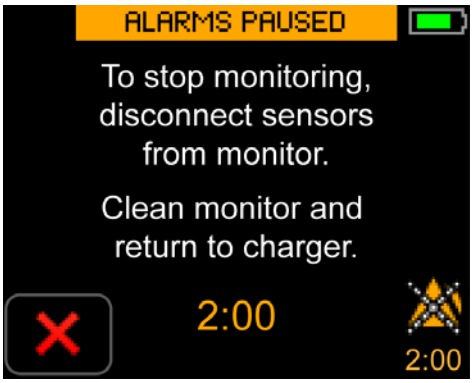
5. Touch **Confirm** to confirm that you want to stop monitoring.

   - or -

   Touch **Cancel**.

   If cancelled, the program returns to the Menu screen and monitoring continues uninterrupted.

   If confirmed, the Stop-Disconnect Sensors/Clean Monitor *screen is displayed showing a 2 minute countdown timer.*



6. Remove all the sensors and the Monitor from the patient.

   All sensors must be removed from the patient and/or the Monitor to stop monitoring. When the countdown has elapsed, if vital sign measurements are still being detected (at least one sensor is still connected to the patient and Monitor), monitoring will continue without interruption.

7. To remove the sensors from the Monitor, grasp the sensors near the plug, and while holding the Monitor firmly, pull out the plug.

   Once all the sensors are disconnected from the Monitor, the Monitor Status screen appears briefly before the System transitions into the Hibernate mode.

8. Dispose of disposable components per your facility's procedures.

If you want to stop monitoring temporarily or change the Monitor, you will need to stop monitoring on the current Monitor and start monitoring again using the steps outlined in section *Applying ViSi Mobile Monitoring System / Initiate Monitoring on page 50*.

To clean and prepare reusable components

1. Clean and prepare the reusable components of the System (Monitor, Chest Sensor Cable, Thumb Sensor, and Cuff Module) in accordance with your facility's procedures and the cleaning recommendations in this manual. *See 7.User Maintenance on page 107.*
2. Place the cleaned Monitor and Cuff Module into the Charger.

Never place the ViSi Mobile Monitor or the ViSi Mobile Cuff Module into the ViSi Mobile Charger while connected to a patient.

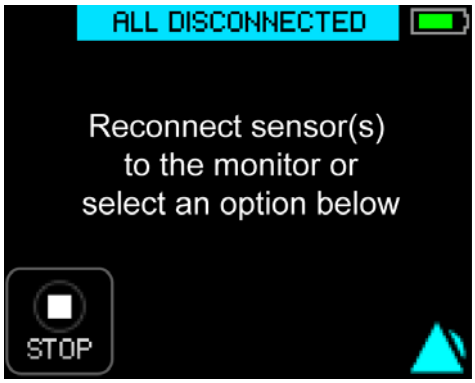
Never connect the ViSi Mobile Monitor directly to an AC power outlet. To recharge the battery, disconnect the Monitor from the patient, and then place it in the ViSi Mobile Charger.

Never connect the ViSi Mobile Cuff Module directly to an AC power outlet. To recharge the battery, disconnect the Cuff Module from the patient, and then place it in the ViSi Mobile Charger.

To prevent possible cross-contamination, properly clean and disinfect all reusable components between patients.

5.3 All Sensors Disconnected

The “All Sensors Disconnected” screen will be displayed when the last sensor is disconnected from the ViSi Mobile Monitor without going through the proper “Stop Monitoring” procedure. (*see 5.2.9Stop Monitoring on 82*). An “All Disconnected” alert will be generated.



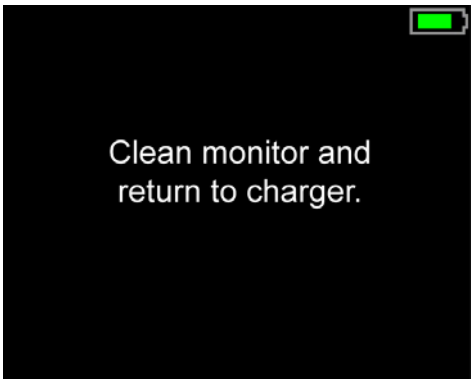
1. To stop monitoring the patient, touch **Stop** to initiate the Stop Monitoring process.

   - or -

   to resume monitoring, connect the sensor(s) to restart monitoring.
   Monitoring will automatically continue.

2. Enter your PIN code if required. *(See To unlock the Monitor on page 65.)*

   The Clean Monitor screen appears.



6. Alarms and Alerts

6.1 Introduction

The ViSi Mobile Monitoring System provides a comprehensive alarm system that alarms on changes to the patient's physiologic status. The system provides default alarm limits or the clinician can manage the alarm limits per patient to provide individualized care. Equipment alerts are provided to alert the clinician of situations that may impede the ability to monitor your patient.

6.2 Managing Alarms and Alerts

A responsible clinician must be within audible range of the assigned patient wearing the ViSi Mobile Monitor at all times.

6.2.1 Turning Alarms On/Off

Alarm limits for each vital sign parameter are predefined and turned on automatically whenever a sensor is connected to the patient and to the Monitor. Sometimes it is desirable to adjust the alarm limits to meet a patient's monitoring requirements.

When alarms are turned OFF, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarms are turned OFF.

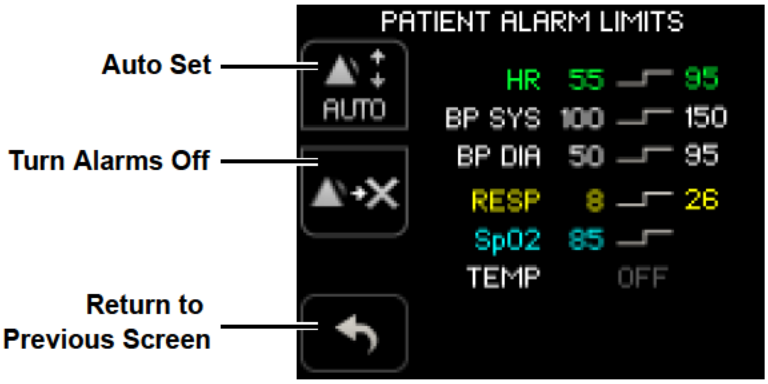
To turn all alarms off

1. Touch **Menu** on the **Vital Signs** screen.

   The Menu screen appears.

2. Touch **Alarms Settings.**

The Patient Alarm Limits screen appears. Alarm limit settings are only displayed for the connected sensors.



Note: Systolic, diastolic and MAP alarm limits will be displayed in red when measuring NIBP continuously (cNIBP).

3. To turn all alarms off, touch **Turn Alarms Off**.

   The Turn Alarms Off confirmation screen appears.

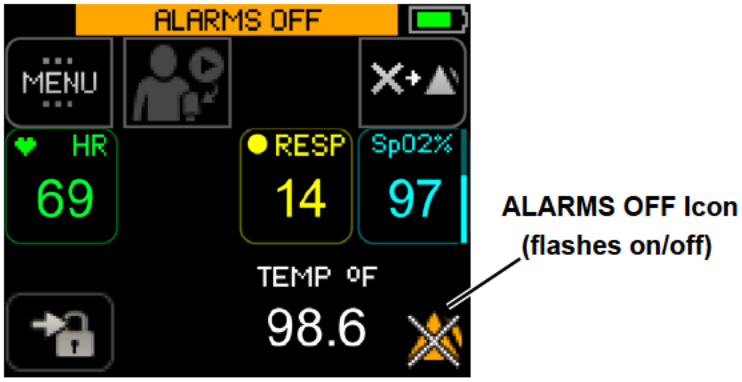
4. Touch **Confirm** to confirm that you want to turn all alarms off.

   -or-

   Touch **Cancel** to leave the alarms turned on.

   If cancelled, the system returns to the Patient Alarm Limits screen and the alarms remain turned on.

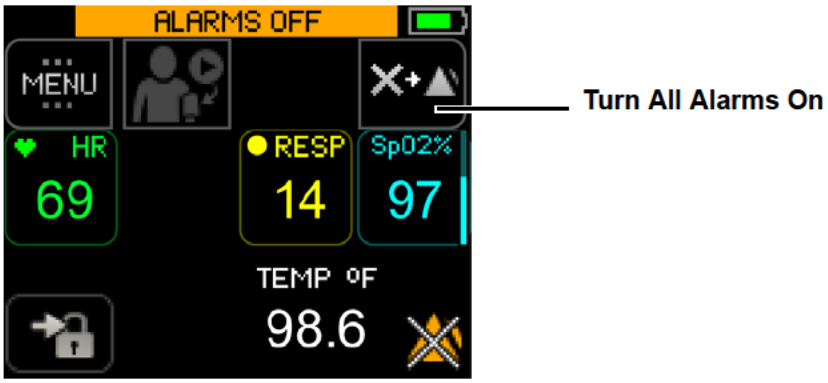
If confirmed, the alarms are turned off and the Vital Signs screen appears. The words ALARMS OFF are displayed at the top of the screen and an ALARMS OFF icon is displayed in the lower right corner of the screen.



Note: Alerts that indicate the Monitor is unable to measure a vital sign (such as ECG Lead Fail) can not be turned off.

To turn all alarms on

From the **Vital Signs** screen, touch **Turn All Alarms On.**



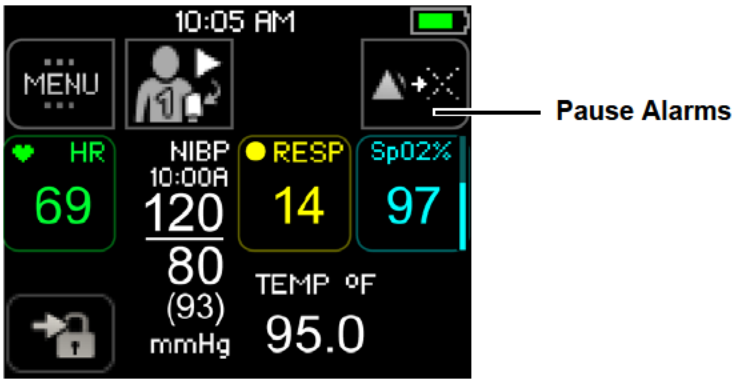
When the alarms are turned back on, the previous alarm settings will be enabled.

6.2.2 Pause/Resume Alarms

When alarms are paused, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarms are paused.

To pause the alarms

From the **Vital Signs** screen, touch **Pause Alarms.**

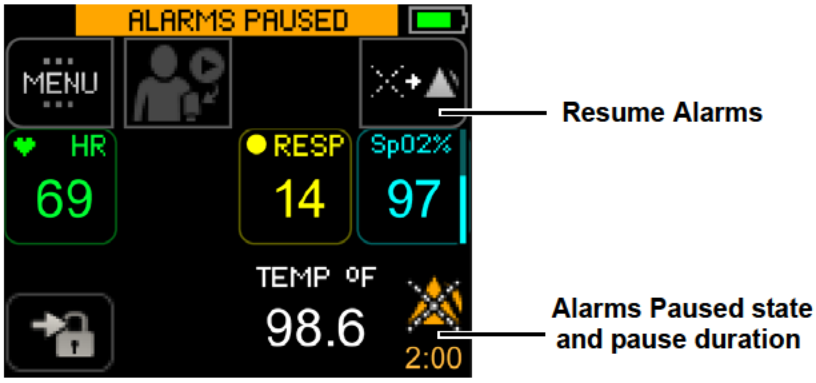


The alarms are paused for 2 minutes.

When paused, the words ALARMS PAUSED are displayed at the top of the screen and an ALARMS PAUSED icon is displayed in the lower right corner of the screen.

To resume the alarms

From the **Vital Signs** screen, touch **Resume Alarms.**



When the alarms are resumed, the previous alarm settings will be enabled.

6.2.3 Auto Set Alarms

The Auto Set function sets alarm limits based on the current vital signs measurements for all connected sensors. If the alarms are turned off prior to initiating the Auto Set process, the alarms are turned back on when the new alarm limits are confirmed.

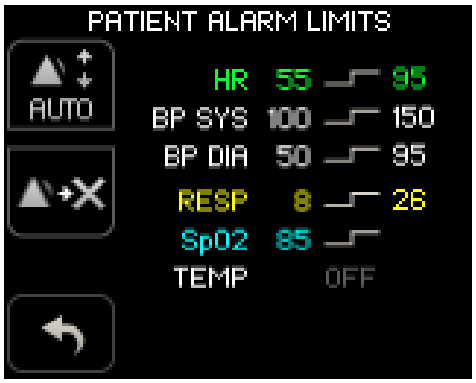
Once new alarm limits are confirmed, they cannot be changed back to the original pre-set limits. Once Auto Set is selected, review the newly calculated alarm limits carefully before deciding to confirm or cancel the new alarm limits.

To change alarm limits using Auto Set

1. Touch **Menu** on the **Vital Signs** screen.

2. Touch **Alarms Settings.**

   The Patient Alarms Settings screen appears.



Note: Alarm limit settings are only displayed for the currently monitored vital signs.

Note: Systolic, diastolic and MAP alarm limits will be displayed in red when measuring NIBP continuously (cNIBP).

3. Touch **Auto Set**.

   Alarm limits for all currently monitored vital signs are recalculated based on the current vital signs measurements. The Confirm New Alarm Limits screen appears.

Note: Upper and lower alarm limits cannot be set for TEMP.

4. Touch **Confirm** to confirm that you want to accept the new alarm limits.

   -or-

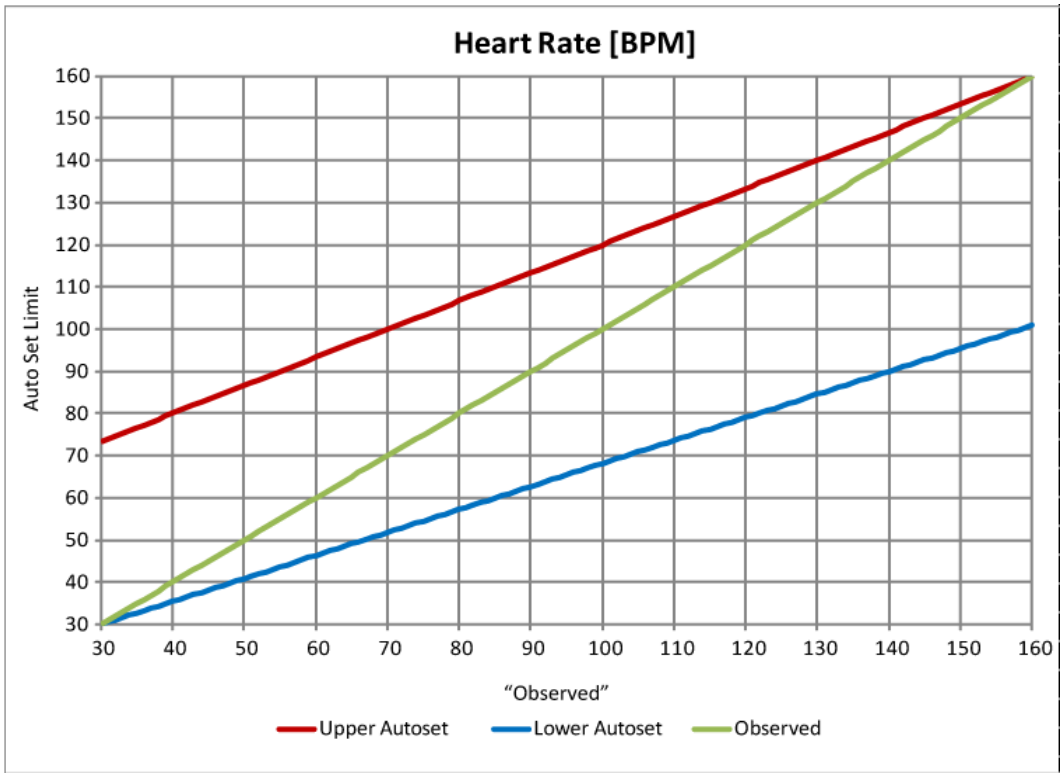
   Touch **Cancel** to return to the **Patient Alarm Limits** screen.
   The previous alarm limits are retained.

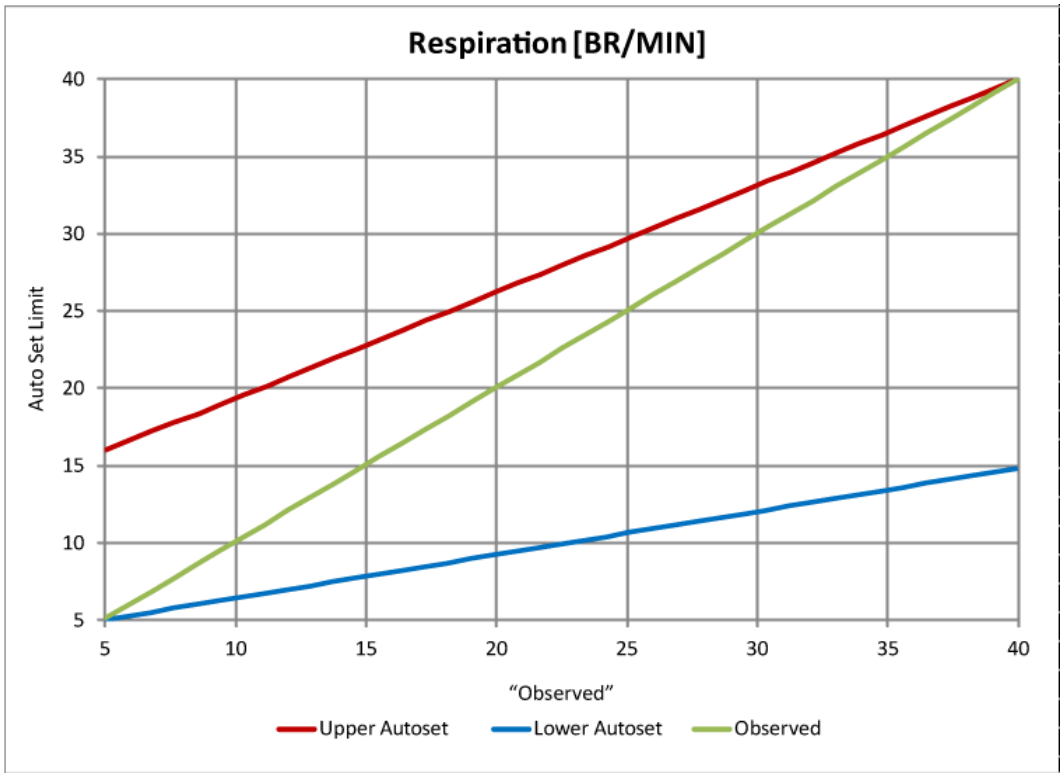
   Once confirmed, the system returns to the Vital Signs screen.
5. Navigate to the **Patient Alarm Limits** screen to review the current alarm limits.

When selecting Auto Set, alarm limits are calculated to clinically relevant values based on the patient's present condition. Auto Set is not available for SpO2 and temperature. The minimum and maximum values to which auto set will adjust the limits are listed in the table below.

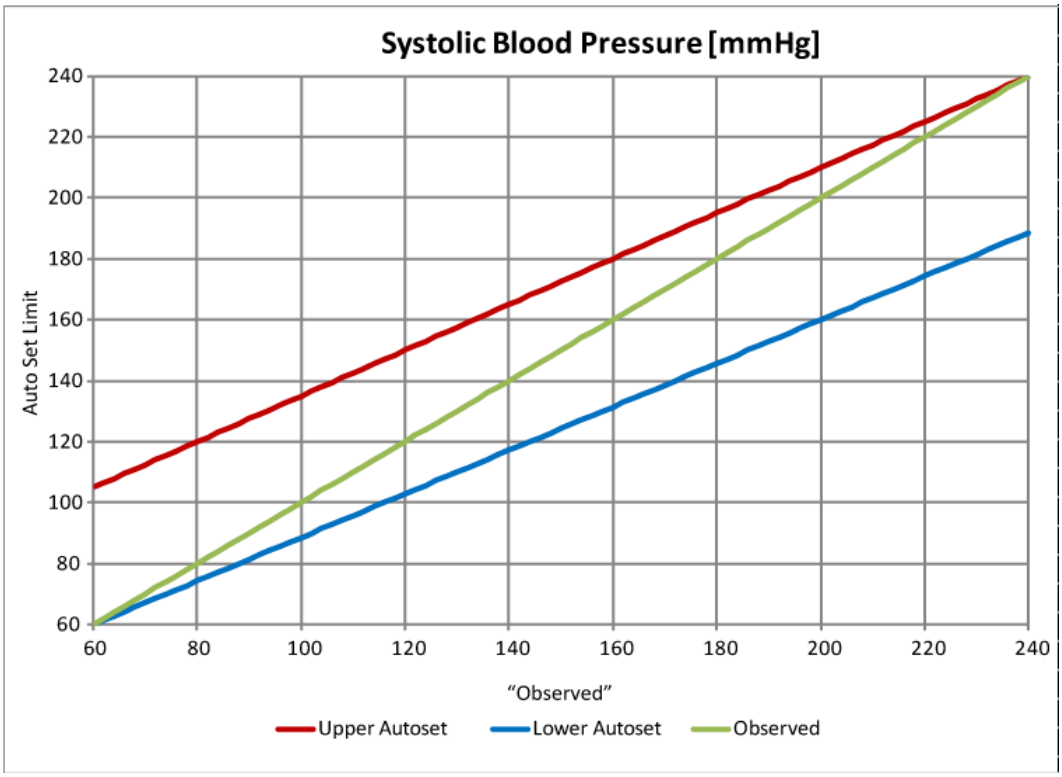
Auto Set Alarm Limits				
Alarm	**Limit**	**Default Limits**	**Auto Set Range**	**Auto Set Limit Calculation (based on current reading)**
Heart Rate (BPM)	High	140	90-160	HR x 0-66 + 53.3
	Low	40	30-80	HR x 0.54 + 13.6
Pulse Rate (BPM)	High	140	90-160	PR x 0-66 + 53.3
	Low	40	30-80	PR x 0.54 + 13.6
BP Systolic (mmHg)	High	190	160-240	BP x 0.75 + 60.0
	Low	90	60-120	BP x 0.71 + 17.1
BP Diastolic (mmHg)	High	120	95-150	BP x 0.60 + 60.0
	Low	40	30-90	BP x 0.72 + 8.3
Respiration (BR/M)	High	35	12-40	RR x 0.69 + 12.5
	Low	6	5-8	RR x 0.28 + 3.6

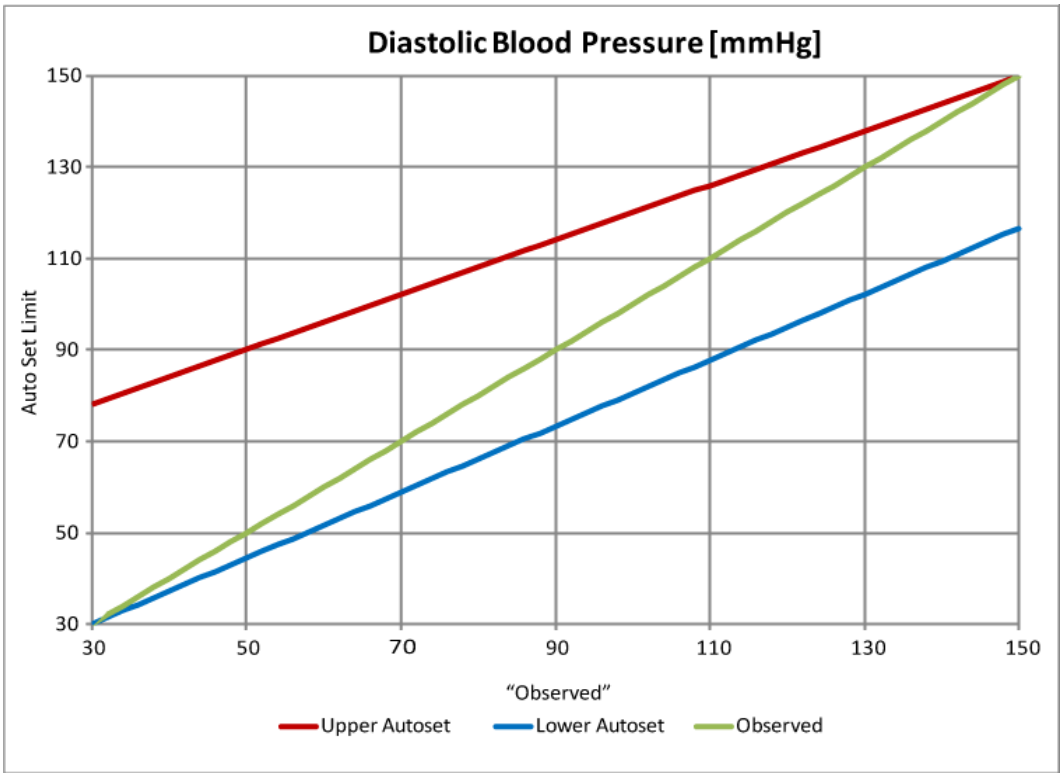
Note: There is no manual way set individual alarm limits. Auto Set recalculates all alarm limits.





Auto Set Alarm Limits
(Heart Rate / Respiration)



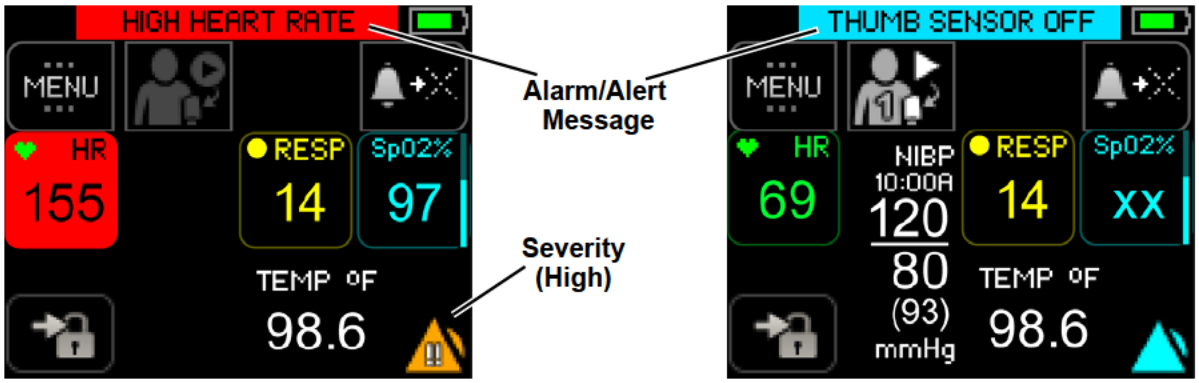


Auto Set Alarm Limits
(Blood Pressure)

6.3 Alarm and Alert Annunciation

Alarms and alerts are generated audibly and visually. Colors, tonal patterns, and messages are used to quickly identify the severity of the alarm or alert that is occurring.

Note: The battery in the Monitor will deplete at a faster rate when alarms are in progress.



Patient alarms indicate a condition that potentially puts the patient at risk and requires a clinician response. Alarms are generated when a patient's vital signs are outside the present alarm limits.

Alarms			
Priority/Severity	**Description**	**Unacknowledged Alarms**	**Acknowledged Alarms**
Life Threatening	Urgent clinician response required **Note:** The banner area will alternate between red and white	 Audio annunciation in progress	 No audio annunciation
High	Immediate clinical response is required	 Audio annunciation in progress	 No audio annunciation

For a complete listing of all patient alarms, *see 6.4Patient Alarms on page 99.*

Note: There are no medium or low priority alarms.

Line isolation monitor transients may resemble actual cardiac waveforms and inhibit heart rate alarms. Ensure correct electrode placement and cable arrangement to minimize line isolation monitor transients.

Equipment alerts are technical alert conditions annunciated to the clinician that require a response to ensure (or restore) the system's proper function and ability to reliably monitor the patient. An equipment alert does not indicate that the patient is in immediate danger, but states a technical condition that may prohibit the detection of a patient's alarm. Alerts occur when a sensor's ability to continue monitoring is impeded or no longer possible.

Alerts			
Priority/Severity	**Description**	**Unacknowledged Alerts**	**Acknowledged Alerts**
High	High risk of affecting the ability to monitor the patient and detect patient alarms	Audio annunciation in progress	No audio annunciation
Medium	Medium risk of affecting the ability to monitor the patient and detect patient alarms	Audio annunciation in progress	No audio annunciation
Low	Low or no risk of affecting the ability to monitor the patient and detect patient alarms	No audio annunciation	No audio annunciation

For a complete listing of all equipment alerts, see Equipment Alerts on page 100

Note: There are no Life Threatening alerts.

6.3.1 Unacknowledged Alarms / Alerts

An Unacknowledged Alarm or Unacknowledged Alert is defined as being *in progress*, where there has been no clinician response. Alternatively, the condition that caused the alarm or alert can resolved itself before a clinician response.

When a life threatening alarm occurs and the alarming condition resolves itself before a clinician is able to respond, visual indications of the Life Threatening alarms continues to annunciate until the clinician acknowledges the alarm.

When a high alarm occurs and the alarming condition resolves itself before a clinician is able to respond, the high alarm message will be displayed for up to 5 minutes in the message area of the **Vital Sign** screen.

When a high, medium or low alert conditions resolves itself before a clinician is able to respond, the high, medium or low alert will not continue to annunciate.

To avoid possible hearing damage, do not place your ear too close to the ViSi Mobile Monitor that is alarming audibly.

When the ViSi Mobile Monitor alarms or alerts, check the patient first to confirm that there is no immediate danger to the patient.

Audio Tones

Audio tones are associated with unacknowledged alarms/alerts:

	Severity	Audio Tones	Duration (ms)	Spacing (ms)
Alarms	Life Threatening	BBB P BB P BBB PP... B - Beep / P - Pause.	100	50
	High	BBB P BB P BBB PPP... B - Beep / P - Pause.	200	100
Alerts	High	Beep Beep There will be a 3 second pause after each sequence.	250	250
	Medium	Beep Beep There will be a 5 second pause after each sequence.	250	250
	Low	No audio tones	N/A	N/A

6.3.2 Acknowledged Alarms / Alerts

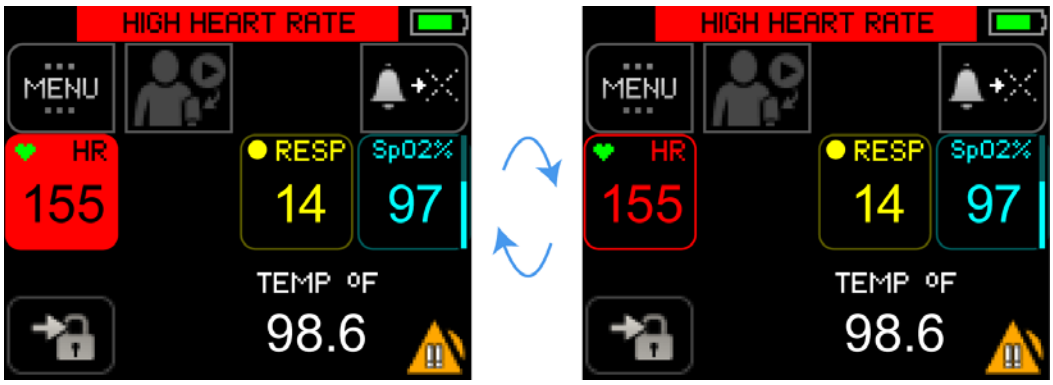
An Acknowledged Alarm or Acknowledged Alert is defined as being *in progress*, where there has been a clinician response.

The Acknowledge Alarm function is used to acknowledge and temporarily silence alarms and alerts. Visual indicators continue as long as the associated condition causing the alarm or alert persists. If the associated condition is still present after the temporary acknowledgement (2 minutes), a new alarm or alert will be generated.

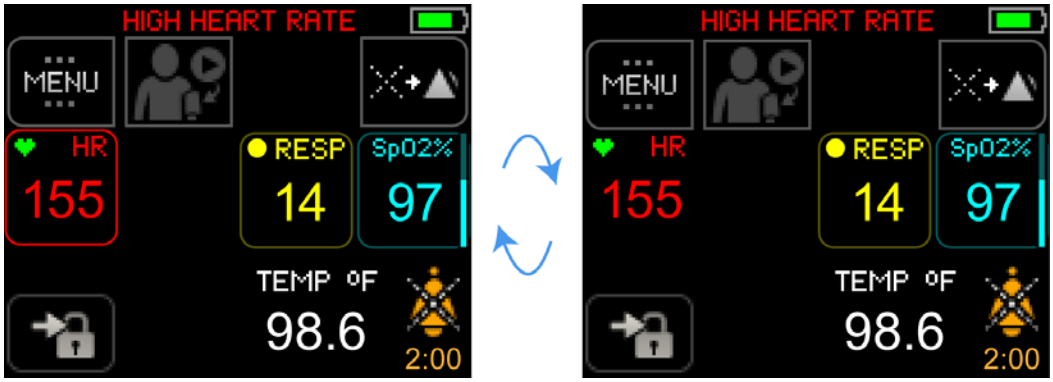
- When a life threatening alarm occurs during **Quiet Monitoring** or **Patient View**, the **Vital Signs** screen immediately appears.
- When a high alarm or alert occurs during **Quiet Monitoring**, the **Patient View** screen immediately appears.
- When an alarm or alert occurs at any other time, there is no automatic navigation from the currently displayed screen.

To acknowledge the alarm

Touch **Acknowledge Alarm** in the upper right side of the **Vital Signs** screen.



Acknowledge Alarm changes to Resume Alarms and an acknowledged countdown is displayed in the bottom right-hand side of the screen.



Note: The Menu and Start NIBP options are unavailable on the Vital Signs screen during an unacknowledged alarm or alert.

Note: Once the alarm or alert is acknowledged, you can change the limits or turn off the alarms and alerts using the Patient Alarm Limits screen.

Once the cause of the alarm or alert is resolved, all audio and visual indications cease and are cleared.

To resume alarm notification before the countdown elapses

Touch **Resume Alarms**.

Alarms will automatically be re-enabled.

6.3.3 Testing Alarms

Whenever a sensor is connected to the Monitor, a self-test of that sensor is initiated automatically to verify the sensor is in good working order. If the sensor and Monitor speaker are in good working order, you will hear a double beep.

Note: Do not cover the microphone of the Monitor during the self-test.

6.4 Patient Alarms

6.4.1 Life Threatening Alarms

Display Message	Alarm Summary	Cause
CUFF BATTERY TEMP	Cuff Module - Battery Over-Temperature Failure	Battery in the Cuff Module has exceeded a safe temperature.
LOW HEART RATE	Low Heart Rate	Patient's heart rate is less than 18 BPM.
MONITOR BATTERY TEMP	Monitor - Battery Over-Temperature Failure	Battery in the Monitor has exceeded a safe temperature.

6.4.2 High Alarms

Display Message	Alarm Summary	Cause
CUFF NO PULSE	Cuff Module - No Pulse Detected	Chest Sensor Cable and Thumb Sensor are not connected. Cuff Module is the only source of PR. Unable to detect a pulse from the cuff inflation.
HIGH BP DIASTOLIC	BP - High Diastolic	Diastolic pressure exceeds the defined upper alarm limit.
HIGH BP SYSTOLIC	BP - High Systolic	Systolic pressure exceeds the defined upper alarm limit.
HIGH HEART RATE	High Heart Rate	Heart rate exceeds the defined upper alarm limit.
HIGH PULSE RATE	High Pulse Rate	Pulse rate exceeds the defined upper alarm limit.
HIGH RESP	High Respiration	Respiration exceeds the defined upper alarm limit.
LOW BP DIASTOLIC	BP - Low Diastolic	Diastolic pressure is less than the defined lower alarm limit.
LOW BP SYSTOLIC	BP - Low Systolic	Systolic pressure is less than the defined lower alarm limit.
LOW HEART RATE	Low Heart Rate	Heart rate is less than the defined lower alarm limit.
LOW PULSE RATE	Low Pulse Rate	Pulse rate is less than the defined lower alarm limit
LOW RESP	Low Respiration	Respiration is less the defined lower alarm limit.
LOW SPO_2	Low SpO_2	SpO_2 is less the defined lower alarm limit.

Display Message	Alarm Summary	Cause
SPO_2 NO PULSE	SpO_2 Module - No Pulse Detected	Chest Sensor Cable is not connected. Thumb Sensor is the only source of PR. Unable to detect a pulse from the Thumb Sensor.

6.5 Equipment Alerts

6.5.1 ViSi Mobile Monitor Alerts

Display Message	Severity	Cause	Solution
AUDIO FAILURE	High	Either the microphone or the speaker on the Monitor has failed.	Replace the Monitor and return it to Sotera Wireless, Inc.
BATTERY CRITICAL	Medium	Monitor battery charge is critically low.	Replace the Monitor.
BATTERY LOW	Low	Monitor battery charge is low.	Prepare to replace the Monitor.
CONNECT TO PATIENT	Low	A sensor has been connected to the Monitor but not yet applied to the patient. No vital sign measurement has been detected.	Apply the sensor to the patient.
MONITOR FAILURE	High	This can indicate various failure modes related to the Monitor.	Replace the Monitor and return it to Sotera Wireless, Inc.
UNABLE TO MONITOR	High	Battery in the Monitor is too low to continue monitoring.	Replace the Monitor.

6.5.2 ViSi Mobile Chest Sensor Cable and ECG Alerts

Display Message	Severity	Cause	Solution
CHEST SENSOR	High	The Chest Sensor Cable is disconnected from the Monitor and not yet acknowledged by the clinician.	Acknowledge the alert and remove the Chest Sensor Cable from the patient, or reconnect the Chest Sensor Cable to the Monitor.
	Low	More than one Chest Sensor Cable is simultaneously connected to the Monitor.	Remove the extra Chest Sensor Cable(s) from the Monitor.
	Medium	Various failure modes related to the Chest Sensor Cable.	Replace the Chest Sensor Cable and return it to Sotera Wireless, Inc.
ECG LEAD (+ lead label)	Medium	One or more lead wires have failed.	Reconnect the ECG electrode, if necessary. Replace the ECG electrode, if necessary.
ECG LEADS	Medium	All ECG lead wires have failed.	Reconnect the lead wires to the ECG electrodes. Replace the ECG electrodes if necessary.

If ECG electrodes need to be replaced, use all of the same type of ECG electrode on the patient. Mixing ECG electrode types can adversely affect ECG monitoring.

6.5.3 ViSi Mobile Thumb Sensor and SpO2 Alerts

Display Message	Severity	Cause	Solution
SpO_2 SIGNAL LOST	Medium	No pulse rate detected from the Thumb Sensor. Another pulse rate / heart rate source is available.	Reposition the Thumb Sensor.
THUMB SENSOR	High	The Thumb Sensor has been disconnected from the Monitor and has not yet been acknowledged by the clinician.	Acknowledge the alert, or reconnect the Thumb Sensor to the Monitor.
	Medium	This can indicate various failure modes related to the Thumb Sensor.	Make sure the Thumb Sensor is securely wrapped around the thumb. Replace or reposition the sensor if necessary.
THUMB SENSOR OFF	Medium	The optical signal has been lost.	Reposition the Thumb Sensor at the base of the patient's thumb. Replace the Thumb Sensor.

6.5.4 ViSi Mobile Cuff Module and NIBP Alerts

Display Message	Severity	Cause	Solution
CUFF EMPTY BATTERY	Medium	Battery in the Cuff Module is empty. No measurements are possible.	Replace the Cuff Module with one that has a full battery charge.
CUFF FAILURE	Medium	Cuff accuracy "zero pressure" test failed.	Return the Cuff Module to your Bio Med. Replace with another Cuff Module.
	Medium	This can indicate various failure modes related to the Cuff Module.	Replace the Cuff Module and return it to Sotera Wireless, Inc.
CUFF LEAK	Medium	An air leak from the Cuff is detected.	Check the connection between the Cuff and the Cuff Module. Check the Cuff for damage.
CUFF LOW BATTERY	Low	Battery in the Cuff Module is low.	Replace the Cuff Module with one that has a full battery charge.

Display Message	Severity	Cause	Solution
CUFF MODULE	High	The Cuff Module is disconnected from the Monitor and the alert is not yet acknowledged by the clinician.	Acknowledge the alert and either reconnect the Cuff Module to the Monitor or remove the Cuff Module from the Cuff and remove the Cuff from the patient.
	Low	More that one Cuff Module is simultaneously connected to the Monitor.	Remove the extra Cuff Module(s) from the Monitor.
CUFF MODULE 300 mmHg	Medium	A pressure of 300mmHg was reached when inflating the Cuff.	Check the patient. Make sure that the Cuff is positioned on the arm correctly, and wrapped snugly around the arm.
CUFF NO PULSE	Medium	No pulse detected from the NIBP measurement, but a pulse is detected from another source (SpO_2 or ECG).	Make sure that the Cuff is positioned on the arm correctly, and wrapped snugly around the arm.
CUFF OCCLUDED	Medium	Something is blocking the air from being pumped into the Cuff.	Check for a kinked hose. Check to make sure that the connection between the Cuff and the Cuff Module is not blocked.
NIBP UNOBTAINABLE	Medium	NIBP measurement is unobtainable.	Make sure that the Cuff is positioned on the arm correctly, and wrapped snugly around the arm.
CUFF NIBP NEEDED	Low	Continuous NIBP measurements (cNIBP) needs to be recalibrated.	Connect the Cuff Module and recalibrate by touching the Calibrate cNIBP button.
CALIBRATION FAILED	High	An attempt to calibrate the continuous NIBP measurements has failed.	• Make sure that the Cuff is positioned on the arm correctly, and wrapped snugly around the arm. • Ensure the patient is sitting in a reclined position and remains still during the calibration process.

6.5.5 Miscellaneous Alerts

Display Message	Severity	Cause	Solution
INVALID PLUG	Low	During monitoring the Bio Med or Shipping Plug has been connected to the rounded end of the Monitor.	Remove the invalid Plug.
MONITORING INTERRUPTED	Medium	During a monitoring session, all cables were disconnected from the Monitor and the Monitor was placed in the Charger without going through the Stop Monitoring procedure.	Remove the Monitor from the Charger and perform the Stop Monitoring procedure.
MOTION ARTIFACT	Low / Medium	Excessive motion is preventing a PR measurement.	Stabilize the patient's movements. You may need to reposition the Thumb Sensor and/or Monitor.
	Low / Medium	Excessive motion is preventing a NIBP measurement.	Stabilize the patient's movements. You may need to reposition the NIBP Module and/or Monitor.
	Low / Medium	Excessive motion is preventing a RESP measurement.	Stabilize the patient's movements. You may need to reposition the sensor.
	Low / Medium	Excessive motion is preventing a SpO_2 measurement.	Stabilize the patient's movements. You may need to reposition the Thumb Sensor and/or Monitor.
PATIENT TAMPERING	Low	Someone has unsuccessfully attempted to log into the Monitor.	Enter the correct PIN and check settings to confirm nothing has changed.
SENSORS DISCONNECT	High	All sensor connections to the Monitor have been removed without going through the Stop Monitoring process.	Either reconnect the sensor(s) to the Monitor or stop monitoring using the Stop Monitoring process.
SHOCK HAZARD	High	Cuff Module has been placed in the Charger while still connected to the Monitor.	Remove the Cuff Module from the Charger or disconnect the Cuff Module from the Monitor.

6.5.6 ViSi Mobile Charging Alerts

Display Message	Severity	Cause	Solution
CHARGE CURRENT FAULT	High	Monitor charging over current protection error.	Remove the Monitor from the Charger and contact Sotera Wireless, Inc. Customer Service.
CHARGE TEMP FAULT	High	Monitor charging over temperature protection level.	Remove the Monitor from the Charger and contact Sotera Wireless, Inc. Customer Service.
CHARGE VOLTAGE FAULT	High	Voltage level has exceeded the limit when the Monitor is in the Charger.	Remove the Monitor from the Charger and contact Sotera Wireless, Inc. Customer Service.

- Notes -

7. User Maintenance

7.1 Introduction

This section of the manual outlines routine maintenance that should be performed by the user. The ViSi Mobile Monitoring System is designed for stable operation over long periods of time and, under normal circumstances, should not require technical maintenance beyond that described in this section. However, it is recommended that routine maintenance (including checking components for damage), calibration, and safety checks be performed at least once a year as required by your facility administration practice.

Routine testing of functionality, alarms and alerts can be verified using standard electronic patient simulators.

In the event any component needs to be returned to Sotera Wireless, Inc; contact the Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area. Prior to shipping, ensure the returned components have been properly disinfected.

The ViSi Mobile Cuff Module contains an air filter that should be inspected by the Bio Med in accordance to the service schedule as described in the Technical Reference Manual. The ViSi Mobile Disposable Cuff should be used on one and only one patient.

For more technical information, refer to the ViSi Mobile Monitoring System Technical Manual.

The ViSi Mobile Monitoring System components should only be serviced by Sotera Wireless, Inc. technicians or authorized service providers.

7.2 Cleaning and Disinfection

The ViSi Mobile Monitor, Cuff Module, Chest Sensor Cable and Thumb Sensor require cleaning and disinfection prior to reuse on a different patient.

To prevent possible cross-contamination, properly clean and disinfect all reusable components between patients.

Do not clean the ViSi Mobile Monitor with detergents while worn by the patient.

Do not clean the ViSi Mobile Monitor while it is plugged into the ViSi Mobile Charger.

Do not clean the ViSi Mobile Cuff Module while it is plugged into the ViSi Mobile Charger.

Do not apply liquid to the ViSi Mobile Cuff Module. To clean, use a damp cloth.

Ensure the sensor connector contacts are thoroughly dried to prevent possible malfunction.

Thumb sensors which are saturated with fluid should be allowed to air dry thoroughly before re-use.

Prior to cleaning and disinfecting:

1. Pre-clean at the point of use to remove and prevent drying of soil and contaminants.
2. Ensure all components are disconnected, including the ViSi Mobile Monitor from the Wrist Cradle and Thumb Sensor from the Thumb Cradle.

After cleaning and disinfection is complete, inspect the System components for wear, damage, discoloration, fraying and cracking. Replace any System components that show evidence any of these anomalies.

To clean the ViSi Mobile Monitoring System components

1. Hand wash the System components using mild soap or detergent and water. Use moistened lint-free cloths to remove residual cleaner.

   A soft-bristled brush may be used for heavily soiled areas, where needed.
2. Dry the System components using a lint-free cloth.
3. Visually examine each System component to ensure all soil contaminants have been removed.
4. Repeat the above cleaning process as required.

To disinfect the ViSi Mobile Monitoring System components

Do not use abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.

Use only recommended cleaning / disinfecting agents to prevent damage to the device and components.

Do not autoclave the ViSi Mobile Monitor, its components, or accessories.

Do not use excessive amounts of liquid when cleaning the ViSi Mobile Chest Sensor Cable or the ViSi Mobile Thumb Sensor.

1. Disinfect all System components by wiping components with a lint-free cloth moistened with isopropyl alcohol.
2. Dry thoroughly using a lint-free cloth.

7.3 Inspecting Equipment and Accessories

After cleaning and disinfecting, you should visually inspect the ViSi Mobile Monitoring System components:

1. For each component, examine the exteriors for cleanliness and general physical conditions. Ensure the housings are not cracked or broken, that everything is present, there are no spilled liquids and no signs of abuse.
2. Inspect all component cables for damage. Check their strain relief for general condition. Ensure there are no breaks in the insulation. If any cables show signs of damage, do not use.
3. Inspect all disposable accessories (Wrist Cradle, Cuff, Thumb Strap, Securements, etc). If any show signs of damage or pre-use, do not use.

7.4 Product Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the ViSi Mobile Monitoring System components appropriately before disposing of them in accordance with your country's laws for equipment containing electrical and electronic parts.

The ViSi Mobile Monitoring System components are designated for separate collection at an appropriate collection point. Do not dispose of as household waste. Refer to your facility's procedures.

After patient use, the disposables from the ViSi Patient Kit may contain bio-hazard materials.

Disposables from the ViSi Patient Kit should be disposed of per your facility's procedures for bio-hazard materials.

Contact the Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area to obtain additional information about cleaning and disinfecting the ViSi Mobile Monitoring System components or product disposal.

8. Troubleshooting

8.1 Introduction

The ViSi Mobile Monitor is designed to alert you to technical issues that may occur while monitoring a patient's vital signs.

The following tables provide troubleshooting solutions to potential problems that may be encountered while monitoring a patient

8.2 ViSi Mobile Monitor

Problem	Potential Cause	Solution
The screen is blank	The display is in Quiet Monitoring Mode.	Touch the screen with one finger for two seconds to activate display. Plug in a sensor to initiate monitoring.
	The display is in Hibernation Mode.	Plug in a sensor to initiate monitoring.
	The battery charge is too low.	Disconnect all sensors from the Monitor, clean the Monitor, and place it in the Charger.
Sensors won't Plug into the Monitor	Plug is oriented with the connector contacts facing downwards.	• Orient the Plug so that the connector contacts are facing upwards.
	Trying to Plug into wrong end of the Monitor.	Only the Thumb Sensor is designed to be Plugged into the rounded end of the Monitor. All other sensors can be Plugged into any port on the flat end of the Monitor.

8.3 ViSi Mobile Chest Sensor Cable

Problem	Potential Cause	Solution
Chest sensor Cable is too short to Plug into the Monitor	Monitor is oriented in the wrong direction.	Make sure that the flat end of the Monitor is oriented towards the elbow.
	The Chest Sensor Cable is secured to the side of the chest opposite the arm with the Monitor.	Secure the Chest Sensor Cable midway between the sternum and the shoulder of the same arm that the Monitor is on.
No HR numeric	ECG electrodes not connected to lead wires.	Ensure that the lead wires are snapped securely onto the ECG electrodes.
	ECG electrodes not firmly attached to the patient's chest.	Ensure that the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	ECG electrode gel is dry.	Replace ECG electrodes.
	Broken/damaged lead wires.	Replace damaged Chest Sensor Cable.
	Chest Sensor Cable not securely Plugged into the Monitor.	Make sure that the Chest Sensor Cable is securely Plugged into the Monitor.

Problem	Potential Cause	Solution
HR is erratic	ECG electrodes are not all the same.	Use all the same ECG electrode type, size, materials, and manufacturer.
	ECG electrode gel is dry.	Replace ECG electrodes.
	ECG electrodes not firmly attached to the patient's chest.	Check the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
No ECG waveform	*See No HR numeric above.*	*See No HR numeric above.*
ECG waveform too small	Using a 3-lead Chest Sensor Cable: Lead II has a low amplitude. Lead II only available with a 3-lead Chest Sensor Cable.	• Select alternate ECG electrode sites; prepare skin sites; connect lead wires to new ECG electrodes and place on the chest. • Replace 3-lead Chest Sensor Cable with 5-lead Chest Sensor Cable.
	Using a 5-lead Chest Sensor Cable: Selected lead has low amplitude.	5-lead Chest Sensor Cable: select a different lead to view.
ECG waveform is noisy; looks like pacer indicators in the waveform	ECG electrodes not firmly attached to the patient's chest.	Ensure that the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	ECG electrode gel is dry.	Replace ECG electrodes.
No RESP numeric	See No HR numeric above.	See No HR numeric above.
	The Monitor is not capable of measuring RESP.	See Bio Med.
RESP is erratic	ECG electrodes not firmly attached to the patient's chest.	Ensure that the ECG electrodes are securely attached to the chest; ECG electrode sites are clean and free of excess hair.
	ECG electrode gel is dry.	Replace ECG electrodes.
No TEMP numeric	The Chest Module sensor is placed on the patient with the Temperature Sensor facing away from the patient.	Place the Chest Module sensor on the patient such that the Temperature Sensor is in direct contact with the patient's chest.
	Sensor is not attached to the patient's chest.	Secure the Chest Sensor Cable to the chest. Make sure that a change in position does not affect the sensor's contact with the skin.

Problem	Potential Cause	Solution
TEMP is erratic	Chest Sensor Cable is not in contact with the skin completely/ securely.	Secure the Chest Sensor Cable to the chest. Make sure that a change in position does not affect the sensor's contact with the skin.
	Skin is not clean and dry.	Clean and dry the skin thoroughly and secure the Chest Sensor Cable to the chest.

8.4 ViSi Mobile Thumb Sensor

Problem	Potential Cause	Solution
Sensor cable too short to Plug into Monitor	Monitor is oriented in the wrong direction.	Make sure that the rounded end of the Monitor is oriented towards the hand.
	Thumb sensor is routed wrong.	Make sure the cable is routed around the outside of the thumb.
No SpO_2 numeric	Broken/damaged Thumb Sensor.	Replace the Thumb Sensor
	Something is blocking the optics or detector in the Thumb Sensor.	Make sure nothing is blocking the optics or detector.
	Thumb Sensor not secured in the Thumb Sensor Cradle.	Place the Thumb Sensor securely in the Thumb Sensor cradle.
	Thumb Sensor not secured to the base of the thumb.	Secure the Thumb Sensor to the base of the thumb.
	Thumb Sensor not securely Plugged into the Monitor.	Make sure that the Thumb Sensor is securely Plugged into the Monitor.
SpO_2 is erratic	Something is partially blocking the optics or detector in the Thumb Sensor.	Make sure nothing is blocking the optics or detector.
	Thumb Sensor not secured to the base of the thumb.	Secure the Thumb Sensor to the base of the thumb.
	Thumb Sensor is not in the correct location.	Reorient the Thumb Sensor at the base of the thumb and secure with the Thumb Wrap.
	Thumb Strap is too tight.	Loosen the Thumb Strap making sure that it is still secure.

8.5 ViSi Mobile Cuff Module

Problem	Potential Cause	Solution
Cuff Module cable is too short to Plug into Monitor	Monitor is oriented in the wrong direction.	Make sure that the flat end of the Monitor is oriented towards the arm.
	Cuff Module is on the arm opposite the Monitor.	Place the Cuff Module on the same arm that the Monitor is on.

Problem	Potential Cause	Solution
No NIBP measurement	Battery charge is too low.	Replace the Cuff Module.
	Cuff Module not Plugged securely into the Monitor.	Make sure that the Cuff Module is Plugged securely into the Monitor.
	Not set up for automatic measurements.	From the NIBP Settings screen, select an automatic interval.
	The time from the last measurement exceeds the period of time to display a measurement.	Initiate a measurement from the Vital Signs screen.
NIBP measurement doesn't match an auscultatory measurement	Measurements were not taken at the same time.	Measurements are taken at the same time.
	Measurements were taken on different arms.	The BP in both arms is the same, sometimes there is a difference between arms.
	Different size cuffs were used.	Ensure the BP cuff size is the same on both arms, and the correct size for the arm.
	Both arms were not at the same level when the BP was measured.	The arms are positioned at the same level relative to the heart.
LED on Cuff Module displays red when in the Charger.	Voltage level has exceeded expectation.	• Remove Cuff Module from the Charger. • Report the problem to Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.
	Current level has exceeded expectation.	• Remove Cuff Module from the Charger. • Report the problem to Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.
	Over temperature protection current temperature has exceeded expectation.	• Remove Cuff Module from the Charger. • Report the problem to Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.

8.6 Screen Access

Problem	Potential Cause	Solution
No response to touching any buttons	Touching the screen with more than one finger.	Touch the button with only a single finger.
	Button is not an active button.	Active buttons are those with borders, and are not dimmed in appearance compared to other buttons.
	Touching the screen with a pen or stylus.	Touch the button with only a single finger.
Cannot access the Vital Signs screen	Screen is locked.	Touch the Unlock button and enter the correct PIN.
	Access denied due to entering the wrong PIN code.	Enter the correct PIN code.
Patient has accessed the monitoring functions	Screen was not locked after last clinician interaction.	• Make sure to lock the screen each time you complete your interactions. • Remind the patient that this is a medical device, and that tampering may result in missing important clinical events.
	Patient guessed PIN correctly.	• Define appropriate PIN codes (not 0000 for example). • Remind the patient that this is a medical device, and that tampering may result in missing important clinical events.

8.7 ViSi Mobile Battery Charger

Problem	Potential Cause	Solution
Batteries in the Monitor and Cuff Module do not charge	The Monitor and Cuff Module are not securely seated in the Charger.	Make sure that the Monitor and Cuff Module are securely seated in the Charger. The monitor and Cuff Module are designed to fit into the Charger in one direction.
	The Charger is not completely Plugged in to the wall socket.	• Make sure that the Plug is securely Plugged into an active wall socket and there is a green light on the Battery Charger. • Make sure that the power cord is not damaged.
	AC Adapter is not Plugged into the Charger.	• Plug the AC Adaptor into the Charger.

9. Specifications

9.1 Introduction

This section provides specifications regarding measurement ranges, accuracy levels and environmental operating conditions for the ViSi Mobile Monitoring System.

Do not use the ViSi Mobile Monitoring System in neonatal or pediatric patients under the age of 12 years since the System has not been tested for these patient groups.

9.2 Vital Sign Measurements

9.2.1 Heart Rate

Heart Rate	
Display Range	0 to 240 BPM
Accuracy Range	30 to 240 BPM
Accuracy	3BPM or ±3% of reading, whichever is greater
Resolution	1BPM
Pacemaker	• The monitor detects and rejects pacemaker impulses in accordance with AAMI EC13:2002 • Performs heart rate calculations on a patient with a pacemaker • Will not recognize a pacemaker impulse as a QRS • Displays pacer markers on ECG waveforms
Pacemaker Pulse Rejection Without Overshoot	Tested per EC13:2002, 4.1.4.1: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms **Note: Amplitude li mited t o 6 60mV for pulse widths from 1.5 to 2.0ms** Indicated Heart Rate: Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM Atrial / Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM
Pacemaker Pulse Rejection With Overshoot	Tested per EC13:2002, 4.1.4.2, Method A: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms **Note: Amplitude limited to 660mV for pulse widths from 1.5 to 2.0ms** **Note: For pulse width > 1.0mS, recovery time limited to 25mS.** Indicated Heart Rate: Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM Atrial / Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM

Heart Rate	
Pacer Pulse Detector Rejection of Fast ECG Signals	Tested per EC13:2002, 4.1.4.3: • Minimum Slew Rate: 25 V/s
Defibrillation Response	• Defibrillator protected • Displays HR measurement < 30 seconds after a defibrillation event • Displays an ECG waveform < 10 seconds after a defibrillation event **Note: Defibrillation events may be implanted or external.** **Note: Defibrillation recovery is dependent upon using proper disposable electrodes. Use only Ag-AgCl disposable electrodes.**
T-Wave Rejection	Tested per EC13:2002, 5.1.2.1: • T-waves up to 1.2 mV in amplitude: • T-waves not detected, no change in indicated heart rate.
Heart Rate Averaging	Tested per EC13:2002, 5.1.2.1 d): • 10 second moving average
Heart Rate Accuracy and Response to Irregular Rhythm	Tested per EC13:2002, 5.1.2.1 e): • Waveform 3a: 80 BPM • Waveform 3b: 30 BPM • Waveform 3c: 120 BPM • Waveform 3d: 60 BPM
Change in Heart Rate	Tested per EC13:2002, 5.1.2.1 f): • 80 BPM to 120 BPM: < 8 seconds • 80 BPM to 40 BPM: < 8 seconds
Time to Alarm for Cardiac Standstill	Tested per EC13:2002, 4.2.8.4: • < 10 seconds
Time to Alarm for Tachycardia	Tested per EC13:2002, 5.1.2.1 g): Figure 4a: • Gain = 1.0x: 22 secs • Gain = 2.0x: 21 secs • Gain = 0.5x: 10 sec with HR = 0 Figure 4b: • Gain = 1.0x: 16 secs • Gain = 2.0x: 18 secs • Gain = 0.5x: 31 sec with HR = 0
Input Impedance	> 20 Mohms
Frequency Response	0.5 to 125Hz
Lead Off Detection Current	< 6 nA
Common Mode Rejection Ratio	> 85 db

9.2.2 Respiration

Respiration	
Method	Impedance Pneumography
Display Range	0 to 50 BR/MIN
Accuracy Range	3 to 50 BR/MIN
Accuracy	± 3 BR/MIN or 10% of reading, whichever is greater
Resolution	1 BR/MIN
Respiration Drive	Voltage: 1.00 V P-P ±5% Frequency: 32.0 KHz ±2%

9.2.3 Pulse Oximetry (SpO_2, Functional Oxygen Saturation)

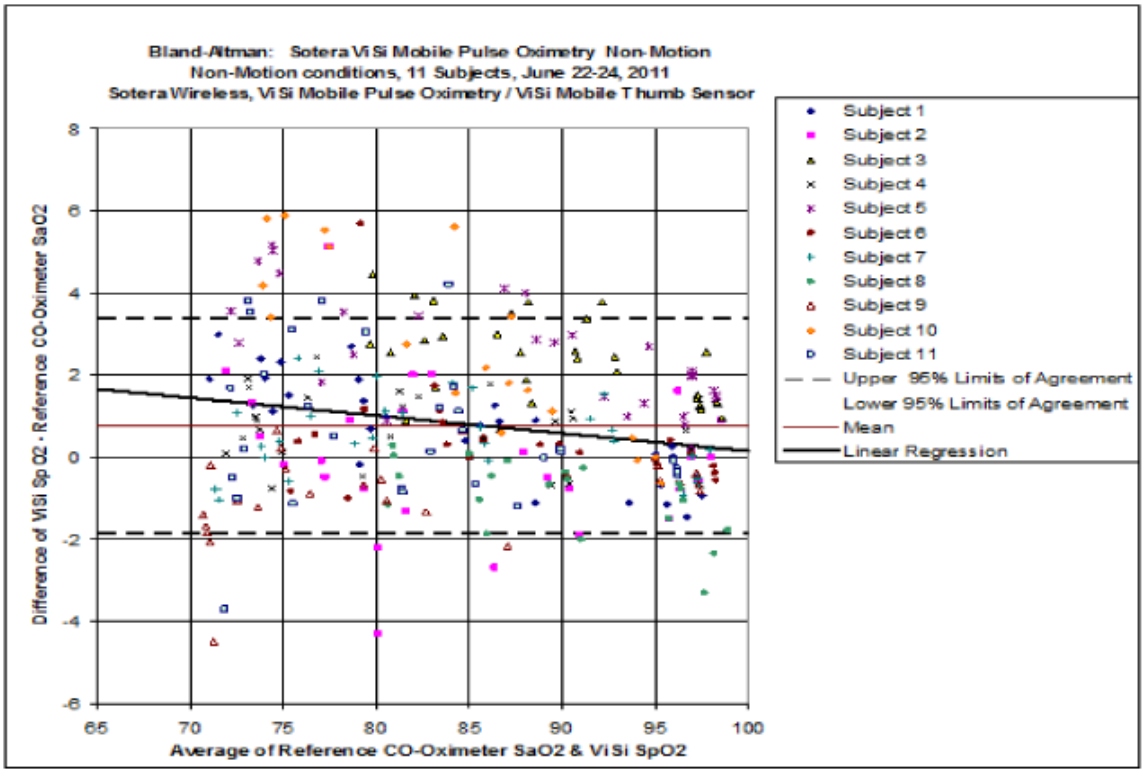
Pulse Oximetry (SpO_2, Functional Oxygen Saturation)		
Normative Reference	ISO 9919: 2005	
SpO2	Display Range	49 to 100%
	Accuracy Range	70 to 100%
	Accuracy	≤ 2% from 70-100% (no motion)[a] Unspecified from 49-69%
	Resolution	1%
Pulse Rate	Display Range	0 to 240 BPM
	Accuracy Range	30 to 240 BPM
	Accuracy (No Motion)	± 3 BPM; < 50 BPM @ ≥ 0.6% Pulsatile Modulation ± 3 BPM; ≥ 50 BPM @ ≥ 0.4% Pulsatile Modulation
	Accuracy (RMS Error)	≤ 3 BPM
	Rate Resolution	1 BPM
Validation Study	Per ISO 9919. The ViSi SpO2 is calibrated to display functional oxygen saturation and validated against human subjects arterial blood sample reference measured with CO-Oximeter (see table below). **Note: A functional tester cannot be used to asse ss the accuracy of a pulse oximeter probe or a pulse oximeter monitor.**	
Calculation Rate	Every pulse	
Display Refresh Rate	Every 3 seconds	
Averaging	12 beat average following initialization	
Alarm Range	Low - Fixed at 85%	
Alarm Delay	30 seconds (fixed)	
Waveform Display	• Amplitude is normalized • Sweep speed is scaled to 25mm/sec to match ECG	
Sensor Application Time	Sensor should be checked every 8 hours	
Optical Wavelengths / power	Red: 660nM / max 6.5mW (±15%) Infra-Red: 905nM / max 5.2mW (±15%)	
Interference	SpO2 can be adversely effected by the presence of dyshaemoglobins, ambient light (including photosynamic therapy); electromagnetic interference; electrosurgical units; dysfunctional hemoglobin; presence of certain dyes; inappropriate positioning of the pulse oximeter probe.	
Toxicity	Thumb sensor uses white silicone which has no known toxicity effects.	

a. Bench testing indicates accuracy may be compromised at pulse rates below 50BPM at modulations less than 0.6% and extremely low pulse rates of 30BPM at modulations less than 0.8%.

The table below shows A_{rms} values measured using the ViSi Mobile Thumb Sensor (Model 92-10020) with the ViSi Mobile Monitoring System in a clinical study:

Validation Data (per ISO 9919)				
Age of Volunteers	18 - 45			
SpO2 Accuracy (No Motion)				
Spo2 Range	70-100%	90-100%	80-90%	70-80%
Accuracy (A_{rms}) - No Motion	1.9	1.2	1.9	2.4

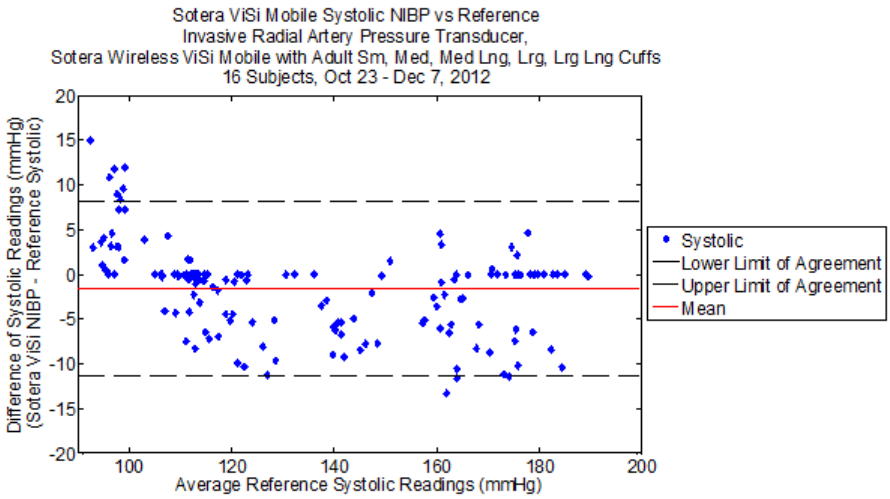
Bland-Altman: ViSi Mobile Pulse Oximetry



9.2.4 Non-Invasive Blood Pressure (NIBP)

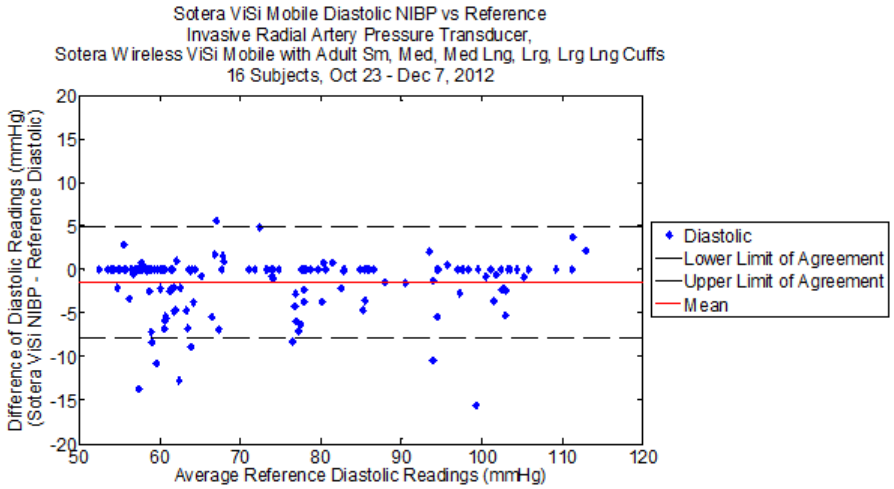
Non-Invasive Blood Pressure (NIBP)	
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.
Principle of Operation	Oscillometry
Systolic	Range: 60 to 240 mmHg Accuracy: Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Diastolic	Range: 40 to 160 mmHg Accuracy: Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Mean Arterial Pressure (MAP)	Range 50 to 185 mmHg Accuracy Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution 1 mmHg
Pulse Rate	Accuracy (NIBP) <3 BPM
Validation Study	Invasive blood pressure (radial artery) reference Number of subjects: 16 Subject age range: 19-48 years

Systolic Bland Altman Analysis (NIBP)



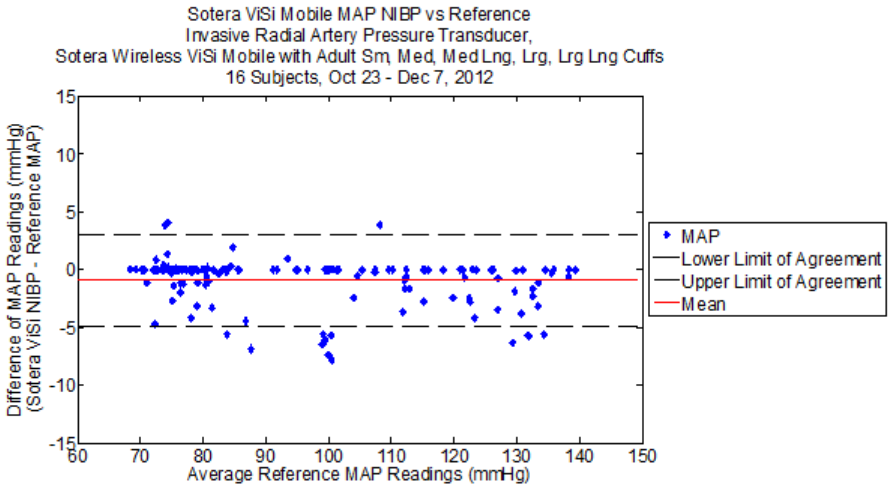
Sample Size:	152 data points
Mean:	-1.65 mmHg
Standard Deviation:	5.01 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	8.2 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-11.5 mmHg

Diastolic Bland Altman Analysis (NIBP)



Sample Size:	152 data points
Mean:	-1.49 mmHg
Standard Deviation:	3.22 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	4.8 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-7.8 mmHg

MAP Bland Altman Analysis (NIBP)

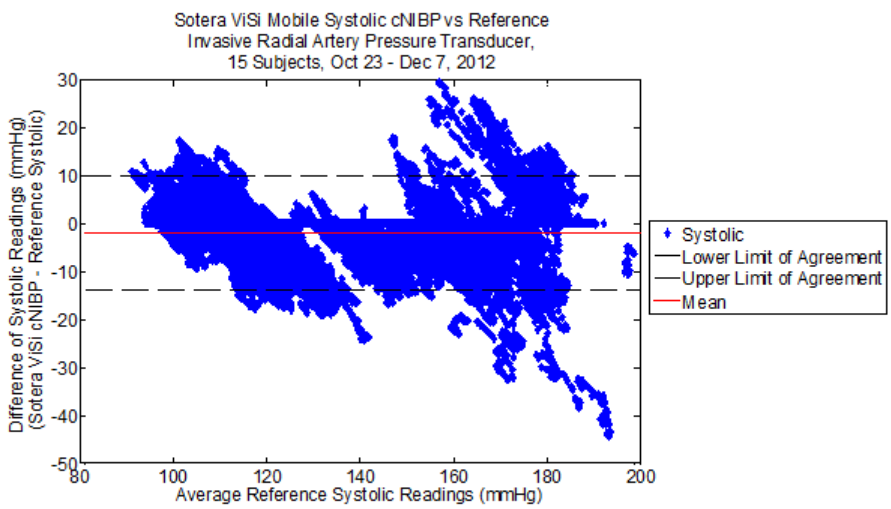


Sample Size:	152 data points
Mean:	-0.91 mmHg
Standard Deviation:	2.04 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	3.1 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-4.9 mmHg

9.2.5 Continuous Non-Invasive Blood Pressure (cNIBP)

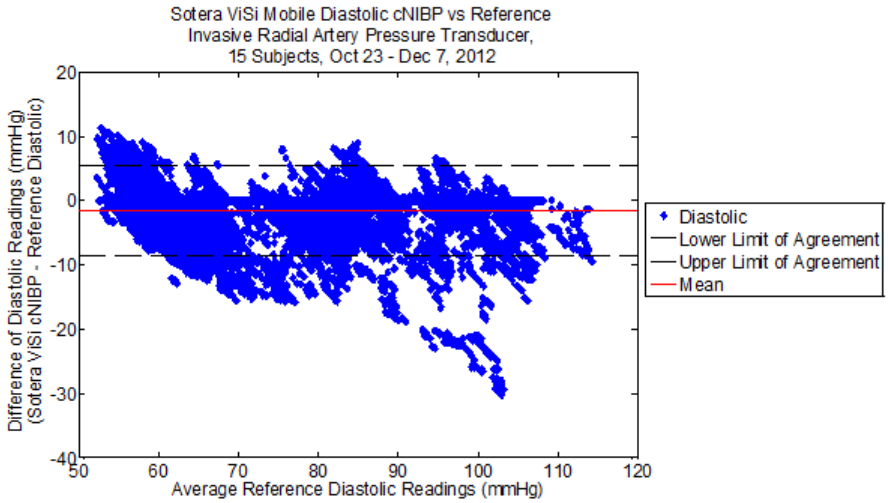
Non-Invasive Blood Pressure (NIBP)	
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.
Principle of Operation	cNIBP is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location.
Systolic	Range: 60 to 240 mmHg Accuracy: Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Diastolic	Range: 40 to 160 mmHg Accuracy: Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Mean Arterial Pressure (MAP)	Range 50 to 185 mmHg Accuracy Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution 1 mmHg
Validation Study	Invasive blood pressure (radial artery) reference Number of subjects: 15 Subject age range: 19-48 years

Systolic Bland Altman Analysis (cNIBP)



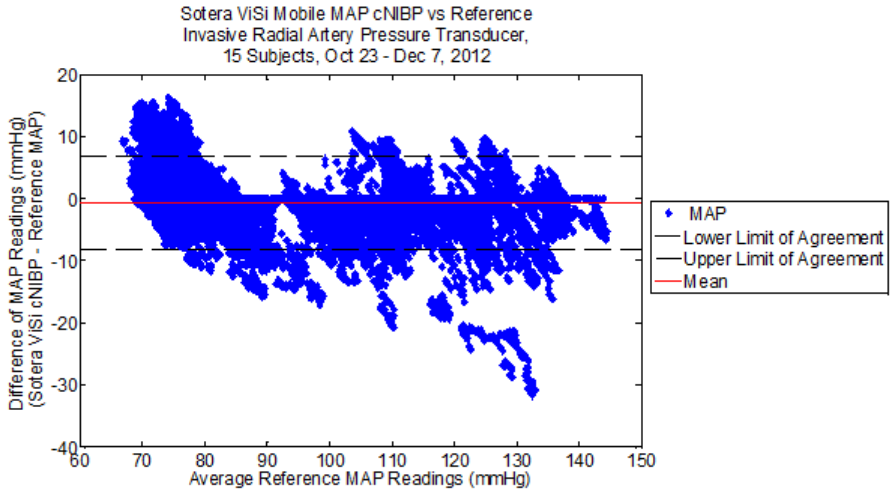
Sample Size:	54166 data points
Mean:	-2.05 mmHg
Standard Deviation:	6.07 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	9.8 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-13.9 mmHg

Diastolic Bland Altman Analysis (cNIBP)



Sample Size:	54166 data points
Mean:	-1.71 mmHg
Standard Deviation:	3.58 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	5.3 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.7 mmHg

MAP Bland Altman Analysis



Sample Size:	54166 data points
Mean:	-0.72 mmHg
Standard Deviation:	3.82 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	6.8 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.2 mmHg

9.2.6 Temperature

Temperature				
Scale	^{o}C		^{o}F	
Range / Accuracy (measurement at approximately 102 kPa / 768 mmHg)	Range	Accuracy	Range	Accuracy
	0° - 19.9^{o}	$\pm 0.3^{o}$	32° - 67.9^{o}	$\pm 0.5^{o}$
	20° - 24.9^{o}	$\pm 0.3^{o}$	68° - 76.9^{o}	$\pm 0.5^{o}$
	25° - 35.9^{o}	$\pm 0.2^{o}$	77° - 96.7^{o}	$\pm 0.3^{o}$
	36° - 39.9^{o}	$\pm 0.1^{o}$	96.8^{o} - 103.9^{o}	$\pm 0.2^{o}$
	40° - 41.9^{o}	$\pm 0.2^{o}$	104° - 107.5^{o}	$\pm 0.3^{o}$
	42° - 50.0^{o}	$\pm 0.3^{o}$	107.6^{o} - 122°	$\pm 0.5^{o}$
Resolution	$\pm 0.1^{o}$		$\pm 0.1^{o}$	
Transient Response	< 6 min (25° - 37°)		< 6 min (77° - 98.6^{o})	

9.3 Physical Components

9.3.1 ViSi Mobile Monitor

ViSi Mobile Monitor		
Physical Characteristics	Dimensions	2.59 cm H x 4.85 cm W x 9.35 cm L 1.02 in. H x 1.91 in. W x 3.68 in. L exclusive of connectors and Wrist Cradle
	Weight	110g / 3.92oz
Monitor	Display	OLED, 160 x 128 pixels, full color
	Audio	Alarm annunciation, QRS, self-test
	Waveforms	One waveform, user selectable Aspect Ratio: 0.4 Sec/mV Scaled equivalent to 25 mm/sec sweep speed Respiration waveform scaled equivalent to 6.25 mm/sec sweep speed
Battery	Operating Time	> 12 hours
	Fuel Charge Display	Battery Symbol Charge Level with Full Indication
	Charge Time	Less than 4 hours
	Battery Type	Li-Ion, 3.7 V., 2000 mAh, single cell
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Green soap

Mode Plugs

Mode Plugs	
Shipping Plug	Turns device off completely
Bio Med Plug	Enables configuration and test functions
Locking Plug	Secures Monitor into Wrist Cradle

Alarms and Alerts Visual Display

The following table outlines the visual display when alarms are in progress:

Severity	Indicator Attributes	Toggle / Flash Speed	Duty Cycle
High Priority	Red	1.5Hz	50% ON
Life-Threatening Priority	Red / White	1.5Hz	50% ON

The following table outlines the visual display when alerts are in progress:

Severity	Indicator Attributes	Toggle / Flash Speed	Duty Cycle
All Severities	Cyan (Blue)	Constant (ON)	100% ON

Alarms and Alerts Audio Tones

The following table outlines the audio tones when alarms are in progress:

Severity	Melody	Volume [db]	Frequency (f_o) [Hz]	Duration (t_d) [ms]	Spacing (t_s) [ms]	5th-6th [s]	Inter-Burst (t_b) [s]
Life Threatening	b5.b5.b5..b5.b5	78	987.767	100	50	0.35	2.5
High	b5.b5.b5..b5.b5	78	987.767	200	100	0.35	5

The following table outlines the audio tones when alerts are in progress:

Severity	Melody	Volume [db]	Frequency (f_o) [Hz]	Duration (t_d) [ms]	Spacing (t_s) [ms]	Inter-Burst (t_b) [s]
High	e5.c5	68/63	659.255, 523.251	250	250	3
Medium	e5.c5	68/63	659.255, 523.251	250	250	15

Note: There are no audio tones associated with low severity alerts.

9.3.2 ViSi Mobile Chest Sensor Cable

ViSi Mobile Chest Sensor Cable		
Mechanical	Complies with EC53	
Length	54 cm (21.25 in)	
Weight (5 lead-wire / 3 lead-wire)	72 g / 62 g (2.54 oz. / 2.19 oz.)	
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Green soap

9.3.3 ViSi Mobile Cuff Module

ViSi Mobile Cuff Module		
Physical Characteristics	Dimensions	3.10 cm H x 4.85 cm W x 12.19 cm L (1.22 in. H x 1.91 in. W x 4.80 in. L) exclusive of cable
	Weight	157 g (5.54 oz)
Battery	Operating Time	> 30 cuff inflations or 24 hrs, whichever occurs first
	Charge Display Status	Eight LEDs: Six levels of Green, Yellow, Red
	Charge Time	< 4 hours
	Battery Type	Battery Pack, Li-Ion, 2000mAh
Cuff Sizes	Small	
	Medium	
	Large	
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Green soap

When the ViSi Mobile Cuff Module is connected to the other ViSi Mobile Components, the entire system has an ingress protection rating of IPX0.

9.3.4 ViSi Mobile Thumb Sensor

ViSi Mobile Thumb Sensor		
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Green soap

9.3.5 ViSi Mobile Charger

ViSi Mobile Charger		
Physical Characteristics	Dimensions	7.64 cm. H x 12.7 cm. W x 6.35 cm. L (3 in. H x 5 in. W x 2.5 in. L)
	Weight	1.59kg / 3.5lbs
AC Mains	Power Supply	D.C. Input to Charger: 15VDC
	AC Line Voltage	90-264 VAC, 47-63 Hz
	Power (while charging)	50w max
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• Isopropyl alcohol (IPA) • Green soap

9.4 Environmental Conditions

Environmental Conditions for all ViSi Mobile Components (Monitor, Cuff Module, Chest Sensor Cable, Charger, Cuff, Thumb Sensor)		
Condition	**Storage (Packaged / Unpackaged)**	**Operating (Unpackaged)**
Temperature	-20°C to +55°C (50°C for NIBP) -4°F to +131°F (122°F for NIBP)	0°C to +50°C 32°F to +122°F
Humidity	15% to 95% non-condensing (90% for NIBP)	10% to 95% non-condensing (90% for NIBP)
Atmospheric Pressure Range	107 kPa to 50 kPa 803 mmHg to 375 mmHg 1.06 atm to 0.49 atm	107 kPa to 70 kPa 803 mmHg to 525 mmHg 1.06 atm to 0.69 atm

The ViSi Mobile Monitor may not perform to specification if stored or shipped outside the specified temperature range.

9.5 Agency Compliances

Agency Compliances
• ANSI/AAMI EC13, Cardiac monitors, heart rate meters, and alarms • ANSI/AAMI EC53, ECG cables and lead wires. • CAN/CSA C22.2 No 601.1 M90 Part 1: General requirements for basic safety and essential performance • IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety • IEC 60601-1-2, Med. Elect. Equipment – Part 1-2: General requirements for safety – Collateral standard: EMC – Req. and tests. • IEC 60601-1-4, Medical electrical equipment - Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems • IEC 60601-1-6, Medical electrical equipment – Part 1-6: General requirements – Collateral standard: Usability. • IEC 60601-1-8, Medical electrical equipment – Part 1-8: Gen. req. – Col. Std. Gen. requirements, tests and guidance for alarm systems • IEC 60601-2-27, Medical electrical equipment, Part 2-27: Particular requirements or the safety, including essential performance, of ECG monitoring equipment • IEC 80601-2-30, Medical electrical equipment – Part 2-30: particular requirements for the safety, including essential performance, of auto. cycling non-invasive BP monitoring equipment. • IEC 60601-2-49, Particular requirements for the safety of multifunction patient monitoring equipment. • ISO 9919, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. • ISO 81060-2, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. • UL 60601-1 Part 1: General requirements for basic safety and essential performance

9.6 Safety and Performance Tests

You must observe any national regulations on the qualification of the testing personnel and suitable measuring and testing facilities. See *User Maintenance on page 107* for a list of required tests.

9.6.1 Electromagnetic Compatibility (EMC) Specifications

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your monitoring equipment according to the EMC information provided in this manual. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

Consult your BioMed department or vendors for assistance in identifying EMC compliance status of other medical devices when using the ViSi Mobile Monitoring System.

Accessories Compliant with EMC Standards

All accessories (such as the ViSi Mobile Battery Charger) listed in the *System Components* section comply, in combination with the ViSi Mobile Monitor, with the requirements of IEC 60601-1-2-2007.

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

9.6.2 Electromagnetic Emissions

The ViSi Mobile Monitor is suitable for use in the electromagnetic environment specified in the table below. You must ensure that the Monitor is used in such an environment.

Emissions Test	Compliance	Avoiding Electromagnetic Interference
Radio Frequency (RF) emissions	Group 1	The ViSi Mobile Monitor 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 ViSi Mobile Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations IEC 61000-3-3	N/A	

9.6.3 Electromagnetic Immunity

The ViSi Mobile Monitor is suitable for use in specified electromagnetic environment. The user must ensure that it is used in the appropriate environment as described below.

Immunity Test	IEC 60601-2-1		Electromagnetic Environment Guidance
	Test Level	Compliance Level	
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles	<5% UT (>95% dip in UT) for 0.5 cycles	
	40% UT (60% dip in UT) for 5 cycles	40% UT (60% dip in UT) for 5 cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	
	<5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 5 sec	
Power frequency (50/60Hz) 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 and/or hospital environment.

In the above table, UT (Unit in Test) is the ViSi Mobile Monitoring System.

9.6.4 Recommended Separation Distance

The ViSi Mobile Monitor may be temporarily interrupted by UHF RFID Systems (860-960MHz).

Portable and mobile RF communications equipment should be used no closer to any part of the ViSi Mobile Monitor, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with this symbol:

In the following table, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Immunity Test	IEC 60601-1-2 Test Level	ViSi Mobile Monitoring System Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 V_{RMS} 150 kHz to 80 MHz	3 V_{RMS}	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance: 80 MHz to 800 MHz 80 MHz to 800 MHz $d = 3.5\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ 2.0 to 2.3 GHz for short radio $d = 7.0\sqrt{P}$

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 access 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 ViSi Mobile Monitor is used exceeds the applicable RF compliance level above, the Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Monitor.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

From Portable and Mobile RF Communication Equipment

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

In the following table, P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Frequency	**150 KHz to 80 MHz**		**80 MHz to 800 MHz**		**800 MHz to 2.5 GHz**	
Equation	**d = 1.2√P**		**d=1.2√P**		**d=2.3√P**	
Rated max. output power of transmitter	**Separation Distance**		**Separation Distance**		**Separation Distance**	
	(m)	**(ft)**	**(m)**	**(ft)**	**(m)**	**(ft)**
0.01 W	0.1	0.4	0.1	0.4	0.2	0.8
0.1 W	0.4	1.2	0.4	1.2	0.7	2.4
1 W	1.3	3.9	1.3	3.9	2.3	7.5
10 W	3.8	12.4	3.8	12.4	7.3	23.9
100 W	12.0	39.4	12.0	39.4	23.0	75.5

Electrosurgery Interference/Defibrillation/Electrostatic Discharge

The equipment returns to the previous operating mode within 10 seconds without loss of any stored data. Measurement accuracy may be temporarily decreased while performing electrosurgery or defibrillation. This does not affect patient or equipment safety. Do not expose the equipment to x-ray or strong magnetic fields (MRI).

Fast Transients/Bursts

The equipment will return to the previous operating mode within 30 seconds without loss of any stored data.

Appendix A - Symbols

Introduction

This section lists all the icons that are used by the ViSi Mobile Monitor.

Alarms / Alerts

Alarm / Alert States

Symbol	Description
	Unacknowledged life threatening severity alarm in progress.
	Unacknowledged high severity alarm in progress.
	Unacknowledged alert in progress (any severity).
	All alarms in progress have been acknowledged by the clinician.
	Alarm annunciation (visual and audio) has been paused for 2 minutes.
	Alarm annunciation (visual and audio) has been turned off.

Alarm Management

Symbol	Description
	Pause alarm annunciation (visual and audible) for 2 minutes.
	Turn off alarm annunciation (visual and audible).
	Resume alarm annunciation from a paused state.
	Turn alarm annunciation back on.
	Acknowledge an alarm/alert that is in progress.

Battery States

Symbol	Description
	Battery good: the Monitor's battery is fully charged.
	Battery Low: the Monitor's battery voltage is low.
	Battery Critically Low: the Monitor's battery voltage is critically low.

General Icons

Navigation

Symbol	Description
	Unlock the ViSi Mobile Monitor to gain access to the clinical features.
	Lock the ViSi Mobile Monitor to prevent unwanted access to the clinical features.
	Confirm activity.
	Cancel activity.
	Return to the previous screen.

Vital Signs Menu

Symbol	Description
	Access to the clinical menu.
	Start a manual cuff inflation. Cuff inflations are set up to be taken on an ad hoc basis.
	Start a manual cuff inflation. Cuff inflations are set up to be taken automatically at a selected time interval.
	Calibrate NIBP for continuous measurements.
	Stop a cuff inflation currently in progress.

Clinical Menu

Symbol	Description
	Cuff management. Setup the cuff inflation intervals or define as ad-hoc only inflations.

Symbol	Description
	Initiate the stop monitoring sequence.
	Access information regarding the ViSi Mobile Monitor: Monitor Id, MAC address, Serial #, software version installed and battery status.
	Alarm management. Review the patient's current alarm limits, adjust the alarm limits using "Auto Set" or turn off the alarm annunciation.
	QRS beep is turned on.
	QRS beep is turned off.

Other

Symbol	Description
	Change a patient's alarm limits using "Auto Set".
	Turn alarm annunciation off.
	Setup cuff inflation to be on an ad hoc basis.
	Setup cuff inflation such that the cuff will inflate at defined intervals.

Labelling

Symbol	Description
	Warning, refer to accompanying documents
	Caution, refer to accompanying documents
REF	Catalog number
SN	Serial Number
	Manufactured By
	Conforms with EEC directives
	Defibrillator proof type CF equipment
	This product is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.
Li-ion	Lithium Ion battery
IPX0	No special protection.
IPX7	Protected against water immersion. Immersion for 30 minutes at a depth of 1 meter.
LATEX	Latex free
	Do not reuse
	Fragile
CONT	Contents
MR	MRI Unsafe

Appendix B - Model Numbers

Introduction

In the event any component needs to be replaced, contact the Sotera Wireless Inc. Customer Service Department or the Sotera Wireless representative in your area.

If a component needs to be returned, prior to shipping ensure the returned components have been properly disinfected.

ViSi Mobile System Components

Model Number	Description
92-10010	ViSi Mobile Monitor
92-10011	ViSi Mobile Cuff Module
92-10012	ViSi Mobile Chest Sensor (5 lead-wire ECG, AAMI)
92-10014	ViSi Mobile Chest Sensor (3 lead-wire ECG, AAMI)
92-10016	ViSi Mobile Chest Sensor (5 lead-wire ECG, IEC)
92-10018	ViSi Mobile Chest Sensor (3 lead-wire ECG, IEC)
92-10020	ViSi Mobile Thumb Sensor
92-10066	ViSi Mobile Patient Kit (Single-use, adult, S)
92-10067	ViSi Mobile Patient Kit (Single-use, adult, M)
92-10068	ViSi Mobile Patient Kit (Single-use, adult, L)

Accessories

Model Number	Description
92-10023	ViSi Charger

- Notes -

Warranty and Responsibility

Warranty

USA, Canada, Mexico, Puerto Rico

Sotera Wireless Inc. warrants that its products will be free from defects in workmanship and materials for a period of one (1) year from the date of purchase except that disposable or one-time use products are warranted to be free from defects in workmanship and materials up to a date one year from the date of purchase or the date of first use, whichever is sooner. This warranty does not cover consumable items such as, but not limited to, batteries, external cables, sensors, cuffs, hoses, or mounts.

Sotera Wireless Inc. shall not be liable for any incidental, special, or consequential loss,

damage, or expense directly or indirectly arising from the use of its products, liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing at Sotera Wireless Inc. option at the factory or at an authorized Sotera Wireless Inc. Distributor, any product which shall under normal use and service appear to the Company to have been defective in material or workmanship.

No agent, employee, or representative of Sotera Wireless Inc. has any authority to bind

Sotera Wireless Inc. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative shall not be enforceable by buyer.

This warranty is expressly in lieu of any other express or implied warranties, including any implied warranty or merchantability or fitness, and of any other obligation on the part of the seller.

Damage to any product or parts through misuse, neglect, accident, or by affixing any nonstandard accessory attachments or by any customer modification voids this warranty.

Sotera Wireless Inc. makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned when authorized by Sotera Wireless, freight prepaid to Sotera Wireless Inc., San Diego, California 92121. Sotera Wireless Inc. shall not have any responsibility in the event of loss or damage in transit.

Calibration may be performed without the need to disassemble the instrument. It is the responsibility of the purchaser to perform calibration as necessary, in accordance with the instructions provided in the technical manual.

Sotera Wireless Responsibility

Sotera Wireless Inc. is responsible for the effects on safety, reliability and performance of the equipment only if:

1. Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by Sotera Wireless Inc. and
2. The equipment is used in accordance with the instructions for use.

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CNSystems
The Brain & Heart Company

Operator´s Manual CNAP™ Monitor 500

Heartware by CNSystems

The CNAP™ Monitor 500 meets the requirements of CE-mark

CE 0408

according to the European standard for medical devices 93/42/EWG

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1 About this manual

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1.1 STOP, CAUTION, NOTES

In this manual the icons "STOP", "CAUTION", and "NOTE" are used to indicate matters of particular interest to keep in mind when operating the CNAP™ Monitor 500 or dealing with subjects.

STOP

The icon STOP indicates important security-relevant information:

STOP:
- Control the correct positioning of the CNAP™ double finger cuff. Make sure that the cuff is not positioned on the finger joints.

CAUTION

The icon CAUTION indicates important information referring to the correct utilization of the CNAP™ Monitor 500:

CAUTION:
- The life time cycle of a CNAP™ double finger cuff is 6 months if in constant use on subjects, or 12 months at the most.

NOTE

The icon NOTE indicates helpful information referring to the utilization of the CNAP™ Monitor 500 and its components:

NOTE:
- Use the graphics on the CNAP™ cuff controller to determine the correct finger cuff size (3 sizes).
- If the size of a subject's finger is between two finger cuff sizes, use the larger CNAP™ finger cuff for the measurement.

1.2 Cross references

Cross references refer to chapters where the operator can find additional information about specific topics. A cross reference includes the number and title of the chapter referred to (e.g. see chapter 2 – General information).

1.3 Settings

Settings available for menu entries are listed as minimum (increment) maximum:

Menu item	Description	Settings
Brightness	Regulates the brightness of the TFT-display	**20(20)100%, Auto**

2 General Information

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2.1 Warnings

- For USA: Federal law restricts this device to sale by or on the order of a physician (or proper licensed practitioner).
- The CNAP™ Monitor 500 is not designed for intracardial use.
- Do not connect the device's pneumatic connectors to an intravascular system!
- Do not use the oscillometric cuff on subjects with vascular prostheses!
- Keep the CNAP™ Monitor 500 out of reach of children!
- The CNAP™ Monitor 500 is not fit for operation in potentially explosive surroundings, as may arise from usage or storage of flammable anaesthetics, skin detergents or skin disinfectants. Also, do not use the CNAP™ Monitor 500 in possibly combustible atmosphere (i.e., if the ambient air contains more than 25 % of oxygen or nitrous oxide gas).
- The operator has to prevent prolonged impairment of the subject's blood circulation during the measuring process by inspecting the concerned limbs regularly. This is particularly important in the case of continuous blood pressure measurement. During normal use, the pressure in the finger cuff will be the same as in the artery and therefore greater than normal venous pressure. As a result, depending on variables like skin temperature, thickness, subject age, perfusion or presenting state, venous congestion of the finger distal to the cuff may be observed which will quickly subside with the discontinuation of monitoring. Check the monitoring area frequently and discontinue the continuous blood pressure measurement immediately in case of any signs of total arterial compression or if the subject reports severe pain or discomfort.
- Do not use the compressed air supply valves with any devices of a third party manufacturer.
- Each device is designed for the concurrent measurement of only one subject/test subject at a time. Never measure two or more subjects at the same time applying only one device!
- Please pay attention to the precautions regarding electromagnetic compatibility (see chapter 14.3).
- In perioperative settings the CNAP™ Monitor 500 is not to be used without additional ECG monitoring.

2.2 Precautions

2.2.1 General precautions

- The CNAP™ Monitor 500 is a device of protection class II. The input ports of type BF are protected from defibrillation.
- According to the regulations of IEC 601-2-30/EN 60601-2-30, non-invasive blood pressure measurement is fit for use during electrosurgical surgery as well as during discharge of a cardiac defibrillator.
- The CNAP™ Monitor 500 meets the requirements of EN 60601-1-1 and can be used next to subjects without restrictions.
- While using the CNAP™ Monitor 500, avoid compressing the air hoses or reducing their diameter in any way (e.g. by bending the cables) as this could impair the quality of the measuring signals.
- No liquid must ingress the CNAP™ Monitor 500. In case this should happen, the instrument must not be started up again until after inspection by a qualified technician.
- Any chemicals needed for the use and maintenance of the device are only to be prepared and stored in correspondingly designated containers in order to prevent confusions entailing possible serious consequences.
- Medical devices like the CNAP™ Monitor 500 are to be operated only by accordingly trained persons who can guarantee proper handling of the device on the basis of their special training or their skills and practical experience.
- The operator has to be familiar with the operation of the CNAP™ Monitor 500. Before each measurement process, the operator is to check and control the due condition, operational reliability and functional safety of the device.

- Before connecting any cables to a subject, all connecting cables need to be visually inspected for signs of damage. Any faulty parts (e.g. cables or plugs) are to be replaced immediately. Only original CNSystems Medizintechnik AG accessories and replacement parts are to be used.
- Please pay close attention to the proper storage of the device: Do not bend the cables excessively or coil them up too tightly, as this might result in damaging cables and hoses. Any damaged cables or hoses are to be replaced immediately.
- Take care to ensure regular and sufficient air circulation around the device. Also take into consideration the necessary environmental conditions specified in this manual (see Appendix C – Technical specifications).
- A thorough examination of the device for its operational reliability is due on a regular basis (app. once every month).
- This manual is an integral part of the CNAP™ Monitor 500. By adhering to its safety measures and recommendations, the operator ensures the correct use and operation of the device as well as the operators' and the subjects' safety. Notes and precautions of particular importance are highlighted by the following symbols: STOP, ⚠, ➔ (see chapter 1.1).
- In order to ensure the device's faultless functioning, accuracy of measurement and immunity of interference as well as the subjects' safety, use only original CNSystems accessories and replacement parts. CNSystems will not warrant for faultless functioning and operation if third party manufacturer replacement parts and accessories are used.
- CNSystems Medizintechnik AG is not liable for any warranty claim for possible damages if parts of third party manufacturers are used.
- CNSystems warrants for faultless functioning, reliability and safety of this device on the condition that the procedures of installation, extensions and enhancements, new settings, alterations, maintenance and repair are exclusively carried out by CNSystems or an authorized company. In addition, the appliance and operation of the CNAP™ Monitor 500 must be in accordance with the instructions in this operator's manual.
- All copyrights concerning the devices, procedures, electronic circuits, software programmes and labels mentioned in this manual are reserved to CNSystems Medizintechnik AG.
- Never touch the AUX, ethernet and USB interface together with the subject.
- All devices that get connected to the AUX, ethernet and USB interfaces must meet EN 606950-1 standards.

2.2.2 Blood pressure

CNAP™:

- In rare cases it might happen that the device is unable to detect a continuous blood pressure signal. Usually, the middle and index fingers are best suited for applying the finger cuffs as their phalanges are longest. If it is not possible to obtain a continuous blood pressure signal, it is, in most cases, caused by a vasospasm. Warming the hand, for example in warm water, may solve the problem.
- If no continuous blood pressure waveform is displayed within a few minutes, it is probably due to an insufficient blood flow in the fingers. In this case try using another pair of fingers or the other hand. If this is not successful, please check if the labelling on the CNAP™-double finger cuff (symbol) is on the back of the hand.
- In case of a definite insufficiency of blood flow you have to abandon the continuous blood pressure measurement completely.
- To avoid mechanical damage to the finger cuffs, never start measuring without a finger in the blood pressure cuff. Also, remove all objects (e.g. rings) from the fingers before measuring.

NBP:

- Under the following conditions there might be a decrease in accuracy of the oscillometric blood pressure signal:
  - weak pulses
  - irregular pulses
  - subject movement artifacts
  - tremor artifacts
  - respiratory artifacts

2.3 Disposal

Packing material

- The packing material of the CNAP™ Monitor 500 is to be disposed of according to the respective national regulations.

Device and accessories

- Dispose of the CNAP™ Monitor 500 and any accessories at the end of the products' lifecycles in accordance with respective national regulations or send the parts back to CNSystems Medizintechnik AG.

2.4 Declaration of intended use

The NIBP100D (CNAP™ Monitor 500) is intended for the monitoring of noninvasive continuous blood pressure and pulse rate.
The device displays the blood pressure waveform and generates trends, beat-to-beat numerics and alarms for the parameters blood pressure and pulse rate. The NIBP100D (CNAP™ Monitor 500) is to be used for adults and pediatric subjects from the age of 4 year and is to be operated by trained staff.

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3.1 General information

The CNAP™ Monitor 500 is suitable for monitoring in grown-up and pediatric subjects (from the age of 4 years). The CNAP™ Monitor 500 is in principle designed for being operated as a stand-alone device. If required, however, it can be integrated into other subject monitoring systems (BP Wave Out port for CNAP™ blood pressure waveform) and other devices (USB, Ethernet).

3.2 System components

The basic configuration of the monitor consists of the following components:

- CNAP™ monitor
- CNAP™ hardware (CNAP™ double finger cuffs, CNAP™ controller, CNAP™ cable)
- NBP cuff

3.2.1 CNAP™ Monitor 500 - BIOPAC Part Number: NIBP100D

① Carrying handle

② Display

③ Battery LED

④ Click-wheel control

⑤ Power LED

⑥ Control panel

Illustration 1: Front view

① CNAP™ cable port

② BP Wave Out: analog output port

③ NBP cuff connector

Illustration 2: Subject connectors

① Thermal printer

② Mains power port

③ USB connector: software updates

④ Ethernet connector

⑤ AUX: analog output port

Illustration 3: Printer, interface, power supply

① Holding device channel (optional)

② Type plate

Illustration 4: Back view

CNAP™ Monitor 500 symbols
The following table describes all symbols in use on the CNAP™ Monitor 500 and its components:

No.	Symbol	Description
1	Power On/Off	• Power On/Off (monitor on/off)
2	Setup	• Setup (monitor-, measurement-, service settings)
3	Main Screen	• Main Screen (return to main screen)
4	Print	• Print
5	Start/Stop	• Start/Stop (of a measurement)
6	Alarm Pause/Off	• Alarm Pause/Off
7		• Input port of type BF is protected from defibrillation pulses
8		• Ethernet connector
9		• USB connector
10	⎓ +18V	• 18 V DC supply required
11	AUX	• Analog output port
12	2007 01	• Production date
13	CE 0408	• Device meets the European standard for medical devices 93/42/EWG
14	Pb	• Recycle damaged sealed lead gel battery
15		• Caution: see accompanying documents
11		• Separate disposal of electric and electronic appliances

3.2.2 CNAP™ hardware

① CNAP™ monitor

② CNAP™ hardware

③ NBP hardware

Illustration 5: CNAP™ Monitor 500

3.2.2.1 CNAP™ double finger cuff

The CNAP™ double finger cuff comes in three sizes, each size being marked by a differently colored hood.

Size	Diameter (mm)	Colour
L	24 - 28	Dark red
M	18 - 24	Dark blue
S	10 - 18	Light blue

Illustration 6: CNAP™ finger cuff

3.2.3 CNAP™ controller

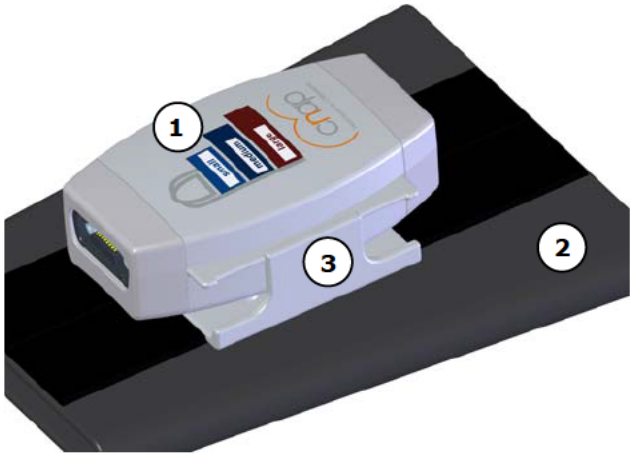


Illustration 7: CNAP™ controller

The CNAP™ controller connects the CNAP™ double finger cuff and the monitor via the CNAP™ cable. The jacks for the CNAP™ double finger cuff and the CNAP™ cable are adequately designed so as to avoid any confusion when putting the cables into the corresponding jacks.

- ① The graphics on the upside of the CNAP™ controller help choosing the right size of CNAP™ double finger cuff.
- ② The CNAP™ controller is fastened to the subject's lower arm by means of the CNAP™ forearm fixing cuff with Velcro fastener.
- ③ The fixture for CNAP™ controller connects the CNAP™ forearm fixing cuff mechanically to the CNAP™ controller.

3.2.3.1 CNAP™ cable

The CNAP™cable connects the monitor and the CNAP™ controller.

Illustration 8: CNAP™ cable

3.2.4 NBP cuff

The NBP cuff is intended for oscillometric blood pressure measurement and is available in four sizes:

Size	Arm circumference (cm)
Child	12 - 19
Small Adult	17 - 25
Adult	23 - 33
Large Adult	31 - 40

Illustration 9: NBP cuff

3.3 Power supply

The CNAP™ Monitor 500 is supplied with power by means of either mains operation via an external power adapter or by an integrated sealed lead gel battery. In case of power supply interruptions or even power outage, the monitor will automatically switch to battery operation.

CAUTION:
- Carefully read and keep in mind the precautions regarding power supply.

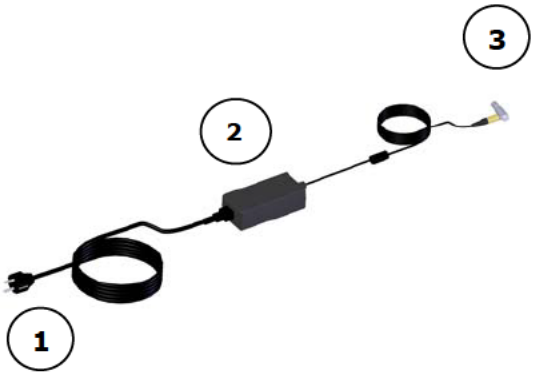
3.3.1 Mains operation

During mains operation the CNAP™ Monitor 500 is connected to a power adapter suited for a supply voltage of 100-240 VAC (± 10%) and a mains frequency of 50/60 Hz (see Appendix C – Technical specifications). When the CNAP™ Monitor 500 is connected to the mains power supply the integrated sealed lead gel battery is recharged as well. There is no time limit on the monitor being on mains operation.

The CNAP™ Monitor 500 can be connected to a supply network system according to CISPR 11.

NOTE:
- The battery recharge symbol on the battery status of the TFT-display shows when the integrated battery is being recharged.
- The battery status indicates the present battery charge status when the monitor is running on battery (without mains power supply).

CAUTION:
- Do not use any power supply accessories but those intended and authorized by CNSystems Medizintechnik AG for utilization with the monitor!



① Power cord

② Power adapter

③ Cable connecting power adapter and monitor

Illustration 10: Power cord

3.3.2 Battery operation

The integrated sealed lead gel battery enables the CNAP™ Monitor 500 to operate on battery for up to 120 minutes, depending on the CNAP™ calibration intervals, printer use and brightness of display. If the monitor runs on battery, the battery charge status will be indicated on the TFT-display in 25 % steps. The battery charge status is also indicated via the battery LED on the front side of the monitor.

LED colour	Battery charge status
Green	Device runs on battery, battery charge status 100 – 25 %
Orange	Device runs on battery, battery charge status ≤ 25%
Red	Device runs on battery, automatic shut-down within 15 minutes

In addition, a low battery charge status (5 minutes of remaining operation time on battery) is indicated by a status report on the TFT-display (alarm window). For security reasons, the measurement is stopped and the monitor shut down automatically. While the CNAP™ Monitor 500 runs on mains power, the integrated sealed lead gel battery is automatically recharged.

STOP:
- Damaged or time-worn batteries might considerably reduce maximal operating time on battery. The accuracy of the device's battery charge status is only guaranteed when using undamaged batteries and under normal operation conditions.

CAUTION:
- High temperature might impair your battery performance. For optimal operability, charge and use the battery at temperatures < 35°C (95°F).
- When disposing of used batteries, adhere to your local waste disposal regulations.
- Do not use any batteries but those authorized by CNSystems. Use of non-authorized batteries might damage the monitor.
- Before turning on the appliance for the first time, be sure to charge the integrated sealed lead-gel battery for 4.5 hours.
- In order to guarantee safe operability of the CNAP™ Monitor 500, the battery has to be replaced after 24 months in the course of maintenance service.

NOTE:
- When switching from mains operation to battery operation, it can take up to a minute until the battery charge status is displayed.
- The thermal printer cannot be operated when the battery charge status is ≤ 25 %.

Battery status

Symbol	Battery charge status	Resulting measure
	• Battery charge status 100%	
	• Battery charge status 75%	
	• Battery charge status 50%	
	• Very low battery charge status (< 25%), battery operation still possible	• Printing deactivated • Current print job cancelled • Switching to mains operation via power adapter recommended • Technical alarm "Battery Low"
	• Battery depleted, operation possible for at least 15 minutes	• Immediately switch to mains operation via power adapter • Current measurement discontinued, monitor switched off automatically
	• Battery depleted, operation possible for 5 minutes at most; monitor is switched off	• Immediately switch to mains operation via power adapter • Technical Alarm „Battery Depleted" • Current measurement discontinued, monitor switched off automatically
	• Battery malfunction, acoustic technical alarm signal	• Call a service technician
	• Battery is being recharged	

3.4 First steps

3.4.1 Power On/Off

The key **Power On/Off** is located in the left lower corner on the front side of the device.

Illustration 11: Front view

Switching on the monitor

The CNAP™ Monitor 500 is switched on by pressing the key **Power On/Off** located on the front side of the device for two seconds. While the CNAP™ Monitor 500 is booting up, device and software information is displayed on the screen. The green power LED indicates the operation status of the device. The operating system of the monitor initializes and performs a system self-test, then the main screen is displayed. In addition, the monitor also performs an automatic function test of its alarm system during starting-up time (see chapter 6 – Alarm system).

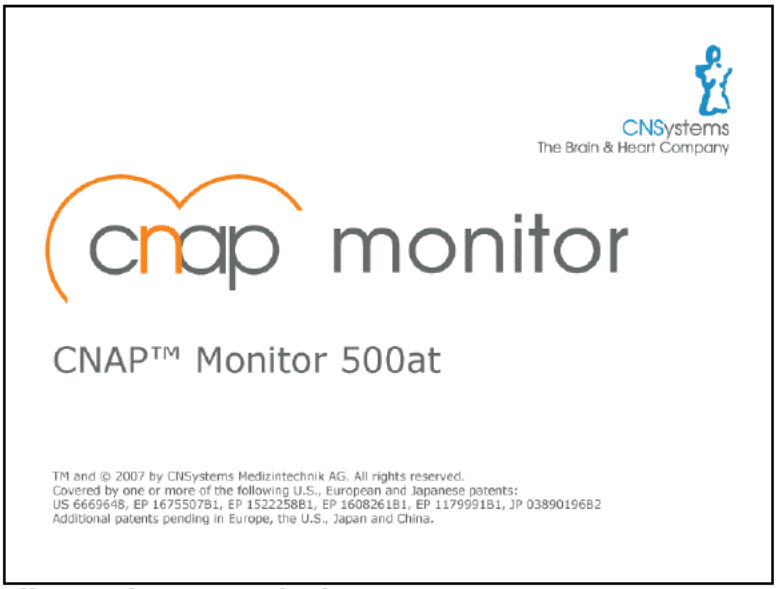


Illustration 12: Splash screen

Switching off the monitor

The CNAP™ Monitor 500 is switched off by pressing the key **Power On/Off** for 2 seconds.

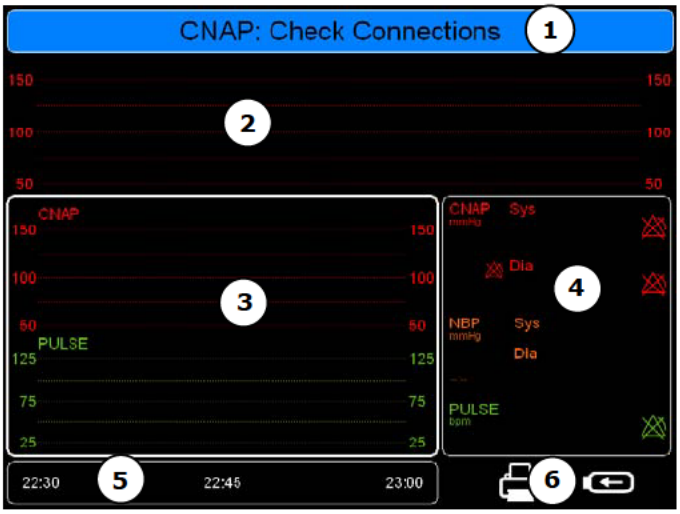
CAUTION:

- The key **Power On/Off** does not interrupt the monitor's power supply. In order to interrupt power supply, the operator needs to disconnect the power cord.

3.4.2 Access/return to Main Screen

After having started the monitor, the main screen appears, which displays all measuring parameters and signals and enables to access all menus.

Arrangement of the screen:



① Alarm frame

② CNAP™ signal view

③ Trend frame

④ Parameter frame

⑤ Navigation frame

⑥ Battery charge and printer status

Illustration 13: Main screen

NOTE:

- In order to return to the main screen from any submenu, just press the key **Main Screen** on the front of the monitor.

3.4.3 Fast access keys

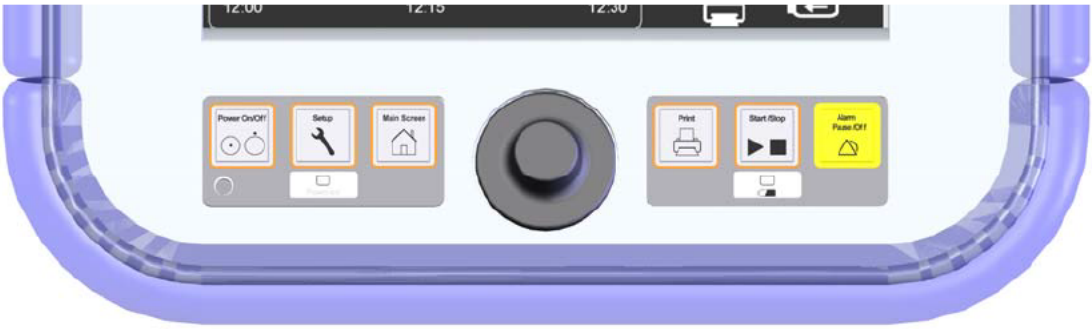


Illustration 14: Fast access keys

Membrane keys on the front side of the CNAP™ Monitor 500 enable fast access to important functions:

	Key	Function
1	**Power On/Off**	Switching on/off the monitor
2	**Setup**	Access to configuration menu
3	**Main Screen**	Return to main screen from any submenu
4	**Print**	Start/stop printing
5	**Start/Stop**	Start/stop measurement
6	**Alarm Pause/Off**	Alarm functions control: Press key Alarm Pause/Off once: set alarm reminder Press key Alarm Pause/Off twice: set alarm pause Press key Alarm Pause/Off three times: re-activate alarm function

CAUTION:

- The key **Start/Stop** controls all CNAP™ measurements. In case of an active NBP measurement, the operator first stops the NBP measurement by pressing the key **Start/Stop** once. Only pressing the key **Start/Stop** for a second time will stop the active CNAP™ measurement.

3.4.4 Menu navigation – click-wheel control

Illustration 15: Click-wheel control

The monitor's click-wheel control enables the operator to navigate through menus and setups and to access certain functions. Wheeling the control enables the operator to navigate through menus, while pressing on the control ("clicking") confirms the menu choice.

Selection and confirmation of functions/menu items:

1. Select the desired function/menu item by wheeling the control (green bar).
2. Pressing the click-wheel control then confirms the selection. Subsequently, either a drop-down list appears or the function is activated automatically (e.g. from **on** to **off**).
3. Wheeling the click-wheel control – drop down menu.

3.4.5 Menu selection

Menus can be accessed to in 2 ways:

- Frequently used functions can be selected by the monitor's fast access keys (see chapter 3.4.3 – Fast access keys).
- Or, menus and their functions can be selected by means of the click-wheel control (see chapter 3.4.4 – Click-wheel control).

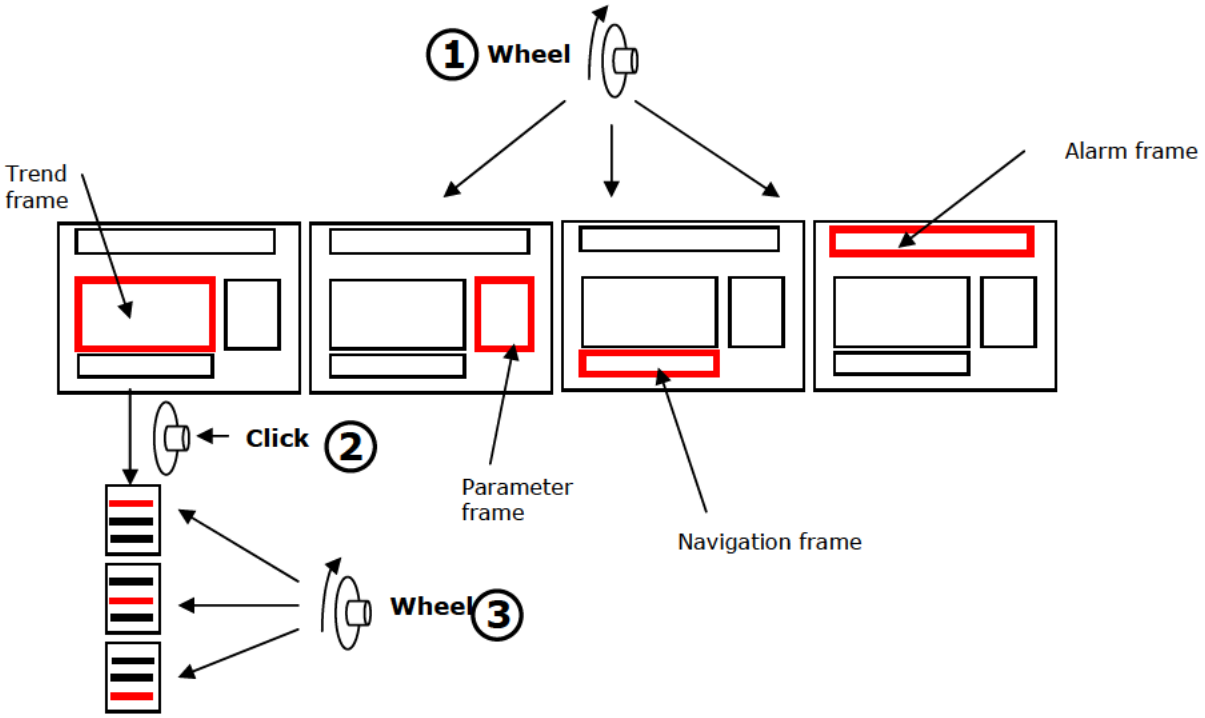


Illustration 16: Menu selection

3.5 Quick setup

Illustration 17: Subject setup

1. Starting up the CNAP™ Monitor 500:
Press **Power On/Off** and confirm the alarm self-test (test alarm signal) by pressing **Alarm Pause/Off**.

2. Subject setup:
   a. Choose the correct CNAP™ double finger cuff size by means of the graphic on the CNAP™ controller. If a subject's finger size is between two cuff sizes, choose the larger cuff.
   b. Assemble the CNAP™hardware by connecting the CNAP™ double finger cuff, the CNAP™ controller, the CNAP™ cable with the CNAP™ Monitor 500. All plugs and connectors are designed so as to making it impossible to switch them accidentally.
   c. Equip the subject with the CNAP™ hardware: The CNAP™ double finger cuff is placed on the proximal joints of the index and middle fingers. Ensure that the cuff cables run along the upper side of the subject's arm.
   d. Fasten the CNAP™ controller to the subject's forearm by means of the fixing cuff (with Velcro fastener) and make sure that the hand with the CNAP™ double finger cuff is placed at heart level (see illustration above).

3. Donning of the NBP cuff:
   a. Make sure that only NBP cuffs authorized by CNSystems are used and that you apply the correct size to the subject (**Child**, **Small Adult**, **Adult**, **Large Adult**).
   b. Place the blood pressure cuff on the subject's upper arm at the heart level. The marker on the NBP cuff should be directly above the brachial artery.
   c. Connect the NBP cuff with the NBP air connector on the left side of the CNAP™ Monitor 500.

4. Subject entry:
   a. Quick (default) entry of adult or pediatric subjects:
   The functions **New Patien t: Adult De faults** or **New Patient: Pediatric Defaults** can be selected in the setup window immediately; the measuring process can start immediately by pressing the Start/Stop key. Detailed subject data input can be performed at a later time.
   b. Use Current Subject Data:
   When selecting the option **Use Current Patient Data** all subject data remains unchanged; the measuring process can start immediately by pressing the Start/Stop key.

Start the CNAP™ measurement by pressing the key **Start/Stop** on the front side of the device.

4 Monitor configuration

Monitor settings 4-1
Measurement settings 4-1
Service settings 4-2
BP Wave Out (subject monitors) 4-3
Interfaces (optional) 4-5

4.1 Monitor settings

Menu item	Description	Settings
Brightness	Regulates the brightness of the TFT display	**20(20)100%, Auto**
Language	Language selection	**EN, DE, FR, ES, IT**
Date	Date setting	**yyyy/mm/dd** e.g. 1970/MAR/10
Time	Time setting	**hh:mm:ss**

NOTE:
- Monitor settings are saved automatically. Loss of settings only occurs in case of interruption of power supply (no mains operation, followed by battery depletion).

4.2 Measurement settings

Menu item	Description	Settings
CNAP: Cal Interval	Setting of intervals for automatic change of signal source in the CNAP™ double finger cuff	**5(5)60min**
NBP: Interval	Setting of time interval for automatic NBP measurements	**off, 5(5)30, 45 , 60**
Audio Trend	Setting of source and volume of audio-trend	Submenu
Display Options	Setting of trend view: Display and scaling	Submenu
Print Options	Setting of print options: Delay time for snapshot prints, activation of **Print on Alarm** (see chapter 6.3)	Submenu
Parameter Averaging	Averaging of displayed numeric parameters	**off, 5, 10, 15 sec**

NOTE:
- Measurement settings are saved automatically for any current or future measurement.
- Loss of power supply (interruption of mains operation, followed by depletion of battery) entails the loss of measurement settings.

4.3 Service settings

NOTE:
- The service menu is divided into 2 layers which can be accessed by entering a password.
- You find the password for the user menu in the CNAP™ Monitor 500 "Service manual for users".
- You find the password for the service menu in the CNAP™ Monitor 500 "Instructions for service".

NOTE:
In this manual we distinguish between two groups of users: operators and users.
- Operator: a person actually working with this device (doctors, nurses, medical staff, ...)
- User: either the supervisor of the operator or technical employees responsible for general settings (nominated by the owner or chosen according to local regulations).

Menu item	Description	Settings
Restore Factory Settings	Restore factory settings	**yes, no**
Alarm defaults	Enables to adjust alarm limits, reminder, pause and volume for the subject categories (**Adult**, **Pediatric**) within the limits of factory settings. The operator/user can also restore factory settings.	Submenu
Log ...	Lists technical alarms by means of language-independend error codes	Submenu
Function Tests ...	Function tests of the modules IBP analog output, printer and CNAP™ / NBP	Submenu
Advanced ...	Software update	Submenu

4.4 BP Wave Out (subject monitors)

Similar to the BP waveform obtained from an invasive catheter (e.g. radial artery), the CNAP™ registered blood pressure waveform can be interfaced to subject monitors by means of the "BP Wave Out" output port located on the left side of the CNAP™ Monitor 500 (see chapter 3.2.1, illustration 2).

CAUTION:

- In order to connect the CNAP™ Monitor 500 to other subject monitors, the following 2 cables are needed:
  1. CNAP™ transducer cable: interfaces the CNAP™ blood pressure waveform from the CNAP™ Monitor 500 (BP Wave Out connector) - RJ11 6P4C connector is used (e.g. Abbott IBP catheter). The CNAP™ transducer cable is available from CNSystems Medizintechnik AG (refer to chapter 13.4 Connections).
  2. IBP interface cable: connects from the CNAP™ transducer cable to the IBP port of the subject monitor. As there is no cable generally authorized for all brands of subject monitors, we strongly recommend you contact BIOPAC.
     .

Unlike the analog output port (see chapter 4.5), the CNAP™ blood pressure waveform signal via the "BP Wave Out" is standardized. Its sensitivity depends on bridge voltage and amounts to 5 µV/V/mmHg.

If, for example, the supply voltage was 4 V, the sensitivity would be calculated as followed:

5 µV/V/mmHg x 4 V = 20 µV/mmHg.

In order to connect the CNAP™ Monitor 500 to a subject monitor you proceed as follows:

1. Connect the CNAP™ Monitor 500 and your subject monitor using a) the CNAP™ transducer cable and b) the IBP interface cable.

2. Activate "IBP: Zeroing" from the parameters menu

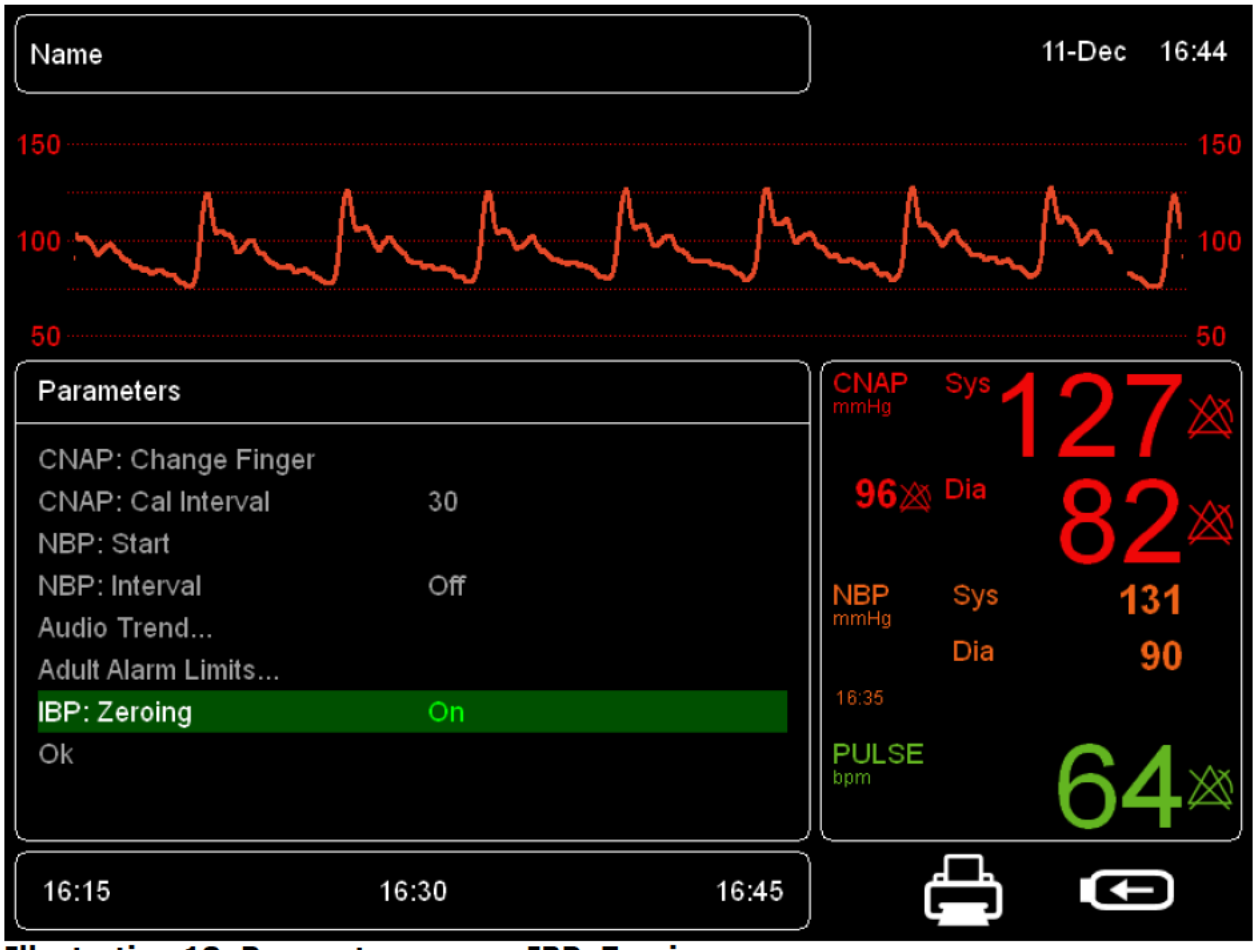


Illustration 18: Parameters menu: IBP: Zeroing

3. Select the pressure sensor on your subject monitor and start the zeroing process. Usually a subject monitor will report successful zeroing (must be within ± 32 mmHg), e.g by signalling "zero completed, offset is xx mmHg".

4. On the CNAP™ Monitor 500 deactivate "IBP: Zeroing" by returning to "OFF" and return to the main menu. Now the CNAP™ blood pressure waveform will also be displayed on the subject monitor.

NOTE:
- If you don't deactivate "IBP: Zeroing" and leave it on "ON", the pressure signal on the subject monitor will display 0 mmHg.

CAUTION:
In order to ensure full accuracy of the CNAP™ blood pressure waveform and its derived blood pressure values to another subject monitor, do not forget to perform an IBP zeroing when connecting the two devices. In addition, the CNAP™ waveform is to be zeroed according to your institute's regulation (but at least once a day). Plus, IBP zeroing should be performed if there is any doubt as to the accuracy of obtained recordings.

NOTE:
- Blood pressure values obtained by means of CNAP™ and invasively obtained reference values may differ for the following reasons:
    1. Difference in beat detection
    2. Different settings for **Parameter-Averaging** (see chapter 4.2 – measurement settings).

CAUTION:
During the initialization of CNAP™ or when changing the signal source in CNAP™ double finger cuff a calibration waveform (rectangle 50 – 150 mmHg) is displayed on the main screen. The same waveform is transmitted to subject monitors via the "BP Wave Out" port. This may cause misinterpretation of blood pressure, if no blood pressure waveform is displayed on a subject monitor and if numerical values of blood pressure are falsely detected from the rectangle calibration signal. Thus always check the blood pressure waveform on the CNAP™ monitor for the calibration signal when receiving unphysiological readings of blood pressure on an external device (i.e. subject monitor).

4.5 Interfaces (optional)

On the right side of the CNAP™ Monitor 500 the following connectors can be found (see chapter 3.2.1, illustration 2):

4.5.1 AUX (analog output port)

The corrected CNAP™ blood pressure waveform is available from the device's analog output port (AUX).

	Channel 1	Channel 2
Voltage range	+-12 V	+-12 V
Reference	0 / 5 V (0 / 500 mmHg)	-5 / +5 V (0 / 500 mmHg)
Sensitivity	100 mmHg/V	50 mmHg/V
Samling frequency	100 Hz	100 Hz

4.5.2 Ethernet

The CNAP™ Monitor 500 may be connected to a PC via Ethernet standard in future at present the Ethernet port is deactivated.

4.5.3 USB

The USB port is reserved for service functions; e.g. software updates.

5 Management of subject data

Input of subject data 5-1
Editing of subject data 5-2
Discharge 5-3

Immediately after a subject has been connected to the CNAP™ Monitor 500 and the setup process has been performed correctly (see chapter 3.5 - Quick setup), the subject set-up window is opened automatically. Select the correct subject category and start the measurement process by pressing **Start/Stop**.

NOTE:
- With regard to the safe operation of the CNAP™ Monitor 500 as well as the unambiguous identification and classification of measurements and prints, the input of subject data is a vital prerequisite of essential importance. Entering the respective subject category, for instance, results in the subsequent adjustment of alarm limits as well as of the NBP cuff inflation pressure.

5.1 Input of subject data

Subject data is entered into the subject set-up window appearing on the main screen immediately after subject setup.

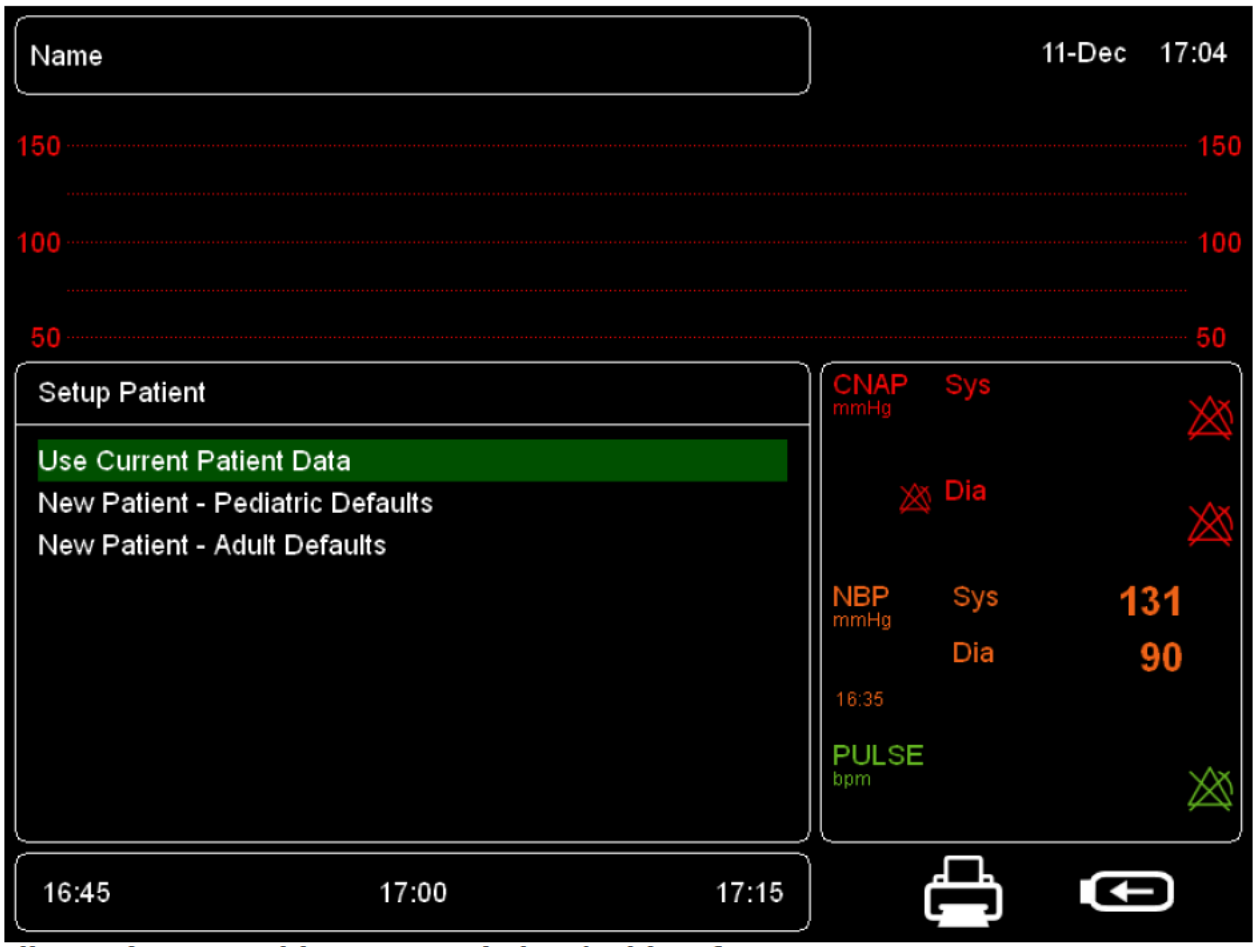


Illustration 19: Subject setup window/subject frame

There are 2 ways of entering subject data before starting a measurement:

a. Quick (default) entry of adult or pediatric subjects:
The functions **New P atient: A dult Defa ults** or **New Patie nt: Pedia tric Defaults** automatically sets the respective subject category; the measuring process can start immediately by pressing the **Start/Stop** key. Detailed subject data input can be performed at a later time via **Alarm frame** and the **Patient menu.**

b. Detailed subject data entry and input:
By selecting the option **New Patient,** the **Patient menu** (see chapter 5.2 – Editing of subject data) appears immediately.

NOTE:
- Default entry should only be resorted if there is not enough time or not all the necessary information available for a complete subject data input. Lacking subject data must, however, be entered at a later time, or the prints will show no subject data.

5.2 Editing of Subject data

At any given time during a measurement, you can enter subject data by using the click-wheel control to select the **Patient frame** on the main screen and to open the **Patient menu**.

Menu item	Description	Settings
Name	surname and first name (max. 20 characters)	Keyboard
ID#	file number, e.g. 12345678 (max. 15 characters)	Keyboard
Gender	gender	**NA, M, F**
Birth Date	birth date, e.g. 1970-MAR-10	YYYY-MMM-DD
Category	category: ADULT > 14 years PEDIATRIC 4 – 14 years	**Pediatric, Adult**
Discharge	discharge information	**yes, no**
OK		

STOP:
- **Subject category:** Entering the correct subject category is an indispensal prerequisite before starting a measurement process. Be sure to select the correct subject category as this determines the adjustment of alarm limits and the inflation pressure of the NBP cuff.

NOTE:
- During a measurement the **Patient menu** can be selected via **Alarm frame** and the menu item **Patient data**.

5.3 Discharge

Subject data needs to be deleted even when only a default entry has been performed before.

The function **Discharge**

- deletes all information in the **Patient menu**
- deletes all trends of data from the monitor
- deletes all entries of the **Alarm history**

Subject data can be deleted in 2 ways:

a) Patient menu:
Open the **Patient menu** by using the click-wheel contol to select the **Alarm frame** on the main screen. Select **Discharge** and confirm your menu entry in the input window.

b) Setup of a new subject:
Immediately after a new subject has been set up with the CNAP™ double finger cuff the subject set-up window appears on the **Main screen**. Select **New Patient–Pediatric Defaults** or **New Patient –Adult Defa ults** and confirm your choice in the input window. This will result in the deletion of any previous data.

NOTE:
- In order to avoid loss of data, all data and entries must be printed before discharging a subject. Deleted data cannot be retrieved.

6 Alarm system

Visual alarm signals 6-2
Acoustic alarm signals 6-3
Alarm system control 6-4
Acknowledgement of alarms –Audio Off, Audio Pause 6-4
Pausing / switching off alarms – Alarms Paused, Alarms Off 6-4
Reactivation of paused alarms - Alarms Off 6-5
Alarm limits 6-5
Display of individual alarm limits 6-5
Alarm set-up 6-6
Auto limits 6-7
Alarm limits – factory settings 6-8
Alarm history 6-9
Alarm system function tests 6-9
Physiological alarms 6-9

The alarm system of the CNAP™ Monitor 500 distinguishes between two alarm levels: physiological alarms (yellow) and technical malfunction alarms (white).

- MEDIUM PRIORITY: **

Yellow alarms are physiological alarms of medium priority (e.g. exceeding the upper or falling below the lower limit for systolic blood pressure).

- LOW PRIORITY: *

Technical malfunction alarms indicate that the CNAP™ Monitor 500 is unable to take a measurement or to reliably detect possible alarm conditions. Instead of numeric values the parameter frame displays "***", accompanied by an acoustic signal which has to be confirmed by the operator (see chapter 6.3.1 – Acknowledgement of alarms). Depending on the indicated malfunction the operator may have to take a measure (e.g. replace a defective CNAP™ double finger cuff).

NOTE:
- The CNAP™ Monitor 500 has no other than the mentioned 2 alarm levels: physiological alarms (yellow) and technical malfunction alarms (white).

STOP:
If several alarms are activated at the same time
- the alarm signals will be displayed alternately in intervals of 5 seconds in the alarm frame
- physiological alarms and technical malfunction alarms will be displayed one after the other in their order of appearance
- the physiological alarm with the highest priority is accompanied by an acoustic signal
- new alarms and technical malfunction alarms are displayed immediately

6.1 Visual alarm signals

Alarm signals are displayed visually in the **Alarm frame** and the **Parameter frame** directly on the **Main screen**.

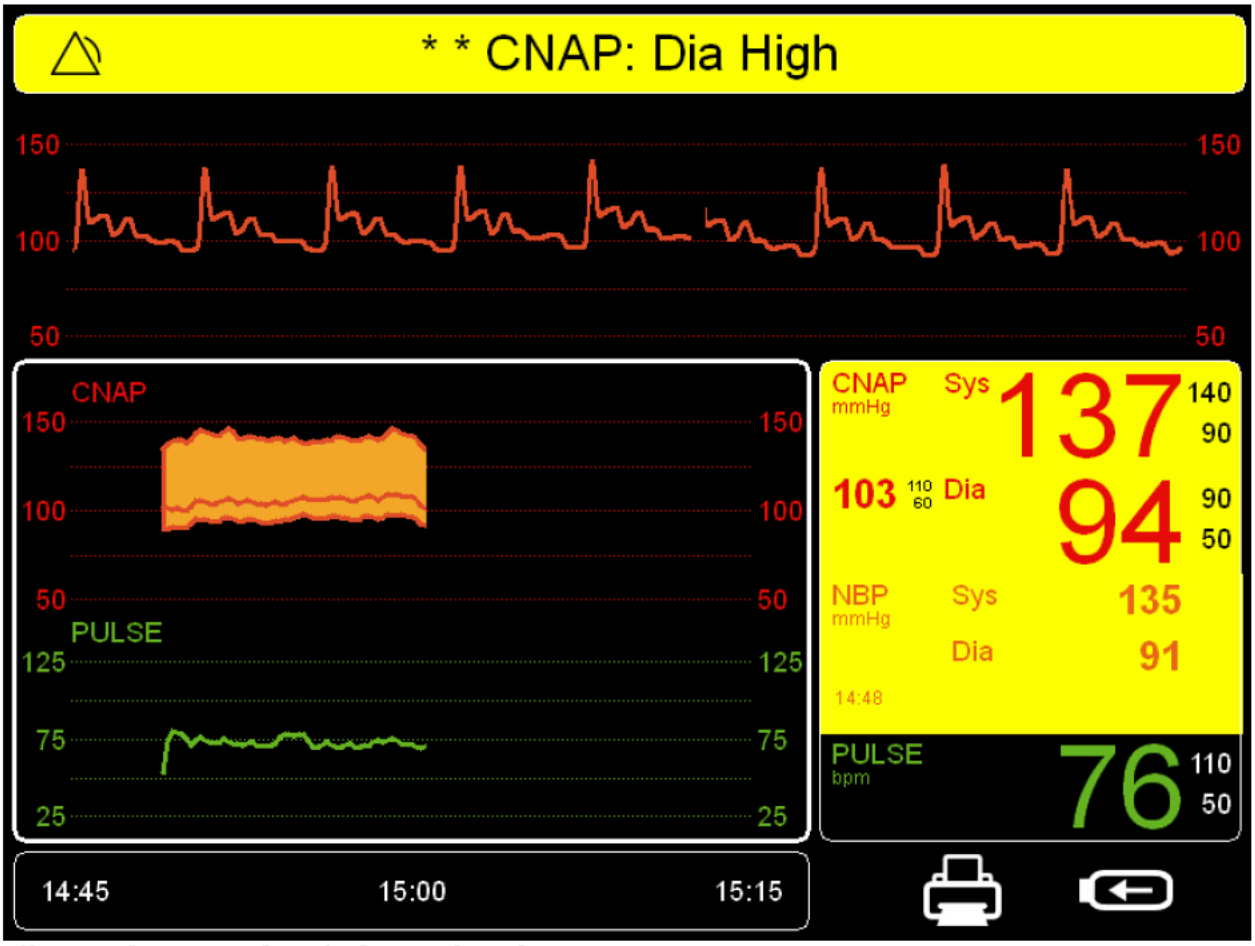


Illustration 20: Visual alarm signals

Alarm frame:

- Background color: YELLOW - Physiological alarms (medium priority)
  WHITE - Technical malfunction alarms (low priority)
  BLUE - Status messages
- Alarm priority: ** - medium priority
  * - low priority
- Alarm system status: - Alarm
  - Alarms Paused
  - Alarms Off
  - Audio Pause
  - Audio Off

- Alarm report: a text with an alarm message describing the cause for the alarm signal appears in the **Alarm frame.**
- Blinking **Alarm frame** for physiological alarms.

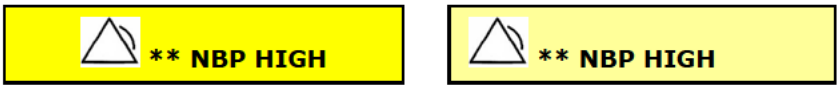


Illustration 21: Alarm frame - alarm conditions

Parameter frame:

- Background color: YELLOW – Physiological alarms (medium priority)
  WHITE - Technical malfunction alarms (low priority)
  BLUE - status messages

- Blinking **Parameter frame**
- Numeric values: unchanged during physiological alarms, blanked during technical malfunction alarms "***"

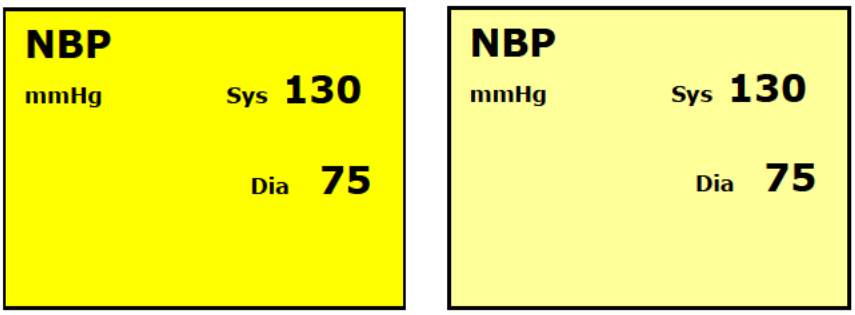


Illustration 22: Parameter frame – alarm conditions

6.2 Acoustic alarm signals

In accordance with the regulations of EN 60601-1-8, the CNAP™ Monitor 500 produces acoustic alarm signals. The differently coded alarm signals are repeated until acknowledged by pressing the key **Alarm Pause /Off**.

NOTE:
Repetition rate for acoustic alarm signals is:
- 5 seconds for physiological alarms
- 18 seconds for technical malfunction alarms.

STOP:
- Do not rely solely on the acoustic alarm signals! Especially if the alarm volume is set low, alarms might be missed which could constitute a possible danger for subjects!

The alarm signal volume is individually adjustable. Factory setting is 80 % of maximum volume and can be adjusted from 20 to 100%. Maximum sound pressure amounts to 93 dB at a distance of 1 meter from the CNAP™ Monitor 500, whereas minimum sound pressure amounts to 60 dB at a distance of 1 meter from the device.

6.3 Alarm system control

6.3.1 Acknowledgement of alarms – "Audio Off", "Audio Pause"

In order to acknowledge all activated alarms (physiological and technical malfunction reports) press **Alarm Pause / Off** once.

Depending on the respective settings of the **Alarm Reminder** feature, the status message "**Audio Off**" or "**Audio Pause**" is displayed.

ALARM REMINDER: If the alarm reminder is activated in the monitor setup, a repeated acoustic signal reminds the operator of alarm conditions that continue to exist after acknowledgement of the alarm signal by the operator. This acoustic reminder may be repeated for a limited or unlimited amount of time.

Menu item	Description	Settings
Alarm Reminder	• Setting of alarm reminder	**off, 1 min, 2 min, 3min**

NOTE:
- During measurements an alarm reminder setting may be entered by using the click-wheel control to open the **Parameter frame** and then to select the menu entry **Alarms Pediatric** or **Adult Alarm Limits**.
- The factory setting of the alarm reminder may be restored by using the click-wheel contro located in the Service Menu.

6.3.2 Pausing /switching off alarms – "Alarms Paused", "Alarms Off"

In order to temporarily deactivate (= pause) physiological alarms, press **Alarm Pause /Off** twice. Temporarily no physiological alarms will be activated, e.g. when a subject is being relocated. Depending on the **Audio Pause** settings either the status "**Alarms Off** " or "**Alarms Paused**" is displayed.

"ALARM PAUSE": Depending on the monitor configuration, the alarms may be paused for a limited or unlimited time. Hence selecting an alarm pause of an unlimited amount of time equals switching off the alarm signal altogether.

Menu item	Description	Settings
Alarm Pause	• Setting of alarm pause	**1 min, 2 min, 3 min, no time out**

NOTE:
- Pausing alarms is only possible if no physiological alarms are activated.
- Technical malfunction alarms or malfunction reports are displayed even when the function "Alarm Pause" has been activated.

NOTE:
- During temporary alarm pauses the remaining pause time is displayed in the **Alarm frame**.
- In case of a temporally unlimited alarm pause the **Alarm frame** displays the message "**Alarm Off**".

6.3.3 Reactivation of paused alarms - "Alarms Off"

In order to reactivate alarms having been paused for an unlimited amount of time, press **Alarm Pause /Off** three times.

6.4 Alarm limits

Alarm limits set the alarm conditions for physiologigal alarm signals.

6.4.1 Display of individual alarm limits

The preset alarm limits (upper, lower) of every measuring parameter are displayed beside the respective measured value in the **Parameter frame** of the main screen. If a parameter's alarm function is deactivated, the symbol for **Alarm off** will appear beside the measured value in the **Parameter frame** (refer to chapter 6.1 – Visual alarm signals).

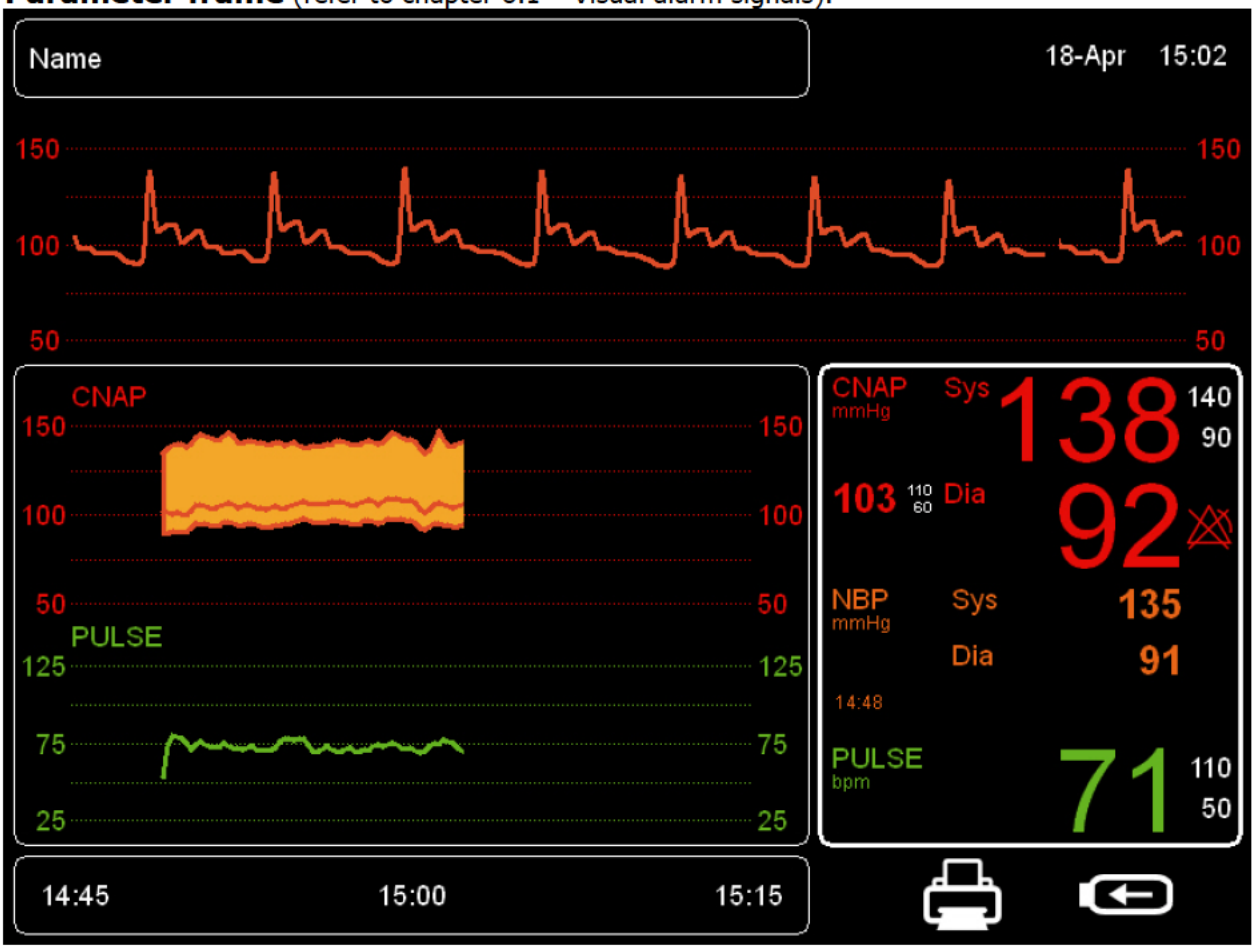


Illustration 23: Parameter frame - alarm limits

In order to view and edit all set alarm limits, use the click-wheel control to select the **Parameter frame** and then to open the **Alarm menu** (see chapter 6.4.2 – Alarm setup).

6.4.2 Alarm setup

The **Alarms Menu** enables the operator to adjust the alarm functions of all parameters.

Menu item	Description	Settings
Auto Limits	Automatic setting of alarm limits for activated alarms	**narrow, wide, Cancel, off**
Sys	Alarm limits for systolic blood pressure	**on, off; lower, upper;**
Mean	Alarm limits for mean blood pressure	**on, off; lower, upper;**
Dia	Alarm limits for diastolic blood pressure	**on, off; lower, upper;**
Pulse	Alarm limits for pulse rate	**on, off; lower, upper;**
Alarm Volume	Volume settings for alarms, (20 – 100 %)	**20(20)100%**
Alarm Reminder	Function to set alarm reminders (see chapter 6.3 – acknowledgement of alarms - "Audio Off, Audio Pause"	**off, 1 m in, 2 min, 3min**
Alarm Pause	Pausing of alarms (see chapter 6.3.2 - Pausing /switching off alarms – "Alarms Paused", "Alarms Off")	**1 min, 2 min, 3 min, no timeout**

NOTE:
- The defined safe limits configurated in the factory settings never leave the physiological area.

SYS, MEAN, DIA, PULSE: Setting of alarm function for every single parameter:

- on, off
- Lower: lower limit
- Upper: upper limit
- Current: Display of current numeric value of a given vital parameter.

STOP:
- The CNAP™ Monitor 500 determines the alarm limits on the basis of the entered category. Thus, be sure to enter the correct subject category before starting a measurement.
- The operator can adjust alarm limits within the **Alarm defaults menu**. Alarm limit settings for the subject categories **Adult** and **Pediatric** are to be performed separately. The respective menu is located in a password protected area of the CNAP™ Monitor 500, which can be accessed via the **Service menu**. The necessary password as well as further information about configurating individual user settings or restoring factory settings can be found in the "Service manual for users"of the CNAP™ Monitor 500.

STOP:
- The parallel use of different alarm settings for the same device (or similar instruments) used in different areas (e.g. in the intensive care unit or in cardiac surgery) might constitute a possible danger for subjects.

6.4.3 Auto limits

By means of the function **Auto limits** the operator is able to adjust alarm limits to a specific subject. Therefore it is necessary to wait for the monitor to display physiological signals of a measurement in order to be able to activate **Auto limits**. Later, if subject data is deleted or new subject data is entered, the function **Auto limits** will be deactivated automatically.
Using this function leads to the alarm limits of activated alarms being adjusted to the currently measured vital parameters. The alarm limits will then be set within a predefined safety range based on the measured individual parameters.

- Narrow: currently measured value Sys/Mean/Dia/Pulse ± 20mmHg
- Wide: currently measured value Sys/Mean/Dia/Pulse ± 30mmHg
- Cancel: return to **Alarm limits** menu without changes
- Off: Alarm limits are restored to user settings (**Alarm defaults**).

Alarm limits set by means of **Auto limits** are based on the patient's parameters measured at the time of function activation.

6.4.4 Alarm limits – Factory settings

The CNAP™ Monitor 500 has been preset to the following factory settings and default settings for alarm limits, which apply to both CNAP™ and NBP.

- Alarm limits (ADULT):

	Lower limits			Upper limits		
Parameter	Lower limits	Defaults	Upper limits	Lower limits	Defaults	Upper limits
sBP [mmHg]	40	90	255	45	140	260
mBP [mmHg]	35	60	250	40	110	255
dBP [mmHg]	30	50	245	35	90	250
Pulse [bpm]	30	50	195	35	110	200

- Alarm limits (PEDIATRIC):

	Lower limit			Upper limit		
Parameter	Lower limist	Defaults	Upper limits	Lower limits	Defaults	Upper limits
sBP [mmHg]	40	70	175	45	120	180
mBP [mmHg]	35	50	170	40	90	175
dBP [mmHg]	30	40	165	35	70	170
Pulse [bpm]	30	75	195	35	130	200

NOTE:

- The operator can adjust alarm limits within the **Alarm defaults menu**. Alarm limit settings for the patient categories **Adult** and **Pediatric** are to be performed separately. The respective menu is located in a password protected area of the CNAP™ Monitor 500 which can be accessed via the **Service menu**. The necessary password as well as further information about configurating individual user settings or restoring factory settings can be found in the "Service manual for users" of the CNAP™ Monitor 500.
- The user can restore all adjusted **Alarm limits** back to factory settings. To do this the user has to select the function **Restore factory settings** which can be accessed via the password-protected **Service menu** (see "Service manual for users").

STOP:

- Setting the **Alarm limits** to extreme and thus unsuitable values results in the alarm system becoming useless and obsolete!

6.5 Alarm history

The **Alarm history** is displayed directly in the main frame and is a list of up to 100 last released alarms and malfunction reports. In order to view the **Alarm history**, use the click-wheel control to first select **Trend frame** and then to open **Alarm history**. Each report of the alarm history includes the following information:

- Date
- Time

Priority: ** (MEDIUM)

- Alarm message

All entries in the **Alarm history** will be deleted either if the CNAP™ Monitor 500 is switched off or if there is a total loss of power supply (e.g. empty battery + no mains power supply).

6.6 Alarm system function tests

When the CNAP™ Monitor 500 is switched on, the alarm system automatically performs a self test in the course of which the operator has to control the functional reliabilty of all acoustic and visual alarm signals.

STOP:
The automatic device self test causes the system to release a technical alarm signal of LOW priority (white alarm), the alarm message reading "**Alarm Self-Test**". Control the functional reliablity of the alarm system during start-up and confirm it by pressing **Alarm Pause/Off**:

- Visual alarm signal: * Alarm message: **Alarm Self-Test**
- Acoustic alarm signal: LOW PRIORITY.

6.7 Physiological alarms

Alarm message	Priority	Source	Description	Alarm signals
NBP: Sys High NBP: Dia High	Medium**	NBP	Measured NBP pressure value exceeds upper alarm limit. In addition, "Sys", "Dia" indicates which parameter has exceeded the alarm limit.	Blinking NBP values, alarm message and acoustic alarm signal
NBP: Sys Low NBP: Dia Low	Medium**	NBP	Measured NBP pressure value falls below lower alarm limit. In addition, "Sys", "Dia" indicates which parameter has dropped below the alarm limit.	Blinking NBP values, alarm message and acoustic alarm signal
CNAP: Sys High CNAP: Dia High CNAP: Mean High	Medium**	CNAP	Measured CNAP™ pressure value exceeds upper alarm limit. In addition, "Sys", "Mean" "Dia" indicates which parameter has exceeded the alarm limit.	Blinking CNAP™ values, alarm message and acoustic alarm signal
CNAP: Sys Low	Medium**	CNAP	Measured CNAP™ pressure value falls	Blinking CNAP™

Alarm message	Priority	Source	Description	Alarm signals
CNAP: Dia Low CNAP: Mean Low			below lower alarm limit. In addition, "Sys", "Mean" "Dia" indicates which parameter has fallen below the alarm limit.	values, alarm message and acoustic alarm signal
CNAP: Pulse High	Medium**	CNAP	Pulse rate (CNAP™) exceeds upper alarm limit.	Blinking CNAP™ values, alarm message and acoustic alarm signal
CNAP: Pulse Low	Medium**	CNAP	Pulse rate (CNAP™) falls below lower alarm limit.	Blinking CNAP™ values, alarm message and acoustic alarm signal

NOTE:
All technical malfunction alarm messages of the CNAP™ Monitor 500 or its components are found directly in the chapters describing the respective system components.

7 Trends

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The CNAP™ Monitor 500 automatically displays the parameters **Sys**, **Mean**, **Dia** and **Pulse** in the **Trend frame** on the **Main screen**. Trends can be displayed as graphical as well as numeric trends. The display of a list of physiological alarms is optional.

NOTE:
- Recorded parameters are saved on a beat-to-beat-basis for a maximum of 24 hours.
- Saved recordings can be displayed in the **Trend frame** at any time (see chapter 7.2.1 – Trend views).

STOP:
- **DISCHARGE**: When a patient is discharged, all recorded data, including the parameters **Sys**, **Mean**, **Dia** and **Pulse** as well as the **Alarm history** are irretrievably deleted.
- **PRINT REPORTS**: The set-up and configuration of the **Trend frame** also determine the selection and the display of the **Print reports (Graphic trend report**, **Numeric trend report** and **Alarm history report)**. Thus, before starting a **Print report**, make sure that the data in the **Trend frame** display is equivalent to the data you wish to include in your **Print report** concerning, for instance, amplitude, time scale and displayed time span (see chapter 8.3).

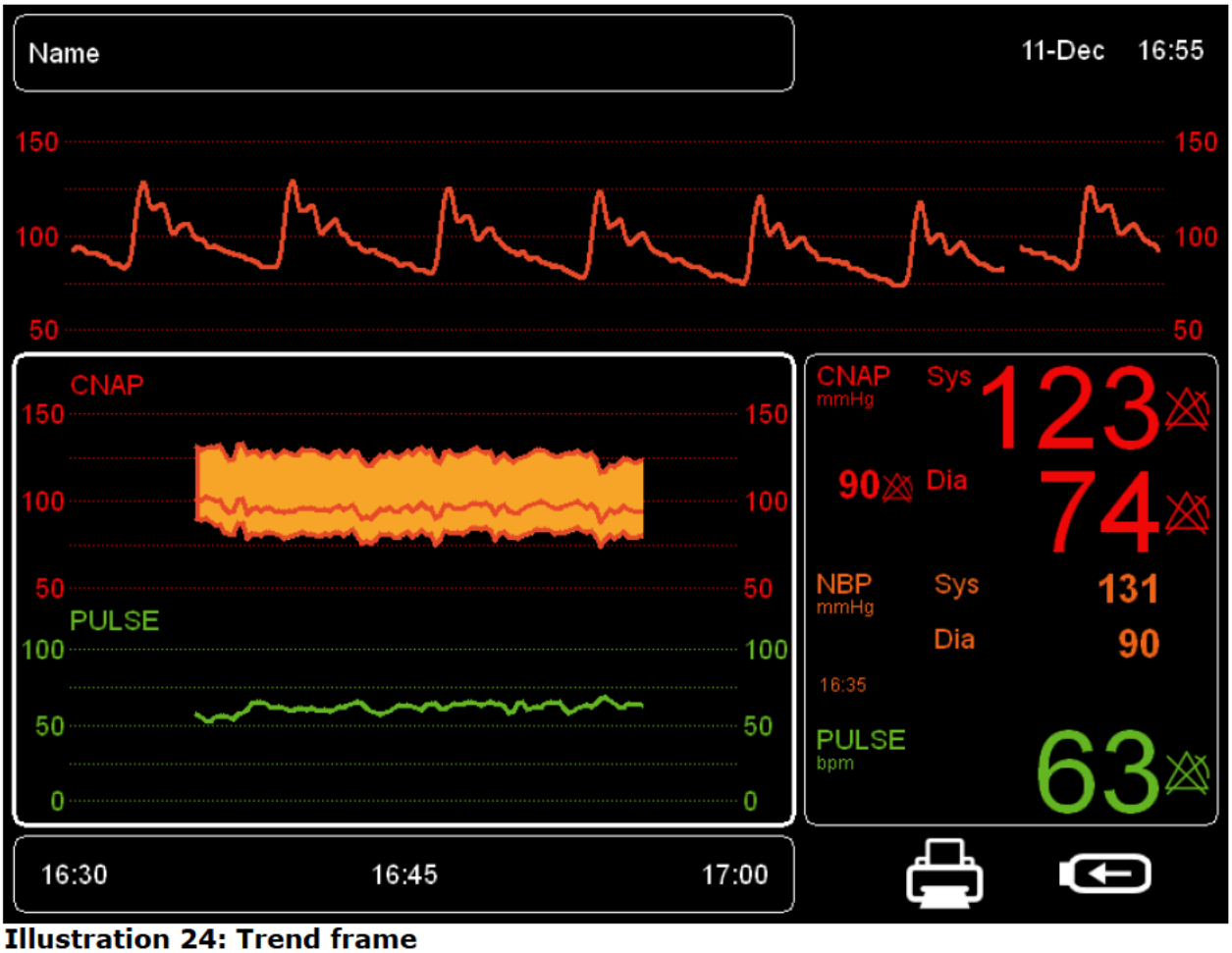

Illustration 24: Trend frame

7.1 Trend – the menu

The menu **Trend**, which can be accessed directly from the Main Screen by means of the click-wheel-control, allows the operator to configure trend views in the **Trend frame**.

Menu item	Description	Settings
Trend Display	Selection of trend view: **Graphic** or **Numeric** display, or **Alarm history**	**graphic, numeric, alarm history**
BP Scale ...	Adjustment of amplitude scales of CNAP™ blood pressure waveform and trend	**BP Mean, BP amplitude**
Pulse Scale ...	Adjustment of amplitude scales of pulse rate trends	**Pulse Mean, Pulse amplitude**
Time Scale	Setting of time scale	Graphic: **30min (default), 1h, 2h, 4h, 8h, 12h, 24h** Numeric: **1 beat, 1min, 5min, 15min, 30min, 1h**

7.2 Setup

7.2.1 Trend views

Recorded data are automatically displayed in the **Trend frame**, including three options:

- **Graphic trend**: graphical trend of measured parameters, displayed on a time axis
- **Numeric trend**: numerical trend of measured parameters; adjustment of time intervals
- **Alarm history**: display of all alarms issued during a measurement

NOTE:
- You can select your trend display option by using the click-wheel control to open the menu **Trend frame** in the main screen, then to select **Trend** and access the menu item **Trend display**.

7.2.2 Graphic trend

The trend view **Graphic trend** allows a graphical view of the following parameters on a time axis:

- CNAP™ blood pressure values: Sys, Dia, Mean
- CNAP™: Pulse

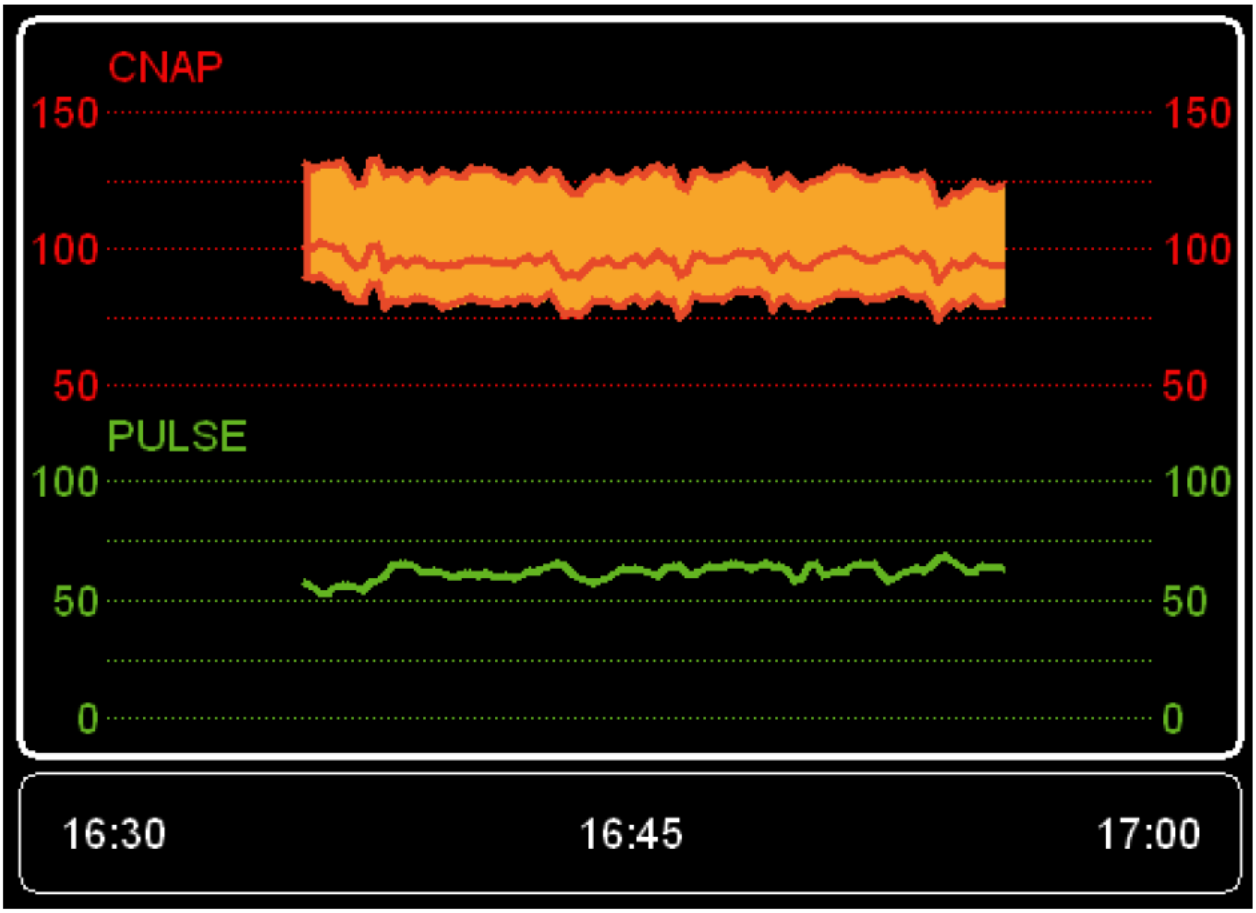

Illustration 25: Graphic trend

NOTE:
- The trend view **Graphic** can be adjusted by changing the following scales: **BP scale**, **Pulse scale** and **Time scale**.
- The displayed data window can be adjusted by means of the click-wheel control in the **Navigation frame** (see chapter 7.2.5 – Scrolling of trend views), which also determines the amount of data to be printed.

BP SCALE:
The scale factor of the CNAP™ blood pressure trend can be configured in the menu entry **BP scale**, which is located in the menu **Trend**. Scales are configured as follows:

Menu item	Description	Settings
BP Scale ...		
BP Mean	Setting of expected mean blood pressure	**20(10)240 mmHg* 50(25)200 mmHg** 100(50)150 mmHg*****
BP Amplitude	Setting of expected mean blood pressure amplitude	**40*, 100**, 200*** mmHg**

Example:
Patient's blood pressure: 130/80 (105)

- BP Mean: 100 mmHg
- BP Amplitude: 100 mmHg

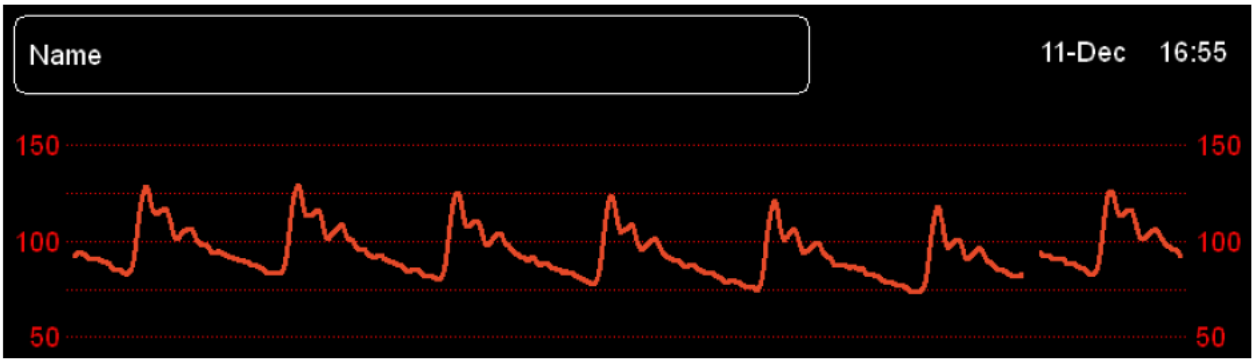

Illustration 26: Example of BP scale

NOTE:
- The scale of CNAP™ blood pressure applies the waveform and trends.

PULSE SCALE:
The scale factor of the CNAP™ pulse rate trend can be configured in the menu entry **Pulse scale**, which is located in the menu **Trend**. Scales are configured as follows:

Menu entry	Description	Settings
Pulse Scale ...		
Pulse Mean	Setting of expected mean pulse rate	**20(10)240 bpm* 50(25)200 bpm** 100(50)150 bpm*****
Pulse Amplitude	Setting of expected mean pulse amplitude (max – min)	**40*, 100* *, 200*** bpm**

TIME SCALE:
The time scale of blood pressure and pulse rate trends can be set in the menu item **Time scale**, which is located in the menu **Trend**.

Menu entry	Description	Settings
Time Scale	Setting of time scale for **Graphic trend**	**30min (default), 1h, 2h, 4 h, 8h, 12h, 24h**

NOTE:
- Time scales of **Graphic trend** always correspond to the entire time slot which is displayed in the **Trend frame**.
- In case of an adjustment of the time scale, the current point of time is displayed on the right end of the **Trend frame**.

STOP:
- Time labels displayed in the **Navigation frame** correspond to the time displayed on the system clock of the CNAP™ Monitor 500. So it is essential to make sure that the monitor's system clock is showing the correct time.

7.2.3 Numeric trends

The trend view **Numeric** allows a numeric view of the following parameters on a time axis:

- CNAP™ blood pressure values: Sys, Dia, Mean
- CNAP™: Pulse

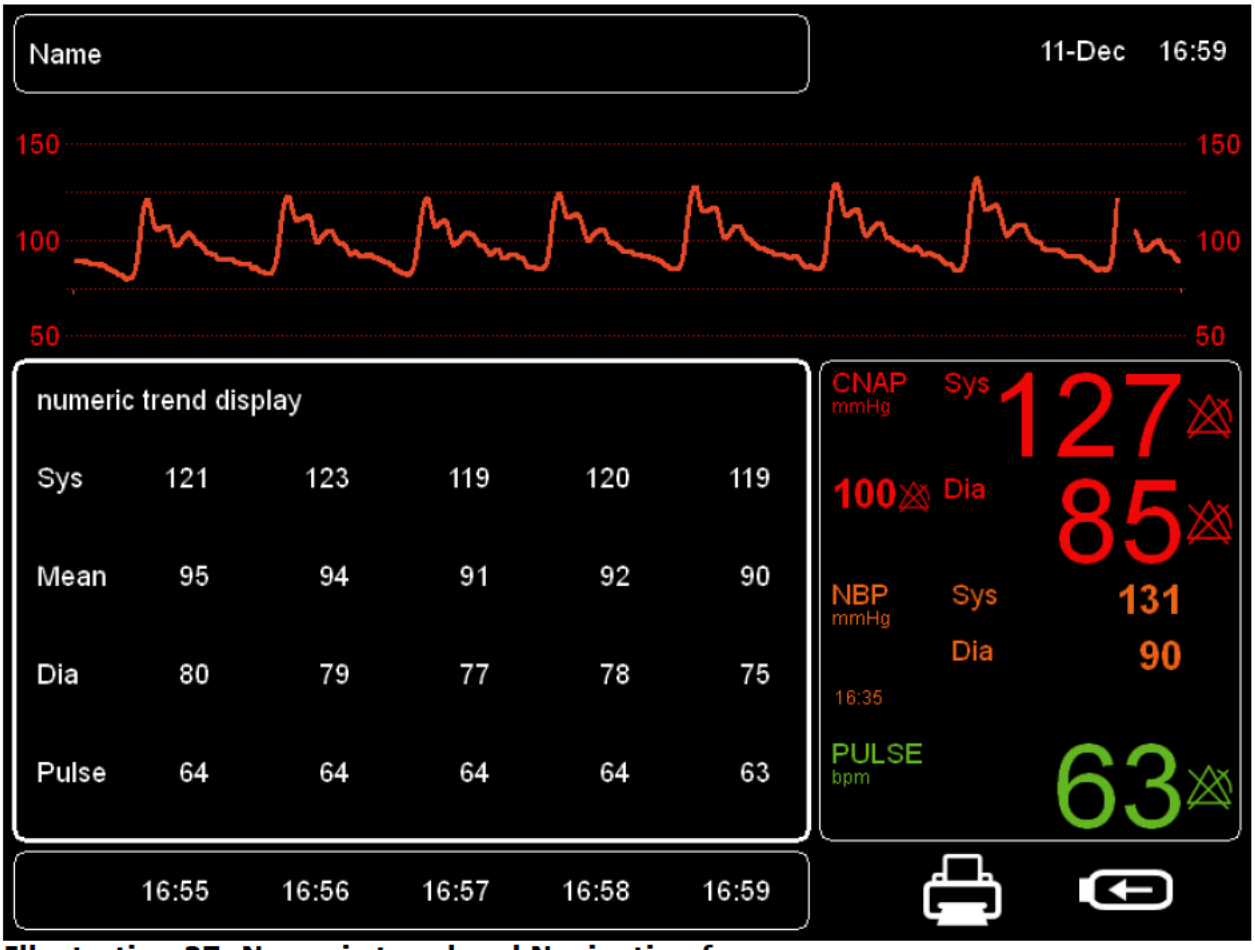

Illustration 27: Numeric trend and Navigation frame

NOTE:

- The trend view **Numeric** can be configured by adjusting **Time scale** from the **Trend menu.**
- The displayed data window can be adjusted by means of the click-wheel control in the **Navigation frame**, which also determines the scope of print reports.

TIME SCALE:
The time scale for the trend views of blood pressure and pulse rate can be set via accessing the menu **Trend** and then selecting **Time scale**.

Menu item	Description	Settings
Time Scale	Setting of time scale for **Numeric trend**	**1beat, 1min, 5min, 15min, 3 0min, 1h**

NOTE:
- The time scale of the **Numeric trend** corresponds to the time interval between 2 displayed measured values.
- The displayed values are averaged on the basis of the selected time scale (time interval).
- In case of an adjustment of the time scale, the current point of time is displayed in the far right column of the **Trend frame**.

STOP:
- Time labels displayed in the **Navigation frame** correspond to the time displayed on the system clock of the CNAP™ Monitor 500. So it is essential to make sure that the monitor's system clock is showing the correct time.

7.2.4 Alarm history

The **Alarm history** is a list of up to 100 last released alarms and malfunction reports. Each report of the alarm history includes the following information:

- Date
- Time
- Priority
- Alarm message

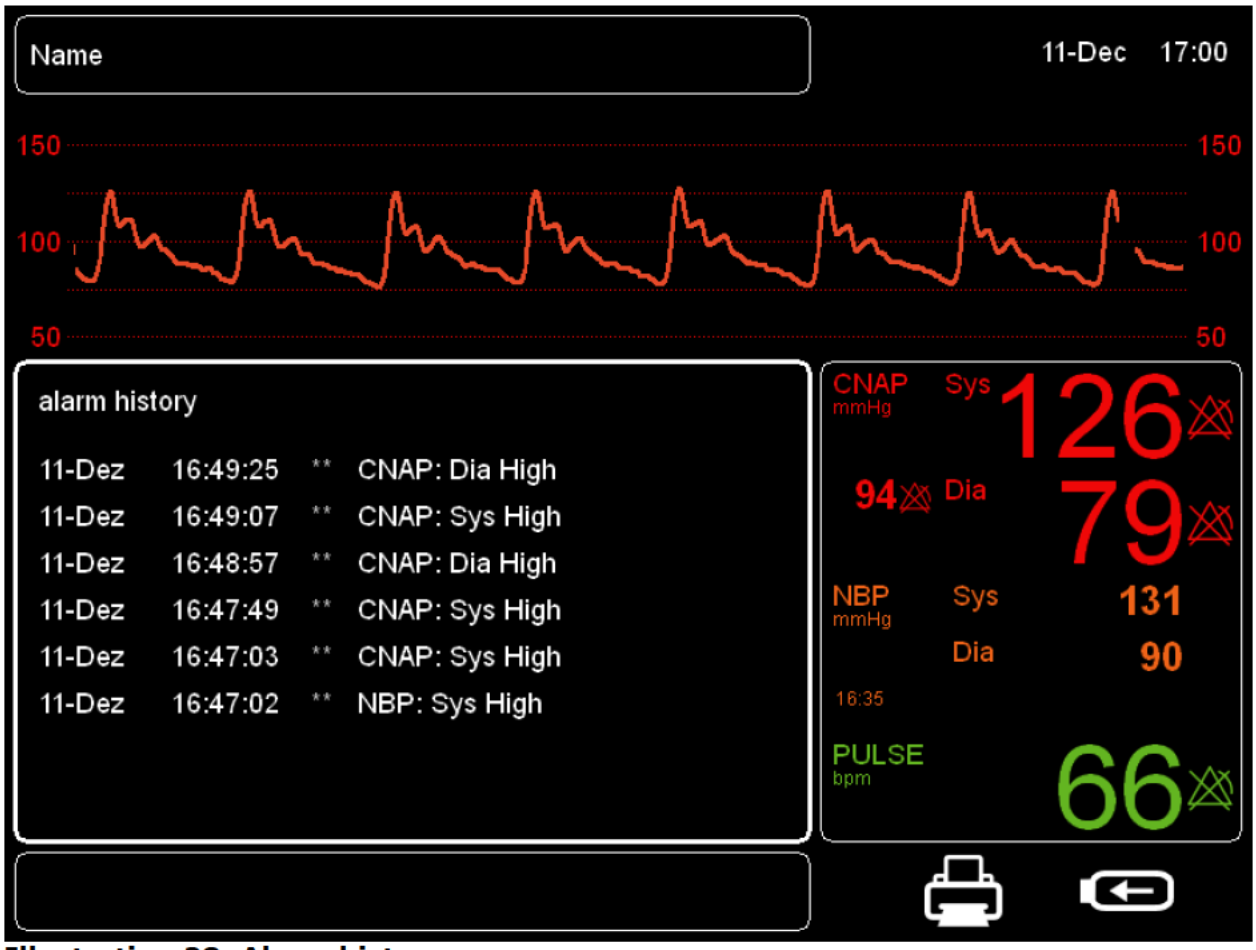

Illustration 28: Alarm history

NOTE:
- The **Alarm history** includes the entire list of the last reported alarms (up to 100 entries). The scroll up and scroll down keys in the Navigation frame can be used to view and complete list of alarms.

STOP: Discharge of a patient
- The deletion of patient data irretrievably deletes all connected recordings, including the parameters **Sys, Mean, Dia** and **Pulse** as well as the **Alarm history** (see chapter 5.3 – Discharge).

7.2.5 Scrolling of trend views

The time slot of the data displayed in the **Trend frame** can be adjusted in the **Navigation frame** by using the click-wheel control:

1) Access the **Navigation frame** using the click-wheel control
2) Select the desired time slot by wheeling the click-wheel control
3) Confirm selection by pressing the click-wheel control

NOTE:
- Scrolling trends by means of the click-wheel control is restricted to the start of a measurement and/or the current time: i.e., the time slot of a trend can neither be scrolled to before the start of a measurement nor to a prospective time.

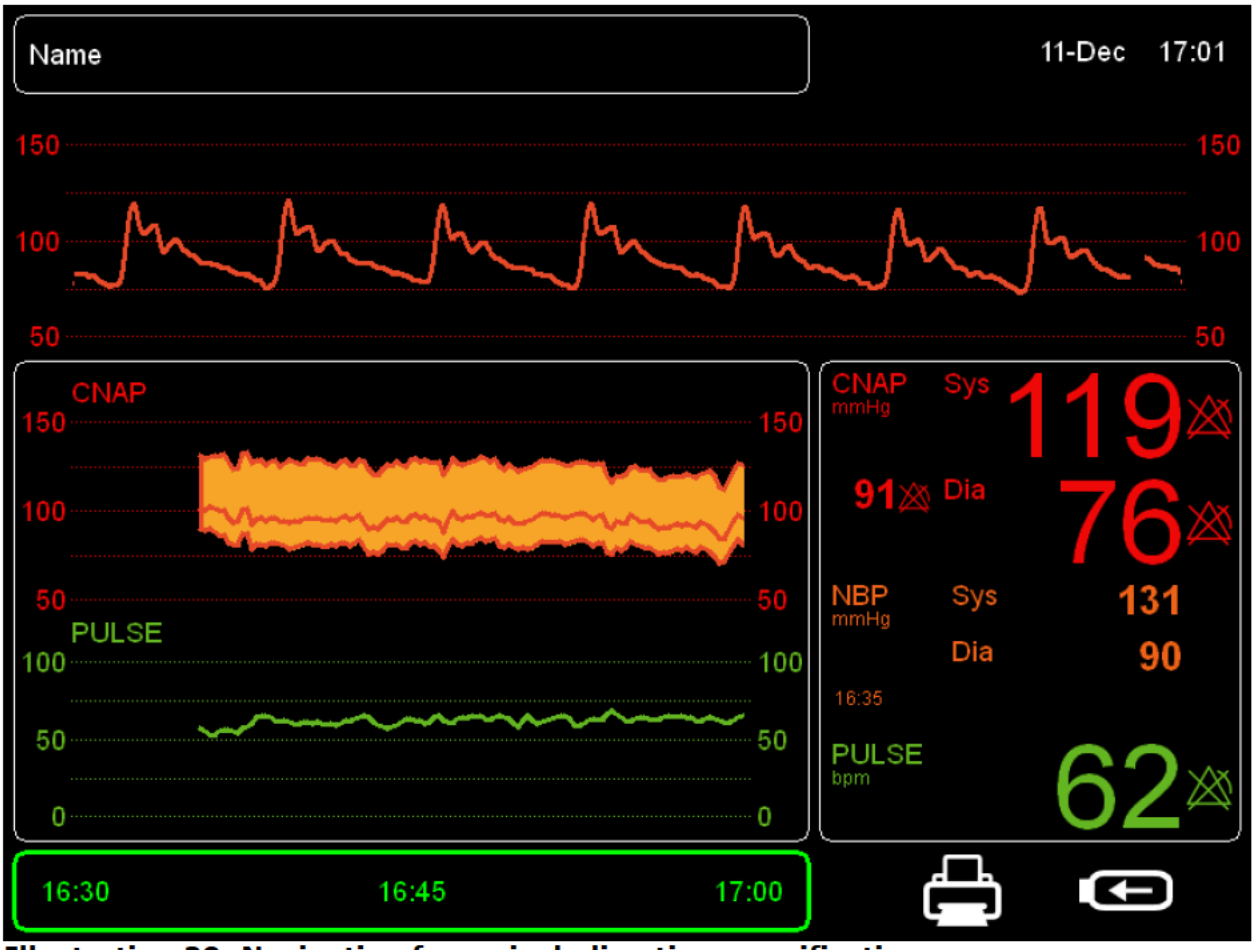

Illustration 29: Navigation frame including time specification

8 Printing

Launching print reports 8-1
Cancelling print reports 8-2
Print reports 8-2
Print options 8-3

The CNAP™ Monitor 500 is provided with an integrated thermal printer enabling the operator to print a range of predefined **print reports**.

8.1 Launching print reports

The operator can launch **print reports** by means of pressing the key **Print** for variable lengths of time and select **print reports** as follows:

a) Depending on how long the operator presses **Print** he or she can select either **Trend reports** or **Snapshot reports**:

- Press **Print** once: **Snapshot reports** printing is selected.
- Press **Print** for longer than 0.5 seconds: printing of **Trend reports,** which correspond to the data displayed in the **Trend frame**, is selected.

NOTE:
- The duration of **Snapshot reports** is limited to 20 seconds. **Snapshot delay** settings are edited in the menu **Measurement**.

b) The way how recordings are displayed in the **Trend frame** automatically determines the selected **Print report**:

- **Graphic trend** (see chapter 8.3, Illustration 30)
- **Numeric trend** (see chapter 8.3, Illustration 31)
- **Alarm history** (see chapter 8.3, Illustration 32).

NOTE:
- Scaling of trend frame: The time slot displayed in the **Trend frame**, including also the time scale settings, is correspondingly printed.
- If necessary, adjust scales (i.e. BP Scale, Pulse Scale, Time Scale) and the displayed time slot (Navigation Bar).

NOTE:
- Depending on the **Print options**, which can be accessed by means of pressing **Setup** in the **Measurement menu**, the CNAP™ Monitor 500 can automatically launch a **Print on alarm report** if a physiological alarm is issued. In this case printing does not depend on the **Trend frame** data display, i.e. BP scale is fixed to 0-250mmHg.

STOP:
- If the CNAP™ Monitor 500 is on battery operation and battery charge status is ≤25 %, printing will be deactivated. Current print jobs will be cancelled immediately for safety reasons.

8.2 Cancelling print reports

In order to cancel any print jobs, press **Print** once.

8.3 Print reports

The CNAP™ Monitor 500 offers a range of predefined **print reports**. All **print reports** have the same header containing the following information:

- Print report type
- Name
- Patient ID
- Gender
- Birth date
- Printed (date and time)
- Last NBP (values and time of the last NBP measurement)

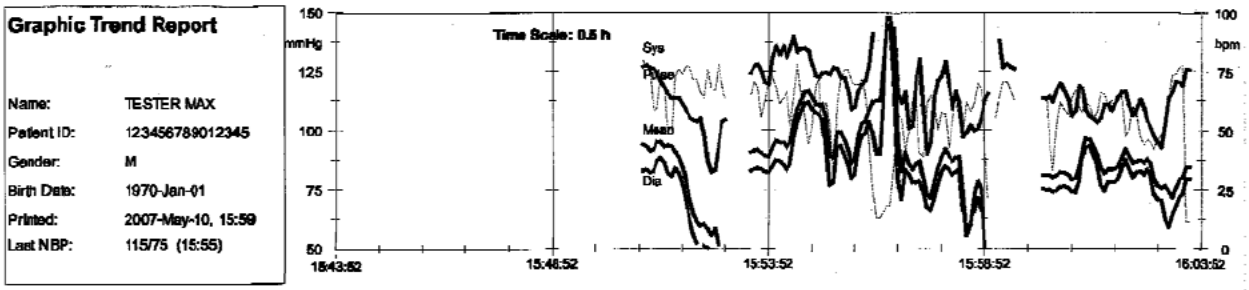

Illustration 30: Graphic trend report

Numeric Trend Report

Name:	TESTER MAX
Patient ID:	123456789012345
Gender:	M
Birth Date:	1970-Jan-01
Printed:	2007-May-10, 15:50
Last NBP:	125/83 (15:48)

Date	2007-May-10	2007-May-10	2007-May-10	2007-May-10	2007-May-10
Time	15:50:51	15:50:54	15:50:54	15:50:55	15:50:56
Sys	125	125	134	124	126
Mean	79	79	104	103	103
Dia	66	66	97	97	96
Pulse	9	9	27	82	78

Illustration 31: Numeric trend report

Alarm History Report

Name:	Last First
Patient ID:	GE-3441_____
Gender:	F
Birth Date:	2007-May-10
Printed:	2007-May-10, 16:02
Last NBP:	125/85 (16:02)

Alarm history			
2007-May-10	16:02:30	**	Alarm Message 1
2007-May-10	16:02:30	**	Alarm Message 2
2007-May-10	16:02:30	**	Alarm Message 3
2007-May-10	16:02:30	**	Alarm Message 4
2007-May-10	16:02:30	**	Alarm Message 5
2007-May-10	16:02:30	**	Alarm Message 6
2007-May-10	16:02:30	**	Alarm Message 7
2007-May-10	16:02:30	**	Alarm Message 8

Illustration 32: Alarm history report

Snapshot Report

Name:	TESTER MAX
Patient ID:	12345678901234 5
Gender:	M
Birth Date:	1970-Jan-01
Printed:	2007-May-10, 15:49
Last NBP:	125/83 (15:48)

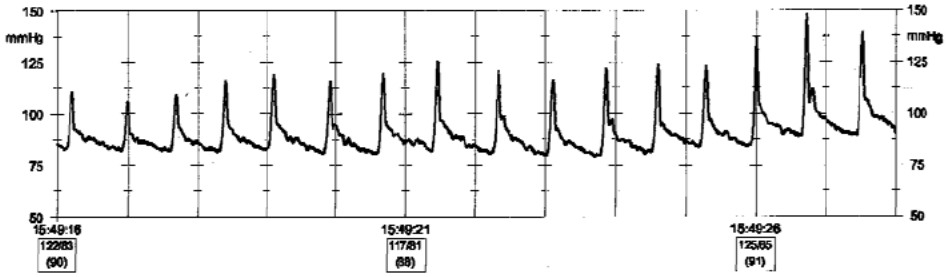

Illustration 33: Snapshot report

8.4 Print options

Menu item	Description	Settings
Snapshot Delay	Setting of delay time of print reports for **Snapshot** and **Print on alarm**	**5sec, 10sec, 15sec**
Print On Alarm	Activation of **Print on alarm** feature	**on, off**

9 CNAP™

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9.1 General information

CNAP™ - Continuous Non-Invasive Arterial Blood Pressure – is a non-invasive method for measuring the continuous blood pressure waveform in adult and pediatric patients from the age of 4 years.

A patient's blood pressure waveform is recorded by the CNAP™ Monitor 500 by means of a double finger cuff with an integrated IR light sensor and air chambers in connection with NBP measurement (oscillometric blood pressure measurement). The NBP cuffs can be placed on the patient's upper arm either on the same or on the other arm as the double finger cuff. NBP measurement is essential to ensure absolute accuracy of the recorded blood pressure values.

CAUTION:

- The accuracy of the CNAP™ measurement depends on the accuracy of the accompanying NBP measurement, which is particularly important during calibrations or before interventions.
- Make sure that no movement artifacts occur during measurement, especially during and until 2 min. after measurement initialization.
- Powerful light sources (e.g. cameras with flashlight) may affect the CNAP™ measurement and cause artifacts.

CAUTION:

- Movements of the patient, which result in changes of position of the CNAP™ double finger cuff regarding heartlevel, will have influence on the accuracy of blood pressure readings. To compensate these physical effects (hydrostatic height), recalibrate the CNAP™ measurement by triggering a single NBP measurement manually (see chapter 10.5 - NBP options).

9.2 Safety precautions

CAUTION:

- Do not use CNAP™ and NBP in patients with vascular prostheses!
- CNAP™ is designed for the concurrent measurement of only one patient at a time.
- Be sure to follow local regulations regarding storage of the CNAP™ Monitor 500, its accessories and packing material.
- Keep the CNAP™ Monitor 500 out of reach of children!
- The CNAP™ blood pressure waveform is calibrated by means of an additional NBP measurement. If the accuracy of the NBP measurement is affected by artifacts (weak pulse, irregular pulse, artifacts from patient movement or tremor, or respiratory artifacts), this may also affect and reduce the accuracy of values measured by the CNAP™ Monitor 500.
- The use of technical surgical devices might cause interference and reduce the quality of CNAP™ recordings.
- Do not ever connect the device's pneumatic connectors to an intravascular system!
- Regularly inspect concerned patient limbs during measurement to avoid possible lasting damages caused by prolonged impairment of the patient's blood circulation! In case of any signs of total arterial compression, immediately discontinue the measurement process by pressing **Start/Stop** on the front panel of the device.
- Pain or strong feelings of discomfort are in no way normal and are not a part of CNAP™ measurements! Should a patient report any of these feelings, stop the measurement process immediately!
- Before connecting any cables to a patient, visually inspect all components for damages or wearout. Any faulty parts (e.g. cables or plugs) are to be replaced immediately.
- Control the correct positioning of the CNAP™ double finger cuff regularly during measurement. Make sure that the cuff is not positioned on the finger joints.

NOTE:

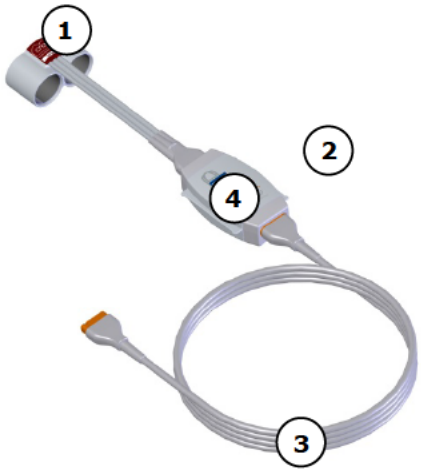
- Avoid compressing the air hoses or reducing their diameter in any way (e.g. by bending the cables) as this could impair the quality of the CNAP™ measuring signals. To avoid mechanical damage to the finger cuffs, remove all objects (e.g. rings) from patient fingers before measuring.

STOP:

- The operating environment for CNAP™ hardware has to comply with the directions regarding ambient temperature, relative humidity and atmospheric pressure (see chapter 14 – Appendix C – Technical specifications).
- Take care to ensure regular and sufficient air circulation around the CNAP™ Monitor 500 by placing the device accordingly (e.g. do not cover it with sheets or blankets).

9.3 Setup

The CNAP™ hardware consists of the following components:



① CNAP™ double finger cuff

② CNAP™ controller

③ CNAP™ cable

④ Graphics to select correct finger cuff size

Abbildung 34: CNAP™ hardware

NOTE:
- CNSystems recommends placing the CNAP™ double finger cuff on the index and the middle finger of a patient. In rare cases – if necessary – the CNAP™ double finger cuff may also be placed on the middle and the ring finger. Thumb and little fingers are not suited for CNAP™ blood pressure measurement.
- The use of a too big/too small CNAP™ double finger cuff may result in faulty blood pressure recordings.

Start/stop a measurement (refer to chapter 3.4 – Quick setup):

- Choose the correct size of a CNAP™ double finger cuff by means of the graphics on the upside of the CNAP™ controller (refer to chapter 3.2.3 CNAP™ controller).
- Assemble the CNAP™ hardware by connecting the CNAP™ double finger cuff, the CNAP™ controller, the CNAP™ cable and the CNAP™ Monitor 500. All the plugs and connectors are designed so as to making it impossible to switch them accidentally.
- Equip the patient with the CNAP™ hardware: The CNAP™ double finger cuff is placed on the proximal joints of the index and middle fingers. Make sure that the cuff cables run along the upper side of the patient's arm.
- Fasten the CNAP™ controller to the patient's forearm by means of the fixing cuff (with Velcro fastener).
- Place the NBP blood pressure cuff on the patient's upper arm (calibration for CNAP™) contralaterally, or, if necessary, on the same arm as the double finger cuff.
- Start the CNAP™ measurement by pressing Start/Stop on the front side of the device.

Illustration 35: Subject setup

NOTE:

- The key **Start/Stop** starts or stops both a CNAP™ measurement as well as the calibration process by means of the NBP measurement.
- A current NBP measurement can be stopped without interfering with a concurrently performed CNAP™ measurement by pressing **Start/Stop**. Pressing the same key a second time also stops the CNAP™ measurement

9.4 View features

CNAP™ determines the following blood pressure values which are displayed directly in the **Main screen** of the CNAP™ Monitor 500:

- Blood pressure waveform (morphology)
- Blood pressure trends:
  - Sys
  - Mean
  - Dia
  - Pulse
- Numeric blood pressure values:
  - Sys
  - Mean
  - Dia
  - Pulse

9.4.1 Blood pressure waveform

The CNAP™ blood pressure waveform is displayed directly in the **Main screen.**

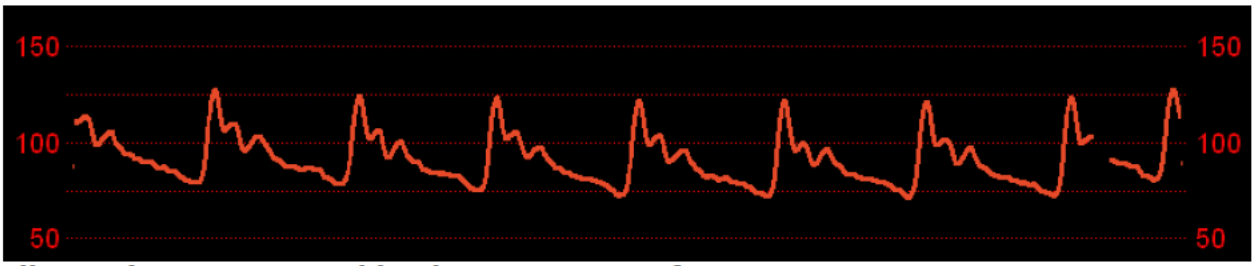


Illustration 36: CNAP™ blood pressure waveform

NOTE:
- The scale of the CNAP™ blood pressure waveform is configured in the same way as the scale of the CNAP™ trend. It is set in the **Menu trend** (see chapter 7 – Trends).
- The signal speed of the CNAP™ blood pressure waveform is set to 12,5 mm/s and cannot be adjusted in any way.

9.4.2 Trend view

The CNAP™ blood pressure trend is displayed in the **Trend frame** directly in the **Main screen** of the CNAP™ Monitor 500. It enables both graphic as well as a numeric view of blood pressure trends.

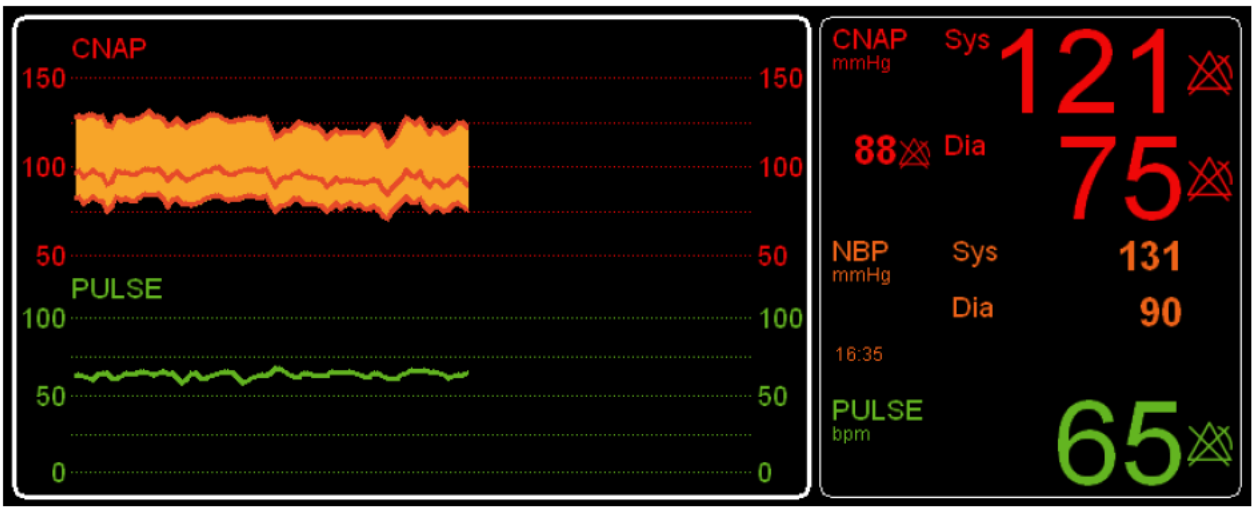
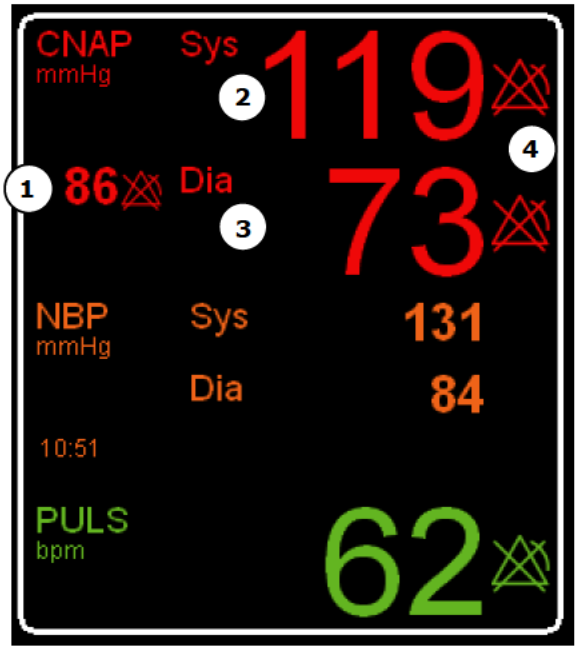


Illustration 37: Graphic trend and numeric values (parameter frame)

NOTE:
- Scales for CNAP™ trends and the CNAP™ blood pressure waveform are set by means of the click-wheel control in the menu **Trend**. Amplitude scales are set likewise for the CNAP™ blood pressure waveform and the CNAP™ trend (see chapter 7 – Trends).

9.4.3 Numeric values

The CNAP™ parameter box displays the current blood pressure parameters **Sys**, **Mean**, **Dia** and **Pulse**:



① Mean blood pressure

② Systolic blood pressure

③ Diastolic blood pressure

④ Alarm limit settings

Illustration 38: Parameter frame

9.5 CNAP™ options

Parameter menu:

Menu item	Description	Settings
CNAP: Ch ange Finger	Change of signal source in CNAP™ double finger cuff	
CNAP: Cal Interval	Setting of automatic change of signal source in CNAP™ double finger cuff [min]	**5(5)60min**
NBP: Start	Start of a single NBP measurement	
	Setting of time interval for automatic NBP measurement [min]	**off, 5(5)30, 45, 60min**
Audio Trend...	Setting of source and volume for audio trend	Submenu
Alarms...	Setting of alarms for the parameters Sys, Mean, Dia, Pulse	
IBP Zeroing	Zeroing for interface to other patient monitors	**on, off**

10 NBP

General information 10-1
Safety precautions 10-2
Set-up 10-3
View features 10-5
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10.1 General information

NBP (Non-Invasive Blood Pressure) uses the oscillimetric method to determine a patient's blood pressure on a non-continuous basis. To achieve this, the NBP module is integrated into the CNAP™ Monitor 500. Blood pressure measurement is conducted by means of a NBP cuff (available in 4 sizes) which is placed around the patient's upper arm and connected to the CNAP™ Monitor 500 on the left side of the monitor (see chapter 3 – Introduction). For measurement purposes, the pressure in the NBP cuff is controlled by the NBP module. The cuff pressure is first increased above systolic blood pressure and decreased step by step. The pulsations in the NBP cuff provide the basis for deriving the blood pressure values Sys, Mean and Dia.

NOTE:
- When a measurement process is started on the CNAP™ monitor, a NBP measurement is also triggered automatically.
- However, it is also possible to trigger an NBP measurement manually at any time during measurement (see chapter 10.5 – NBP options).
- NBP measuring interval is pre-set in the menu **Setup/Measurement** for every new measurement and can be changed via the menu **Parameters** for the current measurement only.
- Inflation pressure of the NBP cuff is determined by the selected patient category (see chapter 5.1 – Input of patient data).

NOTE:
- The CNAP™ blood pressure waveform is calibrated by means of an oscillometric NBP measurement. If the accuracy of the NBP measurement is affected by artifacts (e.g. weak pulse, irregular pulse, artifacts from patient movement or tremor, or respiratory artifacts), this may also affect and reduce the accuracy of blood pressure values measured by the CNAP™ Monitor 500.
- An NBP cuff can be donned on the same arm as the CNAP™ double finger cuff (ipsilaterally) or on the other arm (contralaterally).

10.2 Safety precautions

STOP:

- **Patient category:** Make sure to select the correct patient category before starting a measurement (see chapter 5.1– Input of patient data). The higher adult levels of inflation pressure, excess pressure limits or measuring time, for instance, must never be used for pediatric patients!
- **Intravenous infusion lines:** Never don a NBP cuff to a limb already connected to an intravenous infusion line or an intraarterial catheter. The inflation of the cuff might result in the infusion solution being caught up or even cause tissue damage to the punctured area.
- **Cutaneous lesions:** Never perform NBP measurements in patients suffering from drypanocytemia or from cutaneous lesions, or in patients where cutaneous lesions are to be expected.
- **Unsupervised measurements**: Patients with severe blood coagulation dysfunction may develop hematoma where the NBP cuff has been inflated. In these cases, carefully consider the pros/cons and the necessity of frequent unsupervised blood pressure measurements.
- **Interference by external devices:** Results of NBP recordings are not to be used if the measured oscillometric pulses have been influenced by other devices or techniques (e.g. counterpulsation or contrapulsation).
- **Interpretation:** NBP recordings are to be interpreted only by a physician or medical professional staff.
- **Limitations of NBP measurements:** NBP recordings may be inaccurate or even impossible under the following conditions:
  - lack of detectable regular arterial blood pressure
  - arrhythmia
  - strong and persistent patient movement (e.g. tremor or convulsions)
  - rapid blood pressure fluctuations
  - severe shock or hypothermia with reduced peripheral blood flow
  - obesity, as adipose tissue in the limbs muffles arterial oscillations

NOTE:

- In order to ensure the accuracy of NBP measurings, be sure to choose the right size of the upper arm cuff. Selecting the wrong size or incorrect donning of the cuff may cause significant inaccuracies of recordings!
- In case of longer monitorings, be sure to inspect the correct blood supply of the patient's limbs on a regular basis.
- The NBP cuff is made of latex free and skin friendly synthetic material.

10.3 Setup

The NBP hardware consists of the following components:

- NBP cuff (Child, Small adult, Adult, Large adult)
- NBP module (integrated into the CNAP™ Monitor 500)
- NBP air connector

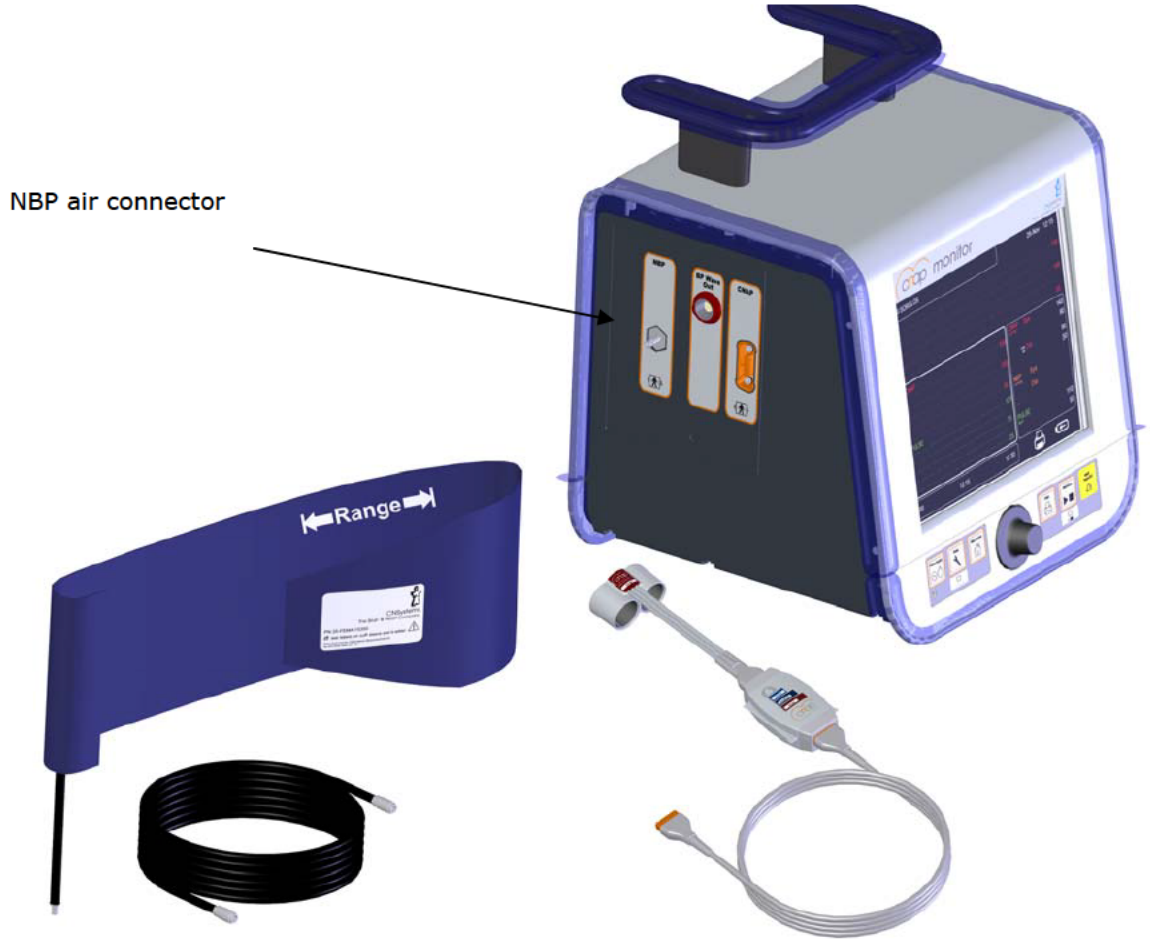


Illustration 39: CNAP™ Monitor 500 with NBP air connector

Start/Stop a measurement:

1. Make sure you are using an NBP cuff authorized by CNSystems and make sure to use the correct size.

NOTE:
- The width of the cuff should be between 37% and 47% of the circumference of the patient's limb. The inflatable part of the cuff should be at least 80% of the respective extremity.
- The following cuff sizes are available:

Size	Arm circumference (cm)
Child	12 - 19
Small Adult	17 -25
Adult	23 - 33
Large Adult	31 - 40

2. Apply the NBP cuff on the upper arm of the patient at heart level. The marker on the NBP cuff should be directly above the brachial artery.

NOTE:
Do not fix the cuff too tightly around the limb as this might cause problems during inflation and deflation of the cuff and lead to ischemia of the extremities. Be sure to inspect the patient's skin (colour, temperature, sensitivity of limb) around the cuffs on a regular basis. Should any signs of alterations of the skin or decreased blood supply be noticeable, immediately change arms or stop the blood pressure measurement altogether.

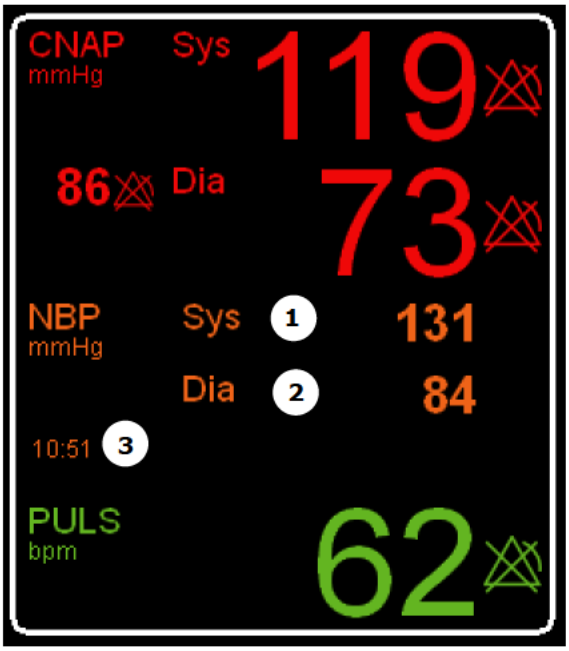
3. Connect the NBP cuff with the NBP air connector on the left side of the CNAP™ Monitor 500.

4. There are 2 ways to start an NBP measurement:
   a) The start of a CNAP™ measurement also automatically starts an NBP measurement. NBP measurements are performed after the calibration phase of the CNAP™ measurement or automatically in defined time intervals. To set the desired time intervals, acces either the menu **Parameter** or the menu **Measurement**.
   b) In order to start a single measurement, use the click-wheel control to access the menu **Parameter**.

NOTE:
- The NBP measurement serves to calibrate the CNAP™ blood pressure measurement at the height of the heart.

10.4 View features

By means of NBP the blood pressure values Sys and Dia are determined and displayed in the Parameter frame of the CNAP™ Monitor 500.



① Systolic blood pressure

② Diastolic blood pressure

③ Time of last NBP measurement

Illustration 40: Parameter frame

NOTE:
- The **Parameter frame** always displays the most recent NBP values as well as the time of measurement.

10.5 NBP options

Parameter menu:

Menu item	Description	Settings
CNAP: Ch ange Finger	Change of signal source in CNAP™ double finger cuff	
CNAP: Cal Interval	Setting of NBP calibration interval for CNAP™ measurement	**5(5)60min**
NBP: Start	Start of a single NBP measurement	
NBP: Interval	Setting of time interval for automatic NBP measurement for the current CNAP™ recording only	**off, 5(5)30, 45, 60min**
Audio Trend...	Setting of source and volume for audio trend	Submenu
Alarms...	Setting of alarms for the parameters Sys, Mean, Dia, Pulse	
IBP Zeroing	Zeroing for interface to other patient monitors	**on, off**

Measurement Setup:

Menu item	Description	Settings
CNAP: Cal Interval	Setting of NBP calibration interval for CNAP™ measurement	**5(5)60**
NBP: Interval	Pre-set time interval for automatic NBP measurement for each new CNAP™ recording	**off, 5(5)30, 45, 60**
Audio Trend...	Setting of source and volume for audio trend	Submenu
Display Options...	Submenu to adjust display settings	
Print Options...	Submenu to set print options	
Parameter Averaging	Averaging of display parameters	

NOTE:

- Adjustments in the menu **Parameter** alter only the current measurement and are transcribed by **Defaults** when a new measurement is started.
- Settings performed in the menu **Measurement**, however, alter both the current as well as future measurements.

11 Cleaning and disinfection

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Cleaning 11-2
Disinfecting 11-2

Only use disinfectants and detergents recommended by CNSystems Medizintechnic AG to clean or disinfect the device and its accessories. CNSystems warranty does not cover any damage caused by the use of unsuitable cleaning agents or methods.
The warranty of CNSystems does not apply to the effectiveness of the mentioned cleaning agents and methods for the purpose of infection prevention and control. When in doubt, the operator is to contact the hospital hygiene department. This particularly applies for the effectivity of disinfectants and detergents against hepatitis B and HI viruses. The operator is to follow the regulations of the respective hospital and country.

11.1 General precautions

The CNAP™ Monitor 500 including all its components and accesssories are to be kept clean and free of dust.
After cleaning and disinfecting the devices, they must be thoroughly inspected before use.
If any components show signs of wear or damage, these components must not be used for patient measurements!
Before sending devices and components back to CNSystems they are to be decontaminated.

CAUTION:
- Always dilute detergents according to manufacturers' instruction, or use in the smallest possible concentration.
- No liquid must ingress the CNAP™ Monitor 500.
- Do not dip instruments, device parts or components in liquid.
- Do not pour any liquid directly on the device.
- Do not let residues of detergents or disinfectants air-dry on any parts of the device. Wipe them off with a cloth moist with water, then dry the instruments with a clean cloth.
- Never use scouring agents or abrasive detergents (e.g. steel wool or silver polish).
- Do not use bleaching agents!
- Wipe off detergents and disinfectants with a moist cloth (water), then dry surfaces with clean cloth.

STOP:
- No liquid must be spilt on any part of the CNAP™ Monitor 500. In case this should happen, carefully dry device/accessory. If in doubt whether liquid has ingressed the device, do not start up the instrument. Contact technical staff or a service partner of CNSystems Medizintechnik AG.

11.2 Cleaning

In order to clean any part of the device use a lint-free cloth, moisted with warm water (max. 40° C), and soap, diluted non-caustic detergents, or ammoniac-/ alcohol- containing tensides or detergents. Do not use strong solvents like dimethylketone or trichloroethylene. Do not dip the device, any part of the device or any accessories (especially not any hoses) into liquid.
As the screen of the CNAP™ Monitor 500 is easily scratched, be particularly careful when cleaning it.
No liquid must enter the CNAP™ Monitor 500, so be sure to not spill any liquid directly on the monitor.
No liquid must enter the connectors of the CNAP™ Monitor 500 or the CNAP™ controller, so take care not to wipe over, but rather around, the connectors when cleaning them.

CAUTION:
- Be particularly careful when cleaning or disinfecting the insides of the CNAP™ double finger cuffs. Wipe them carefully in order to avoid any damage.

11.3 Disinfecting

CAUTION:
- **Disinfecting agents**: Never mix different kinds of disinfectant agents (e.g. bleaching agents and ammoniac), as this might result in the production of dangerous gases!
- **Internal hospital regulations:** Disinfect the product in accordance with your own hospital regulations in order to avoid long-term damage of any kind.

The device is to be cleaned before disinfection. Find recommended detergents and disinfectants listed below:

Disinfectant	Glutar-aldehyde	n-Alkyl/ Alcohol	Succindial-dehyde/ Alcohol	Alcohol Spray/ Wipe	Orthophthal-aldehyd
Concentration	3.4%	0.28% -8%	11%	10%	0,55%
Common brands	Cidex Plus	Theracide	Gigasept FF	Microzid AF Liquid	Cidex OPA

12 Technical alarms and status messages

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BP Wave Out (IBP) – Technical alarms 12-3
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NBP – Technical alarms 12-9

Despite physiological alarms the CNAP™ Monitor 500 displays technical malfunction alarms (white) and device status messages (blue) in the "Alarm Frame":

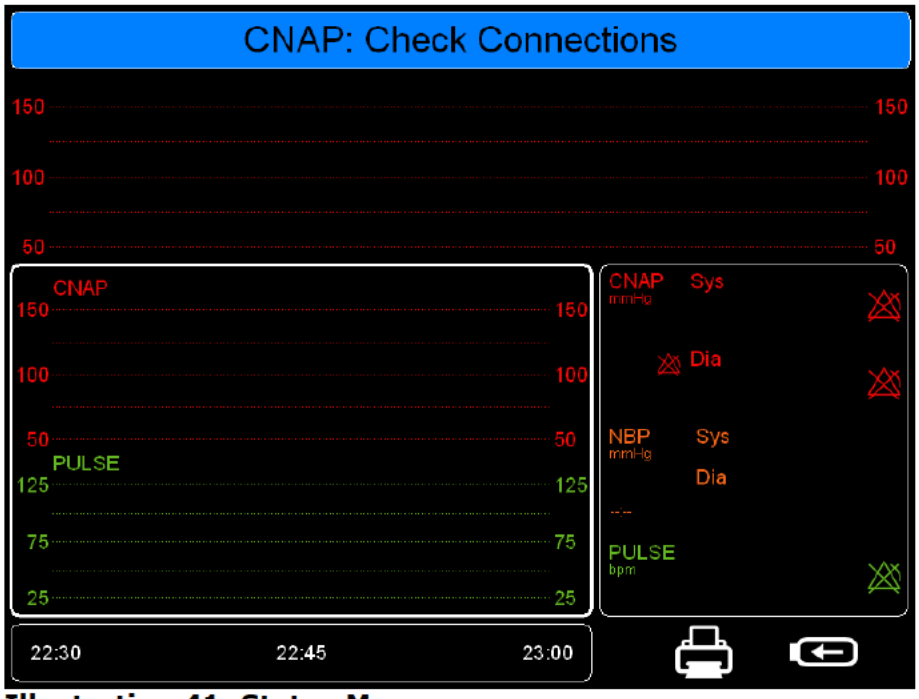

Illustration 41: Status Message

The following documentation lists all technical alarms and device status messages that may occur during the use of the CNAP™ Monitor 500.

NOTE:
- In case you require service support for your CNAP™ Monitor 500 please report the exact technical alarm to the service partner.
- A complete list of technical alarms including error code, time- and date of appearance is available from the Log menu located in the Service Menu. You find the password for the service menu in the CNAP™ Monitor 500 "Instructions for service".

12.1 Main unit

12.1.1 Technical alarms

Message Possible	cause	Measures
MU: Fatal Error – Contact Service	– CNAP™ monitor must not be used for further measurements	– Reboot CNAP™ monitor – In case of persistent error, contact service
MU: CNAP Failure	- Failure in CNAP™ hardware	– Reboot CNAP™ monitor – In case of persistent error, contact service
MU: NBP Failure	- Failure in NBP hardware	– Reboot CNAP™ monitor – In case of persistent error, contact service
MU: IBP Failure	- Failure in IBP component	– Reboot CNAP™ monitor – In case of persistent error, contact service
MU: Battery: Low	– Very low battery charge status (< 25%), battery operation still possible	– Switching to mains operation via power adapter recommended
MU: Battery: Depleted	– Battery depleted, operation possible for at least 15 minutes	– Immediately switch to mains operation via power adapter
MU: Battery: Shutdown	– Battery depleted, operation possible for 5 minutes at most; monitor is switched off	– Immediately switch to mains operation via power adapter – Current measurement discontinued, monitor switched off automatically

12.2 BP Wave Out (IBP)

12.2.1 Status messages

Message Possible	cause	Measures
IBP: Connected	– "BP Wave out" is connected to patient monitor	– Perform zeroing (refer to chapter 4.4) – Make sure to disable zeroing when calibration is complete
IBP: Disconnected	– "BP Wave out" is disconnected from patient monitor	– n.a.

12.2.2 Technical alarms

Message Possible	cause	Measures
IBP: Fault	– Internal controller problem	– Reboot CNAP™ monitor – In case of persistent error, contact service
IBP: Transmission Fault	– Interface problem	– In case of persistent error, contact service
IBP: EEPROM RW Error	– I/O memory chip defective	– Reboot CNAP™ monitor – In case of persistent error, contact service
IBP: Iso Board Fault	– Isolation board failure	– In case of persistent error, contact service
IBP: Iso Board Bridge-Voltage	– Bridge-voltage (BP wave out) exceeds 10V	– Disconnect IBP transducer cable – Check bridge-voltage range (refer to chapter 4.4) – In case of persistent error, contact service

12.3 Printer

12.3.1 Technical Alarms

Message Possible	cause	Measures
PRINTER: Out Of Paper	- Printer is out of paper	– Replenish paper
PRINTER: Fault	– Hardware problem – Excess temperature – Internal voltage supply error	– Problem will be solved automatically – In case of repeated messages, contact service
PRINTER: Failure	– Hardware problem – Interface problem	– Contact service
PRINTER: Communication Error	– Interface problem	– Problem will be solved automatically – In case of repeated messages, contact service

12.4 CNAP™

12.4.1 Status messages

Message Possible	cause	Measures
CNAP: Check Connections	– CNAP™ controller is not connected	– Check connection of CNAP™ controller
CNAP: Check Cuff CNAP: Connections	– CNAP™ double finger cuff is not connected	– Check connection of CNAP™ double finger cuff
CNAP: Check Cuff	– No finger in inactive cuff (before CNAP: Change Finger)	– Put finger in cuff
CNAP: Initializing	– System Self-test	– n.a.
CNAP: Controller Not Calibrated	– CNAP™ controller is not calibrated	– Replace CNAP™ controller – Contact service for calibration of CNAP™ controller
CNAP: Put Finger In Cuff	– CNAP™ has passed self-test and is ready for measurement	– Patient setup
CNAP: Calibration	– CNAP™ calibration phase in progress	– Wait for measurement
CNAP: Calibrating	– NBP measurement to calibrate CNAP™ blood pressure is in progress (end of calibration phase)	– Wait for end of NBP measurement
CNAP: Artifact	– Pressure is not within physiological	– Check and eliminate

Message Possible	cause	Measures
	measuring range – Low signal amplitude in CNAP™ double finger cuff – Interference because of third party measuring devices – CNAP™ hardware is ringing due to artifacts	influence from third party measuring devices – Avoid artifacts (e.g. movements) – Check CNAP™ cables and connectors – Check CNAP™ double finger cuff – Replace CNAP™ double finger cuff and cable
CNAP: Cuff Expiring	– CNAP™ cuff is reaching end of life-cycle, thus providing low quality of measurement	– Replace CNAP™ double finger cuff
CNAP: Cuff Ambie nt Light	– Ambient light interferes with CNAP™ double finger cuff	– Reduce ambient light (i.e. brightness, switch off, ...) – Check setup of CNAP™ double finger cuff

12.4.2 Technical Alarms

Message Possible	cause	Measures
CNAP: Check Connection	– Leakage in CNAP™ hardware	– Check connections of CNAP™ hardware
CNAP: Fault – Reservoir Pressure	– Air reservoir blocked or faulty pressure offset	– Disconnect an reconnect CNAP™controller – In case of persistent error contact service
CNAP: Fault – Zero Offset Controller	– Zero offset of CNAP™controller faulty	– In case of persistent error, contact service for faulty CNAP™controller
CNAP: Fault – Initial Pressure	– Pressure could not reach threshold upon initialization	– Check connections of CNAP™ cable – In case of persistent error message, contact service
CNAP: Fault – Pump/Tubing/Valve Leaky	– Leakage detected upon initialization	– Check connections of CNAP™ cable – In case of persistent error, contact service

Message Possible	cause	Measures
CNAP: Failure – Valve Blocked/Leaky	– Cuff pressure exceeded 450mmHg for more than 10sec in CNAP™ air reservoir	– Disconnect CNAP™ hardware – In case of persistent error, contact service for faulty CNAP™controller
CNAP: Failure – Reservoir Overpressure	– Pressure exceeded 450mmHg for more than 10sec in air reservoir	– Disconnect CNAP™ hardware – Reboot CNAP™ monitor – In case of persistent error, contact service
CNAP: Failure – Cuff Overpressure Left	– Pressure exceeded 330mmHg for more than 10sec in left CNAP™ finger cuff	– Disconnect CNAP™ hardware – Reboot CNAP™ monitor – In case of persistent error, contact service
CNAP: Failure – Cuff Overpressure Right	– Pressure exceeded 330mmHg for more than 10sec in right CNAP™ finger cuff	– Check connections of CNAP™ controller – Reconnect CNAP™ controller – In case of persistent error, contact service
CNAP: Cuff Cannot Deflate/Blocked Line	– CNAP™ finger cuff cannot be deflated	– Replace CNAP™ double finger cuff (check with other cuff size) – In case of persistent error, contact service
CNAP: Check Cuff – Low Light Signal	– CNAP™ detected low signal in measuring finger	– Check for low perfusion – Check size of CNAP™ double finger cuff – Check setup (positioning) of CNAP™ double finger cuff – Check proper optical path in CNAP™ double finger cuff
CNAP: Check Cuff – Ambient Light	– Ambient light interferes with CNAP™ double finger cuff	– Reduce ambient light (i.e. brightness, switch off, …) – Check setup of CNAP™ double finger cuff

Message Possible	cause	Measures
CNAP: Check Cuff – Timeout On Calibration	– Missing NBP calibration – Signal quality insufficient during the calibration cycle (max. 5min) –	– Check NBP for proper setup and measurement – Check size of CNAP™ double finger cuff – Check setup (positioning) of CNAP™ double finger cuff – Warm patient´s hand before measurement
CNAP: Cuff Fault – Overpressure	– Pressure exceeded 330mmHg for more than 2sec in CNAP™ finger cuff	– Check CNAP™ double finger cuff for patient movement (i.e. repositioning) – Disconnect and reconnect CNAP™ hardware – In case of repeated error, contact service
CNAP: Cuff Fault – Light Sensor Left	– Light sensor in left CNAP™ finger cuff defective	– Check influence from ambient light – In case of persitent error, replace CNAP™ double finger cuff
CNAP: Cuff Fault – Light Sensor Right	– Light sensor in right CNAP™ finger cuff defective	– Check influence from ambient light – In case of persitent error, replace CNAP™ double finger cuff
CNAP: Cuff Fault – Memory	– Memory chip in CNAP™ double finger cuff defective	– Replace CNAP™ double finger cuff
CNAP: Cuff Fault – Unlicensed	– CNAP™ double finger cuff is not licensed for CNAP™ Monitor 500	– Check for permutation with equipment from 3rd party devices
CNAP: Cuff Fault – Safety Shutdown	– CNAP™ double finger cuff cannot provide suffient quality for further measurement	– Replace CNAP™ double finger cuff immediately – Order new CNAP™ double finger cuff in corresponding size
CNAP: Cuff Fault – Leakage Left	– Leakage in left CNAP™ finger cuff	– Check connections of CNAP™ hardware – Replace CNAP™ double finger cuff (check with other cuff size): o In case of persistent error contact service

Message Possible	cause	Measures
		○ In case of non-persistent error, replace defective CNAP™ double finger cuff
CNAP: Cuff Fault – Leakage Right	– Leakage in right CNAP™ finger cuff	– Check connections of CNAP™ hardware – Replace CNAP™ double finger cuff (check with other cuff size): ○ In case of persistent error, contact service – In case of non-persistent error, replace defective CNAP™ double finger cuff
CNAP: Cuff Failure – Inflation Timeout	– Inflation of CNAP™ finger cuff exceeded time limit	– Disconnect CNAP™ hardware – Reboot CNAP™ monitor In case of persistent error contact service
CNAP: Controller Fault – Memory	– Memory chip in CNAP™ controller defective	– Disconnect and reconnect CNAP™ controller – In case of persistent error, contact service for faulty CNAP™controller
CNAP: Controller Fault – Unlicensed	– CNAP™ controller is not licensed for CNAP™ Monitor 500	– Check for permutation with equipment from 3rd party devices

12.5 NBP

12.5.1 Status messages

Message Possible	cause	Measures
NBP: Terminated	– NBP measurement was stopped from the user	– n.a.
NBP: Fault	– Checksum error occurred	– Take new NBP – In case of persistent fault, contact service
NBP: Single Measurement	– User has triggered a single NBP measurement	– n.a.
NBP: Automatic Measurement	– Timed NBP measurement (NBP: Interval)	– n.a.
NBP: Checking CNAP	– NBP is triggered to confirm BP trend (CNAP™ differs more than 25mmHg for more than 1min from last NBP	– n.a.

12.5.2 Technical alarms

Message Possible	cause	Measures
NBP: Weak Or No Signal	– Weak or no oscillometric signal	– Check position and fit of NBP cuff – Make sure cuff is placed directly on the skin
NBP: Artifact	– Artifact/irregular oscillometric signal	– Check position and fit of NBP cuff – Avoid artifacts (e.g. movement) – Check for proper NBP cuff size
NBP: Exceeded Retry Count	– In spite of numerous retries, no measurement possible	– Avoid artifacts (e.g. movement) – Check position and fit of NBP cuff – Make sure cuff is placed directly on the skin – Check for proper NBP cuff size
NBP: Measurement Timeout	– Time limit for measurement has been exceeded	– Avoid artifacts (e.g. movement) – Check position and fit of NBP cuff – Make sure cuff is placed directly on the skin – Check for right NBP cuff size

Message Possible	cause	Measures
NBP: Blocked Line	– Blocked line / air hose	– Make sure that NBP air hose is not bent, or twisted too tight – Make sure patient is not lying on NBP cuff or air hose – Check position and fit of NBP cuff
NBP: Leakage	– NBP cuff or air hose leaky or loose	– Check NBP air connections (e.g. for damages, loose fit) – Check NBP cuff for leakage – Check position and fit of NBP cuff – Check for right NBP cuff size
NBP: Safety Timeout	– Safety time limit exceeded	– Check position and fit of NBP cuff – Avoid artifacts (e.g. movement) – Check for right NBP cuff size – Start new NBP measurement
NBP: Overpressure	– Overpressure in NBP cuff	– Check for right NBP cuff size – Make sure NBP air hose is not bent, or twisted too tight – Check position and fit of NBP cuff – Make sure patient is not lying on NBP cuff or air hose
NBP: Hardware Fault	– Voltage supply exceeds limits or other hardware problem	– Reboot CNAP™ monitor – In case of persistent error, contact service
NBP: Autozero Failure	– Autozeroing has failed	– Reboot CNAP™ monitor – In case of persistent error, contact service
NBP: Out Of Range Failure	– Measuring transducer out of measuring range	– Reboot CNAP™ monitor – In case of persistent error, contact service
NBP: ADC Failure	– ADC out of measuring range	– Reboot CNAP™ monitor – In case of persistent error, contact service
NBP: Calibration Failure	– faulty EEPROM calibration data	– Reboot CNAP™ monitor – In case of persistent error, contact service
NBP: Terminated By User	– User has stopped current NBP measurement	n.a.

13 Appendix A - Glossary

A

AC	Alternating current
Ah	Ampere-hour

B

BP Wave Out	Interface to subject monitors (CNAP™ blood pressure waveform)
bpm	Beats per minute
BSA	Body surface area (m^2)

C

CNAP™	Continuous noninvasive arterial pressure

D

Dia or diastolic	Diastolic blood pressure

H

h	Hour
Hz	Hertz
IBP	Invasive blood pressure

L

LED	Light-emmitting diode
LCD	Liquid crystal display

M

Main Screen	Monitor main screen (can be accessed to from any menu via pressing **Main Screen** fixed key)
Mean	Mean arterial blood pressure
min	Minute
mm/sec	Millimeters per second
mmHg	Millimeter of mercury
msec	Millisecond

N

NBP	Non-invasive blood pressure = oscillometric blood pressure measurement
Parameter	Monitored biosignal (e.g. pulse rate, blood pressure)
Pulse	Pulse rate

S

Sys or systolic	Systolic blood pressure
Sec	Second

V

V	Volts

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STOP:
In order to ensure operational reliability, functional safety as well as patients' safety, only original CNSystems Medizintechnik AG accessories and replacement parts are to be used.

14.1 CNAP™

Items	Number
CNAP™ cable (2.5 m)	20-FEKA-10041
CNAP™ controller	21-FHCN-16705
CNAP™ double finger cuff "small"	21-FVMA-15420
CNAP™ double finger cuff "medium"	21-FVMA-15520
CNAP™ double finger cuff "large"	21-FVMA-15620
Fixture for CNAP™ controller	21-FEZU-15401
CNAP™ forearm fixing cuff	20-FEMA-05705

14.2 NBP

Items	Number
NBP cuff „Child" (12 – 19 cm)	20-FEMA-15150
NBP cuff "Small Adult" (17 – 25 cm)	20-FEMA-15250
NBP cuff „Adult" (23 – 33 cm)	20-FEMA-15350
NBP cuff "Large Adult" (31 – 40 cm)	20-FEMA-15450
NBP extension hose	20-FEKA-05050

14.3 Printer

Items	Number
Thermal paper	20-HVZU-00258

14.3.1 Paper recommendation

CNSystems Medizintechnik AG recommends to use the following paper with your CNAP™ Monitor 500: Kanzan KPR 540.

In comparison with standard thermal paper for POS or fax, this high quality paper is characterized by a considerably higher degree of resistance against substances, i.e. alcohol, grease, PVC or plasticizers, oil, hand lotion or cream, etc. This results in your prints being readable and storable for a longer time. If stored properly, Kenzan guarantees archivability of at least 7 to 10 years when using this kind of paper. High quality non-topcoated thermal papers like this are suitable for all uses where the influence of external substances like oil, grease or water can be excluded as much as possible.

In addition, the characteristics of this high quality paper positively influences the product lifetime of your thermal printer. The characteristics of the above KANZAN paper regarding chemical composition, thickness, surface texture ..., have material influence on the printhead as well as the printer mechanism. The use of papers with lower dynamic sensitivity requires a higher level of energy transfer of the printer, while papers with a rougher surface lead, among others, to increased abrasion or mechanical strain. All these parameters automatically entail a considerable reduction of your printhead product lifetime.

For these reasons, only use the recommended paper brands or a thermal paper marked as top-quality by the manufacturer. However, when using other paper brands, CNSystems Medizintechnik AG cannot guarantee for the printers economic lifetime as this can cause damage or staining of the printhead.

14.4 Connections

Items	Nummer
BP Wave Out: CNAP™ transducer cable	20-FEKA-01201
BP Wave Out: IBP interface cable (to subject monitor)	contact BIOPAC
AUX: Analog Out connector	20-FEKA-01100

14.5 Other accessories

Items	Number
External mains adapter	20-FEKA-01010
Power cord for low power devices	20-HEKA-01011
Power cord British Standard	20-HEKA-01012
Power cord USA	20-HEKA-01013
CNAP™ Monitor mount	21-FEZU-15202
Operator's Manual German	21-FHZU-10001
Operator's Manual English	21-FHZU-10002
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Operator's Manual Italian	21-FHZU-10004
Operator's Manual Spanish	21-FHZU-10005

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15.1 CNAP™ Monitor 500

CNAP™ Monitor 500	
Physical properties	
Dimensions	280 x 270 x 250 mm (11 x 10.6 x 9.8 in.)
Weight	7,5 Kg (16.6 lbs) including components and accessories neccessary for operability of device
Battery	Sealed lead gel, operating time ≥ 2h (fully charged battery, normal conditions)
NBP cuff	Latex free
Electrical properties	
Nominal voltage	18 VDC ±10%
Nominal current	3A
Operability	No time-limit if powered by external mains adapter, at least 2h if on battery-operation (fully charged battery)
Environmental conditions for operation	
Temperature	Operation: 10°C - 40°C (50°F - 104°F) Storage: 0°C - 40°C (32°F - 104°F)
Humidity	Operation: 30% bis 85%, non condensing Storage: 20% bis 95%, non condensing, wrapped
Altitude	Operation: 647 bis 1059 hPa Storage: 500 bis 1059 hPa
User interface	
Controls	Fast access keys, click-wheel control
Alarming	Physiological alarms: medium priority Technical alarm messages: low priority
Screen	
Type	TFT-LCD
Size	200 x 150 mm (7.8 x 5.9 in.)
Display	170 x 128 mm (6.6 x 4.9 in.); 8.4 inch diagonally

CNAP™ Monitor 500	
Resolution	800 x 600 pixel
Color resolution	16 Bit
Trend memory	
Data memory	24 h, based on a mean heart rate of 90
Data resolution	Beat-to-beat

15.1.1 External mains adapter

External mains adapter	
Type	PDM60US18 (XP Power)
Connectors	IEC mains power plug, DC-connector for CNAP™ Monitor 500
Cooling system	Convection cooling
Dimensions	119 x 60 x 32 mm (4.6 x 2.3 x 1.2 in.)
Weight	0,650 kg (1.44 lbs)
Nominal voltage	100 – 240 VAC
Power frequency	~50/60 Hz
Power output	18 V, 3,3 A
Safety class	Class II with functional earth
Earth leakage current	< 500 µA
Operability	Continuous

15.1.2 CNAP™ - continuous non- invasive arterial pressure

CNAP™ - continuous non-invasive arterial pressure	
Parameter classification	Sys, Dia, Mean [mmHg] Pulse [bpm]
Measuring range	Sys: 40 - 250 mmHg (5,3 – 33,3 kPa) Dia: 30 - 210 mmHg (4 - 28 kPa) Mean: 35 - 230 mmHg (4 – 30,6 kPa)
Heart rate indication range	20-200 bpm
Accuracy	±5 mmHg (0,6 kPa)
Display resolution	1 mmHg (0,1 kPa)
Inflation pressure	Typ.: 120 mmHg (16 kPa) Min.: 30 mmHg (4 kPa) Max.: 300 ±10 mmHg (41,3 kPa ±1,3 kPa)
Excess pressure limit	300 ±10 mmHg (40 kPa ±1,3 kPa) Response time: < 3 sec. Deflation time: < 15 sec
Protection against electric	Type BF

CNAP™ - continuous non-invasive arterial pressure	
shock	

15.1.3 NBP – non-invasive blood pressure

NBP – non-invasive blood pressure	
Parameter classification	Sys, Dia [mmHg]
Measuring method	Oscillometric: diastolic value oscillometric: diastolic value for phase 5 Korotkoff
Measuring range	Sys: ADULT 40 - 260 mmHg PEDIATRIC 40 - 160 mmHg Dia: ADULT 20 - 200 mmHg PEDIATRIC 20 - 120 mmHg
Heart rate indication range	40-200 bpm
Inflation pressure at start	ADULT: 160 mmHg PEDIATRIC: 120 mmHg
Clinical accuracy	Meets ANSI/AAMI SP10:1992 und 2002
Accuracy of pressure recording	± 3mmHg between 0 - 300 mmHg at operating temperatures of 0 – 50°C
Calibration interval for pressure recording	12 months
Atmospheric pressure	no influence on accuracy of measurement
Measuring time	max. 130 s (ADULT)
Max. inflation time	50 s
Max. cuff pressure	300 mmHg
Automatic deflation after	180 s
Protection against electric shock	Type BF

15.1.4 Printer

Printer	
Type	Integrated thermal paper printer
Width	58mm
Roll diameter	60mm

15.1.5 Product configuration

Product configuration: CNAP Monitor 500i versus CNAP Monitor 500at	
CNAP Monitor 500i	CNAP Monitor 500at
CNAP finger blood pressure	CNAP finger blood pressure
NBP upper arm BP	NBP upper arm BP
8,4'' LCD screen	8,4'' LCD screen
Thermal printer	Thermal printer
BP-Wave Out	BP-Wave Out
Ethernet	Ethernet
USB	USB
	AUX Analog Out

15.2 Connections

BP Wave Out	
Sensor bridge voltage	2 - 10V (external monitor)
Sensitivity	5 µV/V/mmHg
BP Wave Out: CNAP™ transducer cable	0,3m; connector RJ11 6P4C (e.g. Abbott IBP catheter)

AUX (analog output port)		
	Channel 1	Channel 2
Voltage range	+-12 V	+-12 V
Reference	0 / 5 V (0 / 500 mmHg)	-5 / +5 V (0 / 500 mmHg)
Sensitivity	100 mmHg/V	50 mmHg/V
Samling frequency	100 Hz	100 Hz
Output Offset	+/- 50 mV	+/- 50 mV
Output Accuracy	5%	5%
Output Internal Resistor	100 Ohm	100 Ohm
Output Current	max 2 mA	max 2 mA

15.3 Electromagnetic compatibility

Medical electric devices have to comply with special safety regulations regarding EMC (electromagnetic compatibility). Please keep in mind the respective precautions in this operator's manual before installing and operating the CNAP™ Monitor 500. Also, pay attention to the fact that portable and mobile HF-communication devices (e.g. mobile phones) may interfere with medical electric devices.
The CNAP™ Monitor 500 must not be placed immediately beside or stockpiled with other devices. If there is no other way but to operate the CNAP™ Monitor 500 immediately beside or stockpiled with other devices, the CNAP™ Monitor 500 must be closely observed to ensure its normal operability within this arrangment of devices.
Only original CNSystems Medizintechnik Austria accessories and power cords are to be used with this device! Authorized accessories and replacement parts are listed in "Appendix B – Accessories" in this operator's manual. Using third party manufacturer accessories may result in increased emission or in decreased functional immunity of the CNAP™ Monitor 500.
As electric and magnetic fields may interfere with the functional reliability of the device, avoid using the CNAP™ Monitor 500 close to devices emitting powerful electromagnetic fields, e.g. x-ray equipment, diathermy applications or magnetic resonance tomographs.

Guidelines and manufacturer's declaration – electromagnetic emissions		
The CNAP™ Monitor 500 is intended for use in an electromagnetic environment as specified below. The customer or operator of the CNAP™ Monitor 500 is to assure it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidelines
R F emmissions CISPR 11	Group 1	The CNAP™ Monitor 500 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 B	The CNAP™ Monitor 500 is suitable for use in all establishments, including 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	NA	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	NA	

Table 201 from EN 60601-1-2:2003

Guidelines and manufacturer's declaration – electromagnetic immunity			
The CNAP™ Monitor 500 is intended for use in an electromagnetic environment as specified below. The customer or operator of the CNAP™ Monitor 500 is to assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wooden, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
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	Mains power supply quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power supply 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 sec	< 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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the CNAP™ Monitor 500 requires continued operation during power mains interruptions, it is recommended that the CNAP™ Monitor 500 be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz/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.			

Table 202 from EN 60601-1-2:2003

Guidelines and manufacturer's declaration – electromagnetic immunity			
The CNAP™ Monitor 500 is intended for use in an electromagnetic environment as specified below. The customer or operator of the CNAP™ Monitor 500 is to assure that it is used in such an environment.			
Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines
			Portable and mobile RF communication equipment should be used no closer to any part of the CNAP™ Monitor 500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-	3 V_{rms} 150 kHz to 80 MHz	3 → $V1$ in V	$d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz bis 2,5 GHz	3 → $E1$ in V/m	$d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$ for 80 MHz to 800 MHz
			$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ for 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in metres (m). 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 800 MHz, 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.		
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 CNAP™ Monitor 500 is used exceeds the applicable RF compliance level above, the CNAP™ Monitor 500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CNAP™ Monitor 500.		
b	Above the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.		

Table 204 from EN 60601-1-2:2003

Recommended separation distance between portable and mobile RF-communication devices and the CNAP™Monitor 500			
The CNAP™ Monitor 500 is intended for use in an electromagnetic environment with controlled RF disturbances. The customer or operator of the CNAP™ Monitor 500 can avoid electromagnetic disturbances by complying with the minimum distance between portable or mobile RF-communication equipment (transmitter) and CNAP™ Monitor 500, depending on the power output of the communication equipment as specified below.			
Rated power output of the transmitter W	Separation distance depending on the transmit-frequency m		
	150 kHz to 80 MHz $d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$	80 MHz to 800 MHz $d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$	800 MHz to 2,5 GHz $d = \left(\frac{7}{E1}\right) * \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33
The maximum rated power output values of transmitters that are not listed in the above list can be calculated by means of the respective formula, whereas the maximum rated power output is P in watts (W) according to the specification of the manufacturer.			
Note 1	At 80 MHz and 800 MHz, 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.		

Table 206 from EN 60601-1-2:2003

15.4 Standards

The CNAP™ Monitor 500 meets the following standards:

- ÖVE EN60601-1+A1+A2+A12+A13:1996
- ÖVE EN 60601-1-2:2003
- ÖVE EN 60601-1-4:1996 +A1:1999
- ÖVE EN 60601-1-6:2004
- ÖVE EN 60601-1-8:2004+A1:2006
- ÖVE EN 60601-2-30:2000
- ÖNORM EN 1060-1:1995
- ÖNORM EN 1060-3:1997+A1:2005
- ANSI/AAMI SP10:2002

15.5 Declaration of conformity

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CNSystems
The Brain & Heart Company

Konformitätserklärung

Declaration of Conformity
CE-CNS-20080424

Produktspezifikation / *product details:*

Produktbezeichung / *product name*	Continuous non-invasive blood pressure measurement equipment
Type / *type*	CNAP™ Monitor 500at CNAP™ Monitor 500i
Software Version	2.9
Klassifizierung nach RL 93/42/EWG, Anhang IX *Classification according 93/42/EEC, annex IX*	IIb

Angewandte Normen / *used standards:*

EN 60601-1+A1+A2+A12+A13:	1996	EN 1060-1+A1:	1996
EN 60601-1-2+A1:	2003	EN 1060-3:	2006
EN 60601-1-4+A1:	1999	EN ISO 14971:	2007
EN 60601-1-6:	2005		
EN 60601-1-8:	2007		
EN 60601-2-30:	2001		

Wir erklären in alleiniger Verantwortung, dass die oben beschriebenen Produkte den Anforderungen der Richtlinie 93/42/EWG entsprechen. Die Produkte werden mit dem CE-Kennzeichen und der Kennnummer 0408 versehen.

We declare under sole responsibility that the products described above are in compliance with directive 93/42/EEC. The products are CE-marked with the number 0408.

Gültig bis / valid until: 10/2010

Graz, 24.04.2008

Dr. Jürgen Fortin
Geschäftsführer / CEO

Title:

Software Design Specification, cNIBP

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1. Introduction

1.1 Purpose

The purpose of this report is to document the outcome of the software validation activities performed on the implementation of continuous non-invasive blood pressure (cNIBP) measurement, PWD software revision 253.5.1.

1.2 Scope

This document is applicable to the ViSi System cNIBP, 1c. This document does not apply to external accessories that may be used with the ViSi System, except as specified in this document.

1.2.1 Identification

The scope of the software validation testing covered by this report is ViSi System cNIBP 1c submission Software validation test results are based on the following versions of software which culminated in the final validated software release.

- PWD Versions
  - 253.4.0
  - 253.4.1
  - 253.5.0
  - 253.5.1

The following tables list the files that make up each version along with the corresponding CRC identifier.

PWD version 253.4.0		
Description	**SW entity**	**CRC**
GainSpan file	WFW-REL-2_0_44.bin	6356918d
Accelerometer	acc.bin	5d2e61da
Boot Loader	boot_loader.bin	5d2347ed
Boot Reloader	boot_reload.bin	933d7764
Wrist Boot loader	boot_wrist.bin	af8713d7
Wrist Boot Reloader	boot_wrist_reload.bin	55a6d9b2
Cuff module	cuff1.bin	52c56639
Cuff module	cuff2.bin	8164c306
ECG module	ecg.bin	f3654d09

PWD version 253.4.0		
Description	**SW entity**	**CRC**
GainSpan file	s2w-2_3_1-app1.bin	ede5e862
GainSpan file	s2w-2_3_1-app2.bin	29640f28
Wrist Transceiver	wrist.bin	bc467dad

PWD version 253.4.1		
Description	**SW entity**	**CRC**
GainSpan file	WFW-REL-2_0_44.bin	6356918d
Accelerometer	acc.bin	d5a95f3b
Boot Loader	boot_loader.bin	5d2347ed
Boot Reloader	boot_reload.bin	933d7764
Wrist Boot loader	boot_wrist.bin	af8713d7
Wrist Boot Reloader	boot_wrist_reload.bin	55a6d9b2
Cuff module	cuff1.bin	a66d5203
Cuff module	cuff2.bin	ed6c73da
ECG module	ecg.bin	d64e3024
GainSpan file	s2w-2_3_1-app1.bin	ede5e862
GainSpan file	s2w-2_3_1-app2.bin	29640f28
Wrist Transceiver	wrist.bin	eb41c8e2

PWD version 253.5.0		
Description	**SW entity**	**CRC**
GainSpan file	WFW-REL-2_0_44.bin	6356918d
Accelerometer	acc.bin	0b98c644
Boot Loader	boot_loader.bin	5d2347ed
Boot Reloader	boot_reload.bin	933d7764
Wrist Boot loader	boot_wrist.bin	af8713d7
Wrist Boot Reloader	boot_wrist_reload.bin	55a6d9b2
Cuff module	cuff1.bin	95251d8b
Cuff module	cuff2.bin	57d761a5

PWD version 253.5.0		
Description	**SW entity**	**CRC**
ECG module	ecg.bin	6f35ba26
GainSpan file	s2w-2_3_1-app1.bin	ede5e862
GainSpan file	s2w-2_3_1-app2.bin	29640f28
Wrist Transceiver	wrist.bin	d575913d

PWD version 253.5.1		
Description	**SW entity**	**CRC**
GainSpan file	WFW-REL-2_0_44.bin	6356918d
Accelerometer	acc.bin	0b98c644
Boot Loader	boot_loader.bin	5d2347ed
Boot Reloader	boot_reload.bin	933d7764
Wrist Boot loader	boot_wrist.bin	af8713d7
Wrist Boot Reloader	boot_wrist_reload.bin	55a6d9b2
Cuff module	cuff1.bin	95251d8b
Cuff module	cuff2.bin	57d761a5
ECG module	ecg.bin	6f35ba26
GainSpan file	s2w-2_3_1-app1.bin	ede5e862
GainSpan file	s2w-2_3_1-app2.bin	29640f28
Wrist Transceiver	wrist.bin	c11fb165

1.3 System Overview

The PWD is the vital sign front-end of the H1 Monitoring System. It is able to continuously measure and display core vital signs (e.g. NIBP, cNIBP, HR/PR, ECG, SpO2, Skin Temperature, etc.) The PWD standalone device is FDA cleared under K112478.

The measurements obtained from the ECG Cable and the Thumb Sensor provides the means to measure Pulse Arrival Time for cNIBP.

The NIBP Module is used to gather cuff based calibration measurement(s) before the initiation of any cNIBP measurements. This creates a “patient specific vascular profile” which then allows

the measurement of blood pressure on a beat-to-beat basis without a cuff, based on pulse transit time (PTT). Following the completion of the cuff based NIBP calibration measurement(s), the monitor will measure and display cNIBP. The NIBP Module and cuff may be removed at this time.

1.4 Acronyms and Definition of Terms

Refer to Doc # 0-00034 “Definitions and Acronyms Master Document for H1 Product Development”.

1.5 Referenced Documents

The documents listed below have been either directly referenced or used when preparing this Report.

1.5.1 General Documents

Document #	Title	Revision
21 CFR, Part 820	U.S. FDA Quality System Regulation (QSR)	4/01/1998

1.5.2 Sotera Wireless Documents

Title	Doc #
H1 Design Input Requirements Release 1c	0-000868B
Definitions and Acronyms Master Document, H1	0-000034D
Iconology Library	0-000061R
SOP’s	
Software Validation	SOP-016
Software Safety Documents	
Risk Management Plan, H1 Vital Signs Monitoring System	0-000012E
System Hazard Analysis, cNIBP	0-000959A
Software Risk Management cNIBP Report	R-000339-001
Software Requirements Specifications	
Patient Worn Device / Wrist Transceiver – SRS UI	0-000062Y
SRS, H1 Patient Worn Device (PWD) – Functional Specification	0-000095T
Vital Signs – SRS	0-000823E
Alerts / Alarms Attributes and Configurations - SRS (Part II)	0-000119U

SRS, UI, H1, 1c-Submission	0-000994A
Software Verification Documents	
SW Verification Test Report, 1c, H	R-000332-001
Software Validation Documents	
SW Validation Test Plan H1 submission 1c	0-000984A
Software Configuration Summary Reports	
SCSR, PWD Embedded Software, 253.4.0 1c submission	R-000319
SCSR, PWD Embedded Software, 253.4.1 1c submission	R-000328
SCSR, PWD Embedded Software, 253.5.0 1c submission	R-000337
SCSR, PWD Embedded Software, 253.5.1 1c submission	R-000341

2. Summary - Assessment of Overall Software Quality

2.1 Acceptance Criteria

The following is the acceptance criteria agreed upon before the commencement of validation testing:

Criteria	Description
Passed	The software test case step passed and demonstrated the fulfillment of the associated requirement and/or test objective.
Failed	The software test case step failed and demonstrated the failure of the associated requirement and/or test objective.
Accepted	The software test provided a result observation that deviated from that expected. However, upon review, it was determined that the test did demonstrate the satisfaction of the associated requirements.
N/A	Not applicable. A step may be marked as N/A if there is no expected result associated with it. Examples: the step contains a direction, note, information etc.

Requirements that are confirmed failures are to be recorded as an anomaly. Each anomaly will subsequently be assessed to determine its potential impact, including safety and efficacy, in the intended environment.

2.2 Intended Uses and Environments

The ViSi System cNIBP 1c submission intended use is specified in “H1 Design Input Requirements Release 1c “.

3. Software Validation Tasks Summary

The following sub-sections describe the tasks performed as part of the software validation process for ViSi System cNIBP 1c submission software.

3.1 Design Input Analysis

3.1.1 Requirements Review and Evaluation

The following documents were reviewed and analyzed:

- H1 Design Input Requirements Release 1c
- Software Requirements Specifications (SRS)

3.1.2 Risk Analysis

The following documents were reviewed:

- System Hazard Analysis,H1
- Software Risk Mitigations,H1 (SRS)

3.2 Software Validation Test Case Generation

3.2.1 Test Design

Based on the analysis of the above documents, a preliminary test case design process was conducted to determine the set of test cases/Protocols necessary to provide coverage of the software requirements intended for this product release. Test cases/Protocols design was outlined to utilize best approach and test methodologies for generating test cases/Protocols, and recording and analyzing test results. For further details, reference Appendix B.

3.2.2 Test Case Review and Approval

Prior to formal test execution, all test cases have been reviewed and approved by appropriate Sotera Wireless personnel.

Reference Appendix B for the list of the test cases.

3.3 Software Validation Test Case Execution

Software Validation test cases were executed by personnel other than those who developed the software under test.

Reference Appendix B for the list of the test cases.

3.4 Software Validation Test Environment

All ViSi System cNIBP 1c submission software validation tests documented in this report were conducted in the Sotera Wireless facility. The facility provides laboratory space containing ViSi System cNIBP 1c submission test beds dedicated to the test effort.

3.5 Software Verification Summary

The software verification activities performed for the ViSi System cNIBP 1c submission are contained in “SW Verification Test Report, 1c, H” R-000332-001.

3.6 Software Safety Summary

The software safety activities performed for the ViSi System cNIBP 1c submission include a software hazards analysis contained in “Software Risk Management Report,1c,H1” R-000339-001.

4. Software Validation Results Summary

4.1 Software Requirements Specifications

A list of the ViSi System cNIBP 1c submission Software Requirement Specifications and their revisions are provided in section 1.5.2

4.2 Requirements Executed

The list of requirements executed is provided in the “H1 SRS RTM Results Report”. Refer to Appendix B.

4.3 Software Requirements Metrics

The following is a breakdown of the software requirements by V&V Method: contained in the H1 SRS RTM Results Report

V&V Method	Description	SRS Requirements
Software Verification ("white box")	Total number of SRS requirements which could not be covered by traditional validation test cases ("black box"), but had to be covered using verification methods ("white box").	0
Software Validation ("black box")	Total number of SRS requirements which could be covered by traditional validation test cases ("black box").	134
	Total SRS Requirements =	134

4.4 Summary of Software Requirements Test Results

The following table summarizes the assessment of results for ViSi System cNIBP 1c submission software validation testing.

Software Requirements	Total Tested	Passed	Failed	Accepted	DNE
Total Distinct	132	127	5	0	0

Software Requirements	Total Tested	Passed	Failed	Accepted	DNE
Total[1] Instances	134	129	5	0	0

4.4.1 List of Failed Requirements

Requirement	JIRA #	Build Tested
SRS:18535	CNIBP-29	253.4.1
SRS:18552	cNIBP-35	253.5.0
SRS:18560	CNIBP-29	253.4.1
SRS:4200	cNIBP-19	253.5.0
SRS:4209	cNIBP-19	253.5.0

[1] Number of requirements includes counting a single requirement tag multiple times if it appears in multiple test cases (instances).

4.5 Summary of Software Anomalies

JIRA	CNIIBP
CNIBP-17	When a NIBP-derived PR reading exceeds the upper device limit, a "NIBP Fault" alert is produced
CNIBP-19	Word "MOTION" is not displayed in cNIBP box when there is no cNIBP measurement possible for 30 seconds (+/- 1 second) due to the presence of motion and a heart rate measurement is available.
CNIBP-31	When cNIBP is calibrated, "xx/xx, (xx)" is displayed in Red first for up to 10 seconds and then real measurements are displayed after that.
CNIBP-35	"xx/xx", xx" measurements are not displayed in White for NIBP when cNIBP is unobtainable due to the Chest Sensor or Thumb Sensor being disconnected and "disconnected" alert is already acknowledged.
CNIBP-36	"SpO2" is not displaying waveform/numeric values when all sensors are re-connected to PWD from "Clean Monitor, return to charger" screen.
ECHO-6	For "CHEST FAULT" alert, WT displays "xx" instead of removing the vital sign box.
ECHO-7	Issues with "NIBP Unobtainable" alert and "Cuff No Pulse" alert
FEP-16	Stopping the cuff secondary processor does not generate an NIBP_FAULT alert on the WT or RVD.
FEP-36	BP PR value and NIBP systolic/diastolic values take 35 seconds to go stale.
SE-18	When monitoring is stopped and "Cuff" module is removed from WT and re-connected to WT. The "Lock"&"Menu" buttons are displayed as "enabled" but they are actually disabled. They should not be displayed as "enabled" when Cuff is not connected to patient.
SE-21	"Start Cuff" button is still enabled after removing NIBP module from WT
CNIBP-29	PWD keeps re-calibrating as long as PAT time is changed to be more than 12ms. PWD should attempt only two calibration then after failure of second attempt, NIBP measurement should be displayed.
CNIBP-33	"NIBP Fault" alert is generated when all sensors (Thumb, Cuff and ECG) are connected and a blood pressure is taken.
FEP-54	Alarm message display does not change in the message center area of WT from "High HR" to "High PR" as ECG is disconnected and the source is the thumb sensor only. After PR is within the alarm limit boundaries, PR measurement is not displayed in green.
SE-20	"Thumb No Pulse" alarm/alert "30 second no pulse activity/no motion" condition will never be satisfied due to the motion event created from an active alert's audio annunciation

SE-27	HR displays 0, then changes to "xx" and back to 0 on PWD for LT critical low heart rate

4.6 Conclusion

Software validation activities were performed according to 0-000984A, SW Validation Test Plan H1 submission 1c. The results are summarized in this report.

The 16 software anomalies (section 4.5) which included the 5 failed software requirements (section 4.4.1) were evaluated as part of Sotera's risk management process. The disposition is documented in Software Risk Management Report, R-000339-001. Based on these results, the ViSi System cNIBP submission software (PWD: 253.5.1) is acceptable for its intended use in the intended environment.

5. List of Appendices

Appendix A: H1 DIR to SRS Trace Report

This appendix provides detailed traces of the system level requirements contained in the DIR to the derived requirements in the Software Requirement Specifications.

Appendix B: H1 SRS RTM Results Report

This appendix provides detailed traces of the Software Requirement Specifications requirements to the software validation test cases covered by this report and the associated test results.

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Appendix A: H1 DIR to SRS Trace Report

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Sotera WIRELESS

H1 DIR to SRS Trace Report

DIR Tag	SRS Tag
DIR:057	SRS:5066
DIR:069	SRS:18222
DIR:069	SRS:18221
DIR:069	SRS:18220
DIR:069	SRS:18219
DIR:071	SRS:5103
DIR:155	SRS:1037
DIR:156	SRS:1038
DIR:165	SRS:1040
DIR:170	SRS:1040
DIR:173	SRS:1037
DIR:174	SRS:1038
DIR:183	SRS:1040
DIR:422	SRS:5578
14	

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H1 DIR to SRS Trace Report

DIR Tag	SRS Tag
DIR:058	SRS:18378
DIR:058	SRS:18346
DIR:058	SRS:18361
DIR:058	SRS:18362
DIR:058	SRS:18377
DIR:074	SRS:18414
DIR:074	SRS:18416
DIR:074	SRS:18415
DIR:074	SRS:18553
DIR:076	SRS:1031
DIR:445	SRS:1039
DIR:445	SRS:18213
DIR:445	SRS:18223
DIR:445	SRS:18224
DIR:446	SRS:18347
DIR:446	SRS:18358
DIR:447	SRS:18375
DIR:450	SRS:18381
DIR:450	SRS:18382
DIR:450	SRS:1041
DIR:450	SRS:18383

DIR Tag	SRS Tag
DIR:451	SRS:18386
DIR:451	SRS:18384
DIR:451	SRS:18385
DIR:451	SRS:1042
DIR:452	SRS:18388
DIR:452	SRS:18389
DIR:452	SRS:1043
DIR:452	SRS:18387

29

Appendix B: SRS RTM Results Report

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Sotera WIRELESS

H1 Software RTM

SRS Tag	Test Case	Passed	Failed	Accepted	Comment
SRS:1037	MTC-010	☑	☐	☐	
SRS:1038	MTC-010	☑	☐	☐	
SRS:1040	MTC-010	☑	☐	☐	
SRS:18008	TC-094	☑	☐	☐	
SRS:18009	TC-094	☑	☐	☐	
SRS:18020	TC-094	☑	☐	☐	CNIBP-16, Tested and passed on Build 253.4.1, 03/01/2013
SRS:18040	TC-083	☑	☐	☐	
SRS:18041	TC-094	☑	☐	☐	
SRS:18128	TC-094	☑	☐	☐	
SRS:18129	TC-094	☑	☐	☐	
SRS:18149	TC-094	☑	☐	☐	
SRS:18178	TC-094	☑	☐	☐	
SRS:18184	TC-094	☑	☐	☐	
SRS:18185	TC-094	☑	☐	☐	
SRS:18198	TC-094	☑	☐	☐	CNIBP-16, Tested and passed on Build 253.4.1, 03/01/2013
SRS:18199	TC-094	☑	☐	☐	
SRS:18211	MTC-016	☑	☐	☐	
SRS:18212	MTC-016	☑	☐	☐	
SRS:18219	MTC-016	☑	☐	☐	

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SRS Tag	Test Case	Passed	Failed	Accepted	Comment
SRS:18220	MTC-016	☑	☐	☐	
SRS:18221	MTC-016	☑	☐	☐	
SRS:18222	MTC-016	☑	☐	☐	
SRS:4269	TC-094	☑	☐	☐	
SRS:4312	MTC-010	☑	☐	☐	
SRS:4313	MTC-010	☑	☐	☐	
SRS:4316	MTC-010	☑	☐	☐	
SRS:4317	MTC-010	☑	☐	☐	
SRS:4318	MTC-010	☑	☐	☐	
SRS:4319	MTC-010	☑	☐	☐	
SRS:5013	TC-003	☑	☐	☐	
SRS:5019	TC-087	☑	☐	☐	
SRS:5066	TC-094	☑	☐	☐	
SRS:5078	TC-087	☑	☐	☐	
SRS:5079	TC-087	☑	☐	☐	
SRS:5103	TC-087	☑	☐	☐	
SRS:5577	TC-094	☑	☐	☐	
SRS:5578	TC-094	☑	☐	☐	
SRS:5579	TC-094	☑	☐	☐	
SRS:5580	TC-094	☑	☐	☐	
SRS:5581	TC-094	☑	☐	☐	
SRS:5582	TC-094	☑	☐	☐	
SRS:5583	TC-094	☑	☐	☐	
SRS:5584	TC-094	☑	☐	☐	
SRS:5585	TC-094	☑	☐	☐	

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SRS Tag	Test Case	Passed	Failed	Accepted	Comment
SRS:5586	TC-094	☑	☐	☐	
SRS:5588	TC-083	☑	☐	☐	
SRS:5673	TC-094	☑	☐	☐	
SRS:5674	TC-094	☑	☐	☐	
SRS:5762	TC-094	☑	☐	☐	CNIBP-16, Tested and passed on Build 253.4.1, 03/01/2013
SRS:5765	TC-087	☑	☐	☐	
SRS:5798	TC-094	☑	☐	☐	
SRS:5808	TC-094	☑	☐	☐	
SRS:5834	TC-003	☑	☐	☐	
SRS:5925	TC-003	☑	☐	☐	
SRS:5967	TC-087	☑	☐	☐	
SRS:5968	TC-087	☑	☐	☐	
SRS:7071	TC-094	☑	☐	☐	
57		57	0	0	

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H1 Software RTM

SRS Tag	Test Case	Passed	Failed	Accepted	Comment
SRS:18217	TC-003	☑	☐	☐	
SRS:18236	TC-087	☑	☐	☐	
SRS:5926	TC-003	☑	☐	☐	
3		3	0	0	

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Sotera WIRELESS

H1 Software RTM

SRS Tag	Test Case	Passed	Failed	Accepted	Comment
SRS:18364	TP-016	☑	☐	☐	
SRS:18365	TP-016	☑	☐	☐	
SRS:18531	TP-020	☑	☐	☐	
SRS:5810	TP-011	☑	☐	☐	
4		4	0	0	

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Sotera WIRELESS

H1 Software RTM

SRS Tag	Test Case	Passed	Failed	Accepted	Comment
SRS:1031	TP-503	☑	☐	☐	
SRS:1039	MTC-500	☑	☐	☐	
SRS:1041	MTC-500	☑	☐	☐	
SRS:1042	MTC-500	☑	☐	☐	
SRS:1043	MTC-500	☑	☐	☐	
SRS:1113	TP-503	☑	☐	☐	
SRS:18213	TP-503	☑	☐	☐	
SRS:18223	TP-503	☑	☐	☐	
SRS:18224	TP-503	☑	☐	☐	
SRS:18346	TP-503	☑	☐	☐	
SRS:18347	TP-503	☑	☐	☐	
SRS:18352	TP-503	☑	☐	☐	
SRS:18358	TP-503	☑	☐	☐	
SRS:18360	TP-503	☑	☐	☐	
SRS:18361	TP-503	☑	☐	☐	
SRS:18362	TP-503	☑	☐	☐	
SRS:18375	TP-503	☑	☐	☐	
SRS:18376	TP-503	☑	☐	☐	
SRS:18377	TP-503	☑	☐	☐	
SRS:18378	TP-503	☑	☐	☐	

SRS Tag	Test Case	Passed	Failed	Accepted	Comment
SRS:18381	TP-503	☑	☐	☐	
SRS:18382	TP-503	☑	☐	☐	
SRS:18383	TP-503	☑	☐	☐	
SRS:18384	TP-503	☑	☐	☐	
SRS:18385	TP-503	☑	☐	☐	
SRS:18386	TP-503	☑	☐	☐	
SRS:18387	TP-503	☑	☐	☐	
SRS:18388	TP-503	☑	☐	☐	
SRS:18389	TP-503	☑	☐	☐	
SRS:18392	TP-502	☑	☐	☐	
SRS:18401	TP-503	☑	☐	☐	
SRS:18402	TP-502	☑	☐	☐	
SRS:18405	TP-502	☑	☐	☐	
SRS:18408	TP-505	☑	☐	☐	
SRS:18409	TP-505	☑	☐	☐	
SRS:18410	TP-505	☑	☐	☐	
SRS:18414	TP-505	☑	☐	☐	
SRS:18415	TP-505	☑	☐	☐	cNIBP-38, Tested and passed on build 253.5.1, 03/12/2013
SRS:18416	TP-505	☑	☐	☐	cNIBP-34, Tested and passed on build 253.5.1, 03/12/2013
SRS:18417	TP-505	☑	☐	☐	
SRS:18420	TP-504	☑	☐	☐	
SRS:18421	TP-504	☑	☐	☐	
SRS:18534	TP-502	☑	☐	☐	
SRS:18535	TP-502	☐	☑	☐	CNIBP-29

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SRS Tag	Test Case	Passed	Failed	Accepted	Comment
SRS:18536	TP-502	☑	☐	☐	
SRS:18552	TP-505	☐	☑	☐	cNIBP-35
SRS:18553	TP-505	☑	☐	☐	cNIBP-37, Tested and passed on build 253.5.1, 03/12/2013
SRS:18559	TP-502	☑	☐	☐	
SRS:18560	TP-502	☐	☑	☐	CNIBP-29
SRS:18561	TP-503	☑	☐	☐	
SRS:18562	TP-502	☑	☐	☐	
SRS:4012	TP-501	☑	☐	☐	
SRS:4013	TP-501	☑	☐	☐	
SRS:4015	TP-503	☑	☐	☐	
SRS:4186	TP-501	☑	☐	☐	
SRS:4187	TP-501	☑	☐	☐	
SRS:4188	TP-501	☑	☐	☐	
SRS:4189	TP-501	☑	☐	☐	
SRS:4200	TP-501	☐	☑	☐	cNIBP-19
SRS:4209	TP-503	☐	☑	☐	cNIBP-19.
SRS:4320	MTC-010	☑	☐	☐	
SRS:4320	TP-501	☑	☐	☐	
SRS:4321	MTC-010	☑	☐	☐	
SRS:4321	TP-501	☑	☐	☐	
SRS:4500	TP-501	☑	☐	☐	
SRS:4515	TP-501	☑	☐	☐	
SRS:5018	TP-502	☑	☐	☐	
SRS:5107	TP-502	☑	☐	☐	

SRS Tag	Test Case	Passed	Failed	Accepted	Comment
SRS:5696	TP-505	☑	☐	☐	
SRS:5821	TP-501	☑	☐	☐	
70		65	5	0	

Title:	**Software Verification Report, ViSi System, cNIBP**

Function	Signature/ Date
Author/ Verification	
Engineering	
Quality	
SW QA	

1. Purpose

This report summarizes the software verification testing conducted on the ViSi Mobile cNIBP submission (1c-sub) feature set. The verification release is version is 253.4.1 with changes through r51077 (see SVR-048) with bootloaders from 253.4.0. 253.4.1 and 253.5.0 are equivalent per release notes of 253.5.0.

2. Scope

This report covers the results from software verification activities conducted on the ViSi Mobile cNIBP submission feature set.

3. Executive Summary

This report summarizes the software verification activities conducted throughout the design output and design verification phases of software development. Code and design reviews were held throughout the design process captured electronically in the Sotera Wireless Crucible code review tool accessible through the CR number (See Appendix A).

4. Referenced Documents

4.1 Internal Documents

R-000333-001 cNIBP Software Validation Report
R-000189 ViSi System IEC 60601-1-8 Compliance and Alarms SRS Tags

5. Acronyms and Definitions

Refer to Doc. #0-000034 ("Definitions and Acronyms Master Document for H1 Product Development") for details.

- µVelocity – Real-time Greens Hills OS used in the STMicroelectronics microprocessors.

6. Software Verification Strategy

6.1 Overview

The H1 PWD software verification employed a white box test based approach that verified the design of critical lower level features, including any features designed and implemented as mitigations of identified risks and hazards. Integration testing was performed with the goal of identifying any issues stemming from interoperability of the core processors, and the communication and interaction between the system's modules.

To the extent that they could not be tested with black-box functional testing methodology, the software requirements were included in SW Verification Testing. All other software requirements fell within the scope of SW Validation Testing.

Software anomalies identified during testing were entered into the bug tracking system. Any remaining software anomalies are listed on the Software Validation Report

6.2 Software Verification Activities

The H1 software units/modules were assigned a software safety classification of "C" in accordance with IEC 62304. The following matrix specifies the H1 verification requirements by classification.

Classification / Activities\Tasks	C
Static Analysis • Green Hills DoubleCheck tool Warnings/Errors • Green Hill Multi IDE C Compiler Warnings/Errors	X
Dynamic Analysis • Stack Overflow testing	X
Code Review	X
Software Unit/Module Testing	X
Software Integration Testing	X
Verify implements software architecture in the SAD	X

6.2.1 Software Static Analysis

Green Hills DoubleCheck Source Analysis Tool was used to perform software static analysis on each engineering release. The release report contained the results of the static analysis and any compiler warnings (See release reports on sections 7.1 to **Error! Reference source not found.**).

6.2.2 Software Technical/Code Reviews

Software Technical Reviews were conducted throughout the development cycle in accordance with the governing Design Control and Software Life Cycle SOPs. Documented Software Technical Reviews were performed electronically using the Sotera Wireless Crucible code-review tool.

The electronic code reviews are accessible through each CR number (See Appendix A).

7. Software Releases

Software verification was responsible for acceptance testing of each software release. The acceptance testing was composed of integration testing that included all major functionality including the ability to successfully load the applications to their target modules. It also included long-term tests (See Attachments on section 10 for the LTTS report) with continuous log message capturing. These were analyzed for failures and behavioral anomalies.

The following PWD software versions were used for testing:

7.1 PWD Versions:

7.1.1 253.4.0

7.1.2 253.4.1 extended to r51077 (See SVR-048)

7.1.3 253.5.0

An analysis was conducted between each software release to determine if the changes required regression testing or impacted any of the pivotal vital signs clinical testing, electrical safety testing, medical standards testing, risk mitigation testing, or software verification testing.

Retesting was conducted on each anomaly if necessary and tracked through the JIRA tool. Any remaining software anomalies are listed on the Software Validation Report (R-000333-001).

8. Software Verification Test Cases

8.1 The following is a table of SW Verification Test Cases

Test number	Test Name	Test Description
SVT-000026	PAT Calculation	PAT determination, filtering, processing, measurement.
SVT-000029	Calibration	NIBP measurement, PAT collection, model fitting and alternative calibration methods.
SVT-000030	Numeric Calculation	PAT aggregation, MAP determination, running average filter.
SVT-000031	Arm Height and Posture	Accelerometer processing, arm height and posture determination.

8.2 Software Verification Test Case Results

All test objectives passed in each SVT procedure, executed on 7 March 2013 with software version 253.4.1 r51077.

8.2.1 SVT-000026

SVTT-000026-001: cNIBP task is updated with ECG lead II normal QRS peaks and peak direction is classified. Peaks that switch shall be removed. If the QRS peak direction changes we will call for recalibration.

SVTT-000026-002: ECG lead II QRS pick shall pick at the peak of the waveform, the R point.

SVTT-000026-003: Given the ECG QRS sequence number, determine the corresponding PPG onset sequence number. Calculate PAT and screen the PAT value for inclusion in the PAT buffer.

SVTT-000026-004: Update_ArmHeight_Posture and RLS_ArmHeight_Posture are called if a calibration has been made. PAT offset shall be removed from the PAT value and saved in the VTT array.

SVTT-000026-005: During cuff inflation PAT values will be stored; if the PATcal is valid enter Primary cNIBP Cal Gradient Decent.

SVTT-000026-006: I2C driver shall support module low-power management.

SVTT-000026-007: I2C driver shall maintain data integrity when transmitting and receiving data.

8.2.2 SVT-000029

SVTT-000029-001: Process_NIBP_Numeric() prepares cNIBP parameters in a NIBP measurement.

SVTT-000029-002: Process_NIBP_Sample() collects PAT values when cuff pressure exceeds 10 mmHg in the first 30 seconds in an inflation, and computes cnibpCal.pat from a median filter.

SVTT-000029-003: Primary_cNIBP_Cal_GradientDescent() identifies two unknown parameters a and pwv_0 by the gradient descent algorithm. If the fit of the model doesn't meet the requirements, a secondary calibration function will

be implemented. The calibration parameter K is determined by arm_length/*a*.

SVTT-000029-004: Secondary_cNIBP_Calibration() employs an empirical formula to estimate the calibration parameter K once the primary gradient descent function fails to yield acceptable estimation.

8.2.3 SVT-000030

SVTT-000030-001: In order to calculate a new cNIBP numeric, an ECG QRS must have been identified within the last 10 seconds or a PPG pulse must have been identified with the last 30 seconds.

SVTT-000030-002: In order to calculate a new cNIBP numeric, check that at least 25 PAT values were added to PAT_ECG_SN array in the last 60 seconds.

SVTT-000030-003: The function cnibp_median_val calculates the median value of the pulse arrival time measurements in the VTT_MS arrays, that are also no more then 60 seconds old and store the results in newVTT.

SVTT-000030-004: The function cnibp_median_val calculates the median value of the pulse arrival time measurements in the PAT_MS arrays, that are also no more then 60 seconds old and store the results in newPAT.

SVTT-000030-005: If this is the first cNIBP numeric update after the NIBP inflation, the calibration PAT (cal.pat) must be within ±12 milliseconds of the median PAT value (newPAT).

SVTT-000030-006: The function calc_MAP_PWV calculates the current MAP value based on the offset corrected median PAT value (newVTT).

SVTT-000030-007: If four or more MAP values have been calculated since calibration, the MAP numeric value will be re-calculated as an average of the last four MAP numeric values.

8.2.4 SVT-000031

SVTT-000031-001: Upper arm attitude and lower arm attitude is determined using the accelerometers in the WT and UAA, respectively.

SVTT-000031-002: Arm height is the summed vertical projection of the upper and lower arm segments.

SVTT-000031-003: Posture attitude is determined using the accelerometer in the ECG.

SVTT-000031-004: Posture adaptively aligns to the initial posture state.

9. Conclusion

The results from executed tests, as summarized in this report, met acceptance criteria. Software revision PWD 253.5.0 with 253.4.0 bootloaders are recommended for release.

10. Attachments

1. SVT-000026 (PWD, cNIBP PAT Calculation) 7 March 2013.pdf (13 pages)
2. SVT-000029 (PWD, cNIBP Calibration) 7 March 2013.pdf (10 pages)
3. SVT-000030 (PWD, cNIBP Numeric Calculation) 7 March 2013.pdf (13 pages)
4. SVT-000031 (PWD, cNIBP Arm Height and Posture) 7 March 2013.pdf (11 pages)
5. LTTS PWD cNIBP 253.5.0.docx (1 page)

11. Appendix A

11.1 PWD Code Reviews:

11.1.1 cNIBP

- CR-547
- CR-548
- CR-549

Sotera Wireless	SW Verification Test Protocol	SVT-000026
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	Considered "controlled" if viewed on-line or if hardcopy includes signed/dated "controlled copy" stamp.	Page 1 of 13

Title:	PWD, cNIBP PAT Calculation
	Subversion Revision # 51564

Software Version UUT (N/A if not used)	PWD r51077 PDS 1.4.3 RVD N/A
Hardware Version UUT (N/A if not used)	WT : AAAA20120800485 SPO2 : ABBA20120909283 NIBP : ADAA20120800416 ECG : ACBE20120800168 & AFBE20120800164 ACC : ACBE20120800168

Verification Engineering Test Case Approval

	Name	Signature	Date
Author	Scott McCombie	Scott McCombie	6 Mar 2013
Engineer	Daniel Walker	Daniel Walker	6 Mar 2013
Quality	Minh-Duc Nguyen	Minh-Duc Nguyen	6 Mar 2013

Verification Engineering Test Results

Test Date:	2/21/2013	**Time Test Took:**	180 minutes	**Result:**	Pass

	Tester	Reviewer
Name	Scott McCombie	Daniel Walker
Sign and Date	Scott McCombie 3/7/2013	Daniel Walker 7 March 2013

Failed Test Steps (include step, tag, and JIRA numbers):

References

1. 0-0000996_1 (SDS – Continuous Non-Invasive Blood Pressure)

Terms / Acronyms

- PAT Pulse Arrival Time
- cNIBP Continuous Non-Invasive Blood Pressure

Equipment List

Device Name	Resolution Requirements or Description	Device Serial Number	Calibration Date (if applicable)
cNIBP Simulator	N/A	AS06110004	N/A
M311 ECG Simulator	N/A	16198	27 Jun 2012 -13
Wrist Transceiver	N/A	AAAA20120800485	N/A
SpO2 Sensor	N/A	ABBA201209283	N/A
ECG module (3 wire)	N/A	ACBE20120800168	N/A
ECG module (5 wire)	N/A	AEBE20120800164	N/A
NIBP module	N/A	ADAA20120800416	N/A

Objectives

SVTT-000026-001: cNIBP task is updated with ECG lead II normal QRS peaks and peak direction is classified. Peaks that switch shall be removed. If the QRS peak direction changes we will call for recalibration.

SVTT-000026-002: ECG lead II QRS pick shall pick at the peak of the waveform, the R point.

SVTT-000026-003: Given the ECG QRS sequence number, determine the corresponding PPG onset sequence number. Calculate PAT and screen the PAT value for inclusion in the PAT buffer.

SVTT-000026-004: Update_ArmHeight_Posture and RLS_ArmHeight_Posture are called if a calibration has been made. PAT offset shall be removed from the PAT value and saved in the VTT array.

SVTT-000026-005: During cuff inflation PAT values will be stored; if the PATcal is valid enter Primary cNIBP Cal Gradient Decent.

SVTT-000026-006: I2C driver shall support module low-power management.

SVTT-000026-007: I2C driver shall maintain data integrity when transmitting and receiving data.

Procedure

SVTT-000026-001: cNIBP task is updated with ECG lead II normal QRS peaks and peak direction is classified. Peaks that switch shall be removed. If the QRS peak direction changes we will call for recalibration.

1. Via code review, verify that:
    a. ECG lead II is being used.
    b. QRS peaks are correctly identified as positive or negative.
    c. Switching peaks are removed.
    d. Recalibration occurs if QRS direction changes.
    e. Valid ECG lead II peaks are stored.

Observations: _____

Result: Pass

SVTT-000026-002: ECG lead II QRS pick shall pick at the peak of the waveform, the R point.

The following test should be administered on both a 3-wire and 5-wire ECG cable.

1. Modify and program the test code:
   a. Add logging statement to print the ECG_QRS in Process_ECG_II() after the Sequence Number is stored.
2. Collect Data using PDS
   a. With the wrist connected to the PDS and ECG cable attached, collect ECG waveform data from the M311 ECG Simulator.
3. Download/Copy ECG lead II Data and Log File
   a. Using the export tool collect the data.
   b. Copy the log file from the PDS
      i. File location: pds-instances/[server_name]/logger/logs/
      ii. Copy the pwd-remote.log file
4. Verify ECG peak detection
   a. Using the sequence numbers printed in the log file, determine the location on the ECG lead II waveform that the QRS detection occurs.
   b. Verify that the peak detection occurs at the peak of the QRS complex.

Observations: _____

Result: Pass

SVTT-000026-003: Given the ECG QRS sequence number, identify the corresponding PPG onset sequence number. Calculate PAT. Evaluate PAT is valid and remove PAT outliers using slope screening. Update PAT, PPG sequence number, and ECG sequence number arrays.

1. Modify and program the test code:
    a. Add logging statement to print ECG sequence number, PPG sequence number used, and pat value in Calculate_PAT() after PAT is set.
    b. Add logging statement to print last three PAT values in PAT_MS in Calculate_PAT() after sumPATdSN is set.
    c. Add logging statement to print Reject slope check in Calculate_PAT() after the slope check condition is met where PAT_MS(i-1) is bad.
    d. Add or enable logging statement to print Sending i/QRS/PPG/PAT where PAT is the Arm Height adjusted PAT value in Calculate_PAT() after PATData is set.
2. Collect Data Using PDS
    a. With Visi System attached to the cNIBP simulator and the Wrist transceiver connected to the PDS.
        i. Set HR to 70 BPM and PAT delay to 160 ms with BP set to 120/70
            1. Collect data for 1-3 minutes
        ii. Set HR to 150 BPM and PAT delay to 160 ms with BP set to 120/70
            1. Collect data for 1-3 minutes
        iii. Set HR to 80 BPM and PAT delay to 375 ms with BP set to 120/70
            1. Collect data for 1-3 minutes
        iv. Set HR to 80 BPM and PAT delay to 85 ms with BP set to 120/70
            1. Collect data for 1-3 minutes
3. Collect the Log File
    a. Copy the log file from the PDS
        i. File location: pds-instances/[server_name]/logger/logs/
        ii. Copy the pwd-remote.log file
4. Via Logging statements, verify that:
    a. The correct PPG onset is being used.
    b. The PAT calculation is correct. (ppgSN – ecgSN – PPG_FILTER_DELAY)*2 = pat
    c. The PAT screening is correct
        i. Slope check works as intended and calculations are being done properly.
            1. [(PAT(i) – PAT(i-1))*1E6/(ecgSN(i)-ecgSN(i-1))] – [(PAT(i+1) – PAT(i))*1E6/(ecgSN(i+1)-ecgSN(i))]
            2. If absolute value of (1) is greater than 75000, reject slope check.
        ii. Invalid values (PATs >= 350 or <= 75) are excluded from the buffer.
    d. The PAT values (PAT_MS, PAT_ECG_SN, PAT_PPG_SN) are stored.

Observations: _____

_____

_____

_____

Result: Pass

SVTT-000026-004: Update_ArmHeight_Posture and RLS_ArmHeight_Posture are called if a calibration has been made. PAT offset removed from PAT value and saved in VTT array.

1. Via code review, verify that:
    a. The Update_ArmHeight_Posture function is called if calibration has been made.
    b. The RLS_ArmHeight_Posture function is called if calibration has been made.
    c. PAT offset is removed from the PAT value and the new value is stored in the VTT_MS array.

Observations: _____

Result: Pass

SVTT-000026-005: During cuff inflation PAT values will be stored; if the PATcal is valid enter Primary cNIBP Cal Gradient Decent.

1. Modify and program the test code:
    a. Add logging statement to print PAT_CUFF_PRS in Process_ECG_II() after variable is set under NIBP Active.
    b. Add logging statement to print PATcal in Process_ECG_II() after NIBP Complete.
    c. Add logging statement to print Entered Gradient Decent in Process_ECG_II() after call to Primary_cNIBP_Cal_GradientDecent().
2. Collect Data using PDS
    a. With Visi System attached to the cNIBP simulator and the Wrist transceiver connected to the PDS.
        i. Set HR to 80 BPM and PAT delay to 160 ms with BP set to 120/70
            1. Begin data collection
            2. Take a Blood Pressure Measurement
            3. Collect data for 1 minute
            4. Repeat (x2)
3. Collect the Log File
    a. Copy the log file from the PDS
        i. File location: pds-instances/[server_name]/logger/logs/
        ii. Copy the pwd-remote.log file
4. Via Logging statements, verify that:
    a. The PAT values (PAT_CUFF_PRS) during inflation are being stored.
    b. When a good PATcal is received, Primary cNIBP Cal Gradient Decent is called.

Observations: _____

Result: Pass

Tester Comments:

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Revision History

Date	Revision	Author	Description of Key Changes
2/21/2013	1	Scott McCombie	Initial Creation

Sotera Wireless	SW Verification Test Protocol	SVT-000029
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		Page 1 of 10

Title:	PWD, cNIBP Calibration
	Subversion Revision # 51567

Software Version UUT (N/A if not used)	PWD r51077 PDS 1.4.3 RVD N/A
Hardware Version UUT (N/A if not used)	WT : AAAA 2012 07 00429 SPO2 : ABBA 2012 08211 NIBP : AOAA 2012 0800416 ECG : ACBE 2012 0800168 ACC : ACBE 2012 0800168

Verification Engineering Test Case Approval

	Name	Signature	Date
Author	Guanqun Zhang		03/07/13
Engineer	Daniel Walker		7 March 2013
Quality	Minh-Duc Nguyen		7 Mar 2013

Verification Engineering Test Results

Test Date:	03/07/13	Time Test Took:	60 minutes	Result:	PASS

	Tester	Reviewer
Name	GUANQUN ZHANG	DANIEL WALKER
Sign and Date	03/07/13	March, 7, 2013

Failed Test Steps (include step, tag, and JIRA numbers):

References

1. 0-0000996_1 (SDS – Continuous Non-Invasive Blood Pressure)

Terms / Acronyms

- PAT Pulse Arrival Time
- cNIBP Continuous Non-Invasive Blood Pressure
- MAP Mean Arterial Pressure

Equipment List

Device Name	Resolution Requirements or Description	Device Serial Number	Calibration Date (if applicable)
Wrist Transceiver	N/A	AAAA 20120700429	N/A
SpO2 Sensor	N/A	ABBA 201208211	N/A
ECG module (3 wire)	N/A	ACBE 20120800168	N/A
NIBP module	N/A	ADDA 2012 0800416	N/A

Objectives

SVTT-000029-001: Process_NIBP_Numeric() prepares cNIBP parameters in a NIBP measurement.

SVTT-000029-002: Process_NIBP_Sample() collects PAT values when cuff pressure exceeds 10 mmHg in the first 30 seconds in an inflation, and computes cnibpCal.pat from a median filter.

SVTT-000029-003: Primary_cNIBP_Cal_GradientDescent() identifies two unknown parameters a and pwv_0 by the gradient descent algorithm. If the fit of the model doesn't meet the requirements, a secondary calibration function will be implemented. The calibration parameter K is determined by arm_length/a.

SVTT-000029-004: Secondary_cNIBP_Calibration() employs an empirical formula to estimate the calibration parameter K once the primary gradient descent function fails to yield acceptable estimation.

Procedure

SVTT-000029-001: Process_NIBP_Numeric() prepares cNIBP parameters in a NIBP measurement.

1. Via code review, verify that:
   a. Once the NIBP measurement has been successfully completed, set all cNIBP parameters.
2. Modify and program the test code:
   a. Add logging statement to print NIBP_ACTIVE and NIBP_Complete_PAT_Index when the NIBP measurement has been completed successfully.
3. Via logging statements, verify that:
   a. NIBP_ACTIVE is set as FALSE when NIBP measurements are finished.
   b. NIBP_Complete_PAT_Index is determined when NIBP inflation is finished.

Observations: _____

Result: PASS

SVTT-000029-002: Process_NIBP_Sample() collects PAT values when cuff pressure exceeds 10 mmHg in the first 30 seconds in an inflation, and computes cnibpCal.pat from a median filter.

1. Via code review, verify that:
   a. Identify all the PAT values that were measured in the 30 seconds prior to when the cuff pressure exceeded 10 mmHg.
2. Modify and program the test code:
   a. Add logging statement to print confirmation when NIBP_Active is false and the NIBP cuff pressure exceeds 10mmHg.
   b. Add logging statement to print cnibpCal.pat calculated by the median function cnibp_median_val().
3. Via logging statements, verify that:
   a. The sequence number of the first PAT value used in the cNIBP calibration is identified as the index when the NIBP cuff pressure exceeds 10 mmHg.
   b. NIBP_Active is set as FALSE.
   c. The function of cnibp_median_val() yields exact median value of PAT, comparing with the function median() in MATLAB.

	Visi	MATLAB
Median value	176	176

Observations: _____

Result: PASS

SVTT-000029-003: Primary_cNIBP_Cal_GradientDescent() identifies two unknown parameters *a* and pwv_0 by the gradient descent algorithm. If the fit of the model doesn't meet the requirements, a secondary calibration function will be implemented. The calibration parameter K is determined by arm_length/*a*.

1. Via code review, verify that:
   a. Secondary_cNIBP_Calibration() is called to update the cNIBP calibration parameter K if
      i. The cNIBP calibration had less than 7 paired cuff pressure; OR
      ii. The fit of model was below a specified threshold ($r^2 < 0.7$); OR
      iii. The change in PAT during the NIBP inflation was less than 30ms
2. Modify and program the test code:
   a. Add logging statement to print all of the PAT values and cuff pressure values measured during the NIBP inflation.
   b. Add logging statement to print a 3-point moving average filter to the calibration PAT values.
   c. Add logging statement to execute the secondary calibration when the primary gradient descent calibration implemented.
3. Via logging statements, verify that:
   a. Values where the cuff pressure > (MAP - 10mmHg) were not included for cNIBP calibration.
   b. The 3-point moving average median is correct.
   c. The gradient descent algorithm in Visi computes similar *a* and pwv_0, comparing with a MATLAB function which estimates parameters by for-loop searching.

	Visi	MATLAB
a	0.00305	0.00340
pwv_0	0.15879	0.12690

   d. The cNIBP calibration parameter K = Lt/a is correct.

	Visi	MATLAB
K	24561	24561

Observations:

Result: PASS

SVTT-000029-004: Secondary_cNIBP_Calibration() employs an empirical formula to estimate the calibration parameter K once the primary gradient descent function fails to yield acceptable estimation.

1. Modify and program the test code:
   a. Add logging statement to print the approximate linearized cNIBP slope value.
   b. Add logging statement to print the change in PAT.
   c. Add logging statement to print calibration parameter K.
2. Via logging statements, verify that:
   a. The linearized cNIBP slope value is correct.
   b. The change in PAT is correct.
   c. The calibration parameter K is correct.

	Visi	MATLAB
Linearized cNIBP slope	-0.89000	-0.89
Change in PAT	-22.47191	-22.47191
Calibration parameter K	24048.64278	24049

Observations: _____

Result: PASS

Tester Comments:

Revision History

Date	Revision	Author	Description of Key Changes
2/27/2013	1	Guanqun Zhang	Initial Creation

Sotera Wireless	SW Verification Test Protocol	SVT-000030
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		Page 1 of 13

Title:	PWD, cNIBP Numeric Calculation
	Subversion Revision # r51565

Software Version UUT (N/A if not used)	PWD r51077 PDS 1.4.3 RVD N/A
Hardware Version UUT (N/A if not used)	WT : AAAA 2012 0600 347 SPO2 : ABBA 2012 09283 NIBP : ADAA 2012 0800416 ECG : ACBE 2012 0800168 ACC : ACBE 2012 0800168

Verification Engineering Test Case Approval

	Name	Signature	Date
Author	Isaac Henry	[signature]	3/7/2013
Engineer	Daniel Walker	[signature]	7 March 2013
Quality	Minh-Duc Nguyen	[signature]	7 Mar 2012

Verification Engineering Test Results

Test Date:	7 MARCH 2013	Time Test Took:	2 hr 30 min	Result:	PASS

	Tester	Reviewer
Name	ISSAC HENRY	[signature] NH 3/7/2013 DANIEL WALKER
Sign and Date	[signature] 3/7/2013	[signature] MARCH 7, 2013

Failed Test Steps (include step, tag, and JIRA numbers):

References

1. 0-0000996_1 (SDS – Continuous Non-Invasive Blood Pressure)

Acronyms and definitions

- PAT Pulse Arrival Time
- cNIBP Continuous Non-Invasive Blood Pressure
- MAP_PWV_SCALE = 100000
- modCM(*i*): modulus of *i* and 128

Equipment List

Device Name	Resolution Requirements or Description	Device Serial Number	Calibration Date (if applicable)
cNIBP Simulator	N/A	AS06110004	N/A
Wrist Transceiver	N/A	AAAA 2012 0600 347	N/A
SpO2 Sensor	N/A	ABBA 2012 09283	N/A
ECG module (3 wire)	N/A	ACBE 2012 0800168	N/A
NIBP module	N/A	ADAA 2012 0800416	N/A

Objectives

SVTT-000030-001: In order to calculate a new cNIBP numeric, an ECG QRS must have been identified within the last 10 seconds or a PPG pulse must have been identified with the last 30 seconds.

SVTT-000030-002: In order to calculate a new cNIBP numeric, check that at least 25 PAT values were added to PAT_ECG_SN array in the last 60 seconds.

SVTT-000030-003: The function cnibp_median_val calculates the median value of the pulse arrival time measurements in the VTT_MS arrays, that are also no more then 60 seconds old and store the results in newVTT.

SVTT-000030-004: The function cnibp_median_val calculates the median value of the pulse arrival time measurements in the PAT_MS arrays, that are also no more then 60 seconds old and store the results in newPAT.

SVTT-000030-005: If this is the first cNIBP numeric update after the NIBP inflation, the calibration PAT (cal.pat) must be within ±12 milliseconds of the median PAT value (newPAT).

SVTT-000030-006: The function calc_MAP_PWV calculates the current MAP value based on the offset corrected median PAT value (newVTT).

SVTT-000030-007: If four or more MAP values have been calculated since calibration, the MAP numeric value will be re-calculated as an average of the last four MAP numeric values.

Procedure

SVTT-000030-001: In order to calculate a new cNIBP numeric, an ECG QRS must have been identified within the last 10 seconds or a PPG pulse must have been identified within the last 30 seconds.

1. Modify and program the test code:
   a. Add logging statement to print the following values when a value is written to ECG_QRS:
      `ECG_Index, modCM(ECG_Index), ECG_QRS[modCM(ECG_Index)]`
   b. Add logging statement to print the following values when a value is written to PAT_PPG_SN:
      `PAT_Index, modCM(PAT_Index), PAT_PPG_SN[modCM(PAT_Index)]`
   c. Add logging statements to print a "0" if the check fails or "1" if it passes, and the following values at the time of the check:
      `nowTick, ECG_Index, modCM(ECG_Index-1), ECG_QRS[modCM(ECG_Index-1)],`
      `PAT_Index, modCM(PAT_Index-1), PAT_PPG_SN[modCM(PAT_Index-1)`
2. Collect Data Using PDS
   a. With VISI System attached to the cNIBP simulator and connected to the PDS
      i. Set HR to 90 BPM and "Trigger Delay" to 190 ms with BP set to 120/70
         1. Collect data for 1-3 minutes
      ii. Run a NIBP blood pressure measurement / cNIBP calibration
      iii. Wait for cNIBP numerics to appear on the VISI
         1. Collect data for 1-3 minutes
3. Collect the Log File
   a. Copy the log file from the PDS
      i. File location: pds-instances/[server_name]/logger/logs/
      ii. Copy the pwd-remote.log file
4. Using the values in the logging statements:
   a. Using values from logging statements 1a and 1b (above) to keep track of the contents of the buffers ECG_QRS and PAT_PPG_SN
   b. Using buffers ECG_QRS and PAT_PPG_SN and values from logging statement 1c (above) logically evaluate the following statement:
      `ECG_QRS[modCM(ECG_Index-1)] < nowTick - TEN_SECONDS`
      `OR PAT_PPG_SN[modCM(PAT_Index-1)] < nowTick - THIRTY_SECONDS`
   c. Verify via the log statement that if the statement is false the device must have logged "0"; if the statement is true the device must have logged a "1".
5. Observations:_____

Result: PASS

SVTT-000030-002. In order to calculate a new cNIBP numeric, check that at least 25 PAT values were added to PAT_ECG_SN array in the last 60 seconds.

1. Modify and program the test code:
   a. Add logging statement to print the following values when a value is written to PAT_PPG_SN:
      `PAT_Index, modCM(PAT_Index), PAT_PPG_SN[modCM(PAT_Index)]`
   b. Add logging statements to print a "0" if the check fails or "1" if it passes, and the following values at the time of the check:
      `PAT_Index, modCM(PAT_Index-i), PAT_ECG_SN[modCM(PAT_Index-i)], PPG_SeqNum`
2. Collect Data with the PDS:
   a. With Visi System attached to the cNIBP simulator and connected to the PDS:
      i. Set HR to 90 BPM and "Trigger Delay" to 190 ms with BP set to 120/70
         1. Collect data for 1-3 minutes
      ii. Run a NIBP blood pressure measurement / cNIBP calibration
      iii. Wait for cNIBP numerics to appear on the VISI
         1. Collect data for 1-3 minutes
3. Collect the Log File
   a. Copy the log file from the PDS
      i. File location: pds-instances/[server_name]/logger/logs/
      ii. Copy the pwd-remote.log file
4. Using the values in the logging statements:
   a. Using values from logging statements 1a keep track of the contents of the buffer PAT_PPG_SN
   b. Using the buffer PAT_ECG_SN and values from logging statement 1b (above), count the number of values that are less then 60 from the most recent PPG_SeqNum.
5. Check the result against the value printed in the logging statement 1c (above). Verify that when there are more than 25 values meeting the criteria, the device must have logged a "1"; else the device must have logged a "0".
6. Observations:_____

Result: PASS

SVTT-000030-003: The function cnibp_median_val calculates the median value of the pulse arrival time measurements in the VTT_MS arrays, that are also no more then 60 seconds old and store the results in newVTT.

1. Modify and program the test code:
   a. Add a logging statement to print the following values when a value is written to VTT_MS:
      `PAT_Index, modCM(PAT_Index-1), VTT_MS[modCM(PAT_Index-1)]`
   b. Add a logging statement to print the following values when cnibp_median_val calculates the median value of the VTT_MS buffer:
      `i, PAT_Index, newVTT`
2. Collect Data Using PDS
   a. With Visi System attached to the cNIBP simulator and connected to the PDS:
      i. Set HR to 90 BPM and "Trigger Delay" to 190 ms with BP set to 120/70
         1. Collect data for 1-3 minutes
      ii. Run a NIBP blood pressure measurement / cNIBP calibration
      iii. Wait for cNIBP numerics to appear on the VISI
         1. Collect data for 1-3 minutes
3. Collect the Log File
   a. Copy the log file from the PDS
      i. File location: pds-instances/[server_name]/logger/logs/
      ii. Copy the pwd-remote.log file
4. Using the values in the logging statements:
   a. Using values from logging statement 1a keep track of the contents of the buffer VTT_MS
   b. Using the contents of the VTT_MS buffer and the values from logging statement 1b, calculate the median of the non-zero values in VTT_MS between the indices PAT_Index-i and i.
5. Compare this value with the value for newVTT from logging statement 1b. Verify that the values must be equal.

6. Observations:_____

Result: PASS

SVTT-000030-004: The function cnibp_median_val calculates the median value of the pulse arrival time measurements in the PAT_MS arrays, that are also no more then 60 seconds old and store the results in newPAT.

1. Modify and program the test code:
   a. Add a logging statement to print the following values when a value is written to VTT_MS:
      `PAT_Index, modCM(PAT_Index-1), PAT_MS[modCM(PAT_Index-1)]`
   b. Add a logging statement to print the following values when cnibp_median_val calculates the median value of the PAT_MS buffer:
      `i, PAT_Index, newPAT`
2. Collect Data Using PDS
   a. With Visi System attached to the cNIBP simulator and connected to the PDS:
      i. Set HR to 90 BPM and "Trigger Delay" to 190 ms with BP set to 120/70
         1. Collect data for 1-3 minutes
      ii. Run a NIBP blood pressure measurement / cNIBP calibration
      iii. Wait for cNIBP numerics to appear on the VISI
         1. Collect data for 1-3 minutes
3. Collect the Log File
   a. Copy the log file from the PDS
      i. File location: pds-instances/[server_name]/logger/logs/
      ii. Copy the pwd-remote.log file
4. Using the values in the logging statements:
   a. Using values from logging statement 1a keep track of the contents of the buffer PAT_MS
   b. Using the contents of the PAT_MS buffer and the values from logging statement 1b, calculate the median of the non-zero values in PAT_MS between the indices PAT_Index-i and i.
5. Compare this value with the value for newPAT from logging statement 1b and verify the values must be equal.

6. Observations:_____

Result: PASS

SVTT-000030-005: If this is the first cNIBP numeric update after the NIBP inflation, the calibration PAT (cal.pat) must be within ±12 milliseconds of the median PAT value (newPAT).

1. Modify and program the test code:
   a. Add a logging statement in the function Process_NIBP_Sample that will print the value cnibpCal.pat when it is assigned within this function.
   b. Add logging statements to print a "0" if the following statement is false, or "1" if it is true:
      `newPAT - cnibpCal.pat > -12 AND newPAT - cnibpCal.pat < 12`
      and the following values at the time of the check:
      `newPAT, cnibpCal.pat`
2. Collect Data Using PDS
   a. With VISI System attached to the cNIBP simulator and connected to the PDS:
      i. Set HR to 90 BPM and "Trigger Delay" to 190 ms with BP set to 120/70
         1. Collect data for 1-3 minutes
      ii. Run a NIBP blood pressure measurement / cNIBP calibration
      iii. Wait for cNIBP numerics to appear on the VISI
         1. Collect data for 1-3 minutes
      iv. Set "Trigger Delay" to 170 ms
         1. Collect data for 1-3 minutes
      v. Set "Trigger Delay" back to 190 ms
         1. Collect data for 1-3 minutes
3. Collect the Log File
   a. Copy the log file from the PDS
      i. File location: pds-instances/[server_name]/logger/logs/
      ii. Copy the pwd-remote.log file
4. Using the values in the logging statements:
   a. Using the value from logging statement 1a, track the current value of cnibpCal.pat
   b. Using the values from logging statement 1b, check if the value of newPAT is within +/-12 of cnibpCal.pat. Verify that if it is, then the logging statement must have printed a "1", otherwise a "0" must have been logged.

5. Observations:_____

Result: PASS

SVTT-000030-006: The function calc_MAP_PWV calculates the current MAP value based on the offset corrected median PAT value (newVTT).

1. Modify and program the test code:
   a. Add a logging statement in the function Process_NIBP_Sample that will print the value cnibpCal.pat when it is assigned within this function
   b. Add a logging statement in the function Process_NIBP_Numeric that will print the value cnibpCal.nibpMap when it is assigned within this function
   c. Add a logging statement to print the following values when calc_MAP_PWV calculates a new MAP:
      `newVTT, cNIBP_Numeric.data.map`
2. Collect Data Using PDS
   a. With VISI System attached to the cNIBP simulator and connected to the PDS
      i. Set HR to 90 BPM and PAT delay to 190 ms with BP set to 120/70
         1. Collect data for 1-3 minutes
      ii. Run a NIBP blood pressure measurement / cNIBP calibration
      iii. Wait for cNIBP numerics to appear on the VISI
         1. Collect data for 1-3 minutes
3. Collect the Log File
   a. Copy the log file from the PDS
      i. File location: pds-instances/[server_name]/logger/logs/
      ii. Copy the pwd-remote.log file
4. Using the values in the logging statements:
   a. Using the value from logging statement 1a, track the current value of cnibpCal.pat
   b. Using the value from logging statement 1b, track the current value of cnibpCal.nibpMap
   c. Using the value for newVTT from logging statement 1c, and the current values of cnibpCal.pat and cnibpCal.nibpMap, calculate the following:
      i. Cal_K, using the following equation:
      $$Cal_K = 20/((-0.01 \cdot cnibpCal.nibpMap + cnibpCal.pat)/20 - 1/cnibpCal.pat)$$
      ii. MAP, using the following equations:
      $$MAP = \left(\frac{MAP_PWV_SCALE}{newVTT} - \frac{MAP_PWV_SCALE}{cnibCal.pat}\right) \cdot \frac{Cal_K}{MAP_PWV_SCALE} + cnibpCal.nibpMap$$
   d. Verify that the value calculated for MAP must be equal to the value for cNIBP_Numeric.data.map logged in statement 1c.

5. Observations:_____

Result: PASS

SVTT-000030-007: If four or more MAP values have been calculated since calibration, the MAP numeric value will be re-calculated as an average of the last four MAP numeric values.

1. Modify and program the test code:
   a. Add logging statement to print the following values when a value is written to cNIBP_Display_Val: `Display_cNIBP_Count, modCDQ(Display_cNIBP_Count), cNIBP_Display_Val[modCDQ(Display_cNIBP_Count)]`
   b. Add a logging statement to print cNIBP_Numeric.data.map when it is calculated.
2. Collect Data Using PDS
   a. With VISI System attached to the cNIBP simulator and connected to the PDS
      i. Set HR to 90 BPM and PAT delay to 190 ms with BP set to 120/70
         1. Collect data for 1-3 minutes
      ii. Run a NIBP blood pressure measurement / cNIBP calibration
      iii. Wait for cNIBP numerics to appear on the VISI
         1. Collect data for 1-3 minutes
3. Collect the Log File
   a. Copy the log file from the PDS
      i. File location: pds-instances/[server_name]/logger/logs/
      ii. Copy the pwd-remote.log file
4. Using the values in the logging statements:
   a. Using values from logging statement 1a keep track of the contents of the buffer cNIBP_Display_Val
   b. Using the values in cNIBP_Display_Val and the value of Display_cNIBP_Count, calculate the MAP numeric value, for display, using one of the following:
      i. If Display_cNIBP_Count is less then 4, then MAP is the most recent value written to cNIBP_Display_Val
      ii. If Display_cNIBP_Count is greater then or equal to 4, then MAP is the average of the 4 values most recently written to cNIBP_Display_Val
   c. Verify that the value calculated for the MAP numeric value is equal to the value logged in statement 1b.

5. Observations:_____

Result: PASS

Revision History

Date	Revision	Author	Description of Key Changes
02/22/2013	1	Isaac Henry	N/A

Tester Comments:

Sotera Wireless	SW Verification Test Protocol	SVT-000031
	This record contains confidential, proprietary information of Sotera Wireless, Inc. and shall not be copied or reproduced without prior written permission there from.	Version: 1
	Considered "controlled" if viewed on-line or if hardcopy includes signed/dated "controlled copy" stamp.	Page 1 of 11

Title:	PWD, cNIBP Arm Height and Posture
	Subversion Revision # 51564

Software Version UUT (N/A if not used)	PWD r51077 PDS 1.4.3 RVD N/A
Hardware Version UUT (N/A if not used)	WT : AAAA 2012 0680 347 SPO2 : ABBA 201208211 NIBP : ADAA 2012600358 ECG : ACBE 20120760134 ACC : ACBE 20120700134

Verification Engineering Test Case Approval

	Name	Signature	Date
Author	NICHOLAS UTSCHIG	Nicholas Utschig	6 MAR 2013
Engineer	DANIEL WALKER	[signature]	6 MAR 2013
Quality	Minh-Duc Nguyen	[signature]	6 MAR 2013

Verification Engineering Test Results

Test Date:	7 MARCH 2013	Time Test Took:	30 minutes	Result:	PASS

	Tester	Reviewer
Name	NICHOLAS UTSCHIG	DANIEL WALKER
Sign and Date	Nicholas Utschig 7 MAR 2013	[signature] 7 MARCH 2013

Failed Test Steps (include step, tag, and JIRA numbers):

References

1. 0-0000996_1 (SDS – Continuous Non-Invasive Blood Pressure)

Terms / Acronyms

- ACC Accelerometer
- ECG Chest sensor module
- UAA Upper arm ACC
- WT Wrist Transceiver

Equipment List

Device Name	Resolution Requirements or Description	Device Serial Number	Calibration Date (if applicable)
Little Red Board	H1 Programming Interface Board	SM03966475	N/A
Wrist Transceiver	Mid-housing platform to test code	AAAA20120680347	N/A
USART to USB	Access WT console and logger	N/A	N/A
ECG II module	Attached cables not necessary	ACBE20120700124	N/A
Green Hills Probe	Programmer and debugger for Green Hills software	14067	N/A

Objectives

SVTT-000031-001: Upper arm attitude and lower arm attitude is determined using the accelerometers in the WT and UAA, respectively.

SVTT-000031-002: Arm height is the summed vertical projection of the upper and lower arm segments.

SVTT-000031-003: Posture attitude is determined using the accelerometer in the ECG.

SVTT-000031-004: Posture adaptively aligns to the initial posture state.

Procedure

SVTT-000031-001: Upper arm attitude and lower arm attitude is determined using the accelerometers in the WT and UAA, respectively.

1. Via code review of the accel_ua project, verify that:
   a. CAN_Receive() filters are enabled for the WT ACC waveform.
   b. CAN_Receive() parses the WT ACC waveform packet by storing the data into an array.
   c. Accelerometer() stores the UAA ACC waveform into an array.
   d. The arrays referenced in b) and c) are used in ArmHeight() to find the upper arm and lower arm attitude.

Observations: _____

Result: PASS

SVTT-000031-002: Arm height is the summed vertical projection of the upper and lower arm segments.

1. Via code review of ArmHeight(), verify that:
   a. The sine of the UAA attitude and length of the upper arm segment give the vertical contribution of the upper arm segment.
   b. The sine of the WT ACC attitude and length of the lower arm segment give the vertical contribution of the lower arm segment.
   c. These two terms are added together to determine total arm height.

2. Implement code (as found in r50977) which simulates known accelerometer measurements from the UAA ACC in /accel_ua/Accelerometer.c and from the WT ACC and ECG ACC in /accel_ua/CAN_Receive.c with hardware in the loop. Match the simulated states as in the tables below.

   The verification revision of software generates known accelerometer data input from the UAA and WT into the ArmHeight algorithm. Each accelerometer may be in five states, representing an arm parallel to the standing body and raised from nadir to zenith: 0: -90°, 1:-45°, 2:0°, 3:+45°, and 4:+90°.

   The acceleration vectors are projected onto a nearly-nadir vector to account for placement of the hardware on the arm when the arm is rested towards nadir. This adjustment is not corrected for in this pre-computed Excel table.

   The UAA ACC changes state every 30 seconds and the WT ACC changes state every (5x30=) 150 seconds. Thus all states will be observed in (5x150=) 750 seconds, or (750/60=) 12.5 minutes.
3. Enable logging in ArmHeight.c of Elbow Ht, Wrist Ht and Overall Ht. (Found in r50977).
4. Enable logging in Posture.c of Posture and Current_Position. (Found in r50977).

5. e.g.: Logs of simulated UAA ACC and WT ACC state, which is state 4:90° in these examples:
   a. "WT ACC 4"
   b. "UAA ACC 4"
6. e.g.: The measured overall height is logged from the UAA:
   a. "Elbow Ht=-25, Wrist Ht=-29, Overall Ht=-54"
7. Verify the logged overall heights with the pre-computed table below +/- 3cm. This table is Excel based, so that the formula may be verified second-hand.

UAA \ WT	WT 0:-90°	WT 1:-45°	WT 2:0°	WT 3:+45°	WT 4:+90°
UAA 0:-90°	-56.00	-47.21	-26.00	-4.79	4.00
UAA 1:-45°	-48.38	-39.60	-18.38	2.83	11.62
UAA 2:0°	-30.00	-21.21	0.00	21.21	30.00
UAA 3:+45°	-11.62	-2.83	18.38	39.60	48.38
UAA 4:+90°	-4.00	4.79	26.00	47.21	56.00

UAA \ WT	WT 0:-90°	WT 1:-45°	WT 2:0°	WT 3:+45°	WT 4:+90°
UAA 0:-90°	-54	-47	-24	-4	4
UAA 1:-45°	-46	-39	-18	3	12
UAA 2:0°	-28	-21	0	20	30
UAA 3:+45°	-11	-4	18	37	47
UAA 4:+90°	-4	3	24	44	54

Observations: _____

Result: PASS

SVTT-000031-003: Posture attitude is determined using the accelerometer in the ECG.

1. Via code review of the accel_ua project, verify that:
   a. CAN_Receive() filters are enabled for the ECG ACC waveform.
   b. CAN_Receive() parses the ECG ACC waveform packet by storing the data into an array.
   c. The ECG ACC waveform data is the only accelerometer source of data used in Posture.c's Calc_Posture().

Observations: _____

Result: PASS

SVTT-000031-004: Posture adaptively aligns to the initial posture state.

1. Via code review of the accel_ua project, verify that:
   a. Calc_ChestACC_Alignment() runs near the beginning of monitoring.
   b. Calc_ChestACC_Alignment() will use a default if the patient is lying prone, or supine with the ECG attached by the wrong side; detected by the the z axis being > 200 counts.
   c. The gravity vector must be in the same hemisphere (within 170 degrees) of expected nadir. This ensures the patient is in a sitting or reclined position and the sensor is correctly placed.
   d. The horizontal alignment vector is orthogonal to the normal vector of the chest and the gravity vector.
   e. The vertical alignment vector is the cross product of the horizontal and normal vectors.

Observations: _____

Result: PASS

Tester Comments:

Revision History

Date	Revision	Author	Description of Key Changes
2/28/2013	1	Nicholas Utschig	Initial Creation

Long Term Test Results

Software:

PWD version: 253.5.0 and 253.4.0 bootloaders

PDS/RVD version: N/A.

Equipments:

SpO2 Simulator: Human

ECG Simulator: Human

Resp Simulator: Human

NIBP Simulator: Human

Modules:

WT: DEMO20121138251

ECG: AFBE20120800167

SpO2: ABBA201208211

Results: Pass

Observations: The station ran for 14.5 Hours. No errors occurred, and the device was returned to the charger when critically low to monitor. cNIBP ran during most of the test, with manual recalibrations, sensor disconnection and a stop and restart of monitoring.

EXHIBIT 11
VISI CNIBP SOFTWARE ANOMALIES – VERSION 253.5.1

#	JIRA ID	PROBLEM	CRITICALITY
1	CNIBP-17	When a NIBP-derived PR reading exceeds the upper device limit, a NIBP Fault alert is displayed rather than "+++". This only happens for manual NIBP measurements. The nurse is present for the measurement so there is a clinician at the patient side and there is clear indication of a failure to display BP and a need to retake the measurement. This would not result in patient harm.	Minor
2	CNIBP-33	"NIBP Fault" alert is generated when all sensors (Thumb, Cuff and ECG) are connected and a blood pressure is taken. This would result in a delay in measuring NIBP, which would delay initial calibration of cNIBP until the nurse can retry the measurement. This delay in measuring cNIBP is a minor patient safety risk but no harm is caused to the patient.	Minor
3	CNIBP-19	The word "MOTION" (indicating motion artifact in the measurement) is not displayed in cNIBP box when there is no cNIBP measurement due to the presence of motion and a heart rate measurement is available. This does not pose a patient safety risk. This is considered a Negligible issue from a patient safety perspective. There is no patient harm.	Negligible
4	CNIBP-29	If cNIBP Pulse arrival time (PAT) value changes more than 12 milliseconds in the first 30 seconds after a valid NIBP is taken, the ViSi will attempt recalibration with the NIBP cuff. If a 12 ms change is repeated after every NIBP measurement (on a simulator), the ViSi will continue attempting a recalibration (a new NIBP measurement). The specification requires a maximum of two calibrations and then displays the last valid NIBP measurement. However, multiple cuff inflations may be attempted. Since ViSi complies with IEC 80601-2-30 for time between measurements, this is a Negligible patient safety issue. This would not result in patient harm.	Negligible
5	CNIBP-31	When cNIBP is calibrated, "xx/xx, (xx)" is displayed in Red first for up to 10 seconds and then measurements are displayed. The 10 second delay in showing a NIBP value does not pose a patient safety issue – this issue is Negligible. This is a cosmetic issue since the display will convert to cNIPB values as soon as the measurement is available. This would not result in patient harm.	Negligible
6	CNIBP-35	"xx/xx", xx" measurements are not displayed in white for NIBP when the cNIBP measurement is unobtainable due to the Chest Sensor or Thumb Sensor being disconnected and the "disconnected" alert has already been acknowledged. This is a cosmetic issue and is Negligible from a patient safety risk perspective. This would not result in patient harm.	Negligible
7	CNIBP-36	"SpO2" is not displaying waveform/numeric values when all sensors are re-connected to the ViSi monitor from "Clean Monitor, return to charger" screen. All patient monitoring has stopped at this point consistent with labeling. If sensors are being disconnected and reconnected, the clinician is at the bedside and will recognize that SpO2 is not being measured and will address this issue. This issue is Negligible from a patient safety risk perspective.	Negligible
8	ECHO-6	For "CHEST FAULT" alert, ViSi monitor displays "xx" instead of removing the vital signs box. This is a cosmetic issue and is Negligible from a patient safety risk perspective. This would not result in patient harm.	Negligible
9	ECHO-7	A "Cuff No Pulse" alert is annunciated which means there are no pulses detected during a NIBP inflation.. The correct behavior is for the device to defer to the HR sources and display the alert "NIBP unobtainable". This would not result in patient harm.	Negligible
10	FEP-16	Intentionally stopping the cuff secondary processor did not generate an NIBP_FAULT alert on the ViSi monitor. This condition was artificially generated in a verification test. There is redundancy in the pressure transducer controls that will not cause over-pressure on patient even if secondary processor fails. There will also be an indication of failure to take a BP. This will not result in patient harm.	Negligible

EXHIBIT 11
VISI CNIBP SOFTWARE ANOMALIES – VERSION 253.5.1

#	JIRA ID	PROBLEM	CRITICALITY
11	FEP-36	Blood pressure derived PR value and NIBP systolic/diastolic values take 35 seconds to go stale. The requirement is 30 seconds. This is not clinically significant and will not result in patient harm.	Negligible
12	FEP-54	When the ECG cable is disconnected during a high HR event, the alarm message display does not change from "High HR" to "High PR". After PR is within the alarm limit boundaries, PR measurement is not displayed in green. Since there is still a clear indication of high HR/PR, the intent is fulfilled. This issue is cosmetic. This would not result in patient harm.	Negligible
13	SE-18	When monitoring is stopped and the Cuff module is removed from Wrist Monitor and then re-connected, the "Lock"&"Menu" buttons are displayed as "enabled" but they are actually disabled. They should not be displayed as "enabled" until a session has started. In this situation, they should only become enabled after the first NIBP measurement. The button state is a cosmetic issue . This would not result in patient harm..	Negligible
14	SE-20	"Thumb No Pulse" alarm/alert with a "30 second no pulse activity/no motion" condition will never occur due to the motion event created from an active alert's audio annunciation. This issue resolves as soon as the alarm/alert is acknowledged. Therefore this is a Negligible issue. This would not result in patient harm.	Negligible
15	SE-21	The "Start Cuff" button is still enabled after removing NIBP module from Wrist monitor. The fact that the cuff is not inserted is visually obvious to a user so the button state is a cosmetic issue. This is would not result in patient harm.	Negligible
16	SE-27	HR displays “0”, then changes to "xx" and back to 0 on the monitor for Life threatening critical low heart rate. The critically low HR alarm continues to annunciate and it is clear that a critically low heart condition is occurring. This would not result in patient harm.	Negligible

Title:	Protocol, Design Verification, EN 1060-1, EN 1060-3, IEC 80601-2-30 Compliance

Type:	**Design Verification Protocol**				
Owner:	Engineering	Supersedes:	N//A	Release Date:	1 MARCH 2013
Document Control Signature:					

Approver Name	**Approver Signatures**
William Burris Author	
Eben Gordon Regulatory Affairs	
Minh-Duc Nguyen Quality Assurance	
David Stroup Engineering	

Revision	**Date**	**Change Summary**
A	3/1/2013	New release

1 PURPOSE

This protocol identifies the testing required to verify compliance to all applicable requirements within EN 1060-1, EN 1060-3, and IEC 80601-2-30 international standards.

2 SCOPE

This protocol is applicable to the ViSi patient monitoring system.

3 REFERENCES

3.1 Internal

3.1.1 0-000349 NIBP Module Verification

3.2 External

3.2.1 EN 1060-1:1995+A2:2009 Non-invasive sphygmomanometers – Part 1: General requirements

3.2.2 EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

3.2.3 EN 980:2008-08 Symbols for use in the labeling of medical devices

3.2.4 EN 1041:2008-11 Information supplied by the manufacturer of medical devices

3.2.5 EN 60601-1-2:2000 Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

3.2.6 IEC 60601-2-30: 1999-12 Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

3.2.7 IEC 80601-2-30:2009 Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers

3.2.8 ISO 81060-2:2009-05-01 Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type

4 ACRONYMS AND DEFINITIONS

4.1 mmHg – millimeter of mercury, a unit of measure of pressure

4.2 NIBP – Non-Invasive blood pressure

4.3 CNIBP – Continuous Non-Invasive Blood Pressure

4.4 Sphygmomanometer – Blood pressure measurement device

5 ACCEPTANCE CRITERIA

5.1 Compliance with the applicable requirements of EN 1060-1 is considered passing when all requirements listed in this protocol have been tested and passed.

5.2 Compliance with the applicable requirements of EN 1060-3 is considered passing when all requirements listed in this protocol have been tested and passed.

5.3 Compliance with the applicable requirements of IEC 80601-2-30 is considered passing when all requirements listed in this protocol have been tested and passed.

5.4 Each requirement must pass the individual acceptance criteria specified within each section of the standard to be considered passing.

5.5 A minimum sample size of 3 devices shall be tested and all requirements shall be met on each tested sample.

6 EQUIPMENT

6.1 The test equipment used for testing shall be documented in the test report. The manufacturer, model, serial number, and the calibration due date shall be recorded.

6.2 A description of the test configuration and equipment setup shall be documented in the test report. Test equipment programming shall be documented when applicable.

6.3 All software applications used to perform testing shall be documented in the test report.

7 EN 1060-1 and EN1060-3 REQUIREMENTS

EN 1060-1	REQUIREMENT	Applies NIBP	Applies CNIBP
4 – CUFF	The cuff shall contain a bladder. For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents.	YES	NO
5 – DISPLAY	The display shall be designed and arranged so that the information including measured values can be read and easily recognized. If abbreviations are used on the display they shall be as follows: “S” or “SYS” for systolic pressure; “D” or “DIA” for diastolic pressure; “M” or “MAP” for mean arterial pressure.	YES	YES
6 – UNITS	The blood pressure units shall be indicated in either millimeters of mercury (mmHg) or kilopascals (kPa).	YES	YES
7 - REQUIREMENTS	EN1060-1 Section 7 describes the device requirements.		
7.1.1 - Limits of the Error of the cuff pressure indication.	Test to section 8.1 of EN 1060-1 with the following changes: • A nonmetal pressure vessel may be used so long as it is constructed in a suitable way as to not deform under pressures used.	YES	NO
7.1.2.1 – Effects of Storage.	Test to section 8.1 of EN 1060-1 with the following changes: A nonmetal pressure vessel may be used so long as it is constructed in a suitable way as to not deform under pressures used.	YES	NO
7.1.2.2 – Effect of Temperature	Test to section 8.2 of EN 1060-1 with the following changes: • A nonmetal pressure vessel may be used so long as it is constructed in a suitable way as to not deform under pressures used.	YES	NO
7.2 - Safety	Verify that the system complies with EN/IEC 60601-1:1988 as required by section 7.2 of EN 1060-1.	YES	NO
8 – TEST METHODS	EN1060-1 Section 8 describes the test methods used.		
9 – INFORMATION SUPPLIED BY THE MANUFACTURER	Inspect operators manual and verify compliance.		

EN 1060-1	REQUIREMENT	Applies NIBP	Applies CNIBP
9.1 - General	Information supplied must comply with standard EN1041. Symbols must comply with standard EN980. The manufacturer shall state the date of issue or the latest revision of the instructions for use. Inspect operators manual and verify compliance.	YES	YES
9.2 – Instruction leaflet	Inspect instruction leaflet and verify compliance	YES	YES
9.3 – Marking of the device	Inspect device and verify compliance	YES	YES

EN 1060-3	REQUIREMENT	Applies NIBP	Applies CNIBP
4 - CUFF	Section 4 of EN 1060-1 shall apply.	YES	NO
5 - DISPLAY	Section 5 of EN 1060-1 shall apply.	YES	YES
6 - UNITS	Section 6 of EN 1060-1 shall apply.	YES	YES
7 - REQUIREMENTS	EN1060-3 Section 7 describes the device requirements.		
7.1 - General	Section 7.1 of EN 1060-1 shall apply.	YES	YES
7.2 – Limits of error of the cuff pressure indication	Section 7.2 of EN 1060-1 shall apply.	YES	NO
7.3 – Effect of voltage variations of the power source variations			
7.3.1 – Internal electrical power source	Test to section 8.2.1 and 8.3.1 of EN 1060-3	YES	YES
7.3.2 – External electrical power source	Not Applicable	NO	NO
7.4 – Pneumatic System			
7.4.1 – Air Leakage	Perform the Inflation Source, Leakage, and Pressure Transducer Accuracy test from protocol 0-000349 and compare the data gathered with the acceptance criteria of section 7.4.1 of the standard. The test in section 8.4 of the standard would require significant modifications to the system, while the test in 0-000349 measures the same quantity with no system modification.	YES	NO
7.4.2 – Pressure reducing system for devices using the auscultatory method	N/A – The ViSi system does not use the auscultatory method	YES	NO

EN 1060-3	REQUIREMENT	Applies NIBP	Applies CNIBP
7.4.3 – Rapid Exhaust	Perform the Maximum Pressure Measurement test from protocol 0-000349. That test is essentially the same as the test described in section 8.6 of the standard, with the only significant difference being in how the time is measured. 0-000349 does not instruct the tester to find the exact time at which 15 mmHg is reached, but instead only ensures that that time is less than 10 seconds. The alternate measurement method is necessary because of the technical difficulty of connecting the test setup as specified, but it is still fully compliant with the acceptance criteria of section 7.4.3 of the standard.	YES	NO
7.4.4 – Zero Setting	The test described in section 8.7 of the standard cannot be performed for the NIBP module because the NIBP module performs a zero setting immediately before taking a blood pressure measurement and has a valve that connects the pressure system to the ambient pressure while not performing a measurement. In place of the test in section 8.7 of the standard, perform the following test steps: 1. Connect the NIBP module to a cuff connected to a calibrated blood pressure simulator with constant pressure measurement and to a manual pump. 2. Use the manual pump to continuously inflate the cuff to approximately between 20 mmHg and 40 mmHg by observing the current pressure on the simulator. 3. While continuing maintaining pressure by pumping, start a blood pressure measurement, and stop pumping once the NIBP module closes its valve and engages its pump. 4. Consider section 7.4.4 of the standard passing if both systolic and diastolic blood pressure readings are at least 20 mmHg below the target values on the simulator.	YES	NO
7.5 – Environmental Performance			
7.5.1 - Storage	Test to section 8.1 of EN 1060-1 with the following changes: • A nonmetal pressure vessel may be used so long as it is constructed in a suitable way as to not deform under pressures used.	YES	YES
7.5.2 – Temperature, Relative Humidity	Test to section 8.9 of EN 1060-3.	YES	YES
7.5.3 – Electromagnetic Compatibility	Verify that the system complies with EN 60601-1-2 as required by section 7.5.3 of EN 1060-3.	YES	YES

EN 1060-3	REQUIREMENT	Applies NIBP	Applies CNIBP
7.6 – Stability of the cuff pressure indication	Performing 10000 inflations is not required because a majority of the system is electronic and not prone to wear caused by use. Perform the following steps to ensure that the system meets the requirements of section 7.6 and does not lose accuracy over 10000 cycles: 1. Identify any electromechanical parts of the NIBP module which affect accuracy and are prone to wear. 2. Verify by documentation that all electromechanical parts which are affect accuracy and are prone to wear are rated to not lose accuracy over 10000 blood pressure measurement cycles.	YES	NO
7.7 – Pressure Indicating Device			
7.7.1 – Nominal range and measuring range	Verify compliance	YES	YES
7.7.2 – Digital indication	Verify compliance	YES	YES
7.8 – Signal Input and Output Parts	Test to section 8.11 of EN 1060-1	NO	NO
7.9 – Overall System Accuracy	Testing shall comply with EN 1060-4 with the following changes: • Tests conforming with ISO 81060-2 or ANSI/AAMI SP10 may be substituted for EN 1060-4 because those standards are effectively equivalent.	YES	YES
7.10 - Alarms	Verify that the system complies with EN/IEC 60601-1-8 as required by section 7.10 of EN 1060-3.	YES	YES
7.11 - Safety			
7.11.1 – Cuff Pressure	Test to section 8.12 of EN 1060-3.	YES	NO
7.11.2 – Unauthorized Access	Verify compliance	YES	YES
7.11.3 – Tubing and Connectors	Verify compliance	YES	NO
8 – TEST METHODS	EN1060-3 Section 8 describes the test methods used.		
9 – INFORMATION SUPPLIED BY THE MANUFACTURER			
9.1 - General	Section 9.1 of EN 1060-1 shall apply.	YES	YES
9.2 – Instructions for use	Inspect operators manual and verify compliance	YES	YES
9.3 – Marking of device	Section 9.3 of EN 1060-1 shall apply.	YES	YES

8 IEC 80601-2-30 REQUIREMENTS

IEC 80601-2-30	Requirement	Applies NIBP	Applies CNIBP
201.4 – General Requirements	Clause 4 of the general standard shall apply, except as follows:	YES	YES
201.4.3 – Essential Performance	Verify compliance with the clauses listed in table 201.101 of IEC 80601-2-30	YES	YES
201.5 – General requirements for testing ME equipment	Clause 5 of the general standard shall apply.	YES	YES
201.6 – Classification of ME equipment and ME systems	Clause 6 of the general standard shall apply.	YES	YES
201.7 – ME equipment identification, markings and documents	Clause 7 of the general standard shall apply, except as follows:	YES	YES
201.7.2 – Marking on the outside of ME equipment of ME equipment parts	Addition:		
201.7.2.4 – Accessories	Verify compliance	YES	NO
201.7.2.101 – Display of automated sphygmomanometers	Verify compliance	YES	YES
201.7.2.102 – Automated sphygmomanometers for home healthcare environment	Not Applicable	NO	NO
201.7.2.103 – Automated sphygmomanometers with neonatal mode	Not Applicable	NO	NO
201.7.2.104 – Automated sphygmomanometers for public use	Not Applicable	NO	NO
201.7.2.105 – Component replacement	Verify compliance	YES	NO
201.7.2.105 – Disposal	Verify compliance	YES	NO
201.7.9.2 – Instructions for use			
201.7.9.2.1 – General	Inspect operators manual and verify compliance	YES	YES
201.7.9.2.2 – Warning and safety notices	Inspect operators manual and verify compliance	YES	YES
201.7.9.2.5 – ME equipment description	Inspect operators manual and verify compliance	YES	YES
201.7.9.2.9 – Operating instructions	Inspect operators manual and verify compliance	YES	YES
201.7.9.2.13 – Maintenance	Inspect operators manual and verify compliance	YES	NO

IEC 80601-2-30	Requirement	Applies NIBP	Applies CNIBP
201.7.9.2.101 – Compatibility with HF surgical equipment	Inspect operators manual and verify compliance	YES	YES
201.7.9.2.102 – Automated sphygmomanometers for neonatal use	Inspect operators manual and verify compliance	NO	NO
201.8 – Protection against electrical hazards from ME equipment	Clause 8 of the general standard shall apply except as follows:	YES	YES
201.8.5.5 – Defibrillation-proof applied parts	Additional sub-clause:		
201.8.5.5.101 – Patient connections of automated sphygmomanometers	Verify compliance	YES	NO
201.9 – Protection against mechanical hazards of ME equipment and ME systems	Clause 9 of the general standard shall apply	YES	NO
201.10 – Protection against unwanted and excessive radiation hazards	Clause 10 of the general standard shall apply	YES	NO
201.11 – Protection against excessive temperatures and other hazards	Clause 11 of the general standard shall apply, except as follows:	YES	NO
201.11.6.5 – Ingress of water or particulate matter into ME equipment and ME systems	Verify compliance	YES	NO
201.11.8 – Interruption of the power supply/supply mains to ME equipment	Addition:	YES	NO
201.11.8.101 – Switching off	Verify compliance	YES	NO
201.11.8.102 – Supply mains	Verify compliance	NO	NO
201.11.8.103 – Internal electrical power source	Verify compliance	YES	YES
201.12 – Accuracy of controls and instruments and protection against hazardous outputs	Clause 12 of the general standard shall apply, except as follows:	YES	YES
201.12.1 – Accuracy of controls and instruments	Addition:		
201.12.1.101 – Measuring and display ranges	Verify compliance	YES	YES

IEC 80601-2-30	Requirement	Applies NIBP	Applies CNIBP
201.12.1.102 – Limits of the error of the manometer from environmental conditions	Verify compliance	YES	YES
201.12.1.103 – Nominal blood pressure indication range	Verify compliance	YES	YES
201.12.1.104 – Maximum pressure in normal condition	Verify compliance	YES	NO
201.12.1.105 – Maximum pressure in single fault condition	Verify compliance	YES	NO
201.12.1.106 – Manometer test mode	Verify compliance	YES	NO
201.12.1.106 – Limits of the change in error of the blood pressure determination	Verify compliance	YES	YES
201.12.3 – Alarm systems	Addition:		
201.12.3.101 – Alarm systems	Verify compliance	YES	YES
201.13 – Hazardous situations and fault conditions	Clause 13 of the general standard shall apply	YES	YES
201.14 – Programmable electrical medical systems	Clause 14 of the general standard shall apply	YES	YES
201.15 – Construction of ME equipment	Clause 15 of the general standard shall apply, except as follows:	YES	YES
201.15.3.5 – Rough handling test	Addition:		
201.15.3.5.101 – Shock and vibration for other than transport	Verify compliance	YES	YES
201.15.3.5.102 – Shock and vibration for transport	Verify compliance	NO	NO
201.16 – ME systems	Clause 16 of the general standard shall apply	YES	YES
201.17 – Electromagnetic compatibility of ME equipment and ME systems	Clause 17 of the general standard shall apply with additional note: An automated sphygmomanometer is not considered life-supporting ME equipment or ME system as defined in IEC 601-1-2.	YES	YES
Additional Clauses			
201.101 – Requirements for cuffs	Addition:		
201.101.1 – Construction	Verify compliance	YES	NO

IEC 80601-2-30	Requirement	Applies NIBP	Applies CNIBP
201.101.2 – Pressurization	Verify compliance	YES	NO
201.102 – Connection tubing and cuff connectors	Verify compliance	YES	NO
201.103 – Unauthorized access	Verify compliance	YES	YES
201.104 – Maximum inflating time	Verify compliance	YES	NO
201.105 – Automatic cycling modes	Addition:		
201.105.1 – Long term automatic mode	Verify compliance	YES	YES
201.105.2 – Short term automatic mode	Verify compliance	YES	YES
201.105.3 – Self measurement automatic mode	Addition:		
201.105.3.1 – General	Verify compliance	YES	YES
201.105.3.2 – Normal condition	Verify compliance	YES	YES
201.105.3.3 – Single fault condition	Verify compliance	YES	YES
201.106 – Clinical Accuracy	Verify compliance with ISO 81060-2	YES	YES
202 – Electromagnetic compatibility – Requirements and Tests	Verify compliance with IEC 60601-1-2, except as follows:	YES	YES
202.4 – General requirements	Addition:		
202.4.101 – Classification	An automated sphygmomanometer shall not be considered life-supporting ME equipment or ME system	YES	YES
202.6.2 - Immunity	Addition:		
202.6.2.1.10 – Compliance criteria	Verify compliance with criteria replacement	YES	YES
202.6.2.3.1 – Requirements	Verify compliance with requirements replacement	YES	YES
202.6.2.101 – Electrosurgery interference recovery	Verify compliance	YES	YES

Type	**Design Verification Report**				
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Approver Name	**Approver Signatures**
William Burris Author	
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Revision	**Date**	**Change Summary**
A	3/1/2013	New release

1. PURPOSE

This report documents the testing that was performed to verify compliance to all applicable requirements within EN 1060-1, EN 1060-3, and IEC 80601-2-30 standards.

2. SCOPE

This report is applicable to the ViSi patient monitoring system.

3. REFERENCES

3.1 Internal

3.1.1 0-001002 Protocol, Design Verification, EN 1060-1, EN 1060-3, IEC 80601-2-30 Compliance

3.1.2 R-000068 Report, Pivotal Trial, NIBP, H1

3.1.3 R-000085 Report, DVER, EMC, H1

3.1.4 R-000086 Report, DVER, Environmental, H1

3.1.5 R-000087 Report, DVER, NIBP Module, H1

3.1.6 R-000090 Report, DVER, Fluid Ingress, H1

3.1.7 R-000188 Report, DVER, 80601-2-30, 1b

3.1.8 R-000189 Report, DVER, 60601-1-8, Alarm SRS Tags

3.1.9 R-000227 Report, EN1060-1 and EN1060-3 Compliance

3.1.10 R-000231 Report, Disposable Cuff, HRS DVER

3.1.11 R-000333 Report, SW Validation, cNIBP

3.1.12 6-000279-00 ViSi Mobile User's Manual

3.1.13 6-000147-X7 ViSi Mobile Technical Manual

3.2 External

3.2.1 TR# 2012048 Clinimark Report - Accuracy Study of ViSi Noninvasive Blood Pressure Cuff System with ViSi Continuous Noninvasive Blood Pressure Feature in Comparison to Invasive Arterial Blood Pressure

3.2.2 EN 1060-1:1995+A2:2009 Non-invasive sphygmomanometers – Part 1: General requirements

3.2.3 EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

3.2.4 EN 980:2008-08 Symbols for use in the labeling of medical devices

3.2.5 EN 1041:2008-11 Information supplied by the manufacturer of medical devices

3.2.6 EN 60601-1-2:2000 Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

3.2.7 IEC 60601-2-30: 1999-12 Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

3.2.8 IEC 80601-2-30:2009 Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers

3.2.9 ISO 81060-2:2009-05-01 Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type

4. ACRONYMS AND DEFINITIONS

mmHg – millimeter of mercury, a unit of measure of pressure
NIBP – Non-Invasive blood pressure
CNIBP – Continuous Non-Invasive Blood Pressure
Sphygmomanometer – Blood pressure measurement device
DUT – Device Under Test

5. ACCEPTANCE CRITERIA

5.1 Compliance with the applicable requirements of EN 1060-1 is considered passing when all applicable requirements of the standard have been tested and passed.

5.2 Compliance with the applicable requirements of EN 1060-3 is considered passing when all applicable requirements of the standard have been tested and passed.

5.3 Compliance with the applicable requirements of IEC 80601-2-30 is considered passing when all applicable requirements of the standard have been tested and passed.

5.4 A minimum sample size of 3 devices shall be tested and all requirements shall be met on each tested sample.

6. EQUIPMENT USED

6.1 Temperature Testing:

Thermotron Temperature Test Chamber, Sotera equipment ID# E0122, Calibration Due. 23MAY13
Veri-Cal Digital Manometer, Sotera Equipment # E0003, Calibration Due 09AUG13
Sotera Wrist Tx, Serial # AAAA20120700410, Firmware Revision 253.5.0 App/253.4.0 Boot.
NIBP Air Pressure Vessel, 500mL

6.2 Measuring and Display Ranges, Limits of Error Testing:

AccuSim Total Patient Simulator, Model TPS-1, Sotera Equipment #E0424, Calibration Due. 28JAN14

Accupulse NIBP Simulator, Sotera Equipment # E0007

7. DEVICES TESTED

7.1 Temperature Testing:

DUT1 - NIBP Module, Serial # ADAA201200542, Firmware Revision 253.5.0 App/253.4.0 Boot.
DUT2 - NIBP Module, Serial # ADAA201200562, Firmware Revision 253.5.0 App/253.4.0 Boot.
DUT3 - NIBP Module, Serial # ADAA201200581, Firmware Revision 253.5.0 App/253.4.0 Boot.

7.2 Measuring and Display Ranges, Limits of Error Testing:

DUT4 - Sotera Wrist Tx, Serial # AAAA20120800466,Firmware Revision 253.5.0 App/253.4.0 Boot.
Sotera ECG Cable, Serial # ACBE20120300103, Firmware Revision 253.5.0 App/253.4.0 Boot.
Sotera NIBP Module, Serial # ADAA20120800416, Firmware Revision 253.5.0 App/253.4.0 Boot.

DUT5 - Sotera Wrist Tx, Serial # AAAA20120800486, Firmware Revision 253.5.0 App/253.4.0 Boot.
Sotera ECG Cable, Serial # ACBE20120300273, Firmware Revision 253.5.0 App/253.4.0 Boot.
Sotera NIBP Module, Serial # ADAA20120800416, Firmware Revision 253.5.0 App/253.4.0 Boot.

DUT6 - Sotera Wrist Tx, Serial # AAAA20120800489, Firmware Revision 253.5.0 App/253.4.0 Boot.
Sotera ECG Cable, Serial # ACBE20121000220, Firmware Revision 253.5.0 App/253.4.0 Boot.
Sotera NIBP Module, Serial # ADAA20120800416, Firmware Revision 253.5.0 App/253.4.0 Boot

8. TESTS PERFORMED

8.1 IEC 80601-2-30, 201.12.1.102, Limits of the error of the manometer from environmental conditions / EN1060-1, 7.1.2. 2, Effect of Temperature

8.1.1 Temperature Test Setup:
The DUT (DUT1-3) was connected to the NIBP port on the 500mL air pressure vessel. The DUT was placed into the temperature chamber with the air vessel routed through the test port opening. The DUT NIBP cable was also routed through the test port opening and then sealed. Outside of the temperature chamber, the digital manometer was connected to the test port on the air pressure vessel. (The 2 devices not connected to the air vessel were also placed into the temperature chamber to soak.) The temperature chamber was programmed to 10C and the DUT was soaked for 1 hour. After recording the air pressure measurements on DUT1, change to DUT2 and soak for 1 hour, then record the air pressure measurements. Then change to DUT3 and soak for 1 hour, then record the air pressure measurements.

8.1.2 Air Pressure Accuracy Measurement:
The Wrist Tx was placed into the “Service” mode, then the DUT NIBP cable was plugged into the Wrist Tx. The “Device Tests” was selected, then “Cuff Cal:” was selected from the display menu. The NIBP module inflates to the test pressure and stops for the measurement to be made, prompting the operator when to proceed. The measurements of air pressure on the ViSi display and the digital manometer display were recorded for accuracy.

8.2 IEC 80601-2-30, 201.12.1.107, Limits of the change in error of the blood pressure determination

8.2.1 NIBP Test Setup:
The NIBP cuff on the DUT (DUT4-6) was connected to the AccuPulse NIBP simulator. The ECG electrodes and SPO2 sensor were connected to the AccuSim Total Patient Simulator. The AccuPulse NIBP simulator was set to Systolic = 120, Diastolic = 80, MAP = 93, Rate set to 80. The AccuSim Total Patient Simulator was set to achieve a blood pressure transient timing equivalent of Systolic = 120 and Diastolic = 80.

8.2.2 NIBP Accuracy Measurement:
After obtaining WiFi connection to the PDS server, a blood pressure measurement was initiated on the DUT (DUT4-6). About one minute after the NIBP measurement, the CNIBP measurements are shown on the Wrist Tx display in Red text. The CNIBP measurement data was collected for 90 seconds on the PDS server. The DUT was turned off using the shipping plug and the data was retrieved from the PDS server. The DUT was powered up again and the entire test was re-performed and the data was collected again.

9. TEST RESULTS

9.1 IEC 80601-2-30, 201.12.1.102, Limits of the error of the manometer from environmental conditions / EN1060-1, 7.1.2. 2, Effect of Temperature:

DUT- 1 @ 10C				
Pressure at Digital Manometer	Wrist Tx Reading (mmHg)	Pressure difference (mmHg)	Accepted Difference (mmHg)	Pass/Fail
51	51	0	± 3	Pass
149	150	1	± 3	Pass
248	249	1	± 3	Pass

DUT- 1 @ 20C				
Pressure at Digital Manometer	Wrist Tx Reading (mmHg)	Pressure difference (mmHg)	Accepted Difference (mmHg)	Pass/Fail
51	51	0	± 3	Pass
149	150	1	± 3	Pass
248	249	1	± 3	Pass

DUT- 1 @ 40C				
Pressure at Digital Manometer	Wrist Tx Reading (mmHg)	Pressure difference (mmHg)	Accepted Difference (mmHg)	Pass/Fail
51	50	1	± 3	Pass
150	150	0	± 3	Pass

248	249	1	± 3	Pass

DUT- 2 @ 10C				
Pressure at the Digital Manometer	Wrist Tx Reading (mmHg)	Pressure difference (mmHg)	Accepted Difference (mmHg)	Pass/Fail
51	51	0	± 3	Pass
150	150	1	± 3	Pass
243	244	1	± 3	Pass

DUT- 2 @ 20C				
Pressure at the Digital Manometer	Wrist Tx Reading (mmHg)	Pressure difference (mmHg)	Accepted Difference (mmHg)	Pass/Fail
51	51	0	± 3	Pass
150	150	1	± 3	Pass
243	244	1	± 3	Pass

DUT- 2 @ 40C				
Pressure at Digital Manometer	Wrist Tx Reading (mmHg)	Pressure difference (mmHg)	Accepted Difference (mmHg)	Pass/Fail
50	50	0	± 3	Pass
149	149	0	± 3	Pass
248	249	1	± 3	Pass

DUT- 3 @ 10C				
Pressure at Digital Manometer	Wrist Tx Reading (mmHg)	Pressure difference (mmHg)	Accepted Difference (mmHg)	Pass/Fail
48	48	0	± 3	Pass
149	149	0	± 3	Pass
248	249	1	± 3	Pass

DUT- 3 @ 20C				
Pressure at Digital Manometer	Wrist Tx Reading (mmHg)	Pressure difference (mmHg)	Accepted Difference (mmHg)	Pass/Fail
48	48	0	± 3	Pass
149	149	0	± 3	Pass
248	249	1	± 3	Pass

DUT- 3 @ 40C				
Pressure at Digital Manometer	Wrist Tx Reading (mmHg)	Pressure difference (mmHg)	Accepted Difference (mmHg)	Pass/Fail
51	50	0	± 3	Pass
150	150	0	± 3	Pass
249	249	0	± 3	Pass

9.2 IEC 80601-2-30, 201.12.1.107, Limits of the change in error of the blood pressure determination:

9.2.1 DUT4:

	CNIBP SYS (mmHg)	CNIBP DIA (mmHg)	CNIBP MAP (mmHg)
TEST 1:	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	118	80	91
	118	80	91
MEAN VALUE	**119.45**	**80.73**	**91.73**
TEST 2:	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
MEAN VALUE	**120.0**	**81.0**	**92.0**

Difference is less than +/-2mmHg, Limit of error is +/-3mmHg; DUT4 PASSED

9.2.2 DUT5:

	CNIBP SYS (mmHg)	CNIBP DIA (mmHg)	CNIBP MAP (mmHg)
Test 1:	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
	120	81	92
MEAN VALUE	**120.0**	**81.0**	**92.0**
Test 2:	118	81	91
	118	81	91
	118	81	91
	118	81	91
	118	81	91
	118	81	91
	118	81	91
	118	81	91
	118	81	91
	118	81	91
MEAN VALUE	**118.0**	**81.0**	**91.0**

Difference is less than +/-2mmHg, Limit of error is +/-3mmHg; DUT5 PASSED

9.2.3 DUT6:

	CNIBP SYS (mmHg)	CNIBP DIA (mmHg)	CNIBP MAP (mmHg)
Test 1:	120	82	92
	120	82	92
	120	82	92
	118	81	91
	118	81	91
	118	81	91

	CNIBP SYS (mmHg)	CNIBP DIA (mmHg)	CNIBP MAP (mmHg)
	118	81	91
	118	81	91
	118	81	91
	118	81	91
MEAN VALUE	**118.86**	**81.43**	**91.43**
Test 2:	120	83	93
	120	83	93
	120	83	93
	120	83	93
	120	83	93
	120	83	93
	120	82	92
	120	82	92
	120	82	92
	120	82	92
MEAN VALUE	**120.0**	**82.55**	**92.55**

Difference is less than +/-2mmHg, Limit of error is +/-3mmHg; DUT6 PASSED

10. CONCLUSIONS

10.1 EN 1060-1 and EN1060-3 REQUIREMENTS

EN 1060-1	REQUIREMENT	Reference	Complies
4 – CUFF	The cuff shall contain a bladder. For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents.	The User Manual 6-000279-00 states the BP cuff is disposable	YES
5 – DISPLAY	The display shall be designed and arranged so that the information including measured values can be read and easily recognized. If abbreviations are used on the display they shall be as follows: “S” or “SYS” for systolic pressure; “D” or “DIA” for diastolic pressure; “M” or “MAP” for mean arterial pressure.	No indication of Systolic or Diastolic is displayed, only the numbers. Display is described in User Manual 6-000279-00.	YES

EN 1060-1	REQUIREMENT	Reference	Complies
6 – UNITS	The blood pressure units shall be indicated in either millimeters of mercury (mmHg) or kilopascals (kPa).	Verified by visual inspection	YES
7 - REQUIREMENTS	EN1060-1 Section 7 describes the device requirements.		
7.1.1 - Limits of the Error of the cuff pressure indication.	At any single condition within the ambient temperature range of 15C to 25C and the relative humidity range of 20% to 85%, both for increasing and decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the scale range shall be +/-3mmHg.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES
7.1.2.1 – Effects of Storage.	The sphygmomanometer shall maintain the requirements specified in this standard after storage for 24 hours at a temperature of -20C and for 24 hours at a temperature of 70C and a relative humidity of 85%.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES
7.1.2.2 – Effect of Temperature	For the ambient temperature range of 10C to 40C and the relative humidity of 85%, the difference of the cuff pressure indication of the sphygmomanometer shall not exceed 3mmHg.	Verified in report R-000227 and re-verified as part of this report.	YES
7.2 - Safety	Electromechanical sphygmomanometers shall comply with EN/IEC 60601-1:1988 as required by section 7.2 of EN 1060-1.	Verified in IEC 60601-1 report R-000099	YES
8 – TEST METHODS	EN1060-1 Section 8 describes the test methods used.		
9 – INFORMATION SUPPLIED BY THE MANUFACTURER	Inspect operators manual and verify compliance.		
9.1 - General	Information supplied must comply with standard EN1041. Symbols must comply with standard EN980. The manufacturer shall state the date of issue or the latest revision of the instructions for use. Inspect operators manual and verify compliance.	Verified in the User Manual 6-000279-00	YES
9.2 – Instruction leaflet	In addition to 9.1 the device the instruction leaflet shall contain the following information: a) Reference to this European standard and the relevant part, including the full title; b) B) Explanation of the operating steps important for correct application (such as the selection of a suitable cuff size, positioning of the cuff and adjustment of the pressure reduction rate);	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES

EN 1060-1	REQUIREMENT	Reference	Complies
	c) C) A warning to users that, if Luer Lock connectors are used in the construction of tubing, there is a possibility that they might get inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel; d) D) Method for cleaning reusable cuffs; e) The name or trade name and address of the manufacturer; f) The name and address of the authorized representative where the manufacturer does not have a registered place of business in the community.		
9.3 – Marking of the device	In addition to 9.1 the device shall be marked with the following information: a) Indication of the correct positioning of the cuff over the artery; b) B) Marking on the cuff indicating the limb circumference for which it is appropriate; c) The name or trade name and address of the manufacturer; d) The name and address of the authorized representative where the manufacturer does not have a registered place of business in the community.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES

EN 1060-3	REQUIREMENT	Reference	Complies
4 - CUFF	Section 4 of EN 1060-1 shall apply.	The User Manual 6-000279-00 states the BP cuff is disposable	YES
5 - DISPLAY	Section 5 of EN 1060-1 shall apply.	No indication of Systolic or Diastolic is displayed, only the numbers. Display is described in User Manual 6-000279-00.	YES
6 - UNITS	Section 6 of EN 1060-1 shall apply.	Verified by visual inspection	YES
7 - REQUIREMENTS	EN1060-3 Section 7 describes the device requirements.		

EN 1060-3	REQUIREMENT	Reference	Complies
7.1 - General	Equipment or parts thereof, using materials or having forms of construction different from those detailed in this part of EN1060, shall be accepted if it can be demonstrated that an equivalent degree of safety and performance is obtained.		
7.2 – Limits of error of the cuff pressure indication	Section 7.1.1 of EN 1060-1 shall apply.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES
7.3 – Effect of voltage variations of the power source variations			
7.3.1 – Internal electrical power source	a) Automated, cyclical measuring NIBP systems in which the cuff pressure is generated by an electrical pump shall comply with 56.7 c of EN60601-2-30:2000 b) Non-cyclical measuring NIBP systems in which the cuff pressure is generated by an electrical pump shall comply with 56.7 c of EN60601-2-30:2000 c) Outside of the working range, no cuff pressure reading and no result of the blood pressure measurement shall be displayed	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES
7.3.2 – External electrical power source	Not Applicable	Not Applicable	
7.4 – Pneumatic System			
7.4.1 – Air Leakage	Air leakage shall not exceed a pressure drop of 6mmHg per minute.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES
7.4.2 – Pressure reducing system for devices using the auscultatory method	Not Applicable – The ViSi system does not use the auscultatory method	Not Applicable	
7.4.3 – Rapid Exhaust	During the rapid exhaust of the pneumatic system with fully opened valve, the time for the pressure reduction from 260mmHg to 15mmHg shall not exceed 10 seconds.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES

EN 1060-3	REQUIREMENT	Reference	Complies
7.4.4 – Zero Setting	Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting a gauge pressure of 0mmHg shall exist and be displayed thereafter.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES
7.5 – Environmental Performance			
7.5.1 - Storage	Blood pressure measuring systems shall maintain the requirements specified in this part of EN 1060 after storage for 24 hours at a temperature of -5C and for 24 hours at a temperature of 50C and a relative humidity of 85%.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES
7.5.2 – Temperature, Relative Humidity	7.1.2.2 of EN1060-1 shall apply	Verified in report R-000227 and retested as part of this report.	YES
7.5.3 – Electromagnetic Compatibility	Verify that the system complies with EN 60601-1-2 as required by section 7.5.3 of EN 1060-3.	Verified in report R-000085 Report, DVER, EMC, H1	YES
7.6 – Stability of the cuff pressure indication	The change of the cuff pressure indication shall not be more that 3mmHg throughout the pressure range after 10,000 stimulated measurement cycles.	Not Verified, See report R-000227 for rationale.	YES
7.7 – Pressure Indicating Device			
7.7.1 – Nominal range and measuring range	The nominal pressure range for the cuff pressure measurement shall be specified by the manufacturer. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range. Values of blood pressure measurement results outside of the nominal range of cuff pressure shall be clearly indicated as out of range.	NIBP verified in report R-000087-001 CNIBP verified in report R-000333; Report, SW Validation, cNIBP	YES
7.7.2 – Digital indication	The numerical step shall be 1mmHg. Numbers shall be clearly legible in accordance with EN 6060101 If the measured value of a parameter is to be indicated on more than one display, all the displays shall indicate the same numeric value. Measured numeric values on the display(s), and the symbols defining the units of measure shall be arranged in such a way so as to avoid misinterpretation.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES

EN 1060-3	REQUIREMENT	Reference	Complies
7.8 – Signal Input and Output Parts	Not Applicable – The ViSi system does not have any signal inputs or output parts.	Not Applicable	
7.9 – Overall System Accuracy	Except for short term automatic mode and devices in which blood pressure is determined manually with the aid of a stethoscope, the following overall system accuracy values shall apply: A) Maximum mean error of measurement: +/-5mmHg B) Maximum experimental standard deviation: +/-8mmHg	NIBP is verified in report R-000068 Report, Pivotal Trial, NIBP cNIBP Verified for compliance with ISO 81060-2; TR# 2012048 Clinimark Report - Accuracy Study of ViSi Noninvasive Blood Pressure Cuff System with ViSi Continuous Noninvasive Blood Pressure Feature in Comparison to Invasive Arterial Blood Pressure	YES
7.10 - Alarms	If alarms are used, they shall be of at least medium priority and shall comply with EN 60601-1-8	NIBP Verified in report R-000189 cNIBP Verified in report R-000333	YES
7.11 - Safety			
7.11.1 – Cuff Pressure	It shall be possible to abort any blood pressure measurement at any time by single key operation and this shall lead to a rapid exhaust.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES
7.11.2 – Unauthorized Access	All controls that affect accuracy shall be sealed against unauthorized access.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES
7.11.3 – Tubing and Connectors	Luer Lock connectors shall not be used.	Luer Lock connectors are not used on the ViSi Mobile	YES
8 – TEST METHODS	EN1060-3 Section 8 describes the test methods used.		

EN 1060-3	REQUIREMENT	Reference	Complies
9 – INFORMATION SUPPLIED BY THE MANUFACTURER			
9.1 - General	Section 9.1 of EN 1060-1 shall apply.	Verified in the User Manual 6-000279-00	YES
9.2 – Instructions for use	EN1060-1 shall apply with the following additions: a) Nature and frequency of maintenance to ensure that the device operates properly and safely at all times; b) A list of all components belong to the pressure measuring device; c) A description of the operating principles of the blood pressure measuring device; d) Remarks on the environmental or operation factors which may affect the performance; e) Specification of the signal input/output port; f) Specification of the rated voltage, if applicable; g) Specification of the intended power source, if applicable; h) Nominal range for the result of the blood pressure measurement; i) Warm-up time, if applicable; j) A description of the meaning “out of range-signal”, if applicable. k) A description of alarms, if applicable.	Verified in the User Manual 6-000279-00	YES
9.3 – Marking of device	Section 9.3 of EN 1060-1 shall apply.	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES

10.2 IEC 80601-2-30 REQUIREMENTS

IEC 80601-2-30	Requirement	Reference	Complies
201.4 – General Requirements	Clause 4 of the general standard shall apply, except as follows:	Verified in IEC 60601-1 report R-000099	YES
201.4.3 – Essential Performance	Additional Sub clause:		
201.4.3.101 – Additional Essential Performance Requirements	Additional performance requirements for an automated sphygmomanometer are found in the sub-clauses listed in Table 201.101	All sub-clauses listed in table 201.101 verified to comply	YES
201.5 – General requirements for testing ME equipment	Clause 5 of the general standard shall apply.	Verified in IEC 60601-1 report R-000099	YES
201.6 – Classification of ME equipment and ME systems	Clause 6 of the general standard shall apply.	Verified in IEC 60601-1 report R-000099	YES
201.7 – ME equipment identification, markings and documents	Clause 7 of the general standard shall apply, except as follows:	Verified in IEC 60601-1 report R-000099	YES
201.7.2 – Marking on the outside of ME equipment of ME equipment parts	Addition: Marking on the outside of ME equipment or ME equipment parts		
201.7.2.4 – Accessories	A cuff shall be marked with an indication of the correct positioning for the cuff on the designated limb over the artery.	Verified by visual inspection	YES
201.7.2.101 – Display of automated sphygmomanometers	If abbreviations are used on the display they shall be as follows: “S” or “SYS” for the Systolic Pressure, “D” or “DIA” for the Diastolic Pressure, “M” or “MAP” for the Mean Arterial Pressure	Abbreviations are not used on the ViSi displays. User Manual 6-000279-00 describes the display.	YES
201.7.2.102 – Automated sphygmomanometers for home healthcare environment	Not Applicable	Not Applicable	
201.7.2.103 – Automated sphygmomanometers with neonatal mode	Not Applicable	Not Applicable	

IEC 80601-2-30	Requirement	Reference	Complies
201.7.2.104 – Automated sphygmomanometers for public use	Not Applicable	Not Applicable	
201.7.2.105 – Component replacement	If a component can be replaced by the operator or service personnel, and if replacement could affect the basic safety or essential performance of the automated sphygmomanometer, the automated sphygmomanometer or the component shall be marked with either a caution to the effect that substitution of a component different from that supplied might result in measurement error or with a safety sign ISO 7010-M002	Cuff is single use, Not Applicable	YES
201.7.2.105 – Disposal	The automated sphygmomanometer and its parts shall be marked with regard to disposal, ass appropriate, in accordance with national or regional regulations.	Cuff is single use and safe for disposal with no additional warnings.	YES
201.7.9.2 – Instructions for use			
201.7.9.2.1 – General	Replacement of the three dashed items: - The use of the automated sphygmomanometer as intended by the manufacturer; and in particular 10 Intended medical indication, 2) Any know restrictions on use or contraindication(s) to the use of the automated sphygmomanometer, 3) Intended patient population, including whether or not the automated sphygmomanometer is intended: - for use with neonatal patients, - for use with pregnant, including pre-eclamptic, patients, 4) Intended placement of the cuff, 5) Intended conditions of use - The frequently used functions The permissible environmental conditions of use, including at least a temperature range of 10C to 40C with a relative humidity range of 15% to 85%.	Verified in the User Manual 6-000279-00	YES

IEC 80601-2-30	Requirement	Reference	Complies
201.7.9.2.2 – Warning and safety notices	Additional following the note: "The instructions for use shall include a warning:" - Regarding the effect of blood flow interference and resulting harmful injury to the patient caused by continuous cuff pressure due to tubing kinking; - Indicating that too frequent measurements can cause injury to the patient due to blood flow interference; - Regarding the application of the cuff over a wound, as this can cause further injury; - Regarding the application of the cuff and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury to the patient; - Regarding the application of the cuff and its pressurization on the arm on the side of a mastectomy; - Regarding the information that pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring ME equipment on the same limb; - Regarding the need to check (for example, by observation of the limb concerned) that operation of the automated sphygmomanometer does not result in prolonged impairment of the circulation of the blood on the patient.	Verified in the User Manual 6-000279-00	YES
201.7.9.2.5 – ME equipment description	Additional, after the third dashed item in the first paragraph: - A description of the operating principles of the automated sphygmomanometer; - Rated ranges of determination.	Verified in the User Manual 6-000279-00	YES

IEC 80601-2-30	Requirement	Reference	Complies
201.7.9.2.9 – Operating instructions	Addition: The instructions for use shall include the following information: a) Adjustment of the selection of a suitably sized cuff and the application of the cuff to the patient; b) An explanation of the operating steps needed to obtain accurate routine resting blood pressure measurements for the condition hypertension including; - Adjustment of the pressure reduction rate, if applicable, - Patient position in normal use including 1) Comfortably seated 2) legs uncrossed 3) Feet flat on the floor 4) Back and arm supported 5) Middle of cuff at the level of the right atrium of the heart - A recommendation that the patient relax as much as possible and not talk during the measurement procedure, - A recommendation that 5 min should elapse before the first reading is taken; - Operator position in normal use, c) An explanation that any blood pressure reading can be affected by the measurement site, the position of the patient (standing, sitting, lying down), exercise, or the patient's physiologic condition; d) Details of what the operator should do if unexpected readings are obtained; e) Details of the environmental or operational factors which can affect the performance of the automated sphygmomanometer and/or its blood pressure reading; f) A statement, if applicable, that the performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity, and altitude. g) If applicable, an explanation of the need to avoid compression or restriction of the connected tubing. h) The rated range of cuff pressure.	Verified in the User Manual 6-000279-00	YES

IEC 80601-2-30	Requirement	Reference	Complies
201.7.9.2.13 – Maintenance	Additional after the second paragraph: If the automated sphygmomanometer is intended to be dismantled by the operator, the instructions for use shall indicate the correct method of reassembly. If the bladder can be incorrectly inserted into the inelastic part of the cuff, the cuff or the instructions for use shall include a detailed description of the correct manner of insertion of the bladder into the inelastic part of the cuff.	Dismantling is not required. Cuff is single use and contains no inner bladder.	YES
201.7.9.2.101 – Compatibility with HF surgical equipment	If the automated sphygmomanometer complies with the requirements of 202.6.2.101, the instructions for use shall include a statement to the effect that this ME equipment is suitable for use in the presence of Electrosurgery. If parts of the pressure transducer or automated sphygmomanometer are provided with protective means against burns to the patient when used with HF surgical equipment, such means shall be drawn to the attention of the operator in the instructions for use. If such means are absent, such parts shall be indentified in the instructions for use.	The ViSi is not intended for use in the presence of HF electro-surgical equipment. Verified in the User Manual 6-000279-00	YES
201.7.9.2.102 – Automated sphygmomanometers for neonatal use	Not Applicable	Not Applicable	
201.8 – Protection against electrical hazards from ME equipment	Clause 8 of the general standard shall apply except as follows:	Verified in IEC 60601-1 report R-000099	YES
201.8.5.5 – Defibrillation-proof applied parts	Additional sub-clause:		
201.8.5.5.101 – Patient connections of automated sphygmomanometers	If applied part of an automated sphygmomanometer has patient connections, it shall be classified as a defibrillation-proof applied part.	Verified in IEC 60601-1 report R-000099 Applied parts verified in report R-000220 Report, EC13 DVER	YES
201.9 – Protection against mechanical hazards of ME equipment and ME systems	Clause 9 of the general standard shall apply	Verified in IEC 60601-1 report R-000099	YES

IEC 80601-2-30	Requirement	Reference	Complies
201.10 – Protection against unwanted and excessive radiation hazards	Clause 10 of the general standard shall apply	Verified in IEC 60601-1 report R-000099	YES
201.11 – Protection against excessive temperatures and other hazards	Clause 11 of the general standard shall apply, except as follows:	Verified in IEC 60601-1 report R-000099	YES
201.11.6.5 – Ingress of water or particulate matter into ME equipment and ME systems	Replacement: Enclosures of an automated sphygmomanometer, intended for use during the patient transport outside of healthcare facility, shall be designed to give IPX2 degree of protection against harmful ingress of water or particulate matter and shall maintain basic safety and essential performance following the tests in IEC 60529:1989 for IPX2	Verified in report R-000090-001 Report, DVER, Fluid Ingress, H1	YES
201.11.8 – Interruption of the power supply/supply mains to ME equipment	Addition:		
201.11.8.101 – Switching off	When the automated sphygmomanometer is switched off by the operator, with the cuff inflated, the cuff shall deflate within 30s to the values indicated in Table 201.102. Neonatal = ≤5mmHg, Any other mode = ≤ 15mmHg	Verified in report R-000227 Report, EN1060-1 and EN1060-3 Compliance	YES

IEC 80601-2-30	Requirement	Reference	Complies
201.11.8.102 – Supply mains	When supply mains to the automated sphygmomanometer are interrupted, the cuff shall deflate within 30s to the values indicated in Table 202.102 and any indication of blood pressure shall be cancelled. When supply mains is restored the automated sphygmomanometer shall: a) Continue in the same operating mode of operation and with all operator settings unchanged, or b) Remain inoperative and, if equipped with short-term automatic mode or long-term automatic mode, be equipped with an alarm system that includes a technical alarm condition that indicates the automated sphygmomanometer is inoperative. An automated sphygmomanometer that automatically switches over to operation from an internal electrical power source and continues to operate normally shall be exempt from these requirements.	Not Applicable, Device is battery operated.	
201.11.8.103 – Internal electrical power source	An automated sphygmomanometer powered from an internal electrical power source shall incorporate the means: - In case of internal electrical power source failure or depletion, which does not allow the automated sphygmomanometer to meet the basic safety and essential performance requirements of this standard 1) For protective shutdown, and 2) For cancelling the indicated blood pressure: - Of determining the state of the power supply.	Verified in report R-000188 Report, DVER, 80601-2-30	YES
201.12 – Accuracy of controls and instruments and protection against hazardous outputs	Clause 12 of the general standard shall apply, except as follows:	Verified in IEC 60601-1 report R-000099	YES
201.12.1 – Accuracy of controls and instruments	Addition:		

IEC 80601-2-30	Requirement	Reference	Complies
201.12.1.101 – Measuring and display ranges	The measuring and display ranges of the cuff pressure shall be equal to the rated range for cuff pressure. Values of blood pressure outside the rated range shall not be displayed and the automated sphygmomanometer shall be equipped with an alarm system that includes a technical alarm condition that indicates when the determined blood pressure is outside of the range.	NIBP verified in R-000087 Report, DVER, NIBP Module, H1 cNIBP verified in report R-000333 Report, SW Validation, cNIBP	YES
201.12.1.102 – Limits of the error of the manometer from environmental conditions	Over the temperature range of 10C to 40C and the relative humidity range of 15% to 85%, the maximum error for the measurement of the cuff pressure at any point of the nominal measurement range shall be less than or equal to +/-3mmHg or 2% of the reading whichever is greater.	Verified in report R-000227 and retested as part of this report.	YES
201.12.1.103 – Nominal blood pressure indication range	The automated sphygmomanometer shall be capable of indicating Diastolic blood pressure over at least the range of 20mmHg to 60mmHg in neonatal mode and 40mmHg to 130mmHg otherwise. The automated sphygmomanometer shall be capable of indicating Systolic blood pressure over at least the range of 40mmHg to 110mmHg in neonatal mode and 60mmHg to 230mmHg otherwise.	NIBP verified in R-000087 Report, DVER, NIBP Module, H1 cNIBP verified in report R-000333 Report, SW Validation, cNIBP	YES
201.12.1.104 – Maximum pressure in normal condition	The maximum pressure obtainable in normal mode shall not exceed 150mmHg for an automated sphygmomanometer in neonatal mode and not exceed 300mmHg otherwise.	Verified in report R-000087 Report, DVER, NIBP Module, H1	YES
201.12.1.105 – Maximum pressure in single fault condition	A protection device shall be provided, functioning independently of the normal pneumatic system control, which in any single fault condition, shall: - Prevent the pressure in the pneumatic system from exceeding the maximum rated value specified in 201.12.1.104 by more than +10% for more than 3s and - Activate if the pressure in the pneumatic system exceeds the maximum rated value specified in 201.12.1.104 for 15s. When activated, the protective device shall deflate the pneumatic system within 30s to < 15mmHg and to < 5mmHg for an automated sphygmomanometer in neonatal mode. An automated sphygmomanometer that only operates in the self measurement automatic mode, where the patient is the operator or the operator is intended to be in continual attendance, and where the pressure can be released from the cuff by the operator is exempt from this requirement.	Verified in report R-000087 Report, DVER, NIBP Module, H1	YES

IEC 80601-2-30	Requirement	Reference	Complies
201.12.1.106 – Manometer test mode	The automated sphygmomanometer shall have a manometer test mode that permits static pressure measurement over at least the nominal blood pressure indication range. This mode shall not be available in normal use, but restricted to service personnel. The technical description shall include a test method that can be used to verify the calibration of the automated sphygmomanometer.	Verified in technical reference manual 6-000147-X7	YES
201.12.1.107 – Limits of the change in error of the blood pressure determination	The laboratory limits of the change in error of the blood pressure determination of the automated sphygmomanometer shall be less than +/-3mmHg	NIBP is verified in R-000087 Report, DVER, NIBP Module, H1 cNIBP is verified in this report	YES
201.12.3 – Alarm systems	Addition:		
201.12.3.101 – Alarm systems	If an automated sphygmomanometer has an alarm system that includes physiological alarm conditions, it shall have both a physiological alarm condition for low blood pressure and a physiological alarm condition for high blood pressure of at least medium priority. These alarm conditions may be for systolic blood pressure, diastolic blood pressure, or mean arterial pressure.	Verified in report R-000333 Report, SW Validation, cNIBP	YES
201.13 – Hazardous situations and fault conditions	Clause 13 of the general standard shall apply	Verified in IEC 60601-1 report R-000099	YES
201.14 – Programmable electrical medical systems	Clause 14 of the general standard shall apply	Verified in IEC 60601-1 report R-000099	YES
201.15 – Construction of ME equipment	Clause 15 of the general standard shall apply, except as follows:	Verified in IEC 60601-1 report R-000099	YES
201.15.3.5 – Rough handling test	Addition:		

IEC 80601-2-30	Requirement	Reference	Complies
201.15.3.5.101 – Shock and vibration for other than transport	An automated sphygmomanometer or its parts not intended for use during patient transport outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping, and rough handling. A fixed automated sphygmomanometer is exempt from the requirements of this sub clause. After the following tests, the automated sphygmomanometer shall not cause an unacceptable risk and shall function normally. a) Shock test in accordance with IEC60068-2-27:2008 using the conditions of test type 1 or 2: 1) Test Type: Type 1: - Peak acceleration: 100m/s2 (15g); - Duration: 11mS; - Pulse shape: half-sine; - Number of shocks: 3 shocks per direction per axis (18 total) 2) Test Type: Type 2: - Peak acceleration: 300m/s2 (30g); - Duration: 6 mS; - Pulse shape: half-sine; - Number of shocks: 3 shocks per direction per axis (18 total) For a held-held automated sphygmomanometer, the requirements in 15.3.4.1 of the general standard may be substituted for this requirement. b) Broad-band random vibration according to IEC60068-2-64:2008 using the following conditions: 1) Acceleration amplitude: - 10Hs to 100Hz:1.0m/s2)2/Hz; - 100Hz to 200Hz: -3db/octave; - 200Hz to 2000Hz: 0.5 (m/s2)2/Hz 2) Duration: 30 min per each perpendicular axis (3 total)	Verified in report R-000086-002 Report, DVER, Environmental, H1	YES
201.15.3.5.102 – Shock and vibration for transport	Not Applicable	Not Applicable	
201.16 – ME systems	Clause 16 of the general standard shall apply	Verified in IEC 60601-1 report R-000099	YES

IEC 80601-2-30	Requirement	Reference	Complies
201.17 – Electromagnetic compatibility of ME equipment and ME systems	Clause 17 of the general standard shall apply with additional note: An automated sphygmomanometer is not considered life-supporting ME equipment or ME system as defined in IEC 601-1-2.	Verified in R-000085 Report, DVER, EMC, H1	YES
Additional Clauses			
201.101 – Requirements for cuffs	Addition:		
201.101.1 – Construction	The cuff shall contain or incorporate a bladder. The cuff shall be constructed such that when the cuff is applied to a limb, the construction ensures that the cuff is the correct size or the cuff shall be marked with an indication of the range of limb circumference for which the cuff is appropriate.	Verified in report R-000231 Report, Disposable Cuff, HRS DVER	YES
201.101.2 – Pressurization	The cuff and bladder and connection tubing shall be capable of withstanding an internal pressure equal to 180mmHg for an automated sphygmomanometer in neonatal mode and equal to 360mmHg otherwise. The bladder shall be completely retained in the cuff during this pressurization.	Verified in report R-000087 Report, DVER, NIBP Module, H1	YES
201.102 – Connection tubing and cuff connectors	The connections between the automated sphygmomanometer, cuff, and connection tubing shall not be equipped with a connector that couples with a connector complying with ISO 594-1 or ISO 594-2	ViSi uses a unique cuff air attachment to the NIBP module.	YES
201.103 – Unauthorized access	To prevent tampering or unauthorized access, means shall be provided to restrict access to the responsible organization, for all controls, including those for PEMS, which can affect the accuracy of the automated sphygmomanometer.	ViSi utilizes mode plugs to prevent unauthorized access	YES
201.104 – Maximum inflating time	In normal condition in any automatic cycling mode of operation, a pressure relief protection device shall ensure that the cuff shall not inflate above the values in Table 201.103 for more than 90s for an automated sphygmomanometer in neonatal mode, and otherwise for more than 180s. In single fault condition, a pressure relief protection device, functioning independently of the normal condition protection device, shall ensure that the cuff shall not inflate above the values in Table 201.103 for more than 90s for an automated sphygmomanometer in neonatal mode, and otherwise for more than 180s. Neonatal mode: > 5mmHg Any other mode: > 15mmHg	Verified in report R-000087-001 Report, DVER, NIBP Module, H1	YES

IEC 80601-2-30	Requirement	Reference	Complies
201.105 – Automatic cycling modes	Addition:		
201.105.1 – Long term automatic mode	If an automated sphygmomanometer is equipped with a long-term automatic mode, a protection device shall be provided to ensure that: a) In normal condition either: - The total duration of the alternating inflation/deflation periods in an unsuccessful determination shall not exceed the maximum inflation time specified in 201.104; or - After each successful determination; the cuff pressure shall be released and shall remain below the values in Table 201.102 for at least 30s; and b) In single fault condition: c) If the duration of deflation below the values in Table 201.102 is less than 30s, then a pressure relief protection device functioning independently of the normal condition protection device, shall release the cuff pressure to the values in Table 201.102.	Verified in report R-000087-001 Report, DVER, NIBP Module, H1	YES
201.105.2 – Short term automatic mode	If a short term automatic mode is available, a protection device shall be provided to: - Ensure that following each individual determination, the pressure in the cuff shall be reduced to the values indicated in Table 201.102 for at least 2s, to allow venous return, and - Restrict the duration of the short-term automatic mode to a maximum of 15 min. At the end of this time, the automated sphygmomanometer shall revert to the long-term automatic mode or a manual mode. A further period of the short-term automatic mode may be selected by a deliberate action of the operator.	Verified in report R-000087-001 Report, DVER, NIBP Module, H1	YES
201.105.3 – Self measurement automatic mode	Addition:		
201.105.3.1 – General	Not Applicable, ViSi has no self measurement automatic modes	Not Applicable	
201.105.3.2 – Normal condition	Not Applicable, ViSi has no self measurement automatic modes	Not Applicable	
201.105.3.3 – Single fault condition	Not Applicable, ViSi has no self measurement automatic modes	Not Applicable	

IEC 80601-2-30	Requirement	Reference	Complies
201.106 – Clinical Accuracy	Except for the short-term automatic mode, each clinical operating mode of an automated sphygmomanometer shall comply with ISO 81060-2, which contains the requirements for clinical accuracy and the protocols for validating the clinical accuracy.	NIBP is verified in report R-000068 Report, Pivotal Trial, NIBP cNIBP Verified for compliance with ISO 81060-2; TR# 2012048 Clinimark Report - Accuracy Study of ViSi Noninvasive Blood Pressure Cuff System with ViSi Continuous Noninvasive Blood Pressure Feature in Comparison to Invasive Arterial Blood Pressure	YES
202 – Electromagnetic compatibility – Requirements and Tests	Verify compliance with IEC 60601-1-2, except as follows:	Verified in R-000085 Report, DVER, EMC, H1	YES
202.4 – General requirements	Addition:		
202.4.101 – Classification	An automated sphygmomanometer shall not be considered life-supporting ME equipment or ME system	The ViSi is not considered as life-supporting equipment	YES
202.6.2 - Immunity	Addition:		
202.6.2.1.10 – Compliance criteria	Under the test conditions specified in IEC 60601-1-2:2007, 6.2, the ME equipment or ME system shall be able to provide the basic safety and essential performance. Under these conditions, the maximum change of the reading for the measurement of the cuff pressure at any point of the nominal measurement ranges shall be less than or equal to 2mmHg.	Verified in R-000085 Report, DVER, EMC, H1	YES

IEC 80601-2-30	Requirement	Reference	Complies
202.6.2.3.1 – Requirements	An automated sphygmomanometer, except as specified in c) below or in the inclusion band as specified in d) below, shall comply with the requirements of IEC 60601-1-2:2007, 6.2.1.10, at an immunity test level of 3V/m over the frequency range of 80MHz to 2.5GHz. In addition, an automated sphygmomanometer intended for use during patient transport outside of the healthcare facility, except as specified in c) below or in the inclusion band as specified in d) below, shall comply with the requirements of IEC 60601-1-2:2007, 6.2.1.10, at an immunity test level of 20V/m (80% modulation at 1000Hz) over the frequency range of 80MHz to 2.5GHz.	Verified in R-000085 Report, DVER, EMC, H1	YES
202.6.2.101 – Electrosurgery interference recovery	If an automated sphygmomanometer is intended for use with HF surgical equipment, it shall return to the previous operating mode within 10s after exposure to the field produced by the HF surgical equipment, without loss of any stored data.	The ViSi is not intended for use in the presence of HF surgical equipment	YES

Accuracy Study of ViSi Noninvasive Blood Pressure Cuff System with ViSi Continuous Noninvasive Blood Pressure Feature in Comparison to Invasive Arterial Blood Pressure

March 13, 2013

Research Device	• **ViSi Noninvasive Blood Pressure System Model # 92-10010 (NIBP) including 5 cuff sizes** **with** • **ViSi Continuous Noninvasive Blood Pressure Feature (cNIBP)**
Sponsor	**Sotera Wireless**
Sponsor's Representative	**Jim Welch, VP Quality System, Regulatory and Clinical Affairs.**
Clinical Plan Investigation Identification/ Protocol Number	**PR 2012-048 SOTERA VISI System Continuous Non-Invasive Blood Pressure Accuracy Validation - Rev 3**
ISO 14155:2011 **ISO 81060-2:2009**	**The investigation was performed in accordance with ISO 14155:2011** **and 81060-2:2009**
Author of Report	**Paul Batchelder, LRCP, RRT**

Confidentiality Statement

The information contained in this document is confidential and, except to the extent necessary to obtain informed consent or EC approval, cannot be disclosed unless required by governmental regulation. Persons to whom any portion of the contents of this document is disclosed must be informed that the information is confidential and may not further be disclosed by them.

Document Author: Document revision in accordance with ISO 14155

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Principal Investigator	Dave Ransom	David M. Ransom MD.	3/13/2013

Revision History

Document revision in accordance with ISO 14155:2011

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1	03/06/2013	P. Batchelder	Initial Draft
2	03/07/2013	P. Batchelder	Technical edits
3	03/08/2013	P. Batchelder	Data Addition
4	03/11/2013	P. Batchelder	Full Report for Review
5	03/12/2013	P. Batchelder	Full Report Review Edits
6	03/12/2013	P. Batchelder	Final Report
7	03/13/2013	P. Batchelder	Update Appendix C with ROV

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Accuracy Study of ViSi Noninvasive Blood Pressure Cuff System with ViSi Continuous Noninvasive Blood Pressure Feature in Comparison to Invasive Arterial Blood Pressure

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Final Test Report For Sotera Wireless, TR# 2012048
Accuracy Study of ViSi Noninvasive Blood Pressure Cuff System
with
ViSi Continuous Noninvasive Blood Pressure Feature
in Comparison to Invasive Arterial Blood Pressure

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[1] GARDNER, R.M., Direct blood pressure measurement — Dynamic response requirements, Anaesthesiology, 54, pp. 227-236, 1981

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Appendix C - Line Listing of NIBP (Cuff Based) Data

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Appendix D - Line Listing of Unused NIBP (Cuff Based) Data

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Appendix E - Line Listing of cNIBP (Continuous BP)Data

Due to the volume of data, contents of this Appendix are contained in a separate CD which has been supplied with this report.

File name : Appendix E CNIBP Line Listing.xls

Appendix F - Line listing of Reference BP Removed Data Points

Due to the volume of data, contents of this Appendix are contained in a separate CD which has been supplied with this report.

File name: Appendix F Removed Data Listing.xls

Appendix G Protocol

FILENAME: PR 2012-048 SOTERA VISI System Continuous Non-Invasive Blood Pressure Accuracy Validation - Rev 3

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Document Approver: The document approvers are listed below:

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Sotera Sponsor Representative	Eben Gordon	Eben Gordon	10/21/12

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Version 2	August 1, 2012	Sotera Modifications – Final Version
Version 3	October 21, 2012	Final Accuracy Protocol

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[3] International Standards Organization ISO81060-2: Non-invasive Sphygmomanometers – Part 2: Clinical validation of automated measurement type

[4] GARDNER, R.M., Direct blood pressure measurement — Dynamic response requirements, Anaesthesiology, 54, pp. 227-236, 1981

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TITLE:	**ViSi System Human Factors, cNIBP Feature**				
Owner	Engineering	CO #	01814	Release Date:	15 February 2013

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Document Tracking

The following table tracks the modifications made to the document since the initial creation.

Version	Modified By	Comments
X	Caroline M DiBattista	Initial Creation.

1.0 Document Overview

1.1 Purpose

The purpose of this Human Factors study is to validate that the cNIBP feature in the ViSi Mobile Monitoring System ("ViSi System") has been implemented by an engineering process that can prevent or minimize the effects of use errors.

1.2 Scope

1.2.1 Previous Human Factors Activities

Previous Human Factors activities were conducted in support of the ViSi System development in accordance with the principles of IEC 62366, Medical devices - Applications of usability engineering to medical devices and IEC 60601-1-6, Medical electrical equipment – General requirements: Usability. The process involved the identification of both anticipated and unanticipated use-related hazards (derived through formative evaluations) and the determination of how such hazards might occur. Strategies were developed and applied to mitigate or control use-related hazards. Finally safe and effective device use was demonstrated through human factors validation testing.

The Use Error analysis was evaluated for the likelihood of usability or safety problems given the design of the device-user interface. The analysis included consideration for use errors with other monitoring devices, reasonably foreseeable misuse, characteristics of the device use environment, user capabilities, limits, and predispositions, and established human factors principles for good design. Risks identified during the Use Error Analysis are incorporated into the Risk Management Report.

Twenty (20) registered nurses were presented with a series of written questions and physical tasks designed to evaluate the usability of the ViSi System. Proctors administered the test in a one-on-one setting with one test proctor and one clinical user.

The ViSi System was shown to be safe when used by the intended clinical user by demonstrating that issues identified in the Risk Analysis and MMEA have been effectively dealt with. The ViSi System passed the human factors study with the results documented in R-000067, *Human Factors Summative Validation, ViSi Mobile Monitoring System, H1*.

1.2.2 Present Study

The present study will demonstrate the effective implementation of the cNIBP feature into the ViSi System. Criteria for inclusion of items from the Risk Analysis are mitigations that specifically address hazards relating to the use of the cNIBP feature are as follows:

a. All Use Error / Misuse Modes with an "Initial Risk of Intolerable" (I) will be tested for mitigation effectiveness.

b. Items with an Initial Severity of ≥ 3 combined with an "Initial Risk of ALARP" that is mitigated through labeling will be tested for mitigation effectiveness.

Criteria for inclusion are items derived from the Usability Specification which are expected interactions by a typical user which are required to:

a. Initiate the cNIBP reading

b. Re-calibrate cNIBP

The list of step descriptions (risks) and clinical tasks (device interactions), with rationale for inclusion based on the above criteria, is contained in *Appendix A – Required Items for Human Factors Testing* of this document.

1.3 Protocol Overview

This protocol will require answers to questions and completion of scenarios that are designed to evaluate clinical usability of the cNIBP feature. Intended clinical users will be presented with written questions and tasks that are designed to evaluate usability of the feature.

The intended clinical users will be provided with the ViSi System and all appropriate user documentation. They will be asked to review the appropriate documentation after which the Proctor will ask the clinical user to answer a set of questions and complete tasks using the device.

The Proctor will observe the clinical user, record the time to completion of each task and score accuracy of task completion during the test. A test summation report will include an evaluation of results and provide a pass/fail determination.

1.4 References

Ref.	Document Title	Document #
R1	Misuse Modes Effect Analysis, H1	0-000019 J or New #?
R2	H1 Systems Hazard Analysis, cNIBP	0-000959 Rev. A
R4	ViSi Mobile Monitoring System – User Manual	6-000212-01
R5	IEC Standard: General Requirements for Safety – Collateral Standard: Usability	IEC 60601-1-6
R6	Medical devices - Applications of usability engineering to medical devices	IEC 62366
R7	Human Factors Engineering – Design of Medical Devices,	ANSI/AAMI HE75
R8	Human Factors Summative Validation, ViSi Mobile Monitoring System, H1	R-000067 Rev. A
R9	Usability Specification, H1 (ViSi System) 1a, 1b	0-000380 Rev. B

1.5 Terms and Definitions

Term	Definition
Participant	Intended clinical user. Qualified healthcare professional; primarily registered nurses.
Proctor	The Proctor will administer the test and observe, time and score successful completion of tasks during the test. The Proctor will be familiar with the operation of the device under testing, including all appropriate documentation.
cNIBP	Continuous non-invasive blood pressure.
User Manual	Provides the instructions under which the clinician can use the device safely and for its intended purpose. It describes the conditions that should be managed during normal use to maintain the safety and effectiveness of the device.

1.6 Documentation

Test results shall be recorded *Appendix D – Proctor/Evaluator Forms*.

Participant demographic information will be provided in *Appendix E – Participant Demographics Form*, which will be attached to the above mentioned forms.

Upon completion of the protocol by participants, a test summary report shall be generated. Completed evaluation forms shall be attached to the test summary report and released into the controlled Sotera documentation system.

2.0 Test Protocol

2.1 User Profile

The vast majority of intended users of the ViSi Mobile Monitoring System are Registered Nurses who are familiar with physiological monitoring.

2.2 Usability Test Participants

Industry guidance recommends that usability test participants should be representative of the most likely users for the product. The test population will be selected to encompass those users who are likely to use the device. Participants will be chosen from a pool of registered nurses who work in an acute care facility.

2.3 Sample Size Rationale

The sample size of clinical users who will be tested is 15. Per ANSI/AAMI HE75:2009 Human Factors Engineering – Design of Medical Devices, "For later stage summative usability testing, larger sample sizes are recommended to allow meaningful statistical evaluation of acceptance criteria." ". . . summative testing may be done with as few as 15-20 participants per distinct user group to demonstrate with 95% confidence that at least 90% of participants could successfully complete the task. For example, if the objective is that at least 90% of participants be able to complete a task the first time with no instructions, then using a sample size of 15 the usability test would be considered acceptable if 3 or fewer participants do not complete the task successfully".

In consideration of the above guidelines, a minimum 90% success is an acceptable usability metric for the purpose of this test, so testing a minimum of 15 participants is sufficient. As explained previously, the representative participant sample will be considered a homogenous user group for the purpose of this usability test because they will use and interact with the device in the same way with regard to the features to be tested. Participants to be recruited will be familiar with patient monitoring.

2.4 Test Environment

The test environment will include a table with a ViSi System, a set of ViSi Patient Kits, protocol forms, and the section from the ViSi System User Manual that focuses on cNIBP calibration and measurements. The table will be next to a volunteer that will stand in for a patient (so the monitor can be attached to a "patient" as intended). The Proctor may sit (or stand) near the participant in a position that will allow them to watch the participant and the ViSi Mobile Monitor screen without distracting the participant.

2.5 Test Equipment

The equipment listed below will be required for this test protocol.

- ViSi System
- ViSi Mobile Patient Kit
- ViSi Mobile Monitoring System User Manual

2.6 Items under Evaluation

The items listed below will be under evaluation:

- ViSi System – cNIBP feature only
- ViSi Mobile Monitoring System User Manual (Part # 6-000212-04)

2.7 Proctor (Evaluator) Instructions

2.7.1 Setup

The Proctor will arrange the test space to contain a ViSi System (with all cables and sensors), patient kit, and user documentation. A human volunteer will be seated next to a table wearing an operating ViSi System Monitor, Cuff Module, Chest Sensor, and Thumb Sensor. The test space will be arranged with adequate working space (approximately 2 feet) for the participant to interact with the device. The ViSi System will be used and observed at or less than arm's length (<32 inches). The human volunteer will act as the 'patient'.

2.7.2 Getting Started

When the participant arrives, the evaluator will begin by asking the participant to complete the participant background form (*Appendix E*). When the form has been completed, the evaluator will then allow 10 minutes for the participant to review the user documentation and familiarize themselves with the device and the User Manual. The evaluator will then proceed to administer the study by following the Proctor forms located in *Appendix B – Test Scripts*.

2.7.3 Data Collection

The proctor will record all the data required by the proctor forms (*Appendix D*) for each scenario and make notes when they believe necessary. The proctor will not interact with the participant while the participant is working to complete the tasks. However, if the participant misunderstands the question or task, the proctor may explain the question or task. If the participant provides an inaccurate response the proctor will record the actions and steps that were taken by the participant. Periods of time that reference material is referred to will not be included in task completion time. The time to completion of a task will be measured from end of use

of reference material (reading User Manual, etc.) to completion of task. Completion of the last scenario, the proctor will confirm that all forms have been completed and all items have been checked or filled in.

3.0 Acceptance Criteria

Acceptance criteria are defined in terms of the percentage of test participants that must pass the specific test scenario questions in order for the ViSi System and the user manual to be considered to have passed the protocol. Correct answers for questions are based on the User Manual and are listed in *Appendix C – Question Answer Key*.

Accuracy of usability task completion is based on the User Manual. The Proctor will time and score accuracy of usability task completion during the test. If any task is not fully completed that task will be considered to not be completed for that test subject and will receive a score of "fail."

3.1 Time Constraints

The participant must give the correct answer for each question and must complete tasks correctly within the required time. Completion time for each usability task is based on task completion times as generally described in the literature[1][2][3][4].

3.2 Required Pass Rate

The required pass rate for Usability Specification derived questions and tasks is 90%. Required pass rate is documented in *Appendix F – Required Pass rate*

[1] Weinger, Matthew B. M.D.; Herndon, Oliver W. B.S.; Zornow, Mark H. M.D.An Objective Methodology for Task Analysis and Workload Assessment in Anesthesia Providers. Anesthesiology; January 1994 - Volume 80 - Issue 1

[2] Italian Multicenter Group of ICU Research. Time oriented score system (TOSS): a method for direct and quantitative assessment of nursing workload for ICU patients. Intensive Care Med (1991) 17:340-345

[3] M.Vitacca, E. Clini, R.Porta. Preliminary results on nursing work load in a dedicated weaning center; Intensive Care Med (2000) 26: 796±799

[4] Anita L. Tucker, Steven J. Spear. Operational Failures and Interruptions in Hospital Nursing; HSR: Health Services Research 41:3, Part I (June 2006), Health Research and Educational Trust DOI: 10.1111/j.1475-6773.2006.00502 x

Appendix A – Required Items for Human Factors Testing

Risk Analysis and MMEA

- There are no Use Error / Misuse Modes with an "Initial Risk of Intolerable" (I).
- There are no items with an Initial Severity of ≥ 3 combined with an "Initial Risk of ALARP" that is mitigated through labeling.

Usability Specification

The table below includes a list of cNIBP features derived from the Usability Specification that were determined to require inclusion in the study.

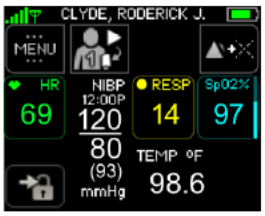
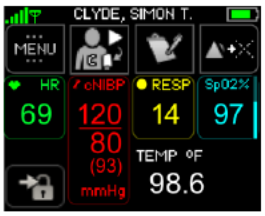
Task #	Document	Function	Task Description	Time to Complete
1	0-000380	Monitor cNIBP	Initiate cNIBP Reading	< 3 min.
2	0-000380	Monitor cNIBP	Recalibrate cNIBP reading	< 3 min.

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: _____ **Date:** _____

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading.  *Image 1*  *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Participant Form: Tasks

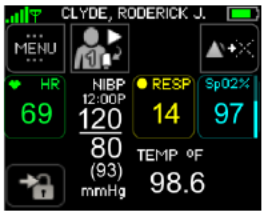
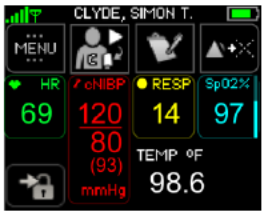
Participant Form: Tasks

Clinician: _____ **Date:** _____

Initial Setup:
- Chest sensor and thumb sensor are connected to the ViSi Mobile Monitor and monitoring is in progress.
- The Vital Signs screen is displayed.

Task #	Scenario	Task Description	User Manual Page #
4.	You want to calibrate NIBP for continuous readings.	a. Connect the Cuff Module to the ViSi Mobile Monitor b. Press the "Calibrate cNIBP" button. c. Disconnect the Cuff Module.	79
5.	A vasoactive drug has been administered. Perform a recalibration.	a. Place the cuff on the patient and connect the Cuff Module to the ViSi Mobile Monitor b. Press the "Calibrate cNIBP" button.	80

Appendix C – Question Answer Key

Question #	Question	Answer
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	 *Spot Check*  *Continuous*
2	Do you need to recalibrate cNIBP? Yes No	Yes
3	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions		
Proctor: Caroline M DiBattista **Clinician:** _____ **Date:** _____		
Question #	**Question**	**Notes / Proctor Observations** (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	
2	Do you need to recalibrate cNIBP? Yes No	
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks				
Proctor: Caroline M DiBattista **Clinician:** _____ **Date:** _____				
Task #	**Description**	**Time to Completion**	**Completed Successfully Y/N**	**Notes / Proctor Observations** (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___	❒ YES ❒ NO	
5	Recalibrate cNIBP	Min: ___ Sec: ___	❒ YES ❒ NO	

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	
Participant's Name:	
Medical Qualifications:	
Hospital Area:	
Years of Experience: *(with physiological monitoring)*	

Appendix F – Required Pass Rate

The required pass rate for Usability Specification derived questions and tasks is 90%.

Question/Task #	Required Pass Rate	# Required Correct Responses
1	90%	13
2	90%	13
3	90%	13
4	90%	13
5	90%	13

Document Type:	**Design Validation Test Report**				
Owner:	Engineering	Supersedes:	N/A	Release Date:	1 MARCH 2013
Document Control Approval:					

Approver Name	Approver Signatures
Caroline DiBattista Author/ Engineering	
Eben Gordon Regulatory Affairs	
Jim Welch Quality Assurance	
Gary Manning Sales	
Jim Moon CTO	

Revision	Date	Change Summary
A	3/1/2013	New release

1. Purpose

The purpose of this Human Factors study is to validate that the cNIBP feature in the ViSi Mobile Monitoring System ("ViSi System") has been implemented by an engineering process that can prevent or minimize the effects of use errors.

2. Scope

2.1. Previous Human Factors activities were conducted in support of the ViSi System development in accordance with the principles of IEC 62366, Medical devices - Applications of usability engineering to medical devices and IEC 60601-1-6, Medical electrical equipment – General requirements: Usability. The process involved the identification of both anticipated and unanticipated use-related hazards (derived through formative evaluations) and the determination of how such hazards might occur. Strategies were developed and applied to mitigate or control use-related hazards. Finally safe and effective device use was demonstrated through human factors validation testing.

The Use Error analysis was evaluated for the likelihood of usability or safety problems given the design of the device-user interface. The analysis included consideration for use errors with other monitoring devices, reasonably foreseeable misuse, characteristics of the device use environment, user capabilities, limits, and predispositions, and established human factors principles for good design. Risks identified during the Use Error Analysis are incorporated into the Risk Management Report.

Twenty (20) registered nurses were presented with a series of written questions and physical tasks designed to evaluate the usability of the ViSi System. Proctors administered the test in a one-on-one setting with one test proctor and one clinical user.

The ViSi System was shown to be safe when used by the intended clinical user by demonstrating that issues identified in the Risk Analysis and MMEA have been effectively dealt with. The ViSi System passed the human factors study with the results documented in R-000067, *Human Factors Summative Validation, ViSi Mobile Monitoring System, H1*.

2.2. This protocol will require answers to questions and completion of scenarios that are designed to evaluate clinical usability of the cNIBP feature. Intended clinical users will be presented with written questions and tasks that are designed to evaluate usability of the feature.

The intended clinical users will be provided with the ViSi System and all appropriate user documentation. They will be asked to review the appropriate documentation after which the Proctor will ask the clinical user to answer a set of questions and complete tasks using the device.

The Proctor will observe the clinical user, record the time to completion of each task and score accuracy of task completion during the test. A test summation report will include an evaluation of results and provide a pass/fail determination.

3. Executive Summary

The Human Factors study using fifteen clinical participants validated that the cNIBP feature of the ViSi System was implemented in a manner that strongly suggests there will be minimal potential for use error.

4. References

4.1. 0-001000 Rev. A – ViSi System Human Factors, cNIBP Feature Test Protocol

4.2. 6-000212-01 - ViSi Mobile Monitoring System – User Manual

4.3. IEC 62366 Medical devices -- Application of usability engineering to medical devices

5. Test Method

5.1. The study was conducted per 0-001000, Rev. A, *ViSi System Human Factors, cNIBP Feature* Test Protocol

5.2. Questions and Tasks:

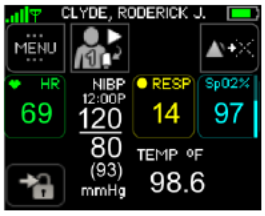
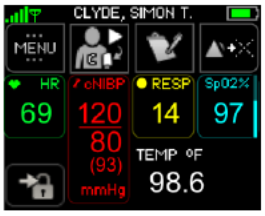
#	Scenario	Question
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading.  *Image 1*  *Image 2*	What type of NIBP reading is image 1? a. Spot-Check (1-Time) b. Continuous What type of NIBP reading is image 2? a. Spot-Check (1-Time) b. Continuous
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? a. Yes b. No
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.

Table 1: Test Questions

#	Scenario	Task Description
4.	You want to calibrate NIBP for continuous readings.	a. Connect the Cuff Module to the ViSi Mobile Monitor b. Press the "Calibrate cNIBP" button. c. Disconnect the Cuff Module.
5.	A vasoactive drug has been administered. Perform a recalibration.	a. Place the cuff on the patient and connect the Cuff Module to the ViSi Mobile Monitor b. Press the "Calibrate cNIBP" button.

Table 2: Test Questions

6. Deviations from Protocol

6.1. The Time to complete was recorded for all tasks rather than the individual tasks.

6.2. The protocol specified a time limit for each manual task of less than 3 minutes. This did not take into consideration the time required to do a retry when the initial cuff inflation failed due to a motion artifact. When performing a "retry", the PWD may take up to 60 seconds to complete the second cuff inflation. As a result of this, 4 participants exceeded the 6 minute criteria.

7. Results

7.1. Testing was conducted at St. Joseph Mercy Oakland, 44405 Woodward Avenue, Pontiac, MI in accordance with protocol 0-001000 on February 13, 2013.

7.2. The tabulation of each individual participant test results can be found in Appendix A. Individual Participant Results can be found in Tables 2-4.

7.3. Participant demographics

	Qualification	Experience (years)	Hospital area
1	RN	25	CCU
2	RN, MSN, MSA	42	3G, Cardiac/Med/Surgery
3	RN	8	3G, Cardiac/Med/Surgery
4	RN, Clinical leader	27	3G, Cardiac/Med/Surgery
5	RN, BSN	25	Not specified
6	RN	3.5	3G, Cardiac/Med/Surgery
7	PA-C	15	Cardiology
8	RN, BSN	7	2G, Surgical
9	MD	13	Family medicine
10	RN	25	Case manager
11	RN, BSN	26	NICU

	Qualification	Experience (years)	Hospital area
12	RN	15	Case management
13	RN, BSN	21	Cardiac Cath Lab
14	RN, BSN	22	Not specified
15	RN	3.5	3G, Cardiology

Table 3: Patient Demographics

7.4. Results Summary

#	Questions			Tasks		Explanation
	1	2	3	4	5	
1	Pass	Pass	Pass	Pass	Pass	
2	Pass	Pass	Pass	Pass	Pass	
3	Pass	Pass	Pass	Pass	Pass	
4	Pass	Pass	Pass	Pass	Pass	
5	Pass	Pass	Pass	Fail	Pass	Delay in enabling of activation button caused confusion.
6	Pass	Pass	Pass	Pass	Pass	
7	Pass	Pass	Pass	Pass	Pass	
8	Pass	Pass	Pass	Pass	Pass	
9	Pass	Pass	Pass	Pass	Pass	
10	Pass	Pass	Pass	Pass	Pass	
11	Pass	Pass	Pass	Pass	Pass	
12	Pass	Pass	Pass	Pass	Pass	
13	Pass	Pass	Pass	Pass	Pass	
14	Pass	Pass	Pass	Pass	Pass	
15	Pass	Pass	Pass	Pass	Pass	

Table 4: Results Summary

7.5. Overall Results

Results for each question or task were combined (across all participants for that question or task) and an overall Pass/Fail determination was made for each question or task. The required percentage of clinical participants answered each question correctly and completed each task correctly.

Question/Task #	Required Pass Rate	Number Correct	Number Incorrect	Conclusion
1	90%	15	0	Pass (100%)
2	90%	15	0	Pass (100%)
3	90%	15	0	Pass (100%)
4	90%	14	1	Pass (93%)
5	90%	15	0	Pass (100%)

Table 5: Overall Results

8. Discussion

8.1. All questions and tasks were answered correctly by the required percentage of clinical participants.

8.2. Clinical Participant #5 missed Task #4. Task #4 required the user to perform a calibration by depressing the cNIBP button. Since there is a delay in the enabling of the button, the user became confused and began depressing other buttons. After the button became enabled, the clinician pressed the calibration button correctly but then pressed the "Stop Calibration" button. The user error does not result in a hazard to the patient.

9. Conclusion

This Human Factors study validated that the ViSi System's cNIBP feature was implemented in a satisfactory manner in which strongly suggests the feature can be used with minimal potential for use errors.

10. Appendices

10.1. Appendix 1 - ViSi Mobile Monitoring System User Manual (Part # 6-000212-04), Calibrate cNIBP section only.

10.2. Appendix 2 – Completed Patient Demographics, Test Scripts, and Proctor/Evaluator Forms for each Clinical Participant

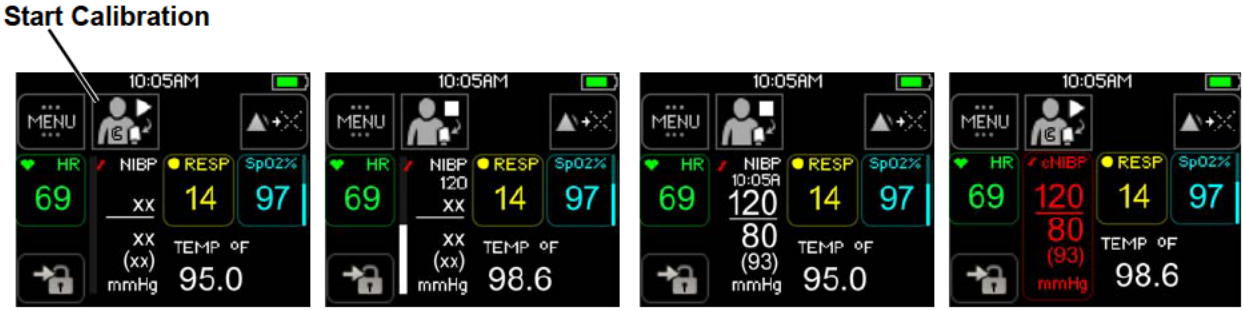
5.2.8 Continuous NIBP Monitoring

Sotera's continuous blood pressure monitor (cNIBP) is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed based on averaging PAT calculations from the previous 30 seconds and updating the display every three seconds. The ViSi Mobile Monitor is able to continuously measure NIBP without further cuff inflations.

The accuracy of cNIBP is dependent on the initial cuff calibration. Use good clinical practice to confirm cNIBP accuracy before initiating or treating a patient.

Note: Continuous NIBP monitoring is an optional feature that requires an additional license key.

To calibrate cNIBP



Chest Sensor, Thumb Sensor and Cuff Module connected | NIBP Reading In Progress | Spot-Check Reading | cNIBP Calibrated

1. Connect the ViSi Mobile Chest Sensor, Thumb Sensor and Cuff Module and navigate to the **Vitals Signs** screen.

   The Start Cuff button *will change to the Calibrate cNIBP button.*

2. Touch **Calibrate cNIBP** on the **Vital Signs** screen.

   The Cuff will start to infl ate, indicating the calib ration process has started. After a single NIBP measurement has been t aken, t he V iSi Mobile Monitor will calibrate cNIB P. The NIBP measurement will be displayed in white during the calibration process.

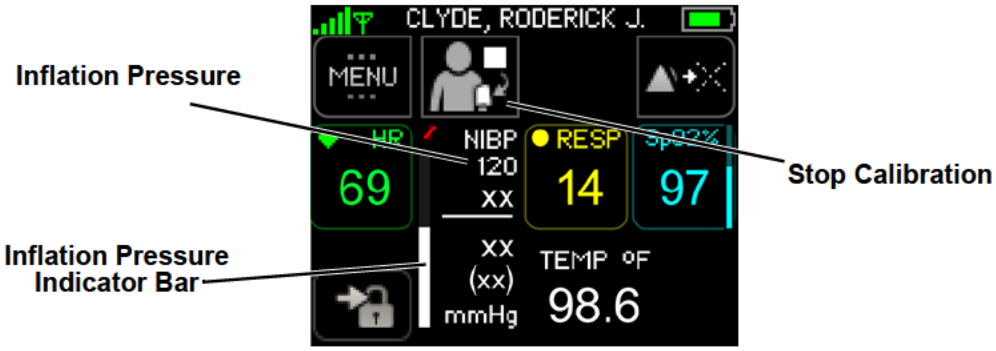
Once cNIBP has been calibrated, Systolic, Diastolic and MAP measurements will be displayed in red. The displayed measurement will be refreshed every 3 seconds.

Note: The calibration process will take approximately 1 to 2 minutes to complete.

Note: If the first calibration is not successful, a second calibration attempt will automatically occur. A failure to calibrate will be indicated by a "Calibration Failed" alert and the Cuff will inflate for again.

To stop the cNIBP calibration

A cNIBP calibration currently in progress may be stopped at any time.



Touch **Stop NIBP** to stop the cuff inflation and NIBP measurement.

The cuff will deflate.

To recalibrate cNIBP

To manually recalibrate cNIBP, following the steps outlined in section *To calibrate cNIBP on page 79*.

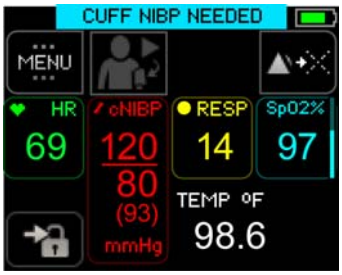
There are several reasons why cNIBP will require recalibration:

- A vasoactive drug is administered to the patient.
- Any of the cNIBP measurements exceed the upper or lower alarm limits.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 15mmHg for a normotensive patient over a period longer than 60 seconds.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 20mmHg when in a hypertensive range (systolic above 190mmHg or diastolic above 140mmHg) over a period longer than 60 seconds.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 10mmHg when in a hypotensive range (systolic below 90mmHg or diastolic below 60mmHg) over a period longer than 60 seconds.

- An unexpected interruption of monitoring occurred, such as all sensors being disconnected. If the interruption is less than 30 seconds, no recalibration is required. *See section All Sensors Disconnected on page 84.*

Note: When a recalibration event is detected and the Cuff Module is connected, the ViSi Mobile Monitor will automatically recalibrate cNIBP.

Note: When a recalibration event is detected and the Cuff Module is not connected, the ViSi Mobile Monitor will display the Cuff NIBP Needed alert. Connect the Cuff Module and recalibrate manually.



You should manually recalibrate cNIBP after any drug administration.

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2-13-13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN
Hospital Area:	CCU
Years of Experience: (*with physiological monitoring*)	25yrs

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** _____

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician:** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Passed
2	Do you need to recalibrate cNIBP? Yes No	Passed
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Passed

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ 6 minutes to complete both tasks.	☑ YES ☐ NO	Passed Questioned when the calibrate button was as it is not enabled immediately the cuff plugged in.
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	Passed Comment made afterwards – "That was easy!"

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2/13/13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN, MSN, MSN
Hospital Area:	3G
Years of Experience: *(with physiological monitoring)*	42

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2/13/13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Passed
2	Do you need to recalibrate cNIBP? Yes No	Passed
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Passed

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ 5 minutes to complete both steps/tasks.	☑ YES ☐ NO	Talked through the steps to himself when completing the task. Commented that
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	the calibration process takes a long time, however everything was easy.

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2/13/13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN - Clinical Nurse Education
Hospital Area:	3G - Cardiac/med/surg
Years of Experience: *(with physiological monitoring)*	8

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2/13/13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Passed
2	Do you need to recalibrate cNIBP? Yes No	Passed
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Passed

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ Not tried	☑ YES ☐ NO	
5	Recalibrate cNIBP	Min: ___ Sec: ___ Not tried	☑ YES ☐ NO	

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2/13/13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN - clinical leader
Hospital Area:	3G
Years of Experience: *(with physiological monitoring)*	27

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2/13/13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician:** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Passed
2	Do you need to recalibrate cNIBP? Yes No	Passed
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Passed

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ 5 minutes to complete both tasks	☑ YES ☐ NO	
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2/13/13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN, BSN
Hospital Area:	SJMO
Years of Experience: *(with physiological monitoring)*	25

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** _____

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician** (b)(6) [redacted] **Date:** 2/18/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Passed
2	Do you need to recalibrate cNIBP? Yes No	Passed
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Passed

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ Took 8 mins to complete both tasks.	☐ YES ☑ NO	The calibrate button takes a long time to enable – during this time, clinician pressed multiple buttons. Once enabled, pressed the button and then pressed it again, which stopped calibration. Had to point out the user manual many times.
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	No issues on recalibration.

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2/13/13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	Registered Nurse
Hospital Area:	3G cardiac unit
Years of Experience: *(with physiological monitoring)*	3.5 years

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2/13/13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinicia** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ Took 5 1/2 mins to complete both tasks.	☑ YES ☐ NO	Touched the couple of buttons trying to find the calibrate button (before enabled). Verbalized the steps once calibration initiated.
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2/13/13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	PA-C
Hospital Area:	Cardiology
Years of Experience: (with physiological monitoring)	15 yrs.

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2/13/13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinicia** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ Took 8 mins to complete both tasks.	☑ YES ☐ NO	Additional time to complete was due to the cuff not getting a reading first time. When recalibrate button re-enabled after the NIBP reading complete - questioned if they needed to press the button again. Commented they really liked the cNIBP measurement.
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2-13-13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN BSN
Hospital Area:	2G - Surgical
Years of Experience: (*with physiological monitoring*)	7 years

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2-13-13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ 5 minutes to complete both tasks	☑ YES ☐ NO	Comment made – "Awesome"
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	02/13/13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	MD
Hospital Area:	FAMILY MEDICINE.
Years of Experience: *(with physiological monitoring)*	13

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 02/13/13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician:** (b)(6) [redacted] **Date:** 2/13/2013

(b)(1)(A)

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ 7 1/2 minutes to complete both tasks	☑ YES ☐ NO	Additional time required as the initial NIBP reading required a retry due to a motion artifact. Asked if they could disconnect
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	the cuff after the NIBP reading displayed. Directed them to the IFU.

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Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2-13-13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN.
Hospital Area:	Case Manager.
Years of Experience: (with physiological monitoring)	25 yrs.

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2-13-13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician:** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ 5 minutes to complete both tasks	☑ YES ☐ NO	Initially did not recognize the Calibration button as disabled and pressed it multiple times.
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	Commented the NIBP/calibration button takes too long to enable.

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date: 2/13/13	
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN BSN
Hospital Area:	NICU / 4N
Years of Experience: (with physiological monitoring)	26 yrs

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2/13/13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of ~~NIBP reading~~ is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is ~~image 2~~? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician:** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ Tasks took 7 mins for both to completed	☑ YES ☐ NO	Commented that it takes a very long time for cNIBP to be calibrated.
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	Touched the cuff in the middle of the inflation which caused the cuff to fail initially and then retry.

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date: 2/13/12	
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN
Hospital Area:	Outcomes Mgmt (casemanagement, SW)
Years of Experience: (with physiological monitoring)	15 yrs.

Appendix B – Test Scripts

Participant Form: Questions

(b)(6) [redacted] Form: Questions

Clinician: [redacted] Date: 2/13/12

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician:** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ 5 mins to complete both tasks.	☑ YES ☐ NO	Comments made – - Certainly easy enough - Got to have decent vision
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date: 2/13/13	2/13/13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN BSN
Hospital Area:	Cardiac Catheterization Lab
Years of Experience: *(with physiological monitoring)*	21 years Clinical Educator

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2/13/13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician:** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ Time to complete both tasks was 6 minutes	☑ YES ☐ NO	Comments made – "Wow"
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2-13-13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN, BSN
Hospital Area:	(b) (4) [redacted]
Years of Experience: *(with physiological monitoring)*	22yrs.

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinician: (b)(6) [redacted] **Date:** 2-13-13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician:** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ Time to complete both task was 5 minutes	☑ YES ☐ NO	Initially thought NIBP was calibrated when NIBP displayed but then referred to user manual.
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	

Appendix E – Participant Demographics Form

	Participant Demographic Information
Today's Date:	2/13/13
Participant's Name:	(b)(6) [redacted]
Medical Qualifications:	RN
Hospital Area:	3G cardiology
Years of Experience: (*with physiological monitoring*)	3.5

Appendix B – Test Scripts

Participant Form: Questions

Participant Form: Questions

Clinicia (b)(6) [redacted] **Date:** 8/13/13

Question #	Scenario	Question (Circle best answer)	User Manual Page #
1	The two images below show a Spot-Check (1-time) NIBP reading and a continuous NIBP (cNIBP) reading. *Image 1* *Image 2*	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	75, 79
2	A vasoactive drug has been administered to the patient.	Do you need to recalibrate cNIBP? Yes No	80
3	A "CUFF NIBP NEEDED" alert is being displayed.	What action is required: a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed. c. Attach the cuff module and recalibrate cNIBP because a cNIBP recalibration event has occurred.	81

Appendix D – Proctor/Evaluator Forms

Proctor Forms – Questions

Proctor Evaluation Form: Questions

Proctor: (b)(6) [redacted] **Clinician:** (b)(6) [redacted] **Date:** 2/13/2013

Question #	Question	Notes / Proctor Observations (Note which reference material was used, if any)
1	What type of NIBP reading is image 1? Spot-Check (1-Time) Continuous What type of NIBP reading is image 2? Spot-Check (1-Time) Continuous	Pass
2	Do you need to recalibrate cNIBP? Yes No	Pass
3	What action is required when the "CUFF NIBP NEEDED" alert is being displayed? a. The battery in the Cuff Module needs to be recharged. b. The Cuff Module has failed c. Attach the Cuff Module and recalibrate cNIBP	Pass

Proctor Forms – Tasks

Proctor Evaluation Form: Tasks

Proctor: (b)(6) [redacted] **Clinician:** _____ **Date:** _____

Task #	Description	Time to Completion	Completed Successfully Y/N	Notes / Proctor Observations (Describe any significant issues)
4	Calibrate cNIBP	Min: ___ Sec: ___ Time to complete both tasks was 7 minutes	☑ YES ☐ NO	Pressed the Menu button when waiting for Calibrate button to enable.
5	Recalibrate cNIBP	Min: ___ Sec: ___	☑ YES ☐ NO	

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

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
Sotera Wireless, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
03/13/2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
9444 Waples St.
Suite 280
San Diego, CA 92121

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 858.373.4841
(Fax) 858.427.4639

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)
(Attach extra pages as necessary)

ViSi Mobile Monitoring System

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)*

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, enacted by 121 Stat. 823, Public Law 110-85, 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, enacted by 121 Stat. 823, Public Law 110-85, 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, enacted by 121 Stat. 823, Public Law 110-85, 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.

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 *(Attach extra pages as necessary)*

NCT Number(s): NCT00881829

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.

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Pulse Transit Time as an Indicator of Arterial Blood Pressure

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Biomedical Engineering Center, Purdue University

ABSTRACT

The relationship between pulse-arrival times and diastolic blood pressure was measured in 10 anesthetized dogs. The pulse-arrival time was measured using the R-wave of the electrocardiogram (ECG) as a time reference. Pulse-transit time was also measured between the carotid and femoral pulses. Blood pressure was raised with epinephrine injected intravenously and lowered with vagal stimulation. In all cases, pulse arrival and transit times decreased with an increase in diastolic pressure for diastolic pressures ranging from 15 to 250 mmHg. The correlation between pulse-arrival time and pressure was poorest when the ECG was used as a timing reference. The best correlation was found with true pulse-transit time and diastolic pressure. When pulse-transit time was used to compute pulse-wave velocity, it was found to increase nearly linearly with blood pressure. From 90–100 mmHg, the pulse-wave velocity increased typically by slightly less than six percent.

DESCRIPTORS: Pulse transit time, Diastolic blood pressure, Dogs.

In psychophysiology and in clinical medicine, there has been a long-standing need for a non-invasive and non-occlusive method for continuous blood pressure measurement. In principle, the pulse-transit time technique meets this need. This paper presents data on the correlation between pulse-transit and appearance times and diastolic pressure in the anesthetized dog in which blood pressure was manipulated.

Propagation of the arterial pulse is a physical phenomenon. The velocity of propagation (pulse-wave velocity) depends on the dimensions of the vessel and wall stiffness. Elastic theory (Geddes, Hughes, & Babbs, 1969) predicts that an increase in diastolic pressure increases pulse-wave velocity. Therefore, pulse-transit time, which is the difference in time between two pulses detected at different distances from the heart, decreases with increasing blood pressure.

Pulse-transit time can be measured in two ways. One method employs two arterial pulse pickups located at different distances from the heart. The other method, which really measures pulse-arrival time, employs one arterial pulse pickup and the R-wave of the electrocardiogram as a timing signal. Fig. 1 illustrates these times; T is pulse-transit time and R-C and R-F are pulse-arrival times. The rela-

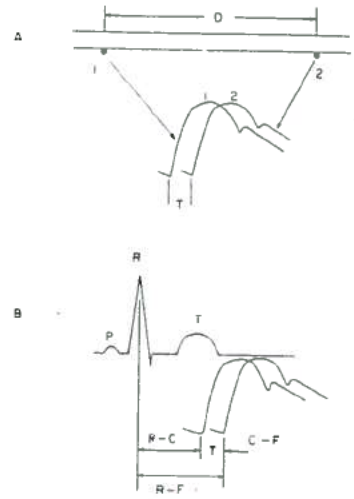

Fig. 1. Method of measuring true pulse-transit time (T) and pulse-arrival time (R-C and R-F) using the R wave of the ECG as a timing reference.

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The authors wish to acknowledge the assistance of Debbie Reiner, Steve James and Tina Parke, undergraduate students in engineering at Purdue University.

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tionship between these times and diastolic pressure was examined over a range of blood pressure in anesthetized dogs.

Materials and Methods

Ten dogs, anesthetized with pentobarbital sodium (30mg/kg, i.v.) were used in this study. Blood pressure was recorded from a carotid artery and from a femoral artery simultaneously using Statham P23DB transducers connected to identical short, stiff-walled catheters. Lead III ECG was recorded. Blood pressure was lowered by right vagal stimulation and raised by intravenous injections of epinephrine (10–50 μg/kg). The range of diastolic pressure studied was 15–250 mmHg.

All data were monitored on a Physiograph graphic recorder (Narco Biosystems, Houston, TX) and recorded with calibrations on a 4-channel tape recorder (Lockheed Electronics, Plainfield, NJ). Pulse arrival and transit times and pressures were measured by replaying the taped recordings into a high-speed galvanometer recorder (Midwestern Instruments, Tulsa, OK). The accuracy of this recording system was confirmed by analysis of test signals of known frequency and period generated by a Wavetek crystal-controlled oscillator (Wavetek, Beach Grove, IN). The overall resolution available for measuring pulse transit and arrival times was about 2 msec.

Pulse-arrival time was measured from the apex of the R-wave of the ECG to the upstroke of the carotid (C) and femoral (F) pulses (Fig. 1). The pulse-transit time (T) was measured as shown in Fig. 1 and plotted as a function of carotid diastolic pressure. The pulse-arrival times (R-C and R-F) were measured at two accessible arterial sites (carotid and femoral) to make the technique analogous to a non-invasive application. In these studies, it was assumed that the aorta stimulates a long elastic tube which transmits the pulse, and the carotid and femoral catheters sample the pressures at each end.

Results

The carotid and femoral pulse-arrival times, as measured relative to the R-wave of the ECG, were plotted versus carotid diastolic pressure as shown in Fig. 2A and 2B. In both cases, the pulse-arrival time decreases with increasing pressure. However, the decrease is nonuniform since pressure is increased by epinephrine injection. The relationship between the reduction in pulse-arrival time and pressure is more distinct for the femoral than for the carotid measuring site, presumably because pulse-arrival time is longer; therefore measurement is more precise. In addition, the isovolumic period is a smaller fraction of the arrival time and variations in the isovolumic period would be less significant.

When true pulse-transit time is plotted as a function of carotid diastolic pressure, the result is shown in Fig. 3. These data are from the same dog as in Fig. 2. As expected from the theory of elastic tubes, the true pulse-transit time decreased progressively with increasing diastolic pressure.

In 6 of the animals, the distances between the tips of the arterial catheters were measured and it was possible to calculate pulse-wave velocity, which is a normalized factor for propagation of the arterial pulse. When pulse-wave velocity is plotted as a function of carotid diastolic pressure, a near-linear relationship exists. Fig. 4 presents the results for the pulse-transit time data shown in Fig. 3. Table 1 presents the linear regression lines and correlation coefficients for the 6 dogs. Table 1 also presents sensitivity data for pulse-wave velocity change with an increase in diastolic pressure from 90 to 100 mmHg. Typically, pulse-wave velocity increased, on the average 5.8% for the 10mmHg change in pressure. These sensitivity data apply only at 90mmHg, which is a typical normal diastolic pressure in the dog.

Discussion

In the early 1920s, many investigators (Nye, 1964; McSwiney, 1924; Bramwell, 1923–24; Bram-

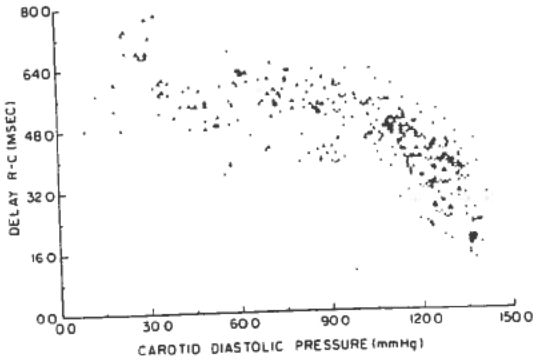

Fig. 2A. The relationship between pulse-arrival time, measured from the apex of the R-wave to the upstroke of the carotid pulse, versus carotid diastolic pressure in a typical dog (#6).

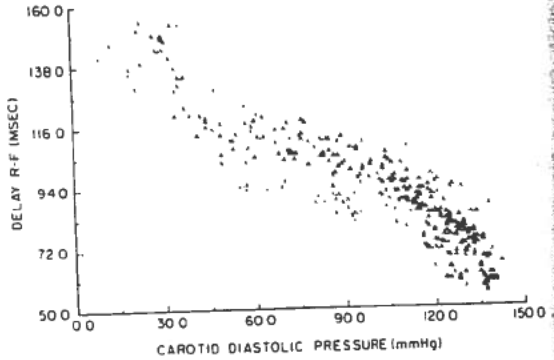

Fig. 2B. The relationship between pulse-arrival time, measured from the apex of the R-wave to the upstroke of the femoral pulse, versus carotid diastolic pressure in a typical dog (#6).

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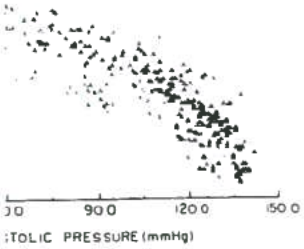

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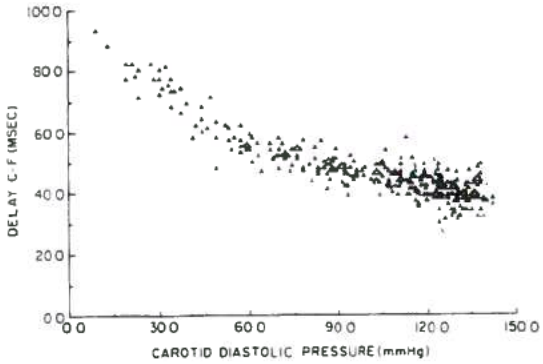

Fig. 3. The relationship between true pulse-transit time (carotid-femoral) versus carotid diastolic pressure in a typical dog (#6).

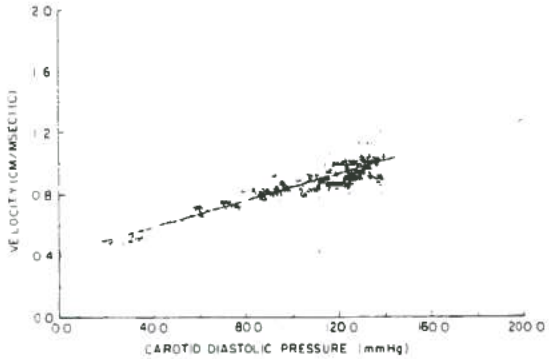

Fig. 4. The relationship between pulse-wave velocity and carotid diastolic pressure in a typical dog (#6). The equation for the linear regression line is $C = 4.27 \times 10^{-3} P + 0.419$, where C is cm/msec and P is in mmHg. The correlation coefficient is .85.

well, Downey, & Hill, 1923; Bazett & Dreyer, 1922–23) pointed out that pulse-wave velocity depends on blood pressure, because arterial compliance depends on pressure. Gribbin, Steptoe, and Sleight (1976) measured brachial-to-radial pulse-wave velocity in humans and correlated it with mean blood pressure changes. Arterial pressure was varied by altering the pressure surrounding the arm which was placed in an airtight box. For a ±80mm-Hg change in pressure, pulse-wave velocity varied linearly with mean pressure.

TABLE 1

Relationship between pulse-wave velocity (C) and diastolic pressure (P)

Animal Number	$C^* = mP^{**} + B$	Correlation Coefficient	Sensitivity (% Change in C, 90–100 mmHg)
5	$C = 5.24 \times 10^{-3} P + 0.474$	.76	5.5
6	$C = 4.27 \times 10^{-3} P + 0.419$	.85	4.6
7	$C = 4.53 \times 10^{-3} P + 0.327$	.82	6.2
8	$C = 4.11 \times 10^{-3} P + 0.289$	.78	6.3
9	$C = 3.73 \times 10^{-3} P + 0.373$	.82	5.3
10	$C = 5.69 \times 10^{-3} P + 0.272$	.86	7.2
		Av.	5.8

*cm/sec.
**mmHg.

Use of the pulse-arrival time as a measure of pulse-transit time was described by Steptoe, Smulyan, and Griffin (1976) who employed the R-wave of the ECG and the radial pulse in humans. Blood pressure was raised and lowered by physiological and pharmacological maneuvers. A linear relationship was found between pulse-arrival time and mean blood pressure. However, these investigators did point out that some agents which alter blood pressure also change the isovolumic contraction period of the left ventricle, making the R-wave of the ECG less suitable as a time reference in such cases.

The present study distinguishes between measurement of pulse-arrival time, in which the ECG is used as a time reference, and the true pulse-transit, i.e. the time between two arterial pulses detected at two different distances from the heart. It was shown that for increasing pressure, there is a non-linear decrease in pulse-transit time and directly measured diastolic pressure in the dog. However, the relationship between pulse-wave velocity and diastolic pressure is very nearly linear. Pulse-wave velocity describes the physical phenomenon of arterial pulse propagation and therefore its inverse, when multiplied by the separation of the measuring sites, is expected to vary non-linearly with diastolic pressure.

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Announcements

THE ARCHIVES OF THE SOCIETY FOR PSYCHOPHYSIOLOGICAL RESEARCH

At the 1976 meeting of The Society for Psychophysiological Research, its Board of Directors authorized the Chairman of its Archives Committee (M. A. Wenger) to attempt to arrange for the archives of The Society to be deposited in one of the libraries of the University of California at Los Angeles. Dr. Wenger has arranged for our archives to be deposited in the Department of Special Collections of the Research Library on the UCLA campus. This Department will care for our collection and make it available to accredited investigators in its Reading Room. Any member having material of historical interest to The Society should submit it c/o Dr. David Shapiro, Department of Psychiatry, UCLA, 760 Westwood Plaza, Los Angeles, CA 90024.

BACK ISSUES OF **PSYCHOPHYSIOLOGY**

All issues of PSYCHOPHYSIOLOGY, Volumes 1 through 17, are now available from the Managing Editor's office. Those issues whose original stock has been depleted have been reprinted and are consequently of somewhat higher cost than the original copies. Recognizing the growing interest in psychophysiology, the Society for Psychophysiological Research has, at considerable cost, made these issues available.

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ULTRASONIC IMAGING 1, 356-367 (1979)

MEASUREMENTS OF YOUNG'S MODULUS OF ELASTICITY OF THE CANINE AORTA WITH ULTRASOUND

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We have developed an ultrasonic technique for determining the dynamic Young's modulus of elasticity (E) of the canine aorta in vivo. Young's modulus was measured in the descending thoracic aorta (DTA) and the abdominal aorta (AA) of 12 dogs over a range of mean blood pressures from 40 - 200 mm Hg. The vessels were excised and dynamic moduli were determined in vitro post-mortem from pressure-volume curves. The data so obtained were compared to the in vivo values. In vivo and in vitro moduli increased exponentially with mean distending pressure (P). The equation of best fit for these data was of the form $E = E_0 \exp(aP)$. E_0 and a depend on the site of measurement (AA or DTA) and upon the particular animal. In vivo and in vitro moduli were not significantly different in the AA (AA: in vivo $E_0 = 667 \pm 382$ mm Hg, $a = 0.017 \pm 0.004$ mm Hg^{-1}; in vitro $E_0 = 888 \pm 367$, $a = 0.016 \pm 0.002$). However, in vivo moduli exceeded in vitro moduli in the DTA. (DTA: in vivo $E_0 = 687 \pm 241$, $a = 0.016 \pm 0.004$; in vitro $E_0 = 349 \pm 64$, $a = 0.018 \pm 0.003$). The increased stiffness of the DTA compared to the AA in vivo may be due to the in situ tethering of the aorta to the spine by the parietal pleura.

Key words: Arterial compliance; arterial elasticity; pulse wave velocity; Young's modulus of elasticity.

INTRODUCTION

The normal mechanical function of the aorta is storage of part of the systolic outflow of the heart as elastic energy in the aortic wall for release to provide flow during diastole. However, stiffening of arteries occurs with age and may be associated with symptomatic and life-threatening cardiovascular disease. An increase in aortic stiffness increases the work load of the heart. The fundamental elastic property of the aortic wall is Young's modulus of elasticity. Young's modulus is an inherent property of any solid or elastomer, and is defined as the ratio of tensile stress to tensile strain. Studies of the mechanical/elastic properties of the aorta have been limited because there has been few methods of measuring the modulus of elasticity of the aorta in vivo. Studies of excised vessels are of limited validity. This paper describes a new ultrasonic method for the in vivo measurement of Young's modulus in the intact, living dog and compares in vivo measurements with in vitro values determined immediately post-

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mortem in these same aortic segments. By comparing the in vivo and in vitro values, differences between aortic elasticity in the living animal and in excised vessels can be discerned.

METHODS AND MATERIALS

In the present study, the in vivo Young's modulus of elasticity (E) was calculated from the aortic pulse wave velocity (V_p), the diameter (d) and thickness (t) of the aorta and the density of blood (p). The mathematical relationship describing these quantities is the Moens-Korteweg equation [1],

$$V_p^2 = Et/pd \quad . \tag{1}$$

Aortic diameter and thickness were measured with a triaxial ultrasound catheter. The density of blood was determined from the hematocrit. The pulse wave velocity was measured in the aorta by determining the difference in pressure pulse arrival time with a catheter-tip pressure transducer at two sites a known distance apart. Due to the small relative diameters of the catheters with respect to the diameter of the aorta, the presence of the catheters in the vessel was not expected to modify blood flow. Using this technique, we determined the modulus of elasticity in the thoracic and abdominal aortae of 12 mongrel dogs. In 8 of the 12 animals, Young's modulus was measured in segments of both the thoracic and abdominal aortae. In each of the 12 dogs, after the in vivo measurements were completed, the aortae were excised and moduli were determined in vitro by a pressure-volume technique.

a. In Vivo Measurements

Twelve dogs anesthetised with sodium pentobarbital (30 mg/kg i.v.) served as subjects. In each animal, measurements of aortic pulse wave velocity and aortic diameter and thickness were made over a wide range of mean aortic blood pressure (40-200 mm Hg). Blood pressure was elevated by intravenous injections of phenylephrine hydrochloride (0.1 mg/kg), a short-acting pheripheral vasoconstrictor. Blood pressure was lowered by intravenous doses of sodium nitroprusside (0.1 mg/kg), a short acting peripheral vasodilator. Atropine sulfate (1 mg, i.v.) was given prior to phenylephrine, and propranolol hydrochloride (1 mg, i.v.) was given prior to nitroprusside to blunt the action of autonomic reflexes.

A specially designed ultrasonic catheter (developed with the Indianapolis Center for Advanced Research, Indianapolis, Indiana) was employed to measure aortic diameter and thickness. This catheter contained three peizoelectric elements spaced equiangularly (120 degrees) around the catheter tip in a plane perpendicular to its long axis. The catheter (7 french) was 60 cm long. The piezoelements were excited by a Panametrics (Waltham, Massachusetts) 5050PR pulser which also provided preamplification for the echo signals received from the aortic walls. A specially-designed electronic commutator was used to excite each piezoelectric element sequentially and

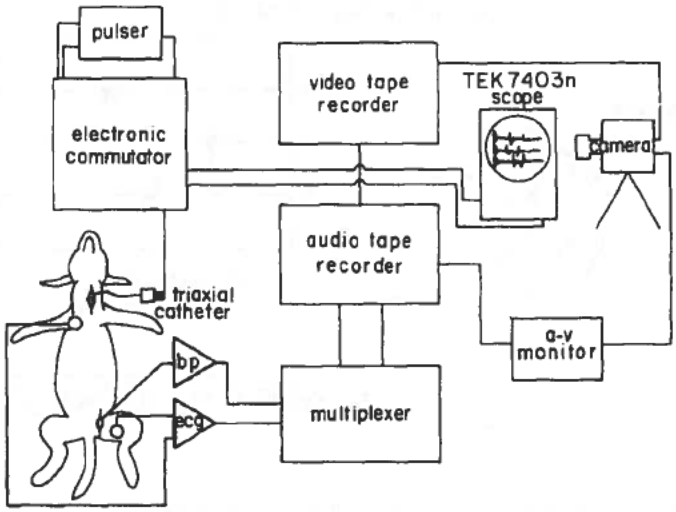


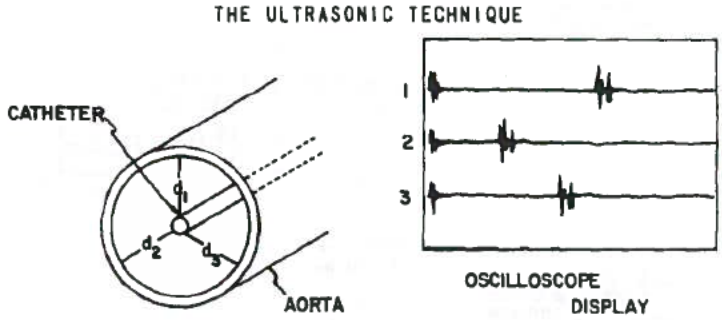
Fig. 1. Diagram of the experimental apparatus for the in vivo measurements.

display the echo patterns on a high-frequency oscilloscope. A pulse repetition frequency of 1 kHz was employed. This ultrasonic catheter-system has been described in detail [2].

Figure 1 diagrams the experimental apparatus for the in vivo measurements. Echo patterns on the oscilloscope were recorded on videotape for later analysis. The videotape recordings allowed determination of aortic pressures and radii every 33 ms [2].

To determine aortic dimensions in vivo, the triaxial ultrasonic catheter was advanced down the right carotid artery into the desired position in the aorta. In eight of the twelve animals, measurements were made at two sites, one in the descending thoracic aorta (DTA) distal to the aortic arch at the mid-thoracic level, and the other in the infrarenal abdominal aorta (AA).

Figure 2 illustrates the technique of measuring aortic diameter from ultrasonic times-of-flight (tof). Three aortic inner- and outer-wall echoes were displayed on an oscilloscope screen, the image of which was recorded on video cassette tape for later analysis. By replaying the video recorded echo signals on a stop-frame video cassette player (Sony VO-2850), ultrasonic times-of-flight to and from the inner- and outer-walls of the aorta could be measured. Using previously-determined values for the speed of 10 MHz ultrasound in canine blood [3], and in canine aortic wall [4], the distances from each piezoelement to the inner- and outer-wall were then computed, as shown in figure 2. By applying the polygon law and the law of cosines to an inscribed triangle whose vertices were the points of intersection of the ultrasonic paths with the circular vessel walls, the inner- and outer-radii of the aorta were computed. Since only veins collapse to any significant extent, the assumption of circular aortic section for



$$R = \frac{1}{3\sqrt{3}}\left[\sqrt{d_1^2+d_2^2+d_1d_2}+\sqrt{d_2^2+d_3^2+d_2d_3}+\sqrt{d_1^2+d_3^2+d_1d_3}\right]$$

Fig. 2. Diagram of catheter location in the aortic lumen, typical A-scan display of echoes and the equation relating vessel radius to intravascular distances.

distending pressures greater than 40 mm Hg should not hinder the application of the polygon toward calculation of vessel dimensions.

To facilitate calculation of mean, systolic and diastolic diameters in the aorta, a blood pressure channel was displayed by the oscilloscope and recorded on video tape, along with ultrasonic echoes. Mean inner-diameter, D_m, was calculated in a manner analogous to mean blood pressure, P_m from systolic and diastolic pressures (P_s, P_d) and diameters (D_s, D_d):

$$P_m = P_s + K*(P_s + P_d) \qquad (2)$$

$$D_m = D_s + K*(D_s + D_d).$$

The parameter K was evaluated from strip-chart records of blood pressure. The difference between mean inner- and outer-wall radii was interpreted as the mean wall thickness t.

The pulse wave velocity is the remaining quantity needed to calculate Young's modulus using Eq. (1). Pulse wave velocity was measured using differential pulse arrival times at two sites a known distance apart. The R-wave of the electrocardiogram was used as the reference time. This method, described by Patel et al. [5], measures the velocity at which the upstroke of the blood pressure waveform travels. Pulse arrival was detected by a strain-gage pressure trandsducer mounted at the tip of a 120 cm long #5 French catheter placed adjacent to the ultrasound catheter-tip transducer.

To calculate pulse wave velocity at the site of ultrasonic measurement, the Millar blood pressure catheter was translated 5 cm cephalad from the tip of the ultrasonic catheter for a few cardiac cycles and then moved 5 cm caudad. By using the R-wave of the ECG (lead II) as a timing refer-

ence, measuring the difference in pulse arrival times, T, over the 100 mm excursion gave the values necesssary to compute the pulse wave velocity, V_p:

$$V_p = 100 \text{ mm}/ T \text{ ms}. \quad (3)$$

Initial adjacent location of the two catheter tips was verified by echoes received from the blood pressure catheter with one of the ultrasound transceivers. Post-mortem examination of catheter positions also confirmed adjacency of the two catheter tips. In theory, blood flow velocity must be subtracted from the calculated pulse wave velocity to obtain the true pulse wave velocity. However, since the flow velocity is of the order of 0.25 m/s compared to 5 m/s for the pulse wave velocity [6], this correction was not made in this study. For calculation of in vivo moduli, values of the pulse wave velocity at specific mean pressures were taken from parabolic regression functions fitted to the pulse wave velocity data [7].

b. In Vitro Measurements

After the in vivo data were obtained, the animal was sacrificed and specimens of the DTA and AA were excised for determination of the in vitro modulus of elasticity. The excised specimens coincided with the points of ultrasonic measurement. Before excision, the in situ length, L , was determined carefully. The specimens were tethered to this length in a room temperature water bath for determination of Young's modulus by the pressure-volume method shown in figure 3. An infusion pump was used to pressurize the vessel with a continuous infusion of saline loaded with india ink. The ink particles inhibited leakage from the vasa vasorum. The rate of infusion was constant at 0.5 cm^3/s. Transmural presssure (P_t) was recorded with a strain-gauge pressure transducer. Movement of the infusion pump shaft engaged a linear potentiometer to record the volume infused. Both transmural pressure and infused volume were recorded on a x-y plotter to produce a pressure-volume curve.

Careful calculation of the internal volume of the vessel (V_0) at zero transmural pressure allowed determination of vessel volume, V, at any pressure from the infused volume. The vessel wall thickness at zero transmural pressure, t_0, was measured directly by a special tissue-micrometer, by applying Archimedes Principle and knowing vessel dimensions and by using a magnifying optical graticule. In each case, the vessel was tethered to the in situ length. Then wall thickness for any distending volume was calculated assuming constant cross sectional area of the vessel wall (Poisson's ratio = 0.5) from the expression:

$$t(V) = t_0 \, V_0/V. \quad (4)$$

Young's modulus was calculated from Eq. (5), as described by Posey [6],

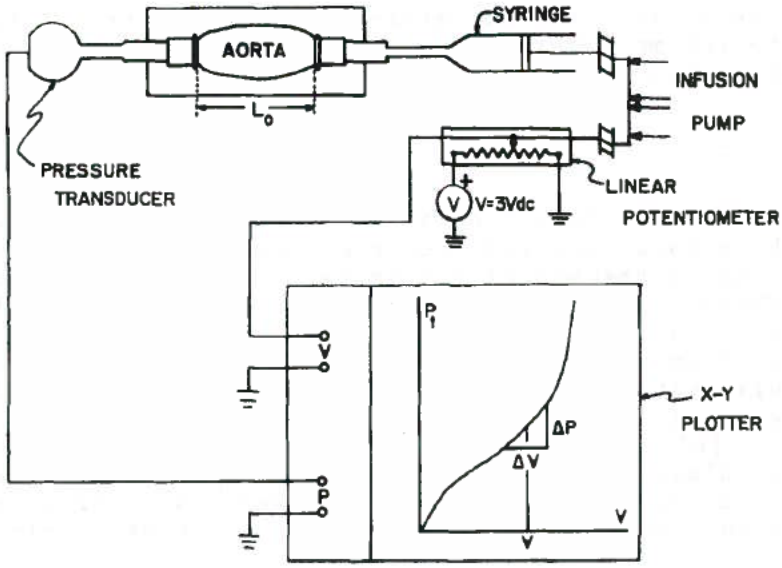


Fig. 3. Diagram of the apparatus used in the in vitro measurements.

$$E = \frac{\Delta P}{\Delta V} \frac{2}{t} \sqrt{\frac{V^3}{\pi L}} \quad . \tag{5}$$

In this expresssion, $\Delta P/\Delta V$ denotes the slope of the P-V curve, t is wall thickness, V is the internal volume, and L is the in vivo length of the vessel.

RESULTS

Typical in vivo and in vitro values of Young's modulus are represented by the semi-log plot in figure 4. The linear relationship obtained suggested an exponential representation of Young's modulus, E, in terms of mean distending pressure, P. This relationship was described by the expression

$$E = E_0 \exp(aP). \tag{6}$$

From semi-log treatment of these data, the constants E_0 and a were determined for each of the 12 dogs. The mean values, E_0 and a, are shown in table I, along with the ratio of in vivo to in vitro results. The correlation coefficients obtained for these exponential fits were in excess of 0.95.

DISCUSSION

The Moens-Korteweg equation, Eq. (1), was derived in 1878 from the wave equation for propagation of a pressure impulse within a thin-walled, perfectly elastic, cylindrical tube [1]. Details of the derivation were reviewed by Hardung [8].

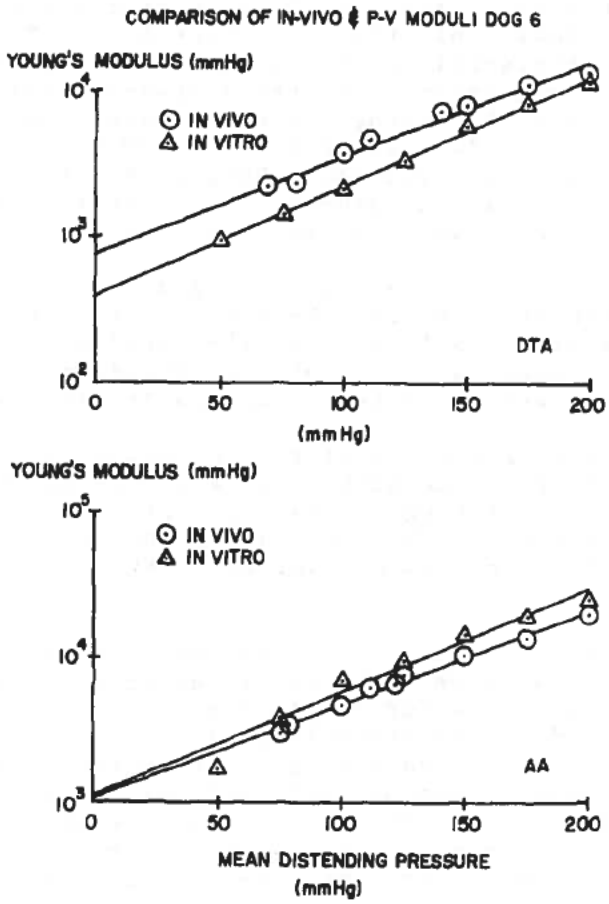


Fig. 4. Young's modulus in vivo and in vitro for the thoracic (a) and abdominal (b) aortae.

Table I. Mean values of E_0 and a.

	E_0 (mm Hg)		
	In vivo	In vitro	In-vivo/In-vitro
DTA	687 ± 241	349 ± 64	1.969
AA	667 ± 382	888 ± 367	0.751
	a $(mm\ Hg)^{-1}$		
	In vivo	In vitro	In-vivo/In-vitro
DTA	.016 ± .0036	.0182 ± .0026	0.885
AA	.017 ± .0043	.0158 ± .0019	1.101

Measurement of Young's modulus of the canine aorta in vivo was made on the basis of this relationship. The moduli so evaluated are necessarily dynamic, that is, they depend on the frequency of application of the distending force. In this investigation, the distending frequency was the heart rate which ranged from 2.0 to 2.5 Hz (120-150/min) due to phenylephrine and nitroprusside. Bergel [9] found that the dynamic modulus was independent of distending frequency for frequencies greater than 2 Hz and less than 10 Hz.

The in vitro measurement of Young's modulus represents values obtained by tethering the aorta to its in vivo length. This tethering prevents longitudinal extension of the vessel, a natural phenomenon in vivo, but the introduction of such end effects is minimized by tethering at the in vivo length [6].

The moduli evaluated in vitro represent dynamic moduli due to the nature of the distension achieved by employing the infusion pump. By setting the rate of infusion at about 0.5 cm^3/s, (yielding a dP_t/dT of about 200 mm Hg/s), the rate of distension in vitro was equivalent to the in vivo rate of distension.

Because Young's modulus of elastomeric materials, such as blood vessels, is known to be strain dependent, the choice of an independent variable for the in vivo measurements was carefully considered. The circumferential elasticity of vessels is primarily related to radius rather than pressure [10]. However, since mean blood pressure and vessel radius are intimately related for the aorta [11], and, because mean blood pressure is directly measurable , it was used as the independent variable for determing the pressure-dependent terms in the Moens-Korteweg equation.

a. Exponential Elasticity

Others have described the nonlinear elastic behavior of blood vessel [6,8,10,12-14]. However, we found the modulus of elasticity to be exponentially dependent upon mean distending pressure (Fig. 4). Our studies indicate that this nonlinear elastic behavior of the aorta, described by Eq. (6), applies to both in vivo and in vitro situations. E_0 and a were the intercept and slope, respectively, of the line resulting from a semi-log plot of E vs. P. Therefore, the aorta can be elastically characterized by E_0 and a over the range of mean pressure.

A similar dependence of the dynamic modulus upon distension was obtained in vitro by Hardung [8]. Subjecting his data to a semi-logarithmic representation yields an exponential equation of best fit:

$$E = 22 \times 10^5 \exp(2.9\ \Delta l/l) \ , \qquad (7)$$

where $\Delta l/l$ is the initial extension of the of thoracic aorta, l being the length of the aortic strip along the direction of extension. The correlation coefficient obtained was 0.975.

Table II. Comparison of values of Young's modulus reported by several investigators (after [19]).

Authors	Artery	Pressure Range (mm Hg)	Young's modulus (mm Hg) Static	Dynamic
Bergel, [15]	DTA	100-200	3230-13600	
	AA	100-220	6680-13520	
Bergel, [9]	DTA	100		3310-3680
	AA	100		6920-8270
Nickerson & Drozic, [17]	DTA	100	9000	28700
Gow & Taylor, [16]	DTA	87-130		1650-5120
	AA	96-130		3450-11030
Posey, [6]	DTA	80-200	5900-44300	
	AA	80-200	10300-48700	
This study	DTA	40-200	(in vivo)	1020-30540
			(in vitro)	700-23650
	AA	40-200	(in vivo)	1020-24690
			(in vitro)	1250-24520

Bergel [15] measured an incremental (or static) Young's modulus in the thoracic aorta of a dog and found a nonlinear dependence with pressure. We have applied an exponential fit to his data with a resulting equation of best fit:

$$E = 717 \text{ (mm Hg)} \exp(0.016\ P). \tag{8}$$

The correlation coefficient for this fit was 0.99.

Others have compared measurements of the static and dynamic modulus of the canine aorta in vivo and in vitro [6,16,17]. Table II summarizes the results reported here and elsewhere. The range of values reported herein compare well with the results of these studies.

Our technique of measuring aortic diameter and wall thickness, unlike many previous methods, was conducted without dissection of the connective tissue surrounding the aorta [2]. In studies of pressure-diameter relationships in dogs, other investigators disturbed the intact vascular geometry to enable implantation of transducers for aortic diameter measurement [1,2,7].

b. In Vivo and In Vitro Elasticity

From comparison of the ratios given in table I, it can be seen that the in vivo moduli in the thoracic aortae were

greater than their in vitro counterparts over the same pressure range. The in vivo and in vitro moduli of the abdominal aortae were approximately the same. We speculated that this in vivo excess might be attributable to the differences in dynamic moduli reported by Bergel [15], due to the frequency dependence of the dynamic modulus. The ratio of the dynamic-to-static modulus for the thoracic aorta increases rapidly from unity at 0 Hz to about 1.07 at 2 Hz. For higher frequencies, this ratio remains essentially constant. Since the ratio of static-to-dynamic moduli was as high as 3.3 (dog no. 3) and consistently above 1.07 in our experiments, the differences were not expected to be due to this frequency effect alone.

A test of statistical significance of the greater magnitude of the modulus in vivo in the DTA was made by applying a paired Students t-test to the values of the zero-pressure modulus, E_0, and to values of Young's modulus calculated in vivo and in vitro at pressures of 75, 100, 125 and 150 mm Hg [20]. For the zero-pressure modulus, the mean difference between in vivo and in vitro moduli was 338 mm Hg and this excess was significant at the $p < 0.005$ level. At 75 mm Hg, the mean excess was 721 mm Hg and the significance level was $p < 0.01$. Similarly, at 100 mm Hg, the mean excess was 1298 mm Hg and the level of significance $p < 0.005$. At 125 mm Hg, the mean excess was 1661 mm Hg and the significance level was calculated to be $p < 0.01$. Finally, at 150 mm Hg, the mean excess was 2131 mm Hg and it was significant at the $p < 0.02$ level.

The difference between in vivo and in vitro moduli in the thorax may be attributable to another factor yet unaccounted for. In our thoracic surgery, we noted that the thoracic aorta was tightly tethered to the spine by the parietal pleura and intercostal arteries plus surrounding connective tissue. The abdominal aorta lacks such tethering. This tethering may account for the increased stiffness in vivo. The indication is for further investigation, repeating the in vivo measurement with the connective tissue bed and intercostal arteries dissected away.

SUMMARY AND CONCLUSIONS

Young's modulus of elasticity was measured in the canine aorta in vivo, in the intact animal, and in vitro in excised vessels of 12 dogs over a mean pressure range of 40-200 mm Hg. Measurements were made by determining the values of the various terms appearing in the Moens-Korteweg equation. Aortic diameter-to-thickness ratio was determined ultrasonically and invasively. The pulse wave velocity was determined from pulse arrival times at a catheter-tip pressure transducer. These same aortae were excised post-mortem for evaluation of in vitro moduli by a standard pressure-volume technique.

Both in vivo and in vitro moduli were found to increase exponentially with mean distending pressure. These moduli were found to compare very well with previously reported moduli. The in vivo moduli of the descending thoracic aortae were in excess of the in vitro moduli of the thorax perhaps due to the tethering of the DTA to the parietal pleura in vivo.

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ACKNOWLEDGEMENTS

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This work was supported by grant # APR-75-1A189, National Science Foundation, Washington, D.C.

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Document Type:		SW RISK MANAGEMENT REPORT			
Owner:	Engineering	CO #:	01864	Release Date:	13 March 13
Document Control Approval:					

1 PURPOSE

This report documents the results of software risk management activities for the Continuous Non-invasive Blood Pressure (cNIBP) feature, ViSi, 1c.

2 SCOPE

2.1 Together with the Software Validation Report and Software Verification Report, this report provides a conclusion regarding the safety of the software released. It also serves as an input to the Summary Risk Management Report to provide a conclusion regarding the overall safety of the ViSi cNIBP product.

2.2 This report applies only to the software changes made for implementation of cNIBP to the existing ViSi System.

3 EXECUTIVE SUMMARY

3.1 The scope of the SW Risk Management activities was limited to the review of cNIBP implementation bugs found during Software Validation testing of 253.4.0, 253.4.1, 253.5.0 and 253.5.1.

3.2 Testing uncovered no safety issues with the software.

3.3 It is concluded that the cNIBP software is adequately implemented to assure safe use.

4 REFERENCES

4.1 0-000868 (H1, Design Input Requirements Release 1c)

4.2 0-000959 (H1, System Hazard Analysis, cNIBP)

4.3 SOP-010 (Product Risk Management)

4.4 R-000340 (Report, System Risk Management, cNIBP)

4.5 R-000332-001 (Report, SW Verification, ViSi System, cNIBP)

4.6 R-000333-001 (Report, SW Validation, cNIBP)

4.7 R-000319 (Report, PWDSW Release 1c submission 253.4.0)

4.8 R-000328 (Report, PWDSW Release 1c submission 253.4.1)

4.9 R-000337 (Report, PWDSW Release 1c submission 253.5.0)

4.10 R-000341 (Report, PWDSW Release 1c submission 253.5.1)

4.11 ISO 14971: 2007

5 RISK MANAGEMENT ACTIVITIES

5.1 Risk Evaluation

Based on severity and probability of the issues, they were grouped into a residual risk category as defined in SOP-010.

5.2 Risk Mitigations

Each risk/hazard identified in any of the SW Hazards Analysis, MMEA, or System Hazards Analysis as being in the ALAP (A) (and S x P > 6) or Intolerable (I) category was assigned a Risk Mitigation with an RM number. Each RM number is handled as a requirement in the Requirements Traceability Matrix (RTM).

5.3 Risk Management Review of Issues

After the conclusion of SW Validation activities, a number of issues were found. The issues fall into two groups. The first group is an issue with a risk mitigation that has already been rated in the SW HA. The second group is unrated issues, and these were subsequently put through a risk assessment and were assigned severity and probability per risk levels defined in SOP-010.

5.4 SW Validation and SW Verification Testing

Refer to the individual reports for details on scope and test results.

5.5 Risk Mitigation Testing

RM tags assigned to risk mitigations were added to the SRS documents and tested as part of the overall SW V&V.

6 SOFTWARE VERSIONS TESTED

Each version of software has an associated SW Release report as follows:

Software Version	Report Number
253.4.0	R-000319
253.4.1	R-000328
253.5.0	R-000337
253.5.1	R-000341

8 RESULTS

8.1 Known anomalies in cNIBP release 253.5.1

Jira #	Description	Severity	Probability	Risk Category
CNIBP-17	When a NIBP-derived PR reading exceeds the upper device limit, the expectation is that “+++” is displayed. Instead, there is an NIBP Fault alert. This only happens for a manual NIBP measurement. The nurse has to be present for the measurement to be initiated so there is a clinician at the patient side and there is clear indication of a failure to BP failure and a need to retake the measurement. Hence, this would not directly result in patient harm.	2	3	ALAP (Minor)
CNIBP-19	Word "MOTION" is not displayed in cNIBP box when there is no cNIBP measurement possible for 30 seconds (+/- 1 second) due to the presence of motion and a heart rate measurement is available. This does not pose a patient safety risk and even though the probability of occurrence is high, this is still considered a Negligible issue from a patient safety perspective.	1	5	ALAP (Negligible)
CNIBP-29	If cNIBP PAT value changes more than 12 ms in the first 30 seconds after a valid NIBP, it will generate a recalibration. However, if this is repeated after every NIBP measurement, it will continue generating a recalibration (a new NIBP measurement). The PWD should only attempt two calibrations and then display the last valid NIBP measurement. However, since NIBP readings are still being acquired, and we continue to adhere to 80601-2-30 for time and pressure between measurements, this is a Negligible patient safety issue.	1	2	ALAP (Negligible)
CNIBP-31	When cNIBP is calibrated, "xx/xx, (xx)" is displayed in Red first for up to 10 seconds and then real measurements are displayed after that. Since a 10 second delay in showing NIBP values does not pose a patient safety issue, this is Negligible.	1	5	ALAP (Negligible)
CNIBP-33	"NIBP Fault" alert is generated when all sensors (Thumb, Cuff and ECG) are connected and a blood pressure is taken. This is an NIBP delay, which would delay initial calibration of cNIBP until the nurse can retry the measurement. This is a minor patient safety risk.	2	3	ALAP (Minor)
CNIBP-35	"xx/xx", xx" measurements are not displayed in White for NIBP when cNIBP is unobtainable due to the Chest Sensor or Thumb Sensor being disconnected and "disconnected" alert is already acknowledged. This is a cosmetic issue and is Negligible from a patient safety risk perspective.	1	3	Broadly acceptable (Negligible)
CNIBP-36	"SpO2" is not displaying waveform/numeric values when all sensors are re-connected to PWD from "Clean Monitor, return to charger" screen. If sensors are being disconnected and reconnected, the clinician is at the bedside. Hence this is Negligible from a patient safety risk perspective.	1	3	Broadly acceptable (Negligible)

Jira #	Description	Severity	Probability	Risk Category
ECHO-6	For "CHEST FAULT" alert, WT displays "xx" instead of removing the vital sign box. This is a cosmetic issue and is Negligible from a patient safety risk perspective.	1	3	Broadly acceptable (Negligible)
ECHO-7	"Cuff No Pulse" alert to indicate that there are no pulses during an NIBP inflation when no other PR/HR source is available. This alert is displayed even when ECG is connected. This is a redundant alert and is a Negligible patient safety issue.	1	3	Broadly acceptable (Negligible)
FEP-16	Stopping the cuff secondary processor does not generate an NIBP_FAULT alert on the WT or RVD. This condition was artificially generated in a verification test. There is redundancy in the pressure transducer controls and will not cause over-pressure on patient even if secondary processor fails. There will also be an indication of failure to take a BP. This is a Negligible patient safety issue.	1	2	Broadly acceptable (Negligible)
FEP-36	BP PR value and NIBP systolic/diastolic values take 35 seconds to go stale. The requirement is 30 seconds. This is not clinically significant and is a Negligible patient safety issue.	1	5	ALAP (Negligible)
FEP-54	Alarm message display does not change in the message center area of WT from "High HR" to "High PR" as ECG is disconnected and the source is the thumb sensor only. After PR is within the alarm limit boundaries, PR measurement is not displayed in green. Since there is still a clear indication of high HR/PR, the intent is fulfilled and this is a cosmetic issue, and is a Negligible patient safety issue.	1	2	Broadly acceptable (Negligible)
SE-18	When monitoring is stopped and "Cuff" module is removed from WT and re-connected to WT. The "Lock"&"Menu" buttons are displayed as "enabled" but they are actually disabled. They should not be displayed as "enabled" when until a session has started. In this situation, they should only become enabled after the first NIBP measurement. The button state is a cosmetic issue and is Negligible from a patient safety risk perspective.	1	2	Broadly acceptable (Negligible)
SE-20	"Thumb No Pulse" alarm/alert "30 second no pulse activity/no motion" condition will never be satisfied due to the motion event created from an active alert's audio annunciation. This issue is resolves as soon as the alarm/alert is acknowledged. This would be a nuisance if the condition could not be resolved, but the workaround is already part of the expected workflow. Hence this is a Negligible issue.	1	3	ALAP (Negligible)
SE-21	"Start Cuff" button is still enabled after removing NIBP module from WT. The fact that the cuff is not inserted is visually obvious to a user so the button state is a cosmetic issue and is Negligible from a patient safety risk perspective.	1	3	Broadly acceptable (Negligible)

Jira #	Description	Severity	Probability	Risk Category
SE-27	HR displays 0, then changes to "xx" and back to 0 on PWD for LT critical low heart rate. The critically low HR alarm continues to annunciate and it is clear that a critically low heart condition is occurring. The 0 vs. “XX” text difference is Negligible from a patient safety risk perspective.	1	3	Broadly acceptable (Negligible)

9 CONCLUSION

Based on the results of all the software testing, which includes the Software Validation and Software Verification activities, and the assessment of the levels of risk of any remaining known issues it is concluded that the software is adequately implemented to assure safe use.

Barlow, Lenny *

From:	Barlow, Lenny *
Sent:	Wednesday, October 09, 2013 12:35 PM
To:	'eben.gordon@soterawireless.com'
Cc:	DCCLetters
Subject:	k130709 Correspondence
Attachments:	k130709.pdf

COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Charles Ho

Subject: 510(k) Number K130709

To: The Record

Please list CTS decision code: SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?	X	
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)	X	
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		
Neonate/Newborn (Birth to 28 days)		
Infant (29 days to < 2 years)		
Child (2 years to <12 years)		
Adolescent (12 years to <18 years)		
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number:	870.2300
Class:	II
Product Code:	MWI
Additional Product Codes:	DRT, DXN, DQA, FLL

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Linda J. Ricci -S 2013.10.06 20:46:52 -04'00'
Division Sign-Off	Digitally signed by Owen P. Faris -S Date: 2013.10.07 14:20:04 -04'00'

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Received

March 29, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: 510(k) No. – K130709
Refuse to Accept (RTA) Response
ViSi Mobile Monitoring System

Dear Sir or Madam:

Sotera Wireless, Inc. submits this correspondence is in response to the deficiencies identified in the Refuse to Accept (RTA) notification dated 27 March 2013 for the ViSi Mobile Monitoring System 510(k) notification. Included in Attachment A is a re-statement of each identified deficiency followed by Sotera's response.

An additional eCopy of this response is provided. The eCopy is an exact duplicate of the paper copy.

If you have any questions or require additional information, please contact me at eben.gordon@soterawireless.com, by telephone at 858.373.4841, or via facsimile at 858.427.4639.

Sincerely,
SOTERA WIRELESS, INC.

Eben Gordon

Eben Gordon
Senior Director, Regulatory

Attachments:

Attachment 1 – Deficiency Response
Appendix 1 – Table of Contents
Appendix 2 - Sotera Responses to Comments dated 17 June 2010
Appendix 3 – Sotera Responses to Comments dated 15 July 2010
Appendix 4 – ViSi Mobile Monitoring System engineering drawings

25

March 29, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Sincerely,
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Eben Gordon

Eben Gordon
Senior Director, Regulatory

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Appendix 2 - Sotera Responses to Comments dated 17 June 2010
Appendix 3 – Sotera Responses to Comments dated 15 July 2010
Appendix 4 – ViSi Mobile Monitoring System engineering drawings

Attachment 1

DEFICIENCY RESPONSE

Organizational Elements
1) Submission contains a Table of Contents
Comments? The Table of Contents does not cover the many exhibits in the submittal.

The Table of Contents has been revised to include the list of exhibits. The revised Table of Contents is provided in **Appendix 1**. The list of exhibits starts on the bottom of page 11. Please note that the page numbering integrity has been maintained for the original submission.

A. Administrative

9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g.,submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE)determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device

a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.

Comments? Regarding item 9a, there was a Pre-IDE I090994 that discussed issues to be resolved with the cNIBP function.

Sotera submitted a pre-IDE (I090994) on 22 December 2009 regarding the ViSi Mobile Monitor. The Company's intent was to market the ViSi Mobile Monitor for use in monitoring patient vital signs (blood pressure, temperature, heart rate, ECG, SpO2). The purpose of the Pre-IDE was to solicit feedback from FDA regarding the proposed clinical validation strategy for testing that the agency would require to support marketing clearance for this indication. A face-to-face meeting with FDA was held on 17 February 2010. The purpose of this meeting was to review the features of the device, describe the overall validation plan and testing, and review the overall design of the continuous non-invasive blood pressure (cNIBP) safety and effectiveness study.

Sotera submitted a supplement to the pre-IDE submission (I090994) on 2 April 2010. The purpose of the pre-IDE supplement was to respond to the questions and discussion points that came up during the face-to-face meeting with FDA on 17 February 2010. In the supplement, Sotera discussed the strategy of submitting two 510(k)s. The first 510(k) would include all vital signs monitoring features previously described in the pre-IDE with the exception of cNIBP. This feature would be added in a second 510(k) submission after the initial 510(k) notice was cleared.

Two sets of comments were communicated to Sotera by FDA. The first set of comments dated 17 June 2010 was related primarily to the pre-IDE supplement. The second set of comments dated 15 July 2010

was related to the Statistical Analysis Plan included in the pre-IDE supplement. Responses to the 17 June 2010 and 15 July 2010 comments are provided in **Appendices 2** and **3**, respectively.

Since the Pre-IDE supplement was submitted, the ViSi's cNIBP measurement has undergone significant evolution. While the basic principle of processing the PPG waveform from the thumb sensor and the ECG waveform from the chest sensor remains the same, the algorithm has undergone considerable refinement. Significant changes include:

- The algorithm no longer uses a batch process to average blood pressure values over the previous 20 seconds. The algorithm used in this submission calculates beat to beat Pulse Arrival Time (PAT) and then applies averaging over 60 seconds to display numeric values for blood pressure.
- The calibration of PAT to blood pressure using an oscillometric cuff reading corrects for vascular stiffness (compliance) by making serial beat to beat measurements during cuff inflation.
- The algorithm uses accelerometer data to accommodate for changes in arm height and patient posture.

Because of the significant algorithm changes, previous cNIBP data collected is not relevant to establish the performance accuracy of the current ViSi device. The technical specifics of these changes are provided in the K130709 notification (Section 11.4).

The clinical study plan was changed since pre-IDE supplement. Upon further investigation with practicing clinicians and review of ISO 81060-2, the clinical study design was based on comparison of cNIBP to a radial arterial line in a controlled laboratory setting rather than use a femoral line in a multicenter study. The vast majority of direct arterial line monitoring in acute care settings is based on a radial arterial line, therefore comparisons to this clinical standard is more appropriate to the intended application. The pre-IDE clinical plan anticipated a multi center study whereby femoral arterial data would be extracted from ICU bedside monitors numeric outputs. There is no standard that defines how these ICU monitors sample the arterial signal, process the signal, filter the signal and then display an output. Variability in the dynamic response of pressure tubing in hospitals is difficult to manage, let alone control. And, the inherent risks of data collection on critical ill patient in an already stressful clinical environment, makes the multi-centered study approach a risk worth avoiding. ISO 81060-2 methodologies can be used as a framework to establish accuracy of cNIBP using the invasive reference method. Since the calibration of cNIBP is dependent on an initial cuff based method, the ISO standard was used for the clinical trial. It represents a fair comparison to FDA cleared devices with similar claims for continuous blood pressure and represents a least burdensome and lowest patient risk approach to determine substantial equivalence.

B. Device Description

11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including dimensions

Comments? There is no diagram showing the dimensions of the subject device.

Dimensioned engineering drawings for the ViSi Mobile Monitoring System are provided in **Appendix 4**. The drawings include:

Sheet 1 of 4: Monitor (wrist-worn "hub" for data and alarm processing)
Sheet 2 of 4: Cuff Module (provides standard, cuff-based NIBP measurements)
Sheet 3 of 4: Thumb Sensor (measures SpO2 and pulse rate)
Sheet 4 of 4: ECG Cable (or chest sensor. measures ECG, heart rate, respiration, and skin temperature)

Attachments:

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Exhibit 3 - ViSi System Risk /Hazard Analysis - cNIBP Module, 0-000959, Rev. A	4 Pages

Exhibit 4 – Summary Risk Management Report, ViSi, cNIBP, R-000340-001, Rev. A	3 Pages
Exhibit 5 - ViSi Mobile Monitoring System User Manual	156 Pages
Exhibit 6 – CNAP Monitor 500 Operator's Manual	91 Pages
Exhibit 7 – Software Design Specification, cNIBP, 0-000996, Rev. A	21 Pages
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Exhibit 9 - Software Validation Summary Report, ViSi, cNIBP, 1c, R-000333-001, Rev. A	24 Pages
Exhibit 10 – Software Verification Report, ViSi System, cNIBP, R-000332-001, Rev. A	58 Pages
Exhibit 11 – ViSi cNIBP Software Anomalies – Version 253.5.1	2 Pages
Exhibit 12 – Design Verification, EN 1060-1, EN 1060-3, IEC 80601-2-30 Compliance, 0-001002, Rev A	10 Pages
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Appendix 2

Sotera Responses to Comments dated 17 June 2010

The Company received comments to the Pre-IDE supplement submitted 2 April 2010. The following responses are provided to FDA's comments:

Clinical

1. *Multiple safety endpoints are proposed, including reporting device failures, all serious adverse events and all adverse events. The endpoints are reasonable, but one (or more) primary endpoints need to be identified with appropriate alpha allocation since at present you have not provided any statistical method to analyze the safety results of the study.*

During previous Sotera clinical studies, it was observed that individual subjects may have exhibited inherent, physiological-dependent differences in brachial blood pressures and femoral blood pressures. These differences may significantly affect the outcome of study results. Subsequently it was decided to use the radial artery as the reference arterial site for the validation study as specified in ISO 81060-2. Careful attention was made to experimental methods to minimize calibration errors or dynamic response limitations in the radial arterial line. The end-points for the clinical study are well defined in the standard (mean error: $\leq \pm 5.0$; standard deviation: ≤ 8.0). *Non-invasive Sphygmomanometers – Part 2: Clinical validation of automated measurement type.* ISO 81060-2 (Section 6.2) was used as the basis for the validation study design. The study sample size, methodology, endpoints, statistical rationale, etc. were derived from the standard.

2. *Please ensure that the study has adequate enrollment of subjects in order to ensure reasonable coverage of the intended patient population. Please refer to the BP and arm circumference coverage requirements of AAMI SP10:2008.*

The blood pressure and cuff size enrollment criteria meet the requirements of the consensus standard, ISO 81060-2.

3. *Please note that the inclusion/exclusion criteria of the study may be translated into labeling restrictions (in terms of arm circumference and the presence of a VAD) on the subject device in any future premarket submittal on the device.*

Section 9.2.5 (Exhibit 5 of the K130709 submission) of the User Manual includes the results of the clinical trial. The User Manual also includes human interface messages displayed on the device recommending when to re-inflate the oscillometric cuff to recalibrate the cNIBP measurement.

4. *Please ensure that if the proposed study is conducted as a Non-significant Risk study, the subject device's measurements should NOT be available to the clinical staff. In particular, page 24 of 47 of the protocol discusses the benefits of study participation. "Access to an alternative investigational medical device that would allow the Subject to have non-invasive blood pressure measurements." We believe that the language included suggests that the measurements produced by the investigational device will be available for review by the clinical staff caring for the subjects. If that is the case, clinical care decisions could be influenced by the investigational device, and the study might not be considered non-significant risk (in which case, an IDE may be required).*

Subsequent to the Pre-IDE submission and prior to the cNIBP clinical study, the protocol was re-written. The revised protocol does not include the language: "*Access to an alternative investigational medical device that would allow the Subject to have non-invasive blood pressure measurements"* nor does it discuss any benefit of the subject's participation in the study.

5. *In addition to recording all adverse events as indicated in section 6 of Attachment 1, please revise the protocol to include:*

a. *Subsequent treatments or interventions required (none, medical therapy, surgical intervention, hospitalization, withdrawal from study, etc.)*
b. *Resolution status (resolved without sequelae, resolved with chronic sequelae, ongoing without sequelae, ongoing with sequelae, death, etc.)*
c. *Whether or not the AE resulted in the subject's discontinuation from the study*

The adverse events section of the study protocol was re-written (K130709, Exhibit 14, Appendix G, page 62 of 68 of the clinical study report) consistent with the adverse events arising from the clinical study of a non-invasive blood pressure monitoring device. The former language no longer exists.

6. *Please provide case report forms (CRF) that will facilitate the recording of all items of information in the study for our review.*

The same style CRF used for the clinical studies of NIBP, SpO2, and Respiration (submitted in K112478) was used for the cNIBP clinical validation.

7. *On pages 20 and 21 of 47 of the protocol (also called Attachment 1), you have provided some definitions of the relationship between an adverse event and the investigational device. Probable and Highly Probable require "Abates upon discontinuation of the treatment" and/or "Is confirmed by the reappearance of the Adverse Event on repeat exposure". Please note that FDA does not agree that either of these conditions is necessarily required to assign relationship of an AE to the investigational device. Hence, FDA recommends that you remove the two conditions. FDA reserves the right to adjudicate any adverse event when the clinical study report is submitted to us.*

As stated in *5* above, the adverse events section of the study protocol was re-written consistent with the adverse events arising from the clinical study of a non-invasive blood pressure monitoring device in a controlled laboratory setting consistent with ISO 81060-2. The former language no longer exists.

8. *Page 23 of 47 of the protocol provides possible reasons for subject withdrawal. One of the reasons is device failure. Please explain how subject withdrawals due to device failure will be handled with respect to endpoint analyses.*

The early termination section of the study protocol has been re-written (K130709, Exhibit 14, Appendix G, page 64 of 68 of the clinical study report). The former language no longer exists.

9. *Page 26 of 47 of the protocol defines various populations (safety, ITT and per- protocol). The ITT population is defined as "All Safety Subjects with any paired BP measurements and no protocol violations that affect the analysis". Your ITT population potentially excludes subjects with missing data or protocol violations. We believe that the proposed definition of an ITT population does not meet the definition we typically see. For example, please clarify how endpoint testing will be handled for subjects that withdraw from (or fail to have complete data for) the study.*

Further, please explain the rationale for using only the PP population for the primary effectiveness population. We believe that the issue of missing data has to be addressed.

Prior to the clinical study, the study protocol was re-written to be consistent with ISO 81060-2 clinical study design. The protocol no longer includes the Analysis Population section.

10. *We have the following comments on the Informed Consent document provided starting on page 41 of 47 of the protocol:*

a. *The document includes a statement about the "investigators' hope"; this is not relevant to the consent process and should be removed. It could be replaced with language to the effect of "an objective of the study is to assess whether or not ... "*
b. *A number of statements are made which could be viewed as claims such as "helpful to other hospitalized Subjects who have their blood pressure monitored occasionally with an arm cuff in that this investigational device can measure blood pressure continuously and would be more comfortable for the Subject and more convenient for caregivers." If the study is redesigned to characterize these objectives, then the consent document could cite them as such (i.e. objectives to be studied rather than presented as statements of truth); otherwise, they should be removed.*
c. *The document states "We believe using this information can develop a model that will allow us to calculate your blood pressure continuously." If this study were intended to develop your device, then this study would not be considered "pivotal" (i.e. would not, by itself, support a marketing application). If the device design is fixed, then this statement should be removed.*
d. *The document states "We will have you sign this consent prior to your up- coming surgery." The language used could be interpreted as a requirement. A preferred statement could be "In order to be in the study, you will need to agree to agree to participate in the study and sign the informed consent document."*
e. *A description of the procedure to place the invasive arterial monitoring catheter should be included. This description can include a statement that placement of the arterial monitoring catheter is part of the patient's care plan (i.e. that the arterial monitoring catheter is not being placed solely due to participation in the study).*

The Informed Consent document was re-written for the current clinical trial. The former language no longer exists. The same style Informed Consent document used for the clinical studies of NIBP, SpO2, and Respiration (submitted in K112478) was used for the cNIBP clinical validation.

Engineering and clinical

11. *It is not clear whether the minimum time of data recording per subject is 4 hours or 8 hours. While exclusion criterion 4.3.2.2, clause 5 of the statistical analysis plan (SAP) refers to 4 hours, page 21 of 22 of the protocol refers to 8 hours. Further, page 11 of 47 in Attachment 1 includes all patients measured between 0 and 8 hours from the initial calibration time. Please clarify this exclusion criterion. Note that this criterion also impacts the definitions of the Safety Population and hence the Intent-to-Treat Population, as described on page 8 of 21 in the SAP. Of interest, the protocol states (page 13 of 47) that you expect at least 21 subjects to have completed BP measurements for at least 8 hours. Please explain why just 21 subjects will provide sufficient information to allow a labeling upper limit of 8 hours after one calibration.*

The original clinical study protocol specified 4 - 8 hours to determine if there was any “drift” in the correlation between PAT and an invasive arterial reference. Differences between measurements (drift) are caused either by experimental error in either the arterial line measurement system, the PAT

measurement, or in patient condition over time. Experimental errors are carefully controlled in the new study. Transducer calibrations were within ± 1 mmHg and dynamic response was greater than 16 Hz as recommended in ISO standard. Timing of PAT is determined by a sampling time (500 Hz) and fiducial marker stability for R wave and PPG wave. Changes in patient condition resulting in differences in the arterial to PAT measurements are controlled by device warnings to the clinicians when cNIBP measurements change by a pre-configured amount. Therefore, no reset recommendation for recalibration is required in the labeling other than recommendations for good clinical practice prior to treatment (K130709, Exhibit 5, User Manual, Section 6.2.8, page 79). The 4 hour test time was selected based on a reasonable time for a volunteer to have a radial arterial catheter placed for continuous monitoring. No drift was noted during the test period consistent with the above rationale.

12. *On page 9 of 21 of the SAP, you have described three criteria of excluding data, as follows:*

1. *ViSi cNIBP reading is displayed as -dash-dash II while the femoral artery measurement is non-zero, which is not physiologically possible and is likely due to excessive patient movement.*
2. *Femoral artery cNIBP reading is displayed as zero or -dash-dash II while ViSi blood pressure reading is non-zero, which is not physiologically possible and is likely due to mechanical issues associated with femoral A-line.*

   [FDA comment: It seems that the term cNIBP here should be BP only.]
3. *Any paired data point containing a blood pressure value, measured with the femoral arterial line that deviates by 2>. ±20 mmHg over a time period of less than 10 seconds*

   Further, page 5 of 22 of the protocol indicates that data collected during the event (+/- 1 min) will be excluded. First of all, please clarify if motion is the only reason ViSi displays dashes.

   Secondly, for Criterion 2, if a subject were in an "arrest" condition, it is physiologically possible for the femoral A-line to read zero while the ViSi present s a non-zero value, due to the 20-second averaging of the device; this possibility must be accounted for.

   Thirdly, we believe that Criteria 1 and 2 can be applied only if there are documented reasons such as the patient being moved for medical reasons, or the femoral A-line being flushed. For Criterion's, please provide a clinically valid justification for the 20 mm Hg in 10 seconds "cut point".

   Finally, in the final study report, please provide an account of the duration and reason for each episode when data were excluded.

The Statistical Analysis Plan (SAP) submitted in the pre-IDE was not used since the clinical study adheres to the requirements outlined in ISO 81060-2. Paired data was excluded only when the patient visited the bathroom (disconnect from pressure transducer data collection) and during periods of re-positioning the arterial transducer. A spreadsheet of excluded is provided in the eCopy, STATISTICAL DATA folder, Exhibit 14, Appendix F, of the 510(k) submission.

13. *In fact, since exclusions of data could produce an important impact on the trial results, we recommend that, in addition to pre-specifying a very specific set of instructions, an independent committee be established to adjudicate the validity of these exclusions that actually occur in the trial.*

As stated in 12 above, data was only excluded when the patient visited the bathroom (disconnect from radial line) and during periods of re-positioning the arterial transducer.

14. *In section 5.8 of the SAP, you have described a method of seating the difference in BP readings between the subject device and the femoral A-line, as follows: "If the test device measurement falls within the range of the arterial line BP values, the error of the test device is set to zero; if it lies outside the range, the error is calculated as the difference between the test device measurement and the adjacent limit of the range." FDA believes that this method, sometimes called the pressure band method, is too generous and tends to exaggerate the merits of the device. However, FDA will agree to a modified pressure band method in which the band width is defined by the mean value +/- one standard deviation of the femoral A-line readings for systolic BP, and separately calculated for diastolic BP. Our "pressure band" is similar to your "range of the arterial line BP values". Further, the standard deviation should be calculated for a continuous stretch of systolic values that is not interrupted by any episode of excluded data. Please analyze the systolic BP readings separately from the diastolic readings. Please note that FDA will need the raw BP dataset recorded before the scoring of the BP differences is applied in order to check the validity of the scoring.*

Sotera agrees with FDA and used the modified pressure band method (also specified in ISO 81060-2, section 6.2.5) to determine blood pressure error. As suggested, all data is analyzed separately. A line listing of data is provided in the eCopy, STATISTICAL DATA folder, Exhibit 14, Appendix F, of the 510(k) submission.

15. *In section 1.3 of the protocol (page 7 of 22), you have provided some analysis on why the equivalence margin for the Sotera cNIBP study should be extended to 12 mmHg. We do not agree since the starting value of your analysis, 6.95 mmHg, comes from the AAMI SP10:2008 standard, and is only the maximum permissible standard deviation of the paired differences, not the maximum permissible mean of the paired difference. And 6.95 mmHg corresponds to a zero mean of the paired differences. Further, page 9 of 22 in the protocol indicates two reported values of bias between femoral and brachial BP values-- 1.5 and 6.9 mmHg. In fact, the study with 107 subjects had the 1.5 mmHg bias while another study with 28 subjects had the 6.9 mmHg bias. (And bias is the same as mean error.) Hence, if you need a correction for the femoral vs. brachial site effect, please analyze more literature values of such bias to come up with a more representative value. Additionally, if you and the FDA can agree on a consistent bias (both direction and magnitude) between the femoral and brachial sites, then wouldn't it be more appropriate to include that bias as an adjustment to the observed cNIBP measurements, rather than add the bias to an allowed equivalence margin*

The revised clinical study protocol does not use the femoral artery for reference measurements. The acceptance criteria outlined in ISO 81060-2 (mean error $\leq \pm 5.0$; standard deviation ≤ 8.0) is used without any bias correction. The method for determining blood pressure error and data analysis is as specified in ISO 81060-2, section 6.2.5 and 6.2.6, respectively.

16. *Page 17 of 47 in Attachment 1 indicates doing a baseline BP measurement using a standard cuff-based method (auscultation). Please clarify if the cuff-based method uses a legally marketed BP monitor, since the subject device has not been cleared to market at this moment.*

The revised clinical study protocol does not require a baseline blood pressure measurement within 30 minutes prior to time zero. This question is no longer germane to the clinical study design.

17. *Page 17 of 47 in Attachment 1 refers to a set of calibration instructions. Please provide such instructions for our review. If the set of calibration instructions involves using the subject device's cuff to measure the subject's BP at the upper arm, you will probably need a prior study to verify*

the accuracy of the subject device's arm cuff-- this will probably involve at least 15 subjects with indwelling radial artery catheters. Alternately, another (non-invasive) study to validate the subject device's arm cuff will involve at least 85 subjects to compare with human observers using the aneroid pressure meter and auscultation, as recommended by the AAMI SPI 0:2008 standard.

The calibration of the cNIBP measurement occurs automatically to the NIBP measurement at the onset of measurement and does not require a set of calibration instructions. The revised clinical protocol used in this trial does not specify a set of calibration instructions.

18. *Page 8 of 8 in Attachment 3 states, "Nor can it test interference between devices that use other types of transmitters not on the 802.11 standard." Please explain the importance of this statement to the interpretation of the test results in this attachment.*

Attachment 3 discusses a wireless testing strategy for the then unapproved ViSi System. The present submission, K130709, applies only to the standalone patient worn device. Therefore, question 18 does not apply to the subject submission.

19. *Just a suggestion: You may be able to compare the subject device's cNIBP readings with that of human observers using an aneroid pressure gauge and auscultation, since the subject device's cuff is removed from the patient's arm immediately after calibration. Thus, the human observers can record BP via auscultation just before, and just after the subject device's cuff calibration, and then every 15 minutes for the duration of at least 4 (or 8) hours and up to 12 hours. This IS then a completely non-invasive study to compare auscultatory BP readings with the cNIBP data from the device, using at least 85 subjects. Of course, this suggestion assumes that the subject device's calibration is not changed by additional cuff inflations during the 8 or 12 hours of the study.*

A reference invasive arterial pressure transducer was selected for comparison in the determination of the accuracy of the ViSi System's continuous blood pressure measurement. Sotera considered the use of dual auscultators for comparison. We determined that comparison to a continuous arterial line was more appropriate for the intended use. Experimental errors from dual auscultators are difficult to control over an extended period of time. Human fatigue in maintaining agreements between dual auscultators could add experimental biases that would not fully represent the true accuracy of the cNIBP over time. Therefore, the invasive blood pressure reference method provided in ISO 81060-2 was used.

Typographical errors or ambiguities:

20. *Page 17 of 21 in SAP, ISO "80160-2" should probably be ISO "81060-2".*
21. *Page 41 of 47 in Attachment 1 states, "the pulse measured from the skin surface of the arm ... " Should the word "arm" be "thumb"?*
22. *Page 14 of 33 in Attachment 5 states, "and a non-breathing value". Should the quoted text be "and a non-rebreathing valve"?*

With the revision to the clinical study protocol, none of the errors or ambiguities noted is applicable.

23. *Please address the following regarding your proposed Human Factors testing: Questions a – g.*

Extensive human factors test results were submitted in the previous submission, K112478. These questions are no longer relevant. Human factors testing pertaining to the cNIBP feature was completed and provided in the K130709 submission (Section 19.2, page 55).

24. *Please address the following regarding your proposed Sp02 clinical trial: Questions a – e.*

The clinical trial for SpO2 has previously (K112478) been submitted for the ViSi System. Again, these questions are no longer relevant.

Comments on EMC/wireless issues:

25. *Clinical study inclusion criteria, Attachment 1, page 5 of 6. The only exclusion mentioned here for other active implantable or other devices on the patient appears to be "Subject has a ventricular assist device in place". The sponsor should clarify if they intend to study possible affects of the ViSi device on all other medical devices beyond the ventricular assist devices. If so, they should list all other devices and the specific testing and protocols they intend to pursue with justifications for each, Otherwise, they should justify the potential risks for the patients with all other devices. Alternatively, the sponsor should exclude subjects with any type of active implantable or body worn device so that the study does not increase patient risk.*

The intent of the clinical study is not to study the possible effects of the ViSi device on all other medical devices. Since the results of clinical study are now known, no patient harm resulted from the use of the ViSi device. Known or potential adverse effects of the ViSi device have been disclosed in the Warnings section of the User Manual (K130709, Exhibit 5, starting on page 10).

26. *EMC-Wireless testing plans, section 2,4.2, Attachment 3. The information in these sections indicates that some EMC testing is planned as well as specific testing and certification for the wireless portions of the ViSi device system. The information remains unclear as to exactly what testing will be done and by whom, the equipment to be tested, the pass/fail criteria, and how much or what portions of the ViSi system would be included. The plans appear to include claims for the device sponsor to conduct on-site wireless surveys and some network and wireless technology testing at the customer clinical facility prior to each installation to assess the characteristics of the facility and network and wireless connections. The information also points to certification through the Wi-Fi Alliance program though we are not familiar with this program at this point. Figure 6 shows "Proximity testing" and other points to be performed in support of the wireless medical device testing. It is unclear if the proposed testing by VeriWave includes all or only portions of the system and wireless components.*

    In addition, there are indicates that the system could include virtually any wirelessly enabled platform or equipment. Generally, we have recommended that only the equipment and accessories used in the testing would be adequately qualified to become part of the device system to be marketed.

    The sponsor should clarify exactly what testing is planned and when, what portions of the device system will be involved and why, and provide summary information on the proposed specifications and claims for the wireless portion of their device system.

The current submission, K130709, only applies to the standalone patient worn device. Therefore, question 25 does not apply to this submission. The device used in the subject submission complies with EMC standards (included in the K112478 submission).

Comments from Sp02 and Human Factors:

Deficiencies for Original Submission Questions 1 -3

SpO2 and Human Factors was the subject of the prior submission, K112478. Questions 1 -3 do not apply to submission K130709.

Appendix 3

Sotera Responses to Comments dated 15 July 2010

The company received comments to the Statistical Analysis Plan of the Pre-IDE supplement submitted 2 April 2010. The following responses are provided to FDA's comments:

General note - Subsequent to the pre-IDE submission, the clinical validation study design was revised to be based on ISO 81060-2, *Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type* (Section 6.0). ISO 81060-2 methodology can be used as a framework to establish accuracy of continuous non-invasive blood pressure measurements using the invasive reference method. The radial artery was selected as the arterial reference site. The study sample size, endpoints, methodology, statistical rationale, etc. were derived from the standard.

Statistical questions and concerns for sponsor:

The following are the major deficiencies for the statistical plan of the cNIBP protocol.

1) *The cNIBP study is to be conducted on subjects with an indwelling femoral artery catheter (a subset of non-ambulatory patients). In addition, study exclusions list patients with AV-pacemaker and those undergoing dialysis. The intended use (page 41) indicates use on both ambulatory and non-ambulatory patients. Please justify why (given the restrictions on the study population) you believe the results of this study can be generalized to your Intended use population.*

The Indications for Use statement (K130709, Section 4, page 12) no longer indicates that the ViSi System is for use with ambulatory and non-ambulatory patients. Subsequent to the Pre-IDE submission and prior to the initiation of the cNIBP clinical study, the protocol was completely re-written. The study exclusion criterion no longer lists patients undergoing dialysis which is consistent with ISO 81060-2. Warnings are provided in the User Manual (K130709, Exhibit 5, page 13) regarding patients with AV-pacemakers.

2) *It appears that you will be comparing average values on device (over last 20 seconds) to femoral a-line values. We have the following comments/questions regarding this:*

   a) This is acceptable if a 20-sec average will always be the value to be provided to the user (change in the length of time over which values are averaged changes the output of your device and will hence require additional validation). Your protocol should be comparing the value(s) provided to the user by your device to the corresponding reference value(s). Please note that since changes in the device output could potentially change the results of the study, it is critical that you clearly and completely pre-specify in your statistical plan and protocol what output(s) will be provided to the user, and how any "sampling" of values to be used for the analysis will be done;

The cNIBP algorithm no longer uses a batch process to average blood pressure values over the previous 20 seconds. The algorithm used in this submission (K130709) calculates beat-to-beat Pulse Arrival Time (PAT) and then applies averaging over 60 seconds to display numeric values for blood pressure. This time was chosen to provide a representative value for blood pressure over several respiratory cycles. Respiratory effort can augment blood pressure values (e.g., Pulsus paradoxis) that modulate blood pressure on a beat-to-beat basis. As stated previously, the clinical protocol was completely re-written. The 60 seconds time period was also used for averaging of the reference invasive measurement. The pre-IDE clinical protocol relied on commercially available ICU monitors for which signal processing, averaging and displaying are proprietary. The new

protocol avoids these unknowns by directly digitizing the radial artery transducer and thus avoiding potential experimental errors due to differences in signal acquisition and processing. The numerical value displayed is updated every 3 seconds to provide the user with timely, stable readings.

b) Please clarify if you will be averaging the femoral a-line values over the 20 second period too

As stated above, the reference measurement (radial artery) is averaged over a 60 second period. Both the reference radial arterial signal and the cNIBP signal use the same algorithms to produce blood pressure numeric values for accuracy comparisons.

c) The "display every 3 seconds" adds a complication to the selection of values provided to the user. It is unclear how you plan to account for this in your analysis plan. Please explain;

The cNIBP pressure measurement value used for the accuracy determination was the 60 second average reading and not the displayed value.

d) We also note that averaging device measurements will results in the loss of several measurements due to a single inevaluable measurement.

There is no loss of measurements since the cNIBP algorithm uses a moving 60 second window on a beat-to-beat basis and compared to the same beat-to-beat data collected from the radial arterial line.

3) *You state that subjects may be in the study from 4 to up to 12 hours. Please explain how you decide the length of time a subject is to be studied. If this decision is made on the basis of (some kinds of) observed subject study data it may invalidate your results.*

The original clinical study protocol specified 4 up to 12 hours to determine "drift" in the correlation between PAT and an invasive arterial reference. Differences between measurements (i.e. drift) are caused by experimental error in either the arterial line measurement system, the PAT measurement, or in patient condition over time. Experimental errors are carefully controlled in the new study. Transducer calibrations were within ± 1 mmHg and dynamic response was greater than 16 Hz as is recommended. Timing of PAT is determined by a sampling time (500 Hz) and fiducial marker stability for R wave and PPG wave. Changes in patient condition resulting in differences in the arterial to PAT measurements are controlled by device warnings to the clinicians when cNIBP measurements change by a pre-configured amount. Therefore, no recommendation for recalibration is required in the labeling other than recommendations for good clinical practice prior to treatment (K130709, Exhibit 5, User Manual, Section 6.2.8, page 79).

The 4 hour test time was selected based on a reasonable time for a volunteer to have a radial arterial catheter placed for continuous monitoring. No drift was noted during the test period consistent with the above rationale.

On Calibration

4) *It is not clear from your protocol what calibration does to your device measurements. Are the measurements simply being reset to the value obtained by a brachial cuff measurement or is some more complex algorithm being applied? Please explain how the device is being calibrated and the potential effect of calibration on subsequent measurements.*

The detailed analytical model is presented in Section 11.4.1 page 28 of the K130709 submission. The oscillometric cuff measurement is used to calibrate the pulse arrival time (PAT) specific to the patient. Cuff inflation modifies the stiffness of the brachial artery during the inflation cycle. The relationship between PAT and cuff pressure for each beat during the inflation cycle produces a unique calibration model at multiple cuff

inflation points. The model considers the relationship of PAT at various blood pressure levels. The completion of the oscillometric measurement yields reference calibration for mean arterial pressure, systolic, and diastolic pressures.

5) *The length of calibration cycle that will be used for your device is not clearly stated in your protocol. Please state this clearly in your protocol. We anticipate that subjects will be enrolled with a view to participation in the study for at least one calibration cycle and that a significant number will be studied for 2 or more cycles so that potential changes in the effect of calibration on later cycles can be assessed especially for complex calibration schemes. Please comment.*

Reference the response to 3) above.

Endpoints and Analyses:

6) *You list 5 safety endpoints in Section 5.1.1 of your clinical protocol but your statistical plan does not specify any safety hypotheses for your study. Please provide such hypotheses.*

The end-points for the clinical study are well defined in ISO 81060-2: mean error ≤ ±5.0 mmHg; standard deviation ≤ 8.0 mmHg. Study sample size, methodology, endpoints, statistical rationale, etc. were derived from the standard.

7) *Please provide details on the bootstrap analysis that you have listed briefly in Section 5.4 of your protocol. Since the distributional assumptions needed for your repeated measures model may not be satisfied, we believe it is critical that a distribution-free analysis plan be pre-specified in detail. Furthermore, we note that the hypotheses for the bootstrap analysis may be different, since they can be more directly stated in terms of expected differences between device and reference measurements. This analysis may be preferable as the primary analysis for your primary effectiveness endpoint.*

The data was analyzed according to ISO 81060-2, Section 6.2.6 requirements. There is no requirement for a bootstrap analysis in the standard.

8) *Per your statistical analysis plan you propose to compare 3 sets of hypotheses each for systolic and diastolic BP to establish effectiveness. All of these 6 primary effectiveness hypotheses must be satisfied for study success. The repeated measures model that will be used to assess these primary effectiveness hypotheses does not model post-calibration drift of device values. Thus it appears that this drift would be included in the measurement error for the model and could result in potentially significant effects being declared insignificant. It would appear that the test, of what you currently list as a secondary effectiveness hypothesis on drift, should be carried out and should not reject the null hypothesis of 0 drift, before the primary effectiveness endpoint can be tested, Please modify your testing plan accordingly or provide the rationale for your approach.*

As stated in 7), data was analyzed according to ISO 81060-2, Section 6.2.6 requirements. The Statistical Analysis Plan submitted in the pre-IDE is obsolete.

9) *The fact that your null hypothesis for the drift endpoint assumes 0 drift, which is what we would like to show, is a weakness of your protocol. Please test this hypothesis at the 10 or 15% level of significance at the least.*

As stated in 7), data was analyzed according to ISO 81060-2, Section 6.2.6 requirements. The Statistical Analysis Plan submitted in the pre-IDE is obsolete. Please refer to 3) above for rationale regarding drift.

10) *When multiple calibration cycles are included for a subject in the analysis, the model for drift is not clearly defined. It would appear that tij is either not correctly defined (if you are using difference from initial calibration) or not uniquely defined (when you use difference from start of current calibration cycle). Please explain and/or modify your model as necessary.*

Differences between measurements (drift) are caused either by experimental error in either the arterial line measurement system, the PAT measurement, or in patient condition over time. Measurement error from all sources is incorporated into the mean error and standard deviation calculations for the entire study period for each subject.

11) *You state in Section 5.4 that dij in your repeated measures model "is the difference between jth ViSi and femoral a-line measurement". Please explain what is meant by jth ViSi measurement and jth femoral a-line measurement. Are you using averages over 20 seconds, per-heartbeat values, or something else? Clearly these will have ramifications on the analyses and performance goals.*

As stated in 7), data was analyzed according to ISO 81060-2, Section 6.2.6 requirements. The Statistical Analysis Plan submitted in the pre-IDE is obsolete.

12) *You use performance goals of 8mmHg, 12mmHg, and 7mmHg for your bias, between-subject standard deviation and within-subject standard deviation hypotheses; acceptability of these performance goals depends on what output you will present to your intended user, and hence what values you will use in your analyses. This is still not clearly defined. Please define this clearly.*

As stated in 7), data was analyzed according to ISO 81060-2, Section 6.2.6 requirements. The Statistical Analysis Plan submitted in the pre-IDE is obsolete.

13) *You present your rationale for using 10mmHg for between-subject standard deviation in Section 1.3. You appear to be basing your arguments on the SP10 upper limits on the standard deviation of paired differences. We have the following comments: a) The 6.95 standard deviation is proposed for a mean difference of 0, i.e., for an average observed difference of 0 over all patients. It does not appear that you expect an average observed difference of 0 in your study; b) You are incorrectly using the 6.95mmHg as the basic point estimate for which you calculate a 95% confidence interval to obtain an upper limit. Please note that the stated upper limit on the standard, 6.95 for example, holds for all values of the point estimate and hence could more correctly be interpreted as the upper limit on the maximum of the point estimates of the standard deviation; c) Your justification does not take into account any averaging of values within patient to generate the output for your device (over 20 seconds, for instance).*

As stated in 7), data was analyzed according to ISO 81060-2, Section 6.2.6 requirements meaning the acceptance criteria is a mean error of not greater than ±5.0 mmHg and standard deviation of not greater than 8.0 mmHg.

14) *In Section 1.2 of your submission (and Section 5.2 of the statistical plan) you state reasons for data exclusion. You also provide what appear to be reasonable scenarios which might results in such data exclusions. We note that these scenarios appear to be sufficient (but not necessary) conditions for values to be excluded, but that excluded values may also result from ViSi device errors. It is preferable that the data exclusions be defined in terms of objectively stated clinical conditions instead of device output.*

The Statistical Analysis Plan submitted in the pre-IDE is obsolete. The data exclusion criteria outlined in the clinical protocol (K130709, Exhibit 14, page 61 of 68) are:

- Data from periods of motion (coughing, talking, limb or body movement, etc.).
- Data from subjects with a BMI >35, conical shaped biceps and bias of >5mmHg between the arterial reference reading and a currently marketed NIBP cuff reading.

15) *Your definition of intent-to-treat and per-protocol patients in Section 5.1 of your statistical plan is neither typical nor acceptable. "Intent-to-treat" should describe patients in the study who are intended to be treated by the device, and may not be defined on the basis of data available for analyses. Please redefine appropriately.*

The Statistical Analysis Plan submitted in the pre-IDE is obsolete. The Data Analysis section of the study protocol (K130709, Exhibit 14, page 61 of 68) does not specify analysis populations.

16) *You propose to use the autocorrelation structure for your repeated measures model. Since the covariance structure will significantly affect the inferences drawn from your model, please propose in your protocol a plan for testing the appropriateness of this covariance structure.*

The Statistical Analysis Plan submitted in the pre-IDE is obsolete. The Data Analysis section of the study protocol (K130709, Exhibit 14, page 61 of 68) does not include a repeated measures model or autocorrelation.

17) *You propose to use the Anderson-Darling test for normality of residuals in your repeated measures model. This is acceptable; but please plan on also providing residual plots.*

The Statistical Analysis Plan submitted in the pre-IDE is obsolete. The data has been analyzed as specified in ISO 81060-2.

18) *For convenience of review please plan on providing at least the following basic plots and analyses: i) for each subject a plot that presents separately the device and reference method measurements for the period that the subject was in the study (X-axis shows time, Y-axis shows cNIBP measurement), missing values should also be indicated on this plot; ii) a plot of the differences of cNIBP measurements for device and reference method for each subject for the period that the subject was in the study, missing values should also be indicated on this plot.*

As is customary for non-invasive blood pressure accuracy measurements, separate Bland-Altman plots have been provided in the clinical study report (K130709, Exhibit 14, starting on page 29 of 68).

19) *You expect 10 of the 56 adult subjects enrolled to be missing. A 17.9% drop-out rate appears rather large for a study that will last no more than 12 hours. Please explain/justify this rate, providing a breakdown into different causes for drop-outs.*

The revised clinical study protocol does not contemplate the drop-out of study subjects. The cause(s) of drop-outs are explained in the clinical study report (K130709, Exhibit 14).

20) *You appear to be assuming subject dropouts and within-subject data will be missing at random and thus propose to ignore missing data in your analyses. Reasons for subject dropouts do not appear to be provided, and it does not appear from your data exclusion criteria that "missing at random" is a reasonable assumption for exclusion of within-subject data. Please provide propose a missing data analysis plan with associated sensitivity analyses or alternatively justification for your assumptions.*

See the response to 19).

21) *You propose to test poolability across sites by adding a fixed categorical effect for site to your repeated measures model for the primary effectiveness endpoint. Since the sites sampled in your study are not a census of all sites that you expect the device to be used at, a random effect for site would be more appropriate. Please modify your analysis plan appropriately or justify your rationale.*

The revised clinical study protocol specifies one study site. The issue of poolability is no longer a factor to be considered.

22) *You propose to test poolability across left or right arms. Please indicate if, and how, you propose to ensure adequate representation of both arms in your study.*

The arterial reference site and the cNIBP measurement are collected from the ipsilateral arm as recommended in ISO 81060-2. There is no longer a question of poolability across arms.

23) *You propose to test poolability across sites and across arms using a 5% level of significance, while also proposing to discuss significant effects at the 10% level. Please note that since the null hypothesis assumes poolability we recommend that these hypotheses be tested at the 10 or 15% levels as opposed to the 5% level. Please modify your protocol/statistical plan accordingly.*

See the response to 22).

24) *Your protocol states some secondary endpoints (e.g. Section 5.4.2.3; note that endpoint is Section 5.5 is not considered to be secondary, see deficiencies above) without a plan for testing primary and secondary hypotheses that accounts for alpha adjustments for multiple endpoints. If you propose to use any of these endpoints for labeling claims or confirmatory analyses please provide such a plan. In the absence of such a plan no claims of statistical significance will be allowed in the labeling, only descriptive statistics may be presented.*

The end-points for the clinical study are well defined in ISO 81060-2: mean error ≤ ±5.0 mmHg; standard deviation ≤ 8.0 mmHg. The Statistical Analysis Plan submitted in the pre-IDE is obsolete.

25) *You provide some details on an interim analysis for futility (Section 5.7, page 12 of 21 of statistical plan). It is critical that such interim looks not influence future trial conduct. You state that the only information conveyed to the study sites as a result of this analysis is whether to stop the study. Please provide details who will conduct the analysis, what information will be conveyed to the sponsor, and measures taken to ensure that this interim look will not influence future study conduct.*

The Statistical Analysis Plan submitted in the pre-IDE is obsolete. There is no provision for interim analysis in the revised clinical study protocol.

26) *Please note that since there are major outstanding deficiencies on your analysis plan your sample size has not yet been verified.*

The sample size selected for the cNIBP clinical study is based on ISO 81060-2, the consensus standard for non-invasive blood pressure measurements.

Some (non-exhaustive) minor points:

27) *The formulas presented on page 11 of 22 of your submission are not clearly legible. Please provide a more legible copy of formulas in future submissions (an electronic copy of the document that generated the pdf may be acceptable).*

The Statistical Analysis Plan containing the illegible formulas is obsolete.

28) *In Section 5.4.2.3 we assume that you intend to stratify the subjects by observed femoral a-line and brachial NIBP differences, since bias is not observable. Please confirm this interpretation.*

The revised clinical study protocol does not use the femoral artery as the reference site for the invasive measurement. The concept of femoral-brachial bias is no longer an issue.

REVISION HISTORY			
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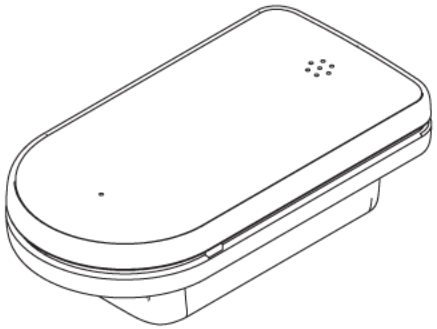

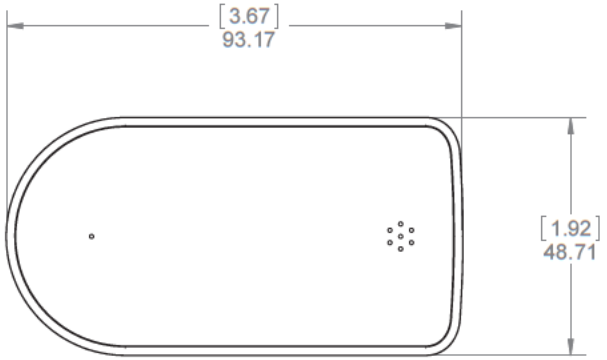

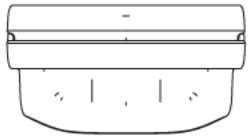

TOLERANCE
(UNLESS OTHERWISE SPECIFIED)
DIMENSIONS ARE IN MILLIMETERS
ONE PLACE DECIMAL (.X) = ± 0.5
TWO PLACE DECIMAL (.XX) = ± 0.25
THREE PLACE DECIMAL (.XXX) = ± 0.05
ANGLES = ± 1°

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DRAWN BY F.JACQUEZ 3/28/2013

Sotera WIRELESS
SOTERA WIRELESS, NC.
9444 Waples St., Ste 280
San Diego, CA 92121

TITLE: ViSi MONITOR

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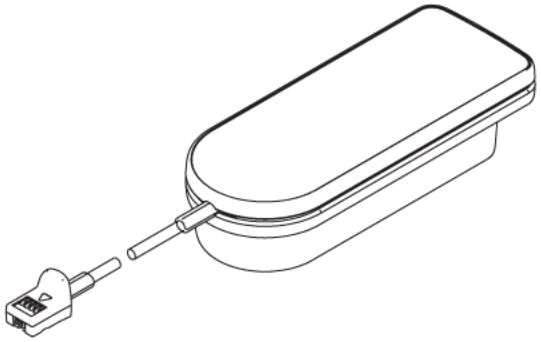

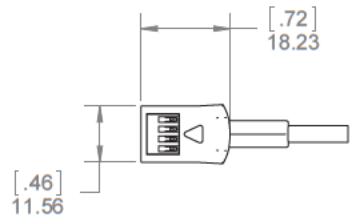

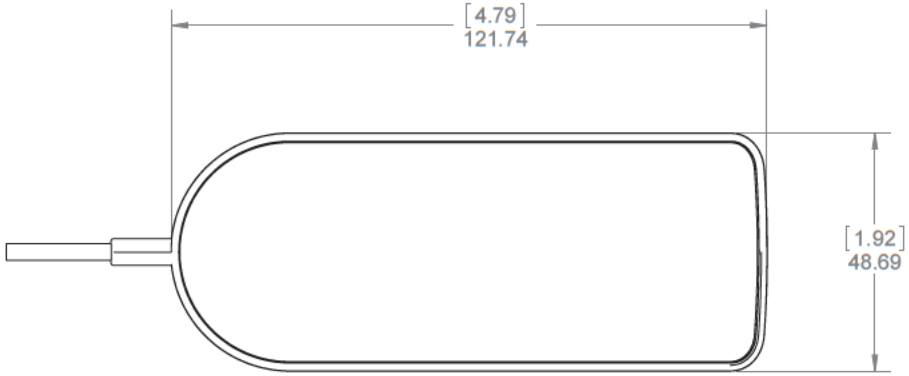

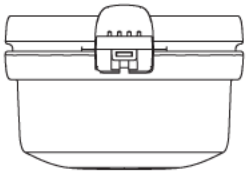

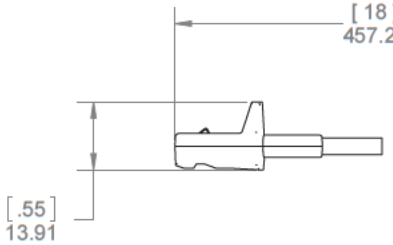

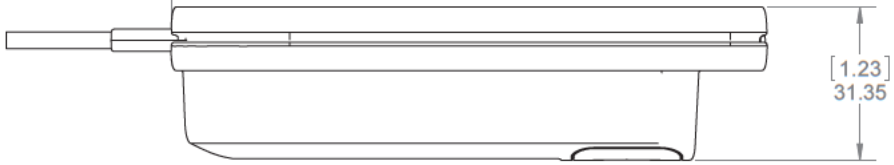

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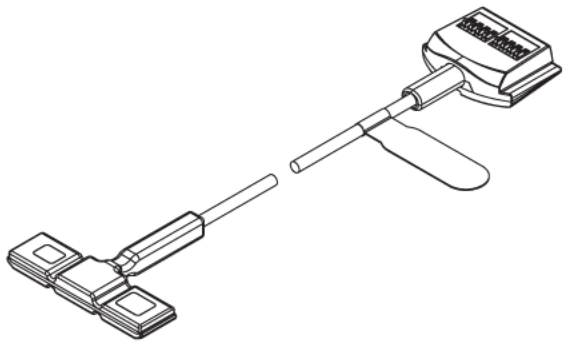

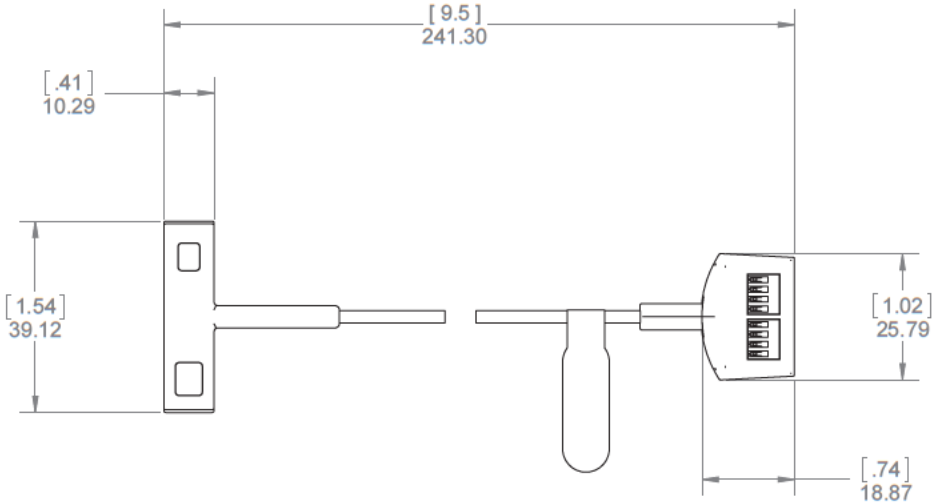

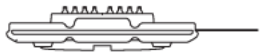

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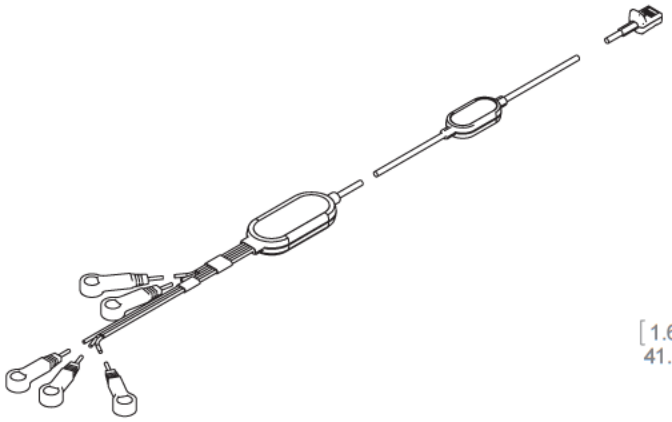

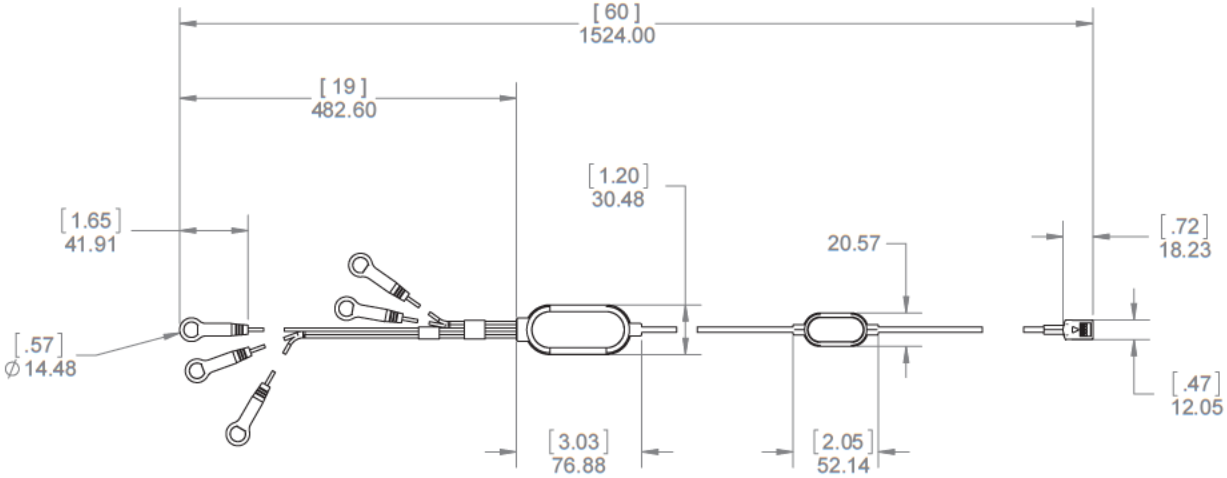

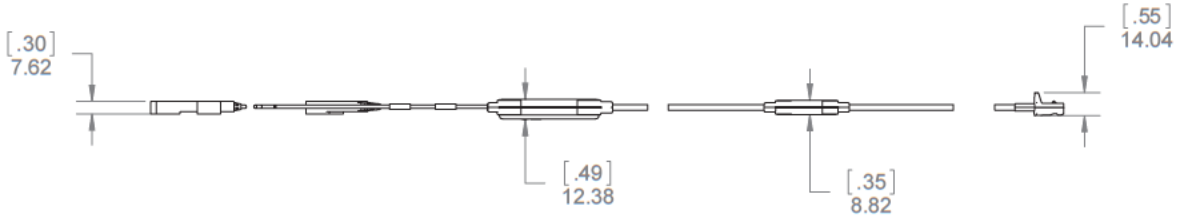

SIZE	DWG. NO.	REV
B	ECG CABLE	-
SCALE: 1:5	SHEET 4 OF 4	

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K130709/S002

June 25, 2013

FDA CDRH DMC
JUN 26 2013
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: REPLACEMENT ECOPY
510(k) No. – K130709/S002
ViSi Mobile Monitoring System

Dear Sir or Madam:

Attached please find a "Replacement eCopy" as requested in your" eCopy Hold Letter" dated June 24, 2013. The eCopy is an exact duplicate of the paper copy.

If you have any questions or require additional information, please contact me at eben.gordon@soterawireless.com, by telephone at 858.373.4841, or via facsimile at 858.427.4639.

Sincerely,
SOTERA WIRELESS, INC.

Eben Gordon

Eben Gordon
Senior Director, Regulatory

Attachments:

eCopy

28

K130709/S002

Sotera WIRELESS

WWW.SOTERAWIRELESS.COM

FDA CDRH DMC

JUN 24 2013

Received

June 21, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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510(k) No. – K130709/S002
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Sincerely,
SOTERA WIRELESS, INC.

Eben Gordon

Eben Gordon
Senior Director, Regulatory

Attachments:

eCopy

S3

K130709/S2

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FDA CDRH DMC
JUN 21 2013
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June 20, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: 510(k) No. – K130709/S002
Response to Request for Additional Information (May 21, 2013)
ViSi Mobile Monitoring System

Dear Sir or Madam:

Sotera Wireless, Inc. submits K130709/S002 in response to the request for additional information (dated May 21, 2013) for the ViSi Mobile Monitoring System 510(k) notification. Included in Attachment A is a re-statement of each identified deficiency followed by Sotera's response.

An additional eCopy of this response is provided. The eCopy is an exact duplicate of the paper copy.

If you have any questions or require additional information, please contact me at eben.gordon@soterawireless.com, by telephone at 858.373.4841, or via facsimile at 858.427.4639.

Sincerely,
SOTERA WIRELESS, INC.

Eben Gordon

Eben Gordon
Senior Director, Regulatory

Attachments:

Attachment A – Additional Information Response
Exhibit 1 – User Manual page 127-129
Exhibit 2 – Indications for Use, 510(k) Summary, User Manual page 19
Exhibit 3 –Subject v03 data
Exhibit 4 – User Manual page 79
Exhibit 5 – Excluded data listing
Exhibit 6 – User Manual pages 85-90

Exhibit 7 – User Manual page 41
Exhibit 8 – Page 3 FDA 3514
Exhibit 9 – Time Vs. Difference charts
eCopy

June 20, 2013

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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: 510(k) No. – K130709/S002
Response to Request for Additional Information (May 21, 2013)
ViSi Mobile Monitoring System

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Eben Gordon

Eben Gordon
Senior Director, Regulatory

Attachments:

Attachment A – Additional Information Response
Exhibit 1 – User Manual page 127-129
Exhibit 2 – Indications for Use, 510(k) Summary, User Manual page 19
Exhibit 3 –Subject v03 data
Exhibit 4 – User Manual page 79
Exhibit 5 – Excluded data listing
Exhibit 6 – User Manual pages 85-90

Exhibit 7 – User Manual page 41
Exhibit 8 – Page 3 FDA 3514
Exhibit 9 – Time Vs. Difference charts
eCopy

ATTACHMENT A
REQUEST FOR ADDITIONAL INFORMATION RESPONSE

General note: In the original K130709 submission, the mean difference between the ViSi cNIBP device and the Arterial–Reference ('bias') and the standard deviation were calculated using an analysis method assuming the measurements were independent. This approach is not suitable for repeated measures data. The data analyses in this response used the Bland-Altman method to determine agreement with repeated measures[1,2].

1 *In your clinical study, several patients had to use the restroom, which required them to change posture. It is unclear if the changes in patient posture (getting in and out of bed, unconnecting and reconnecting to the equipment, etc.) had an impact on the data collection and the calibration of your device. Please describe if these movements are captured in your data set and what impact they had on the data collection, usability, and calibration for your device. It is important to capture this level of information in order to accurately describe the overall utility of your device in the labeling.*

The Arterial-Reference line was disconnected for all 8 test subjects (of 15) when they used the restroom. This decision was made by the study clinician (Clinimark employee) because the data collection system would not reach into the restroom.

When the test subject returned from the restroom, the arterial reference pressure transducer was again re-leveled and re-zeroed to the atrium of the heart, after which data collection was resumed.

The brief periods (~5 minutes) while the Arterial-Reference line was disconnected during the restroom trips, the wireless battery powered DUT remained in operation and was not recalibrated afterwards. This demonstrated the ability of the DUT to continue accurate monitoring after activity without recalibration. The following activities occurred when the volunteer test subject went to the restroom:

1. During a restroom trip the Device-Under-Test (DUT) remained in operation on the test subject and data continued to be collected from the device.
2. Arterial-Reference Line was disconnected [thus, DUT: Arterial-Reference comparison data was not collected during restroom trips].
3. DUT was not recalibrated after return from restroom.
4. DUT:Arterial-Reference comparison data collection resumed (arterial reference pressure transducer was re-leveled and re-zeroed to the atrium of the heart).

2 *Please clarify if the following interpretation of the study is correct or not:*

Initially, the patient was lying supine. Although during the study the patient's torso was raised and lowered several times to various degrees, the actual data taking was done when the patient's torso was returned to the original supine position, and the patient had rested 3 to 5 minutes.

If this interpretation is correct, this part of the protocol is fine. However, if there were data collected when the patient was not completely supine, such data should be analyzed separately from the other data, since posture has an important impact on blood pressure.

Actual data collection occurred in the supine position and during two torso posture changes (i.e. 30° and 60°). Two times during each study the head and torso of the test subject was intentionally raised to 30° above horizontal and then to 60° above horizontal. Immediately after change to each position the Arterial-Reference pressure transducer was re-leveled and re-zeroed so that the pressure transducer would be moved to the same level as the atrium of the heart (this took approximately 60 seconds each time). Data was then collected for 3-5 minutes at both 30° and 60° positions immediately following the change in posture. The head and torso of the study subject was then lowered to supine at which time the Arterial-Reference pressure transducer was again re-leveled and re-zeroed to the atrium of the heart.

The periods of data that occurred when the Arterial-Reference pressure transducer was not level with the heart were removed. In response to FDA request, the data collected at each torso position was analyzed separately and then combined. The results are summarized in **Table 1**.

Subject Position		**Supine**	**30°**	**60°**	**Overall**
Systolic (mmHg)	Bias	-1.61	-4.77	-7.36	-1.88
	Std. Dev.	5.69	7.87	9.97	6.17
Diastolic (mmHg)	Bias	-1.33	-3.97	-8.31	-1.65
	Std. Dev.	3.16	4.49	6.07	3.62
MAP (mmHg)	Bias	-0.33	-3.01	-7.23	-0.67
	Std. Dev.	3.36	5.37	6.67	3.86
Data Points		47,572	1,774	1,724	54,179

Table 1: Ipsilateral mean differences (DUT: Arterial-Reference); n = 15 subjects

Table 1 has been added to the User Manual (page 127) for disclosure of the performance accuracy during posture changes (reference **Exhibit 1**). In addition, a new Warning has been included on the same page of the User Manual:

Warning: Changes in posture can affect ViSi cNIBP accuracy. Recalibrate ViSi cNIBP whenever torso changes by more than 30° above supine position.

These changes to the User Manual have been highlighted in yellow.

3 *Please confirm our interpretation that the cNIBP function and the mean arterial pressure (MAP) function are only intended for adult patients, as your supporting clinical study enrolled only adults 18 years or older. Please modify your intended use statement, 510(k) summary and user manual to reflect such patient characteristics.*

The interpretation that the cNIBP function and mean arterial pressure (MAP) are intended for adult patients is correct. The revised Intended Use, 510(k) Summary, and User Manual page 19 are provided in **Exhibit 2** with the modified text highlighted in yellow.

4 *Your protocol states (Exhibit 14, page 54) that the study was conducted on healthy volunteer test subjects. This does not appear to represent your intended use population that requires continuous blood pressure monitoring in hospital or emergency department use for instance. Please justify why you believe your study results generalize to the intended use population of your device, or provide additional data collected from the intended patient population.*

The cNIBP functionality is not a "requirement" for the intended use population. It is an enhancement to currently FDA cleared functionality for cuff based blood pressure measurement. The cNIBP is a user

selectable option that allows the clinician to: 1) Select an individual cuff-based measurement; 2) Select a periodic repeated cuff-based measurement; or 3) Select cNIBP measurement. The functionality of options 1 and 2 has already been FDA cleared (K112478). The cNIBP capability extends the use of non-invasive blood pressure measurements in intended applications where cuff-based blood pressure measurements are well established and FDA cleared.

The clinical study to add MAP to the ViSi cuff-based NIBP indication and cNIBP was performed at the same clinical test laboratory, Clinimark Laboratories, as was the Sotera predicate device (K112478). The same recruitment criteria for test subjects were used in the former study as was used in the current study to generate data for the same intended use population. The intended use population of the cNIBP device has not changed from the original NIBP device and therefore remains appropriate. Please note that the intended use population does not include critical intensive care areas of the hospital.

The recently cleared Radial-Cuf Non-Invasive Blood Pressure Cuff (K123996) has a similar intended use population as does the ViSi device and was clinically tested with volunteer subjects. The Radial-Cuf is intended to be used with noninvasive blood measurement pressure systems (e.g. Carescape V100 Vital Signs Monitor). The Carescape V100 (K102426) is indicated for NIBP, pulse rate, pulse oximetry, and temperature in various hospital departments including emergency, radiology, recovery, medical/surgical, labor and delivery, endoscopy, cardiac step-down. The Radial-Cuf clinical testing in the demographic group of large upper forearms and not in the generalized intended use patient population was sufficient for the device to receive clearance. Both the Radial-Cuf and ViSi cNIBP device studies were based on ISO 81060-2 requirements that compared a Radial Arterial Line to an NIBP measurement.

While the ViSi cNIBP clinical study subjects were volunteers, they were not all "healthy" since the proscribed number of hypertensive and hypotensive subjects were used to validate cNIBP accuracy. Some of the hypertensive subjects had very high systolic and diastolic pressures; they are, therefore, by definition, "unhealthy". The highest recorded systolic blood pressure in the study was 199 mmHg. This subject was referred to the hypertensive clinic following the study. Hypertension inevitably leads to dramatic cardiovascular events, such as stroke, myocardial infarction, and congestive heart failure. As for the subjects in the hypotensive category, vasomotor instability is not considered normal.

It is standard practice to test accuracy of physiological monitoring devices using healthy volunteer test subjects by either creating the perturbing condition (as in pulse oximetry hypoxia testing) or selecting for those conditions (as in using subjects who exhibit high and low blood pressures and also using subjects with large medium and small biceps). For example, pulse oximetry has long used healthy volunteer test subjects in hypoxia accuracy studies (e.g. ISO 80601-2-61), yet these devices are routinely used in critically ill locations (ex OR and ICU) Similarly, both blood pressure standards, SP10 and ISO 81060-2, use the term 'subjects' for many of the test methods. Accuracy is assessed when specific blood pressure and limb size ranges are tested as listed in the standards. Systolic and diastolic blood pressure ranges specified in ISO 81060-2 were selected to ensure device performance is evaluated over the entire clinically relevant blood pressure range[1]. The blood pressure ranges specified in ISO 81060-2 (section 6.1.5) and met in the clinical study are:

At least 10% of subjects with systolic pressure ≤100 mmHg

At least 10% of subjects with systolic pressure ≥ 160 mmHg

[1] ISO 81060-2 Section 5.1.5

At least 10% of subjects with diastolic pressure ≤ 70 mmHg

At least 10% of subjects with diastolic pressure ≥ 85 mmHg

Automatic recalibration of cNIBP helps assure the accuracy of blood pressure readings. Significant changes (e.g. >10 mmHg for hypotensive, >15 mmHg for normotensive, and >20 mmHg for hypertensives) from the last NIBP measurement triggers a message to the clinician the need to recalibrate. This recalibration ensures accuracy when volatile blood pressure readings are recorded. The term "recalibration" is used although the ViSi monitor is correlating the current pressure dependent pulse wave velocity to a recent oscillometric NIBP reading. The CNAP Monitor predicate device (K082599) similarly triggers a NIBP measurement when the CNAP reading differs by more than 25 mmHg from the last NIBP[2].

The appropriateness of the clinical study subjects to the intended use population is justified based on being the same intended use population as the predicate Sotera cuff-based NIBP device that used the same subject population. Further, the cNIBP device was tested in a clinically relevant blood pressure range as specified in the ISO standard. Finally, similar to the CNAP predicate, confirmation of the NIBP measurement is initiated when there is a significant change in baseline blood pressure.

5 *Your protocol states (Exhibit 14, page 54) that subjects will be "selected to represent a range of BP" but does not describe the selection procedure. Please state how subjects were selected (for instance, was this up to the clinician's discretion? Were sequential subjects who met the inclusion/exclusion criteria selected?). Inappropriate selection methods raise concerns of selection bias and of generalizability of study results to the intended use population.*

Test subjects were selected from a group of subjects in the Clinimark physiology lab database, who in the past had met the limb size and blood pressure distribution ranges required by ISO 81060-2. Prior to enrollment into the study (approximately 3 weeks before the study), biceps were measured and NIBP blood pressures were assessed using a manual mercury manometer (as is used in many physicians' offices). The first subjects who met the limb size and or blood pressure ranges were scheduled for study enrollment.

6 *You state (Exhibit 14, page 55 of 68). "During the 4 hour data collection period the cNIBP Test System will calculate blood pressure values at 10 second intervals; the same update frequency will be applied to the, invasive arterial reference system. Real-time data from the cNIBP Test System will be paired with the real-time blood pressure values as measured by invasive arterial reference pressure waveform over the 4 hour data collection period."*

Since there seems to be a mismatch of time intervals - the l0-second interval is completely different from the 60-second averaging interval of ViSi, and its 3-second display update interval, while your spreadsheets present data collected every 3 seconds-, please explain flow observations from your device and the radial arterial blood pressure monitor (frequency of measurement not indicated) were paired in the study, and at what frequency of comparison. Although you have provided line listings of BP data, they are the results of such processing. What we need are two numerical examples of how the raw data from the ViSi device and the

[2] Operator's Manual CNAP Monitor 500, Page 12-9, Exhibit 6, K130709

invasive reference device were collected, and processed to arrive at the form presented in the spreadsheets.

Summarized below are the flow observations from the ViSi cNIBP device and the reference arterial pressure monitor along with a description of the difference calculations:

- All of the ViSi cNIBP numeric values were calculated and time-stamped by software executed on the ViSi Wrist Monitor (transceiver). The time and numeric values were transmitted wirelessly via 802.11b and recorded electronically in a text file on a personal computer.
- The radial artery pressure waveform for each subject was time-stamped and recorded electronically on a personal computer.
- Beat-to-beat systolic, diastolic, and mean arterial pressure values were identified from the radial artery pressure waveform.
- The ViSi cNIBP numeric values for systolic, diastolic, and mean arterial pressure (MAP) were calculated every 3 seconds. Also, the ViSi display was updated every 3 seconds with the most recent numeric values.
- The ViSi cNIBP numeric values for systolic, diastolic, and MAP were calculated using all the pulse arrival time values measured during the 60 second period prior to the time of the numeric update.
- A reference arterial blood pressure value for systolic, diastolic, and MAP were calculated for each ViSi cNIBP measurement. The reference values were determined using all of the beat-to-beat systolic, diastolic, or MAP values measured during the 60 second period prior to the time of the corresponding cNIBP numeric update (every 3 seconds).
    - Average systolic, diastolic, and mean pressures were calculated from all of the beat-to-beat reference data within the 60-second window.
    - Standard deviations for systolic, diastolic, and mean pressures were calculated from all of the beat-to-beat reference data within the 60-second window.
    - An upper and lower range of variation (ROV) were determined for the reference systolic, diastolic, and mean pressure by adding (upper ROV) and subtracting (lower ROV) the calculated standard deviation from the calculated average pressure value.
- If the ViSi cNIBP measurement was above the upper range of variation the difference between the ViSi measurement and the reference measurement was calculated by subtracting the upper range of variation from the ViSi cNIBP measurement.

  If the ViSi cNIBP measurement was below the lower range of variation the difference between the ViSi cNIBP measurement and the reference measurement was calculated by subtracting the lower range of variation from the ViSi cNIBP measurement.

  If the ViSi cNIBP measurement was within the upper range of variation and lower range of variation the difference between the ViSi measurement and the reference measurement was zero.
- The line listing of data provides the numeric update time, the systolic, diastolic, and MAP differences, the upper ROV, the lower ROV, and the average values that were calculated for systolic, diastolic, and MAP.

Exhibit 14, page 55 of 68 (K130709) incorrectly stated that the cNIBP test system would calculate blood pressure values at 10 second intervals. The correct interval is 3 second intervals. The same frequency was applied to the invasive arterial reference system.

Three numerical examples of how the raw data from the ViSi device and the invasive reference device were analyzed are provided by way of determining the average difference and standard deviation of systolic, diastolic, and MAP for subject v03 at study time of 940.58 seconds.

The raw data to be analyzed is excerpted from spreadsheet cNIBP_IPSILATERAL_LINELISTING.xlsx and Invasive Arterial BP references.xlsx for ViSi cNIBP and invasive reference arterial data, respectively. The data spreadsheets are provided in the STATISTICAL_DATA folder in the accompanying CD and listed in **Exhibit 3**. The collected data from the ViSi cNIBP device and the invasive reference were processed to arrive at the form presented in the spreadsheet as follows:

1. Calculate average reference values from all the beat-to-beat arterial blood pressure data that exists within a 60 second window prior to the ViSi cNIBP numeric.

   m_{sys} = 130.52 mmHg
   m_{dia} = 70.72 mmHg
   m_{map} = 91.16 mmHg

2. Calculate standard deviation values from all the beat-to-beat arterial blood pressure data that exists within a 60 second window prior to the ViSi cNIBP numeric.

   σ_{sys} = 3.45 mmHg
   σ_{dia} = 2.00 mmHg
   σ_{map} = 1.70 mmHg

3. Calculate an upper range of variation (ROV) for systolic, diastolic, and mean pressure.

   Upper ROV_{sys} = 133.97 mmHg
   Upper ROV_{dia} = 72.72 mmHg
   Upper ROV_{map} = 92.86 mmHg

4. Calculate a lower range of variation (ROV) for systolic, diastolic, and mean pressure

   Lower ROV_{sys} = 127.07 mmHg
   Lower ROV_{dia} = 68.72 mmHg
   Lower ROV_{map} = 89.46 mmHg

5. Determine a difference value for systolic (xsys), diastolic (xdia), and mean pressure (xmap)

   Systolic Difference:
   126 < 127.07
   x_{sys} = 126-127.07 = - 1.07 mmHg
   Diastolic Difference:

68.72 < 72 < 72.72
x_{dia} = 0.00 mmHg

MAP Difference:

89.46 < 91 < 92.86
x_{map} = 0.00 mmHg

6. Difference values for systolic (xi,sys), diastolic (xi,dia), and mean pressure (xi,map) were calculated in an identical manner for all of the cNIBP numeric values recorded for each subject.

7 We have several concerns regarding your data rejection/exclusion criteria. data exclusion raises concerns of selection bias that could result in biased estimates of device performance. Please address the following concerns and provide for FDA review all electronic line data for all subjects enrolled in the study prior to any data exclusions (note additional comments regarding electronic data below):

Line listings for all subjects enrolled in the study prior to exclusions are provided in cNIBP_IPSILATERAL_LINELISTING.xlsx. The spreadsheet is found in the accompanying CD in the folder STATISTICAL_DATA.

a. You state that the study included two cNIBP test systems on each subject (one on each side) and paired values for an inflation cycle will be excluded under some circumstances (Exhibit 14, page 54-55). Please note that, unless you plan to use two units of the device simultaneously on subjects in the intended use population after market clearance, the protocol and data analysis of the study should depend on only one unit of cNIBP on each patient. Hence, please clarify if the study utilized any exclusion criteria that are based on use of multiple devices on the same subject. If yes, please clarify which of the two devices is being used as in the intended use setting, and include in your analyses data that have been previously excluded on the basis of the second device.

Data were collected using 2 ViSi cNIBP devices (one on each arm). The reason for 2 test systems was the concern that that the Arterial-Reference line would interfere with the ipsilateral cNIBP reading. Analysis of the study results found both cNIBP devices, independent of one another, met the accuracy specification (bias ± ≤ 5 mmHg; standard deviation ≤ 8 mmHg) as outlined in ISO 81060-2. In an effort to simplify the submission, data from only one device (ipsilateral) were submitted.

The data exclusion criteria were not based on the use of multiple devices on the same subject. The plan after market clearance is to use one ViSi cNIBP device per patient.

The data from the contralateral device has been analyzed in the same manner as was presented in Question 2. The results from the contralateral side ViSi cNIBP device are summarized in **Table 2**.

Subject Position		Supine	30°	60°	Overall
Systolic (mmHg)	Bias	-1.55	-5.28	-6.37	-1.80
	Std. Dev.	4.53	6.31	9.21	4.98
Diastolic (mmHg)	Bias	-1.11	-4.47	-7.92	-1.46
	Std. Dev.	4.40	5.10	6.39	4.72
MAP (mmHg)	Bias	-0.54	-3.48	-6.56	-0.83
	Std. Dev.	3.96	5.18	6.68	4.30
Data Points		46,871	1,698	1,700	53,370

Table 2: Contralateral performance results; n = 15 subjects

Line listings of contralateral data for all subjects enrolled in the study prior to exclusions are provided in cNIBP_CONTRALATERAL_LINELISTING.xlsx. The spreadsheet is found in the accompanying CD in the folder STATISTICAL_DATA.

b. Please explain for each kind of data exclusion criterion how (and by whom) it was decided that it was appropriate to reject data.

Subject v02

Subject v02 was excluded by the study clinician (employee of Clinimark) on the basis of the second exclusion criteria as listed in the protocol. The data rejection criteria from the protocol, page 12 (page 61 of 68 in TR# 2012048; Exhibit 14, K130709 were:

"Data Analysis/ Data Inclusion/ Data Rejection Criteria:

- Data from periods of motion (coughing, talking, limb or body movement, etc.).
- Data from subjects with a BMI >35, conical shaped biceps and bias of >5 mmHg between the arterial reference reading and a currently marketed NIBP cuff reading. (Attachment A)"

The explanation in Attachment A of the protocol, page 18, provides an in-depth explanation of the exclusion criteria (Rationale for Contraindications to Measurement of Noninvasive Cuff-Based Blood Pressure from the Upper Arm [Brachium] in Obese Humans, Donald P. Bernstein, M.D., Senior Scientist, Sotera Wireless).

Subject v02 had a BMI >35 (i.e. 35.5) and a large difference (bias) between a currently marketed NIBP cuff (GE Datex-Ohmeda AS-3) and the arterial blood pressure reference. The BMI for all other subjects in the study ranged from 18 to 33.

	Arterial Reference	GE Datex-Ohmeda AS-3	Bias
Systolic reading	146 mmHg	113 mmHg	33 mmHg
Diastolic reading	76 mmHg	62 mmHg	14 mmHg

Table 3: Subject v02 Bias results

Page 79 of the User Manual has been updated to caution the user that the cNIBP measurement should not be relied upon in patients with BMI >35 (see **Exhibit 4**).

Subject v14

Subject v14 was excluded by the study clinician (Clinimark employee) due to a near complete obstruction of the radial artery by the arterial reference catheter (Test Report, page 21 of 68, "cNIBP Data Exclusion") even after flushing the catheter as allowed by the protocol.

Subject v16

The first data set from subject v16 was excluded by the study clinician because the arterial reference was not in a low range that was required by ISO 81060-2. The majority of the study period was consumed by performing multiple NIBP inflations (> 30) to fulfill the low systolic criteria for NIBP. This subject is a known hypotensive subject in the Clinimark database. It is difficult to locate volunteer test subjects who exhibit radial artery systolic blood pressures low enough to satisfy ISO 81060-2 for the low systolic range.

Subject v16 exhibited consistently low systolic pressures in previous testing recorded in the Clinimark database. However, on the day of testing, the subject's systolic pressure was higher than the low range required by ISO 81060-2 (systolic blood pressure < 100 mmHg). Subject v16 was retested on a later date in order to obtain low blood pressure ranges needed.

Restroom Trips

In all subjects the Arterial-Reference line was disconnected during the restroom trips. This decision was made by the study clinician (Clinimark employee) because the data collection system would not reach into the restroom.

When the test subject returned from the restroom, the arterial reference pressure transducer was again re-leveled and re-zeroed to the atrium of the heart, after which data collection was resumed.

The brief periods (~5 minutes) while the Arterial-Reference line was disconnected during the restroom trips, the wireless battery powered DUT remained in operation and was not recalibrated after. This demonstrated the ability of DUT to continue accurate monitoring after activity without recalibration. The following occurred when the volunteer test subject went to the restroom:

1. During a restroom trip the Device-Under-Test (DUT) remained in operation on the test subject and data continued to be collected from the device.
2. The Arterial-Reference Line was disconnected (thus, DUT:Arterial-Reference comparison data was not collected during restroom trips).
3. DUT was not recalibrated after return from restroom
4. DUT versus Arterial-Reference comparison data collection restarted (arterial reference pressure transducer was re-leveled and re-zeroed to the atrium of the heart).

Data Removed When the Arterial Reference Pressure Transducer Was Not at the Same Level of the Atrium of the Heart in the Volunteer Test Subject

Head and Torso Position Change

Two times during each study the head and torso of the test subject was intentionally raised to 30° above horizontal and then to 60° above horizontal. Immediately after change to each position the arterial reference pressure transducer was re-leveled and re-zeroed so that the pressure transducer would be moved to the same level as the atrium of the heart (this took approximately 30 seconds each time). Data was then recorded for 3-5minutes at both 30° and 60° positions. The head and torso of the test subject was then lowered to horizontal at which time the arterial reference pressure transducer was again re-leveled and re-zeroed to the atrium of the heart.

c. You state on page 61 of Exhibit 14 that a bias (we assume you mean "difference") of greater than or equal to 5 mmHg between the clinical reference standard and the currently

marketed NIBP cuff reading would necessitate data rejection. Please note that since the arterial reference reading will not be available in practice and the NIBP reading from your device is expected to be correlated to the cNIBP reading, this is not a reasonable data exclusion criterion. Please reanalyze the data together with such previously rejected data.

A difference (bias) of >5 mmHg between the clinical reference standard and a currently marketed NIBP cuff reading was not used as a rejection criteria by itself. The 5 mmHg difference rejection criteria was invoked only if the test subject also had a BMI >35. Page 79 of the User Manual has been updated to caution the user that the cNIBP measurement should not be relied upon in patients with BMI >35 (reference **Exhibit 4**).

Subject v02 was the only data set that was excluded on the basis of the second exclusion criteria as listed in the protocol:

Data rejection criteria from the protocol, page 12, "Data Analysis/ Data Inclusion/ Data Rejection Criteria:"

- "Data from subjects with a BMI >35, conical shaped biceps and bias of >5 mmHg between the arterial reference reading and a currently marketed NIBP cuff reading. (Attachment A)"

The explanation in Attachment A of the protocol, page 18, provides an in-depth analysis of the exclusion criteria (Rationale for Contraindications to Measurement of Noninvasive Cuff-Based Blood Pressure from the Upper Arm (Brachium) in Obese Humans, Donald P. Bernstein, M.D., Senior Scientist, Sotera Wireless, Inc.).

Subject v02 had a BMI of 35.5 and a large difference (bias) between a currently marketed NIBP cuff (GE Datex-Ohmeda AS-3) and the arterial blood pressure reference. The BMI of all other subjects in the study ranged from 18 to 33. Reference **Table 3** (above) for mean systolic and diastolic readings for subject v02.

8 You state in your protocol (Exhibit 14, page 54 of 68) that the device-under-test will be calibrated with a calibrated reference source to avoid any error. Please explain what is meant by "calibrated reference source", how the calibration is carried out, and how often the device is intended to be calibrated for your proposed intended use. Please clarify how, when and with what calibration source the investigative devices were calibrated during the study. Your study provides results over a 4-hour period; the FDA concern is whether the study results are generalizable to the intended use of the device.

Clinimark, the originator of the study protocol, was contacted for assistance on question #8. A misstatement occurred in which the "device-under-test" on page 54 of 68 should have read "Invasive Arterial Reference System". The "calibrated reference source" was a mercury manometer that was calibrated to a NIST traceable Fluke DPM3 Digital Pressure Manometer (SN 88501). The calibrated reference source was used to calibrate the Biopac TSD104A Blood Pressure Transducer (invasive arterial line). The device is calibrated yearly and the calibration was current. This paragraph refers to the invasive arterial blood pressure device being calibrated and not the ViSi cNIBP device.

The ViSi cNIBP device is calibrated to a NIST traceable reference source during manufacture. Verification of the calibration of the ViSi device is scheduled for once per year.

9 *Your definitions of means and standard deviations of n paired determinations in your acceptance criteria lack clarity because you have not defined the terms used. Please address the following;*

a) *Clarify for equations (1) and (2) on page 61 of Exhibit 14 whether xi refers to differences between the cNIBP investigational device and invasive radial arterial measurements, and whether n refers to the total number of observations for a subject (i.e., about 4800 measurements with one measurement taken every 3 seconds);*

The bias and standard deviation of the differences for systolic, diastolic, and mean pressure were determined using the technique described by Bland and Altman[1,2] for replicated data in pairs. A summary of the error analysis is presented as follows.

1. Bias
   - A mean difference for systolic ($\mu_{sys,k}$), diastolic ($\mu_{dia,k}$), and mean ($\mu_{map,k}$) pressure was calculated for each subject, k from all of their respective difference values
   - The bias for systolic (μ_{sys}), diastolic (μ_{dia}), and mean (μ_{map}) pressure was calculated as the average of the mean differences of all N subjects

$$\mu_{sys} = \left(\frac{1}{N}\right)\sum_{k=1}^{N} \mu_{sys,k}$$

$$\mu_{dia} = \left(\frac{1}{N}\right)\sum_{k=1}^{N} \mu_{dia,k}$$

$$\mu_{map} = \left(\frac{1}{N}\right)\sum_{k=1}^{N} \mu_{map,k}$$

2. Standard Deviation
   - The variances of the differences for systolic (σ^2_{sys}), diastolic (σ^2_{dia}), and mean pressure (σ^2_{map}) were calculated as the sum of two different variance components.

$$\sigma^2_{sys} = \sigma^2_{b,sys} + \sigma^2_{w,sys}$$

$$\sigma^2_{dia} = \sigma^2_{b,dia} + \sigma^2_{w,dia}$$

$$\sigma^2_{map} = \sigma^2_{b,map} + \sigma^2_{w,map}$$

   - The components of variance can be calculated using one way analysis of variance to determine the within-subject error mean square (MS_w) and the between-subjects mean square (MS_b), where the number of difference values for each subject k is annotated as m_k and the total number of subjects is N.

$$\sigma^2_{w,sys} = MS_{w,sys}$$

$$\sigma^2_{b,sys} = \frac{(N-1)(\sum m_k)}{(\sum m_k)^2 - (\sum m_k)}\left(MS_{b,sys} - MS_{w,sys}\right)$$

$$\sigma^2_{w,dia} = MS_{w,dia}$$

$$\sigma^2_{b,dia} = \frac{(N-1)(\sum m_k)}{(\sum m_k)^2 - (\sum m_k)}\left(MS_{b,dia} - MS_{w,dia}\right)$$

$$\sigma^2_{w,map} = MS_{w,map}$$

$$\sigma^2_{b,map} = \frac{(N-1)(\sum m_k)}{(\sum m_k)^2 - (\sum m_k)}\left(MS_{b,map} - MS_{w,map}\right)$$

b) If n does represent the total number of observations for a subject, the large number of observations will ensure a small standard deviation for the differences that is not meaningful for clinical purposes (agreement between the device and clinical reference standard measurements is of interest). Please explain the rationale underlying your acceptance criterion.

As noted above, all data has now been analyzed using a repeated measures approach including the calculation of the standard deviation. The 8 mmHg standard deviation threshold is appropriate since it was determined based on clinical relevance.

10 You have provided Bland-Altman analyses for mean, systolic and diastolic pressures for the continuous blood pressure measurements. Please note that the standard Bland-Altman analysis assumes independence of measurements and is not appropriate for analyzing the lengthy collections of repeated measurements generated in your study.

As previously noted, the standard Bland-Altman analysis was inappropriately used. All data has been analyzed using a repeated measures approach.

Please consider the following analysis approaches:

a) You have not provided patient-level analyses pertinent to device performance assessment. Please provide for each enrolled subject plots of device and clinical reference standard over the study time period (X-axis representing time) and their differences. We recommend that time periods over which data has been dropped or is missing for the subjects should be indicated by missing values (gaps) in the plots to allow for easy visual interpretation of the data;

Subject level analyses have been provided in **Exhibit 9** for the 17 enrolled subjects in the clinical study. As requested, the difference between the ViSi cNIBP device and the clinical reference standard for systolic, diastolic, and mean arterial pressures are plotted over time. Starts and stops of data for posture changes as well as dropped data (e.g. for bathroom breaks) are indicated in the plots.

b) Device measurements can also be modeled as a function of the clinical reference standard (radial arterial measurement) and time, with random subject and time effects included in the

model. Predictive intervals at clinical reference points and over the measurement range will enable assessment of device's clinical performance.

We fit a mixed-effects model to the supine data, with response equal to the difference between the test device and the clinical reference standard and explanatory variables equal to time (fixed effect) and subject (random effect). The drift effect at 4 hours was less than 1 mmHg in magnitude for all readings (-0.86 mmHg for systolic, 0.63 mmHg for diastolic, and -0.58 mmHg for MAP). A mixed-effects model was then fit with only a random subject effect to conservatively estimate the mean difference, the between-subject and within-subject standard deviation and the total standard deviation (the square root of the sum of the between-subject and within-subject squared standard deviations). The standard deviation estimates were larger in the model without the fixed time effect, since the time effect explained some of the variability. The estimated mean difference or bias for all supine measurements was less than the threshold of 5 mmHg specified in the ISO standard and the estimated total standard deviation was less than the threshold of 8 mmHg for all measurements (systolic, diastolic and MAP). Reference **Table 4** for results.

The same supine data was analyzed using Bland-Altman equation to determine agreement with repeated measures. The results using the Bland-Altman equation and the mixed-effects model are very similar justifying the use of the Bland-Altman methodology of data analysis (reference **Table 4**).

	Systolic (mmHg)		**Diastolic (mmHg)**		**MAP (mmHg)**	
Ipsilateral arm	**Mix-Eff**	**B-A 2007**	**Mix-Eff**	**B-A 2007**	**Mix-Eff**	**B-A 2007**
Bias	-1.61	-1.61	-1.33	-1.33	-0.33	-0.33
Between subject S.D.	3.93	3.91	2.00	2.07	2.08	2.08
Within subject S.D.	4.14	4.14	2.39	2.39	2.66	2.66
Total Std. Dev.	5.70	5.69	3.11	3.16	3.38	3.38
Contralateral arm	**Mix-Eff**	**B-A 2007**	**Mix-Eff**	**B-A 2007**	**Mix-Eff**	**B-A 2007**
Bias	-1.55	-1.55	-1.60	-1.11	-0.54	-0.54
Between subject S.D.	2.65	2.64	3.20	3.29	2.62	2.70
Within subject S.D.	3.68	3.68	2.91	2.91	2.90	2.90
Total Std. Dev.	4.53	4.53	4.33	4.40	3.90	3.96

Table 4: Supine bias, Standard deviation; n = 15 subjects; Ipsilateral & Contralateral

To summarize the errors or differences between test and reference devices, tolerance intervals are more informative than prediction intervals. The 95% tolerance intervals for the ipsilateral error indicate that 91% of systolic and 99.7% of diastolic and MAP blood pressure measurements will be less than 10 mmHg in magnitude.

11 You have stated reasons for dropping one of the subjects from your clinical study but do not appear to have provided a list of data that were either missing or dropped for each study subject. Data exclusions raise potential concerns of selection bias that could impact performance assessments. Please provide for each study subject a list of all periods for which data were dropped, stating reasons for dropping the data at each instance and explaining how the decision to drop the data were made and by whom.

Provided in **Exhibit 5** for each study subject is a list of all periods for which data were dropped, reasons for dropping data, and by whom the decision was made.

12 You have provided electronic data for your continuous blood pressure measurements but do not appear to have provided documentation for your datasets. Please explain contents of electronic datasets and worksheets provided, explain column headings, provide units where appropriate and explain any codes that are used. The following link provides " explanatory details on presentation format: http://www.fda.govlMedicaIDevicesiDeviceRegulationandGuidancelHowtoMarketYourDevicelPremarketSubmissions/ucm 1363 77 .htm

All electronic data has been provided compliant with "Clinical Data for Premarket Submissions" on the accompanying CD. The Excel file "Dataset_Documentation.xlsx" explains the identity of each column in each data set.

13 Your electronic data do not appear to contain demographic and clinical information for your study subjects (age, gender, cuff size and other relevant clinical covariates at baseline). Please provide such data electronically.

The electronic demographic and clinical information has been provided as an Excel spreadsheet file "Demographic-Clinical.xlsx" on the accompanying CD.

14 Although the subject device appears to continuously collect BP data, each displayed data point is a roving [rolling] average of the last 60 seconds of previously collected data. Further, this average is updated to the display screen once every 3 seconds. Hence, as also indicated by item 5 on page 36 of 68 in Exhibit 14, we believe that there is a time delay in the device's reflecting instantaneous change in BP. Thus, please revise labeling to reflect this time delay in the cNIBP data, as its use may be of diminished value in the critical care environment.

The displayed data is updated every 3 seconds based on a rolling average of blood pressure data from the previous 60 seconds. A caution has been added to Section 5.2.8 (Continuous NIBP Monitoring), page 79 of the User Manual to advise the clinician that "Due to cNIBP signal averaging, there is a time delay between the instantaneous blood pressure reading and the displayed reading." The added caution is provided in **Exhibit 4** with the new text highlighted in yellow.

In the Specifications Section 9.2.5 (Continuous Non-Invasive Blood Pressure [cNIBP]), page 127 of the User Manual, the information regarding the rolling 60 second average of cNIBP data and the 3 second display update has been added. The added information to page 127 is provided in **Exhibit 1** with the new text highlighted in yellow.

Please note, while preparing the answer to this question, it was recognized that the introductory paragraph on page 79 incorrectly indicated the averaging period for PAT calculations is 30 seconds. The correct value is 60 seconds. Page 79 has been corrected and as previously noted provided in **Exhibit 4.**

15 Although you have provided a clinical study to support the cNIBP function in the device, we believe that the study cannot cover the ambulatory use of this function, since the subjects in the study were resting in bed, not ambulatory. Further, your theory in recording cNIBP is

based on the idea of pulse arrival time (PAT), which includes a component called pre-ejection period (PEP). You have taken PEP to be constant.

However, we believe that PEP may change if there is significant change in heart rate, which can happen to an ambulatory patient. Hence, please revise labeling (including indications for use) to indicate that the cNIBP function has not been tested on ambulatory patients at this time. Alternately, you can provide data on ambulatory patients or justify why data on the supine patient is the same as that of an ambulatory patient.

Sotera Wireless agrees with FDA's recommendation to specify that cNIBP monitoring should not be conducted while the patient is ambulatory. The revised wording reads: "Continuous non-invasive blood pressure (cNIBP) testing has not been conducted on ambulatory patients."

The revised Intended Use, 510(k) Summary, and User Manual (page 19) are provided in **Exhibit 2** with the modified text highlighted in yellow.

16 In your study, it does not appear that your device required any recalibration. However, it is not clear if a recalibration is necessary throughout the indicated use (which may include stationary or ambulatory patients as discussed above). Please provide information on the recalibration of your device including frequency and provide adequate data to support your claims. lf you claim that there is no need for recalibration, then you will also need to support the statement.

The continuous blood pressure monitor (cNIBP) is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every three seconds. The ViSi Mobile Monitor is able to continuously measure NIBP without further cuff inflations. Recalibration therefore is not related to any set temporal interval.

Recalibration of the ViSi cNIBP device by NIBP is required as follows:

- Normotensive patients - Either the systolic or diastolic measurement indicates a change since NIBP calibration by more than 15 mmHg
- Hypertensive patients - Either the systolic or diastolic measurement indicates a change since NIBP calibration by more than 20 mmHg when in the range: systolic above 140 mmHg or diastolic above 90 mmHg
- Hypotensive patients - Either the systolic or diastolic measurement indicates a change since NIBP calibration by more than 10 mmHg when in the range: systolic below 90 mmHg or diastolic below 60 mmHg

Recalibration was not performed during the study because criteria for recalibration were not met. The triggering of re-calibration of the ViSi cNIBP device after a significant change in baseline blood pressure (actually PAT) is similar to the predicate device, CNAP Monitor, which recalibrates after a change by more than 25 mmHg from the last NIBP measurement.

Recalibration is also recommended after the administration of vasoactive drugs because of the potential impact on PAT.

As indicated in the response to Question 15, since testing has not been conducted while the patient is ambulatory, the Intended Use and User Manual have been revised accordingly (reference **Exhibit 2**).

17 Although you have classified the following anomalies as tolerable, or negligible, we believe otherwise. Please address them:

a. CNIBP-17: "When a NIBP-derived PR reading exceeds the upper device limit, a NIBP Fault alert is displayed rather than "+++". This only happens for manual NIBP measurements. The nurse is present for the measurement so there is a clinician at the patient side and there is clear indication of a failure to display BP and a need to retake the measurement. This would not result in patient harm." We believe that labeling should be revised to indicate this device characteristic.

Software anomaly CNIBP-17 refers to the following behavior: *When a NIBP-derived PR reading exceeds the upper device limit, a "NIBP Fault" alert is displayed rather than "+++".* This software has been fixed, tested, passed, and closed. The existing labeling reflects the behavior of the system.

b. CNIBP-33 "NIBP Fault" alert is generated when all sensors (Thumb, Cuff and ECG) are connected and a blood pressure is taken. This would result in a delay in measuring NIBP, which would delay initial calibration of cNIBP until the nurse can retry the measurement. This delay in measuring cNIBP is a minor patient safety risk but no harm is caused to the patient."

It is not clear if you have identified the root cause for this anomaly. Based on your description, we are concerned that there is a system level issue that is causing this anomaly such as inadequate CPU bandwidth to accomplish all of the necessary tasks. As such, we are concerned that this anomaly has not been adequately addressed and may not allow the device to perform as intended. Please provide your analysis of the root cause for this issue and either fix the issue or provide further justification for why you believe that this anomaly will not impact the intended use of the device or the patient safety.

Software anomaly CNIBP-33 refers to the following behavior: *"NIBP Fault" alert is generated when all sensors (Thumb, Cuff and ECG) are connected and a blood pressure is taken.* The root cause for anomaly was the insertion of a string that was too long and was causing a buffer overflow. This issue has been fixed, tested, passed, and closed.

c. CNBP-36 ''Sp02'' is not displaying waveform/numeric values when all sensors are re-connected to the ViSi monitor from "Clean Monitor, return to charger" screen. All patient monitoring has stopped at this point consistent with labeling. If sensors are being disconnected and reconnected, the clinician is at the bedside and will recognize that Sp02 is not being measured and will address this issue. This issue is Negligible from a patient safety risk perspective."

We do not understand the description. Please provide more information on this anomaly, and why it is tolerable.

Software anomaly CNIBP-36 refers to the following behavior: *"SpO2" is not displaying waveform/numeric values when all sensors are re-connected to PWD from "Clean Monitor, return to charger" screen*. This was a state-machine issue where if the monitoring session was stopped, it would not recognize the Thumb Sensor until the ViSi was placed in the charger and removed (as is the expected workflow). The issue has been fixed, tested, passed, and closed.

> *d. FEP-54 "When the ECG cable is disconnected during a high HR event, the alarm message display does not change from "High HR" to "High PR". After PR is within the alarm limit boundaries, PR measurement is not displayed in green. Since there is still a clear indication of high HR/PR, the intent is fulfilled. This issue is cosmetic. This would not result in patient harm" We believe that this is an issue of the device not displaying a normal heart rate (or pulse rate) value in the correct color. Since color has meaning, we do not believe that it is purely cosmetic and that this anomaly may cause user confusion. Please fix this anomaly.*

Software anomaly FEP-54 refers to the following behavior: *When the ECG cable is disconnected during a high HR event, the alarm message display does not change from "High HR" to "High PR". After PR is within limits PR measurement is not displayed in green*. The software has been fixed, tested, passed, and closed.

> *e. SE-18 "When monitoring is stopped and the Cuff module is removed from Wrist Monitor and then re-connected, the "Lock"&"Menu" buttons are displayed as "enabled" but they are actually disabled. They should not be displayed as "enabled" until a session has started. In this situation, they should only become enabled after the first NIBP measurement. The button state is a cosmetic issue. This would not result in patient harm."*
>
> *We believe that here the device is displaying erroneous information regarding the "Lock" and "Menu" icons. Please fix this error.*

Software anomaly SE-18 refers to the following behavior: *When monitoring is stopped and "Cuff" module is removed from WT and re-connected to WT. The "Lock"&"Menu" buttons are displayed as "enabled" but they are actually disabled. They should not be displayed as "enabled" when Cuff is not connected to patient*. The software had been modified to fix this issue; tested, passed, and closed.

> *f. SE-20 "Thumb No Pulse" alarm/alert with a "30 second no pulse activity/no motion" condition will never occur due to the motion event created from an active alert's audio annunciation. This issue resolves as soon as the alarm/alert is acknowledged. Therefore this is a Negligible issue. This would not result in patient harm." , We do not understand the description. Please provide more information on this anomaly, and why it is tolerable.*

Software anomaly SE-20 refers to the following behavior: *"Thumb No Pulse" alarm/alert "30 second no pulse activity/no motion" condition will never be satisfied due to the motion event created from an active alert's audio annunciation.* The root cause was that the alarm was causing vibration on the accelerometer which looks like motion. During periods of motion, the PPG beat-picker was not picking and so would not raise the Thumb No Pulse alarm until the alarm was acknowledged. The software has been modified to fix this issue; tested, passed, and closed.

18 We note that you provided ViSi System Risk/Hazard Analysis – cNIBP Mode, and Human Factors (HF) test protocol (dated 2/15/2013) and report (dated 3/1/2013). Our review

indicated that your HF study focused on the cNIBP modification. You did not provide information on the MAP modification. Please address the following question:

For the HF study, you focused on the cNIBP modification, and you have evaluated the calibration and recalibration step associated with the cNIBP modification. However, the recalibration step was evaluated only with one use scenario i.e. when a vasoactive drug has been administered to the patient. Your User Manual outlines other use scenarios such as:

• Any of the cNIBP measurements exceed the upper or lower alarm limits.

• Either the systolic or diastolic measurement indicates a change since calibration by more than 15mmHg for a normotensive patient over a period longer than 60 seconds.

• Either the systolic or diastolic measurement indicates a change since calibration by more than 20mmHg when in a hypertensive range (systolic above 190mmHg or diastolic above 140mmHg) over a period longer than 60 seconds.

• Either the systolic or diastolic measurement indicates a change since calibration by more than 10mmHg when in a hypotensive range (systolic below 90mmRg or diastolic below 60mmHg) over a period longer than 60 seconds.

• An unexpected interruption of monitoring occurred, such as all sensors being disconnected. If the interruption is less than 30 seconds, no recalibration is required.

It appears that these scenarios have critical tasks that may result in patient harm but they were not evaluated in the study. Please either provide additional data that demonstrate the users can perform these critical tasks or provide a justification for failures/use errors associated with these tasks would not result in patient harm.

The recalibration procedure is exactly the same for all conditions listed in the User Manual. The purpose of test Question #2 was to evaluate whether the clinician would recognize the scenario that requires Recalibration (i.e. after administration of a vasoactive drug). Recalibration after administration of a vasoactive drug is the only condition in which recalibration doesn't occur automatically. The remaining calibration scenarios listed in this question (i.e. • Any of the cNIBP measurements exceed the upper or lower alarm limits, • Either the systolic…, etc.) occur automatically and do not require the clinician to recognize the need for the recalibration. Recalibration was performance tested in Task #4.

A manual calibration can be performed at any time and is performed using the same procedure as is used for recalibration. Manual calibration was performance tested in Task #3.

Since the critical recalibration task was performance tested in Task #4 and recalibration is the same for all scenarios that would require recalibration, there was no benefit to repeating the same procedure. The only scenario requiring the clinician to recognize the need to recalibrate was tested in Question #2. The study as constructed evaluated the calibration and recalibration scenarios appropriately.

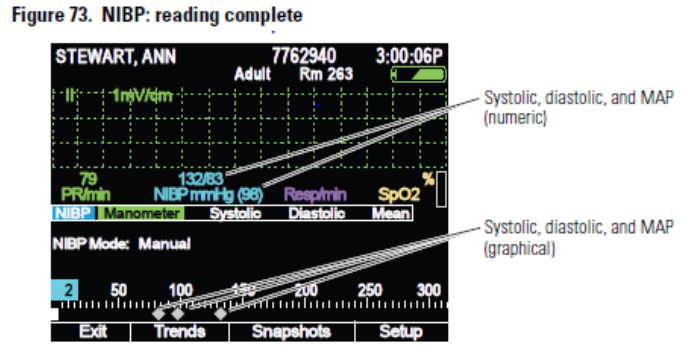
19 Similarly, please address the following question:

In addition to the cNIBP modification, you also propose to add of Mean Arterial Pressure (MAP) to the Non-Invasive Blood Pressure (NIBP) measurement. However, you did not submit information that provides an evaluation of the modification of adding the MAP to NIBP from a Human Factors/usability perspective. You indicated that MAP will be displayed

> *on the monitor screen, and once NIBP has been calibrated, MAP parameter will be displayed in red, and this displayed measurement will be refreshed every 3 seconds. It is possible that the user may not be aware that MAP parameter is being displayed, or they may confuse it with other parameters, etc. As a result, there are some use-related hazards associated with the MAP modification; however, you did not provide a use-related risk analysis for this modification. In addition, you did not provide an evaluation of use performance focusing on critical tasks that could result in patient harm. Please either provide additional data that demonstrate the users can perform these critical tasks or provide a justification for failures/use errors associated with the use of the MAP parameter would not result in patient harm. One example of confusing the two methods of recording MAP can be found in a question on labeling listed below.*

In the initial ViSi Mobile submission (K112478), test report *Human Factors Summative Validation, ViSi Mobile Monitoring System, H1*, R-000067, Rev. 1 was provided. This Human Factors study demonstrated that the intended users can safely and effectively perform critical tasks for the intended uses in the expected environment. This study included Question #27 which tested whether the clinical user could correctly identify the NIBP reading on the ViSi display. Twenty out of twenty clinical users responded correctly to this task.

The ViSi MAP parameter is displayed in a manner common to most commercially available vital signs monitors; the MAP reading is indicated parenthetically. Excerpts from 2 vital signs monitor user manuals illustrate this point:



Propaq LT VSM, Model 802 Series

ViSi Mobile Predicate device (User Manual provided in K122036, Exhibit 8, Page 65)

Welch Allyn Protocol clearance: K033378

Phillips MP5 Intellivue Patient Monitor MP5

User Manual, Page 145

Philips Medizinsysteme Boeblingen Gmbh clearance: K063725

The implementation of the accepted presentation mode of MAP was considered adequate to prevent misuse error.

Since the ViSi blood pressure reading (i.e. systolic and diastolic) was successfully tested in the initial Human Factors study and the MAP parameter is displayed using an approach consistent with current practice, the use error potential for the MAP parameter was considered negligible.

20 *Please clarify if there are alarm limits associated with MAP and cNIBP readings. If yes, please clarify if these alarms can be annunciated wirelessly to a central station. If yes, please provide test report to support this claim. Labeling should be revised to reflect your response.*

There are no alarm limits associated with the MAP parameter. Text has now been added to pages 86, 89, and 90 of the User Manual to inform the user of this information. The revised pages are provided in **Exhibit 6.**

Similar to NIBP, systolic and diastolic alarm limits have been implemented for cNIBP reading.

The current application implements the MAP and cNIBP features into the standalone ViSi Mobile Monitoring System (reference K112478). The annunciation of cNIBP alarms is limited only to the patient worn device and is not communicated to the central station. Therefore, no change in labeling is indicated at this time.

21 *Page 41 of the User Manual states, "Systolic, diastolic and MAP measurements will be displayed in red when measuring NIBP continuously (cNIBP)." Please revise the sentence to state, "Systolic, diastolic and MAP measurements of cNIBP will be displayed in red when measuring NIBP continuously. Normal NIBP measurements are displayed in white." This change is needed to avoid confusing the two methods of collecting BP readings.*

The text on page 41 of the User Manual has been revised to avoid confusion between the 2 methods of collecting blood pressure readings as recommended by FDA. Page 41 with the revised text highlighted is provided in **Exhibit 7**.

22 *On page 3 of 5 of the CDRH premarket review submission cover sheet, Form FDA 3514, you refer to K 122278 as another predicate. However, our records indicate that this is a completely different device. Please check the file number of this predicate.*

Page 3 of 5 of Form FDA-3514 has been corrected to replace the incorrect number (K122278) with the correct related submission (K122036). The revised form is provided in **Exhibit 8**.

---

[1] Bland, J.M., Altman, D.G. (1999). Measuring agreement in method comparison studies. *Statistical Methods in Medical Research*. 8:135-160.

[2] Bland, J.M., Altman, D.G. (2007). Agreement between methods of measurement with multiple observations per individual. *Journal of Biopharmaceutical Statistics*. 17: 571-582.

9.2.5 Continuous Non-Invasive Blood Pressure (cNIBP)

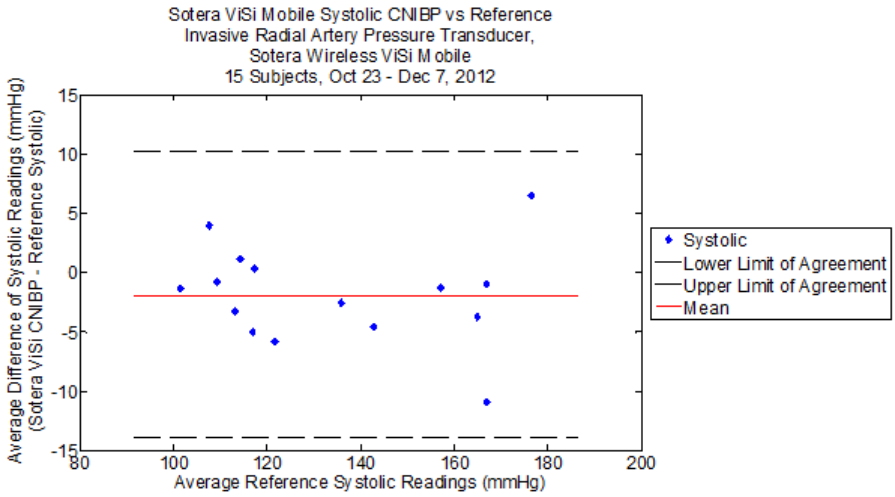
Continuous Non-Invasive Blood Pressure (cNIBP)	
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.
Principle of Operation	cNIBP is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location.
Display Update	Continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every 3 seconds.
Systolic	Range: 60 to 240 mmHg Accuracy: Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Diastolic	Range: 40 to 160 mmHg Accuracy: Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Mean Arterial Pressure (MAP)	Range 50 to 185 mmHg Accuracy Mean error of less than ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution 1 mmHg
Validation Study	Invasive blood pressure (radial artery) reference Number of subjects: 15 Subject age range: 19-48 years

cNIBP Clinical Study Results
Sotera ViSi cNIBP vs. Reference Invasive Radial Artery Transducer (n=15 subjects)

Subject Position		Supine	30º	60º	Overall
Systolic	Bias	-1.61	-4.77	-7.36	-1.88
	Std. Dev.	5.69	7.87	9.97	6.17
Diastolic	Bias	-1.33	-3.97	-8.31	-1.65
	Std. Dev.	3.16	4.49	6.07	3.62
MAP	Bias	-0.33	-3.01	-7.23	-0.67
	Std. Dev.	3.36	5.37	6.67	3.86
Data Points		47,572	1,774	1,724	54,179

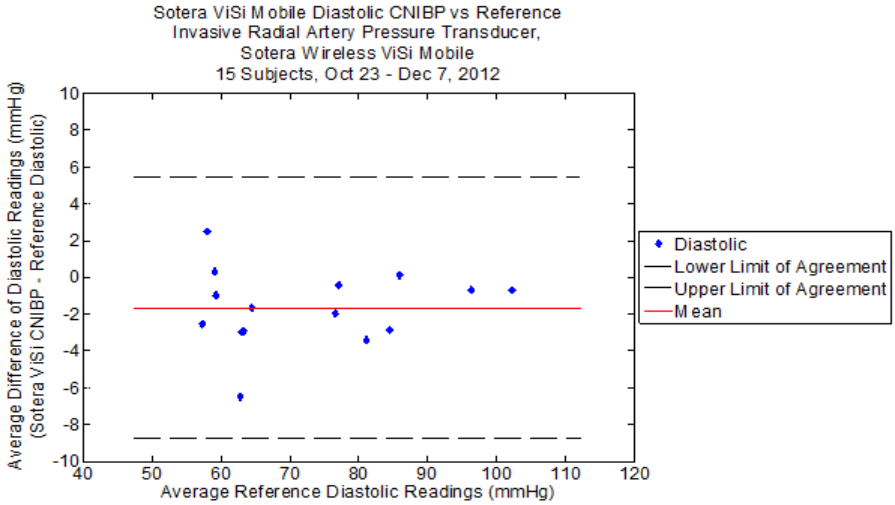
Changes in posture can affect ViSi cNIBP accuracy. Recalibrate ViSi cNIPB whenever torso changes by more than 30º above supine position.

Systolic Bland Altman Analysis (cNIBP)

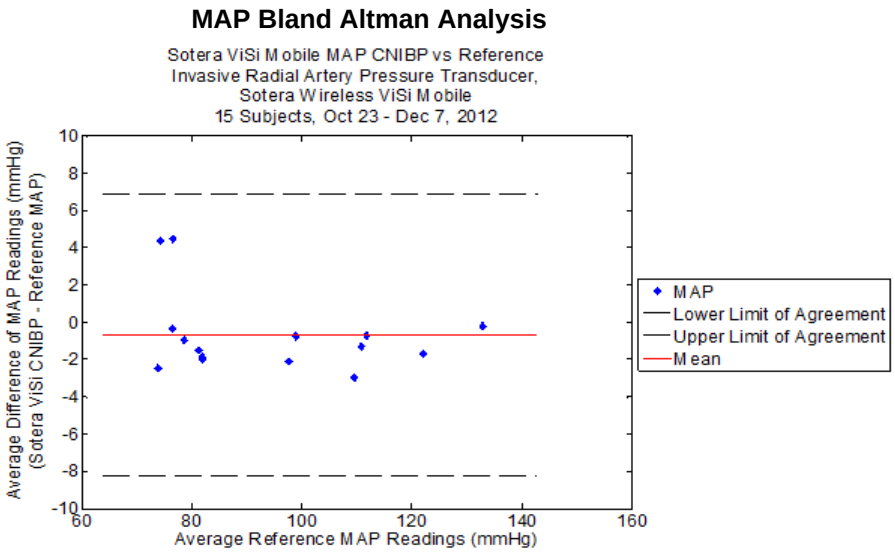


Sample Size:	54,179 data points
Mean:	-1.88 mmHg
Standard Deviation:	6.17 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	10.2 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-14.0 mmHg

Diastolic Bland Altman Analysis (cNIBP)



Sample Size:	54,179 data points
Mean:	-1.65 mmHg
Standard Deviation:	3.62 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	5.4 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.7 mmHg



Sample Size:	54,179 data points
Mean:	-0.67 mmHg
Standard Deviation:	3.86 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	6.9 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.2 mmHg

4 INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: _____ ViSi Mobile Monitoring System _____

Indications for Use:

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult (18 years or older) patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Continuous non-invasive blood pressure (cNIBP) testing has not been conducted on ambulatory patients.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

5 510(K) SUMMARY

Date prepared	June 11, 2013
Name	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.373.4841; F. 858.427.4639
Contact person	Eben Gordon Senior Director, Regulatory
Trade name	ViSi Mobile Monitoring System
Common name	Vital signs monitor
Regulation Name	Cardiac Monitor Including Cardiotachometer and Rate Alarm
Classification number	21 CFR 870.2300
Product code	MWI, DRT, DXN, DQA, FLL
Regulatory class	II
Predicate devices	ViSi Mobile Monitoring System; K112478 (Clearance: 3/27/2012) CNAP Monitor 500i, 500at; K082599 (Clearance: 10/17/2008)
Description	The ViSi Mobile Monitoring System is a lightweight, body-worn vital signs monitor featuring a high resolution, full color touch screen display, with visual and audible alarms and alerts. The ViSi Mobile Monitor is designed to continuously non-invasively measure ECG, heart rate, SpO2, blood pressure, pulse rate, respiration rate, and temperature. The ECG, SpO2, and Respiration waveforms are viewable on demand. The ViSi Mobile Monitoring System is capable of one-time and continuous NIBP measurements.
Indications for use	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult (18 years or older) patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments. Continuous non-invasive blood pressure (cNIBP) testing has not been conducted on ambulatory patients.
Summary of substantial equivalence	The ViSi System has the following similarities and differences with the indicated predicate devices:

- Intended use – The ViSi System has the same vital sign monitoring intended use as the ViSi System and CNAP Monitors. The cNIBP measurement of the ViSi System is the same as the CNAP Monitor.

- Device Performance – The modified ViSi System with intermittent NIBP MAP and cNIBP measurements have been clinically validated to meet the same performance requirements (mean error ≤ ± 5 mmHg; standard deviation ≤ 8 mmHg) as outlined in the consensus standards for automated non-invasive blood pressure monitors.

- Technology – The ViSi System is unchanged from it predicate submission except for the display of intermittent NIBP MAP readings and the continuous non-invasive blood pressure (cNIBP) measurements.

  The intermittent NIBP MAP measurement is based on the same technology as is currently in the cleared ViSi System and is equivalent to the CNAP Monitor. The ViSi's MAP measurement has been validated by comparison to an intra-arterial reference and meets the performance requirements of ISO 81060-2.

  The ViSi's cNIBP measurement has a different principle of operation from that of the CNAP Monitor predicate device. Both methods are similar in that pressure is determined on a beat-to –beat basis and are joint solutions employing automatic calibration to NIBP measurements.

  The question of effectiveness of the cNIBP measurement has been addressed by the clinical performance validation to the requirements of ISO 81060-2, an equivalent consensus standard to which the CNAP Monitor meets (i.e. AAMI/ANSI SP10).

The safety and effectiveness of the design elements implemented into the ViSi System have been confirmed by their compliance to the prevailing standards. The ViSi System has demonstrated compliance with the following consensus standards: IEC 60601-1-8, IEC 80601-2-30, IEC 62304, ISO 81060-2, and IEC 62366.

General Safety and Effectiveness Concerns – The instructions for use for the ViSi System contains the necessary cautions and warnings to provide for safe and effective use of the device.

The ViSi System has successfully undergone functional testing to demonstrate equivalence to the predicate devices. The following quality assurance measures were applied to the device: Risk analysis, Requirements review, Code inspections, Verification and validation, Bench testing, and Clinical performance testing.

The ViSi System have been tested and found to comply with recognized performance standards for medical devices. The results of all the testing demonstrate that the ViSi System is safe, effective, complies with the appropriate

1.3 Description

The ViSi Mobile Monitoring System is a patient worn, portable, battery operated, stand-alone physiological monitoring device indicated for the monitoring of ECG (3 lead-wire or 5 lead-wire), Heart Rate (HR), Pulse Rate (PR), Respiration (RESP), Non-Invasive Blood Pressure (NIBP), Pulse Oximetry (SpO_2), and Skin Temperature (TEMP). The Monitor measures and displays patient vital signs, and generates alarms and alerts.

The industry-standard technique of oscillometry is used for non-invasively taking single measurements of the systolic and diastolic blood pressure (NIBP) as well as pulse rate. The method is based on the observation of oscillations in the sphygmomanometer cuff pressure that are caused by the oscillations of blood flow, i.e., the pulse in the patient's upper arm. It uses a sphygmomanometer cuff like the auscultatory method, but with an electronic pressure sensor (transducer) to observe cuff pressure oscillations, electronics to automatically interpret them, and automatic inflation and deflation of the Cuff. The Cuff Module measures on inflation. The measurement is realized by a Cuff, to which the Cuff Module is attached (pneumatic connection). The electric connection to the Monitor is established through a cable that connects to its upper side.

1.3.1 Intended Use

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (18 years or older). It is indicated for ECG (3 or 5 lead-wire), respiration rate (RESP), heart rate (HR), non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including general medical-surgical floors, intermediate-care floors, and emergency departments.

Continuous non-invasive blood pressure (cNIBP) testing has not be conducted on ambulatory patients.

1.3.2 Contraindications

- Impedance pneumography for the determination of Respiration Rate (RESP) is not recommended for use in the presence of mechanically induced high frequency ventilation.
- The ViSi Mobile Monitoring System has not been tested for use on neonatal or pediatric patients under the age of 12 years.
- Do not use the same ViSi Mobile Monitor System to measure the NIBP of one patient while it is connected simultaneously to another patient.
- Do not use the ViSi Mobile Monitor on a patient with an Intra-Aortic Balloon Pump (IABP), or a Left Ventricular Assist Device (LVAD). The Monitor requires an unperturbed arterial pulse waveform for non-invasive blood pressure calculations. IABP and LVAD perturb the arterial pulse waveform.
- Do not use the ViSi Mobile Monitor System on a patient on cardio-pulmonary bypass.
- Do not use the ViSi Mobile Cuff Module on a patient's arm where the use of a blood pressure cuff is contraindicated.
- Do not use the ViSi Mobile Monitoring System in an MRI Suite.
- The effectiveness of the ViSi Mobile Monitoring System's blood pressure monitoring has not been established in the presence of any dysrhythmias.

Exhibit 3
Response to Question 6 (Analysis Example)
Excerpted Data for Subject v03

V03 – Ipsilateral: ViSi cNIBP Numeric:

Study Time (sec)	SYS_{visi} (mmHg)	DIA_{visi} (mmHg)	MAP_{visi} (mmHg)
940.58	126	72	91

V03- Ipsilateral: Beat-to-Beat Reference Arterial Pressure:

Study Time (sec)	SYS_{ref} (mmHg)	DIA_{ref} (mmHg)	MAP_{ref} (mmHg)
880.91	136.75	75.29	96.48
881.69	135.56	75.86	95.74
882.43	137.62	75.99	95.08
883.28	139.42	72.41	93.20
884.21	137.66	70.22	92.89
885.09	134.54	71.45	90.74
885.96	135.36	70.26	91.30
886.85	135.03	70.20	91.23
887.75	133.29	69.85	92.92
888.54	133.42	73.83	91.79
889.39	136.27	71.21	92.08
890.33	135.34	69.99	91.19
891.29	132.32	69.40	90.63
892.16	131.79	70.65	90.07
893.06	132.29	69.40	90.20
894.00	131.10	68.93	90.22
894.90	128.01	69.58	90.12
895.72	129.33	71.32	89.28
896.65	129.75	68.35	89.89
897.58	127.88	68.65	90.04
898.46	125.25	69.71	90.66
899.25	127.00	72.59	90.73
900.12	128.30	70.70	90.33
901.08	127.29	68.88	90.17
901.99	124.06	69.56	90.20
902.79	125.65	71.51	90.48
903.64	126.67	70.37	90.45
904.53	125.54	69.32	91.12
905.35	124.35	72.45	90.84
906.12	127.35	72.16	91.44
907.01	127.90	70.46	91.00
907.93	126.19	69.66	90.84

Study Time (sec)	SYS_{ref} (mmHg)	DIA_{ref} (mmHg)	MAP_{ref} (mmHg)
908.77	126.98	71.70	90.01
909.66	128.94	69.99	90.50
910.60	128.25	69.17	91.46
911.45	125.33	71.02	91.89
912.18	129.12	74.40	93.81
912.97	131.50	73.74	92.16
913.91	131.44	69.99	91.60
914.83	129.02	69.96	91.48
915.63	130.10	72.33	90.43
916.53	132.35	69.28	90.74
917.45	130.79	69.26	89.80
918.37	127.89	68.82	89.94
919.18	129.81	71.09	89.47
920.09	130.21	68.79	90.23
920.99	129.35	69.13	91.08
921.81	126.52	71.27	91.56
922.54	129.67	73.85	92.11
923.39	132.06	70.92	90.00
924.38	131.31	67.54	88.77
925.37	129.11	67.22	88.05
926.28	129.10	68.08	87.86
927.21	129.19	67.48	88.19
928.15	128.06	67.47	89.42
928.98	127.38	70.63	88.84
929.82	130.36	69.62	90.11
930.76	130.89	69.14	89.77
931.73	129.14	68.05	90.50
932.62	128.93	70.96	90.08
933.51	130.84	70.37	91.16
934.43	130.87	70.05	91.67
935.33	129.97	71.06	92.78
936.15	132.03	73.95	93.14
937.01	133.83	72.40	92.99
937.95	133.67	71.08	93.42
938.85	132.55	72.47	93.93
939.68	135.01	74.31	94.03
940.58	135.89	72.57	93.86

5.2.8 Continuous NIBP Monitoring

Sotera's continuous blood pressure monitor (cNIBP) is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every three seconds. The ViSi Mobile Monitor is able to continuously measure NIBP without further cuff inflations.

The accuracy of cNIBP is dependent on the initial cuff calibration. Use good clinical practice to confirm cNIBP accuracy before initiating or treating a patient.

The accuracy of the cNIBP measurement cannot be relied upon in patients with a BMI greater than 35.

Due to cNIBP signal averaging, there is time delay between the instantaneous blood pressure reading and the displayed reading.

Note: Continuous NIBP monitoring is an optional feature that requires an additional license key.

To calibrate cNIBP

Chest Sensor, Thumb Sensor and Cuff Module connected | NIBP Reading In Progress | Spot-Check Reading | cNIBP Calibrated

1. Connect the ViSi Mobile Chest Sensor, Thumb Sensor and Cuff Module and navigate to the **Vitals Signs** screen.

   The Start Cuff button *will change to the Calibrate cNIBP button.*

2. Touch **Calibrate cNIBP** on the **Vital Signs** screen.

Exhibit 5
Excluded Data

Subject v01: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	5112	5253	141
Excluded*	5427	5475	47
Excluded*	5659	5738	79
Excluded*	5936	6003	67
Excluded*	11044	11163	119
Excluded*	11432	11484	52
Excluded*	11678	11758	80
Excluded*	12019	12075	56

*The start and stop time of the excluded transducer periods were recorded during the study and the data was prior to the analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5110	5431	321
60 Degrees	5656	5942	286
30 Degrees	11040	11437	397
60 Degrees	11679	12030	351

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v02: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	5664	5782	118
Excluded*	5948	6097	149
Excluded*	6390	6492	103
Excluded*	6628	6755	127
Excluded*	11190	11385	195
Excluded*	11651	11749	98
Excluded*	12153	12304	152
Excluded*	12521	12624	104

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5666	5954	288
60 Degrees	6391	6637	246
30 Degrees	11250	11656	406
60 Degrees	12170	12530	360

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Bathroom Break

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded**	8400	9057	657

**The start and stop time of the excluded bathroom periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v03: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	5140	5439	299
Excluded*	5607	5713	106
Excluded*	5899	6056	157
Excluded*	6233	6301	68
Excluded*	11580	11705	126
Excluded*	11887	11973	86
Excluded*	12153	12239	87
Excluded*	12414	12492	78

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5255	5617	362
60 Degrees	5900	6245	345
30 Degrees	11581	11895	314
60 Degrees	12153	12426	273

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Bathroom Break

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded**	6685	7310	625

**The start and stop time of the excluded bathroom periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v04: Events and Exclusions

Tranducer Not At Heart Level

Event	Start (sec)	Stop (sec)	Duration (sec)
Excluded*	5436	5520	84
Excluded*	5712	5779	68
Excluded*	5963	6056	92
Excluded*	6267	6350	83
Excluded*	11634	11713	79
Excluded*	11959	12023	63
Excluded*	12206	12386	180
Excluded*	12586	12658	72

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5436	5714	278
60 Degrees	5964	6271	307
30 Degrees	11635	11964	329
60 Degrees	12205	12596	391

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v05: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	1300	1391	91
Excluded*	5676	5774	98
Excluded*	5962	6035	72
Excluded*	6222	6326	104
Excluded*	6512	6570	58
Excluded*	11059	11237	178
Excluded*	11534	11629	95
Excluded*	11825	11912	87
Excluded*	12130	12230	100

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5679	5967	288
60 Degrees	6222	6515	293
30 Degrees	11086	11539	453
60 Degrees	11827	12142	315

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Bathroom Break

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded**	1970	2425	455

**The start and stop time of the excluded bathroom periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v06: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	6323	6431	108
Excluded*	6603	6709	106
Excluded*	6917	7040	123
Excluded*	7247	7314	67
Excluded*	10925	11045	120
Excluded*	11223	11267	45
Excluded*	11494	11611	116
Excluded*	11821	11865	44

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	6322	6626	304
60 Degrees	6918	7252	334
30 Degrees	10924	11230	306
60 Degrees	11492	11830	338

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v07: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	5598	5683	86
Excluded*	5991	6074	83
Excluded*	6299	6419	120
Excluded*	6613	6686	73
Excluded*	10932	11012	80
Excluded*	11179	11260	81
Excluded*	11454	11616	163
Excluded*	11777	11885	108

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5595	5996	401
60 Degrees	6299	6618	319
30 Degrees	10925	11184	259
60 Degrees	11448	11781	333

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Bathroom Break

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded**	12483	12900	417

**The start and stop time of the excluded bathroom periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Arterial transducer tubing dislodged after returning from bathroom, consequently the study was stopped

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded***	12900	12942	42

*** Data collected after subject returned from the bathroom and the arterial line event was removed prior to analysis by a Sotera Research Engineer due to potenial corruption of the reference

Exhibit 5
Excluded Data

Subject v08: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	5615	5759	144
Excluded*	5951	5997	45
Excluded*	6315	6401	86
Excluded*	6603	6672	70
Excluded*	11129	11249	119
Excluded*	11431	11502	71
Excluded*	11698	11761	63
Excluded*	11939	12032	93

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5616	5957	341
60 Degrees	6314	6609	295
30 Degrees	11129	11435	306
60 Degrees	11698	11945	247

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v09: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	5917.26	6046.3	129.04
Excluded*	6239.83	6289.62	49.79
Excluded*	6576.98	6693.08	116.1
Excluded*	6886.38	6967.9	81.52

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5917	6247	330
60 Degrees	6571	6892	321

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Transducer malfunction and corrupted the reference data

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded***	9919	12733	2814

***The start and stop times of the corrupt data period were determined by the Principal Invetigator and a Sotera Research Engineer and the data was removed prior to analysis by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v10: Events and Exclusions

Tranducer Not At Heart Level

Event	Start (sec)	Stop (sec)	Duration (sec)
Excluded*	5871	5967	96
Excluded*	6241	6322	81
Excluded*	6508	6674	166
Excluded*	6863	7075	212
Excluded*	10931	11010	79
Excluded*	11245	11326	82
Excluded*	11542	11689	147
Excluded*	11885	11955	70

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5871	6250	379
60 Degrees	6507	6866	359
30 Degrees	10931	11253	322
60 Degrees	11540	11888	348

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v11: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	5574	5661	87
Excluded*	5849	5933	83
Excluded*	6254	6349	95
Excluded*	6560	6643	83
Excluded*	9858	10039	182
Excluded*	13198	13273	76
Excluded*	13460	13504	44
Excluded*	13726	13779	54
Excluded*	13985	14031	45

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	5575	5853	278
60 Degrees	6257	6565	308
30 Degrees	13208	13462	254
60 Degrees	13722	13995	273

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Bathroom Break

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded**	3631	4653	1022

**The start and stop time of the excluded bathroom periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v12: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	7566	7630	64
Excluded*	7795	7845	50
Excluded*	8025	8115	90
Excluded*	8316	8385	69
Excluded*	12986	13084	98
Excluded*	13278	13328	50
Excluded*	13554	13616	62
Excluded*	13842	13905	63

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	7560	7798	238
60 Degrees	8024	8324	300
30 Degrees	12986	13286	300
60 Degrees	13554	13855	301

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Bathroom Break

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded**	4711	5460	749

**The start and stop time of the excluded bathroom periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v13: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	6847	6917	70
Excluded*	7112	7174	62
Excluded*	7374	7457	83
Excluded*	7653	7718	65
Excluded*	11943	12021	78
Excluded*	12208	12250	42
Excluded*	12431	12499	68
Excluded*	12690	12767	77

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	6849	7117	268
60 Degrees	7374	7655	281
30 Degrees	11942	12209	267
60 Degrees	12430	12694	264

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v14: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	4846	4918	71
Excluded*	5124	5188	64
Excluded*	5370	5444	74
Excluded*	5648	5754	106
Excluded*	11870	11993	123
Excluded*	12205	12276	71
Excluded*	12482	12554	72
Excluded*	12747	12801	54

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	4845	5130	285
60 Degrees	5370	5655	285
30 Degrees	11871	12209	338
60 Degrees	12482	12754	272

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Bathroom Break

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded**	11259	11536	277

**The start and stop time of the excluded bathroom periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v15: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	5630	5693	63
Excluded*	6571	6697	126
Excluded*	6756	6846	90
Excluded*	7071	7127	55
Excluded*	7425	7492	67
Excluded*	7686	7726	40
Excluded*	11448	11513	65
Excluded*	11715	11750	35
Excluded*	11958	12047	89
Excluded*	12267	12310	43

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	6755	7075	320
60 Degrees	7424	7686	262
30 Degrees	11449	11721	272
60 Degrees	11957	12274	317

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Bathroom Break

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded**	3920	4515	595

**The start and stop time of the excluded bathroom periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v16: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	4368	4464	96
Excluded*	4672	4749	78
Excluded*	4931	5004	73
Excluded*	5320	5372	52
Excluded*	8737	8809	72
Excluded*	8974	9024	50
Excluded*	9217	9276	60
Excluded*	9477	9541	64

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	4383	4678	295
60 Degrees	4931	5324	393
30 Degrees	8737	8983	246
60 Degrees	9217	9494	277

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Exhibit 5
Excluded Data

Subject v17: Events and Exclusions

Tranducer Not At Heart Level

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded*	4827	4990	163
Excluded*	6171	6249	78
Excluded*	6444	6515	71
Excluded*	6730	6814	84
Excluded*	7020	7106	87
Excluded*	10465	10508	42
Excluded*	10694	10743	49
Excluded*	10977	11058	82
Excluded*	11238	11316	78

*The start and stop time of the excluded transducer periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

Posture Changes

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
30 Degrees	6172	6448	276
60 Degrees	6731	7027	296
30 Degrees	10464	10703	239
60 Degrees	10976	11251	275

The start and stop time of the posture changes were recorded during the study by a Sotera Research Engineer

Bathroom Break

Event	Start Event (sec)	Stop Event (sec)	Duration (sec)
Excluded**	5504	6117	613

**The start and stop time of the excluded bathroom periods were recorded during the study and the data was removed prior to analysis by a Sotera Research Engineer

6. Alarms and Alerts

6.1 Introduction

The ViSi Mobile Monitoring System provides a comprehensive alarm system that alarms on changes to the patient's physiologic status. The system provides default alarm limits or the clinician can manage the alarm limits per patient to provide individualized care. Equipment alerts are provided to alert the clinician of situations that may impede the ability to monitor your patient.

6.2 Managing Alarms and Alerts

A responsible clinician must be within audible range of the assigned patient wearing the ViSi Mobile Monitor at all times.

6.2.1 Turning Alarms On/Off

Alarm limits for each vital sign parameter are predefined and turned on automatically whenever a sensor is connected to the patient and to the Monitor. Sometimes it is desirable to adjust the alarm limits to meet a patient's monitoring requirements.

When alarms are turned OFF, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarms are turned OFF.

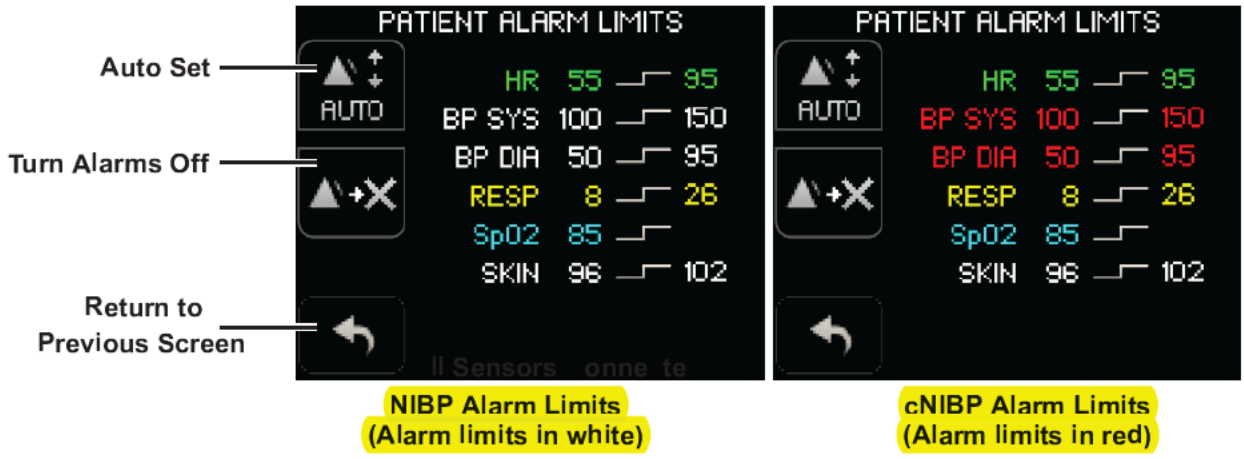
To turn all alarms off

1. Touch **Menu** on the **Vital Signs** screen.

   The Menu screen appears.

2. Touch **Alarms Settings.**

The Patient Alarm Limits screen appears. Alarm limit settings are only displayed for the connected sensors.

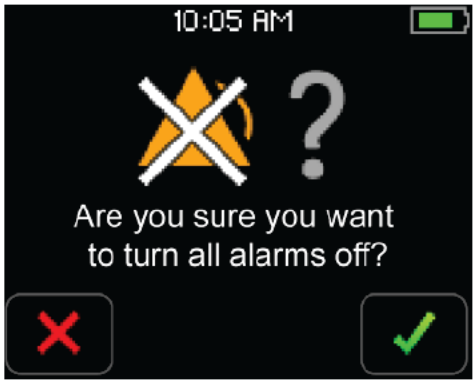


Note: Systolic and diastolic alarm limits of cNIBP will be displayed in red when measuring NIBP continuously. Normal NIBP alarm limits will be displayed in white.

Note: The Monitor will not alarm on the MAP measurement.

3. To turn all alarms off, touch **Turn Alarms Off**.

   The Turn Alarms Off confirmation screen appears.



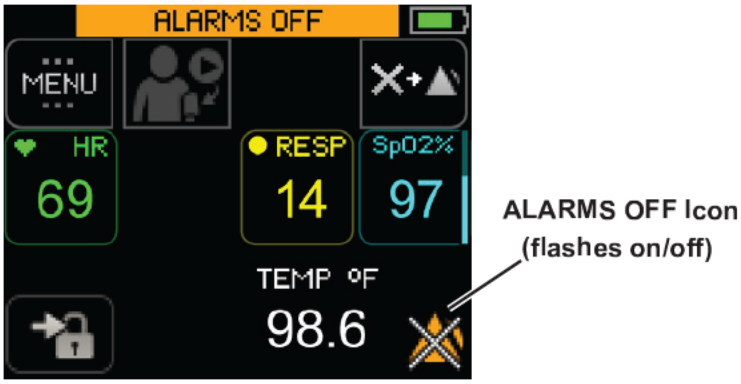
4. Touch **Confirm** to confirm that you want to turn all alarms off.

   -or-

   Touch **Cancel** to leave the alarms turned on.

   If cancelled, the system returns to the Patient Alarm Limits screen and the alarms remain turned on.

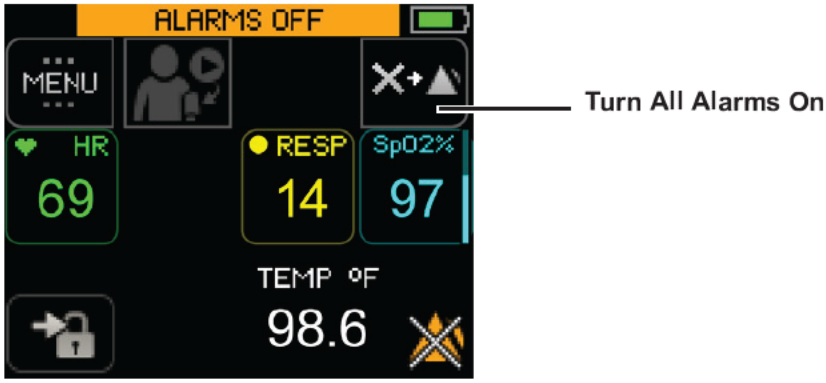
If confirmed, the alarms are turned off and the Vital Signs screen appears. The words ALARMS OFF are displayed at the top of the screen and an ALARMS OFF icon is displayed in the lower right corner of the screen.



Note: Alerts that indicate the Monitor is unable to measure a vital sign (such as ECG Lead Fail) can not be turned off.

To turn all alarms on

From the **Vital Signs** screen, touch **Turn All Alarms On**.



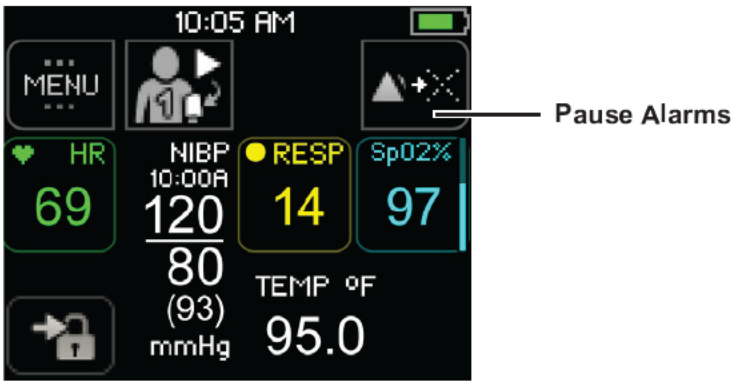
When the alarms are turned back on, the previous alarm settings will be enabled.

6.2.2 Pause/Resume Alarms

When alarms are paused, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarms are paused.

To pause the alarms

From the **Vital Signs** screen, touch **Pause Alarms.**

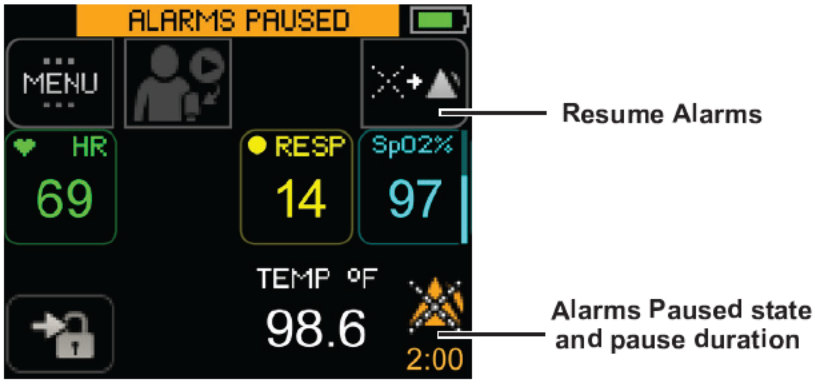


The alarms are paused for 2 minutes.

When paused, the words ALARMS PAUSED are displayed at the top of the screen and an ALARMS PAUSED icon is displayed in the lower right corner of the screen.

To resume the alarms

From the **Vital Signs** screen, touch **Resume Alarms.**



When the alarms are resumed, the previous alarm settings will be enabled.

6.2.3 Auto Set Alarms

The Auto Set function sets alarm limits based on the current vital signs measurements for all connected sensors. If the alarms are turned off prior to initiating the Auto Set process, the alarms are turned back on when the new alarm limits are confirmed.

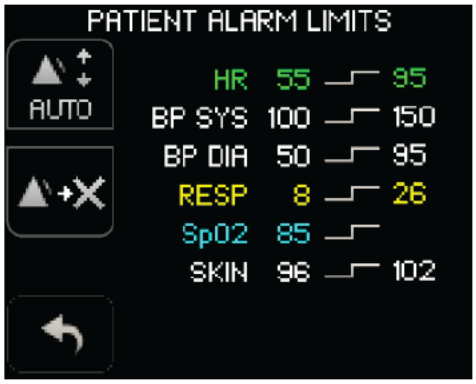
Once new alarm limits are confirmed, they cannot be changed back to the original pre-set limits. Once Auto Set is selected, review the newly calculated alarm limits carefully before deciding to confirm or cancel the new alarm limits.

To change alarm limits using Auto Set

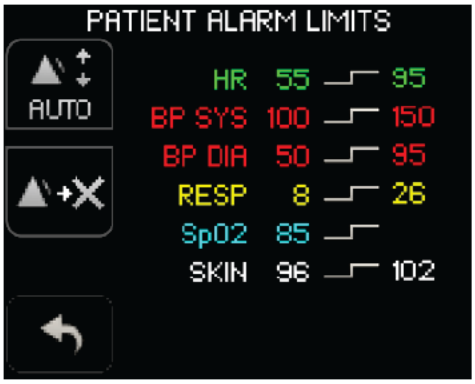
1. Touch **Menu** on the **Vital Signs** screen.

2. Touch **Alarms Settings.**

   The Patient Alarms Settings screen appears.



NIBP Alarm Limits (Alarm limits in white)



cNIBP Alarm Limits (Alarm limits in red)

Note: Alarm limit settings are only displayed for the currently monitored vital signs.

Note: Systolic and diastolic alarm limits of cNIBP will be displayed in red when measuring NIBP continuously. Normal NIBP alarm limits will be displayed in white.

Note: The Monitor will not alarm on the MAP measurement.

3. Touch **Auto Set.**

   Alarm limits for all currently monitored vital signs are recalculated based on the current vital signs measurements. The Confirm New Alarm Limits screen appears.

NIBP Alarm Limits
(Alarm limits in white)

cNIBP Alarm Limits
(Alarm limits in red)

Note: Upper and lower alarm limits cannot be set for TEMP.

Note: Systolic and diastolic alarm limits of cNIBP will be displayed in red when measuring NIBP continuously. Normal NIBP alarm limits will be displayed in white.

Note: The Monitor will not alarm on the MAP measurement.

4. Touch **Confirm** to confirm that you want to accept the new alarm limits.

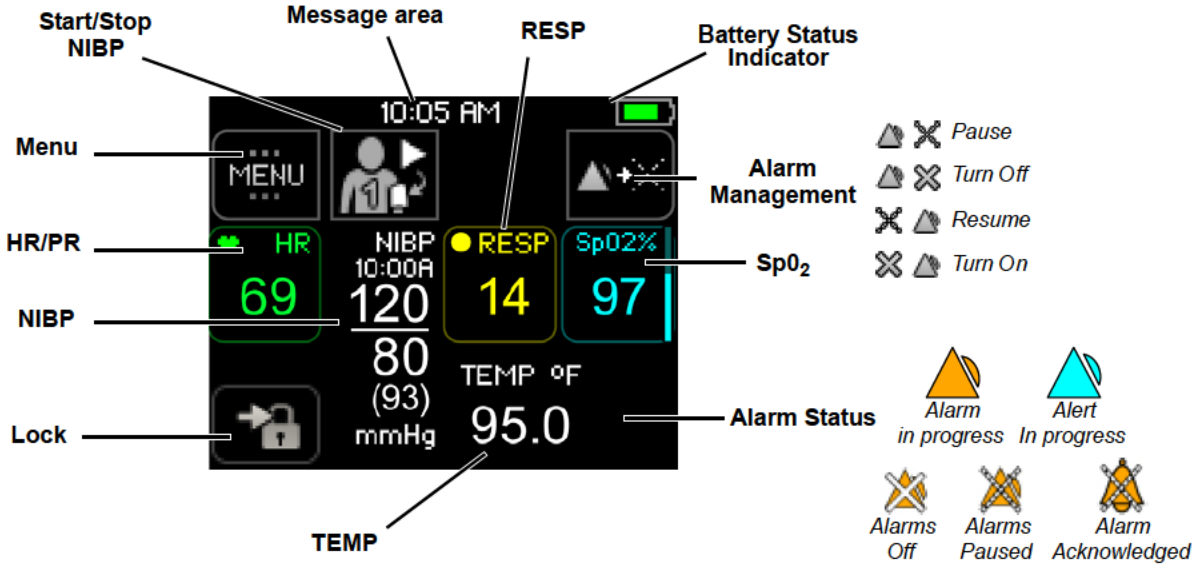
   -or-

   Touch **Cancel** to return to the **Patient Alarm Limits** screen.
   The previous alarm limits are retained.

   Once confirmed, the system returns to the Vital Signs screen.
5. Navigate to the **Patient Alarm Limits** screen to review the current alarm limits.

3.4.3 Vital Signs Screen

The **Vital Signs** screen is the default screen that displays automatically (on initial setup) when sensors are placed on the patient and connected to the Monitor.



Use the **Vital Signs** screen to:

- View current vital sign measurements
- Vital Signs Measurement: Access the waveforms *(see page 68)*
- Alarm Status: View alarm status
- Battery Status Indicator: View the battery status
- Menu: Access the Menu screen *(see page 42)*
- Start/Stop NIBP: Start and stop manual NIBP measurement *(see page 73)*
- Alarm Management: Pause alarms/alerts *(see page 88)*
- Alarm Management: Acknowledge (silence) alarms/alerts *(see page 97)*
- Lock: Lock the Monitor to prevent unauthorized access

Note: A respiration measurement will not be displayed until 60 seconds has elapsed since the time the ECG leads were connected to the patient and 6 breaths have been identified.

Note: Systolic, diastolic and MAP measurements of cNIBP will be displayed in r ed when measuring NIBP continuously. Normal NIBP measurements are displayed in white.

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	MWI	2	DXN	3	DRT	4	DQA
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	K112478	1	ViSi Mobile Monitoring System	1	Sotera Wireless, Inc.
2	K082599	2	CNAP Monitor 500i, 500at	2	CNSystems Medizintechnik Ag
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

Non-invasive blood pressure monitor

	Trade or Proprietary or Model Name for This Device		Model Number
1	ViSi Mobile Monitoring System	1	92-10010
2		2	
3		3	
4		4	
5		5	

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

1 K112478	2 K122036	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] 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
DRT	21 CFR 870.1130	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Cardiovascular Devices

Indications *(from labeling)*

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 leadwire), respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference)

Subject: v01

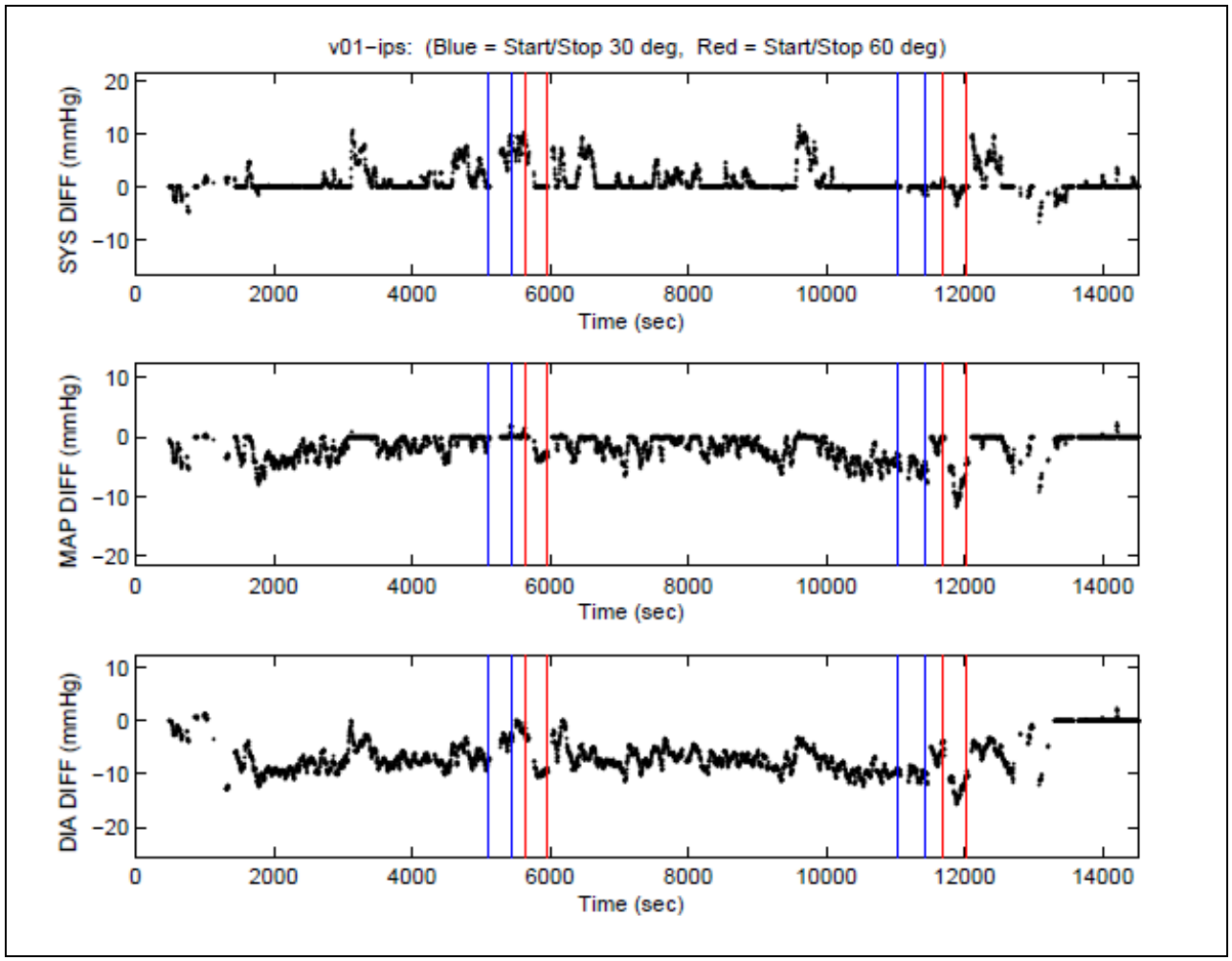


Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v02

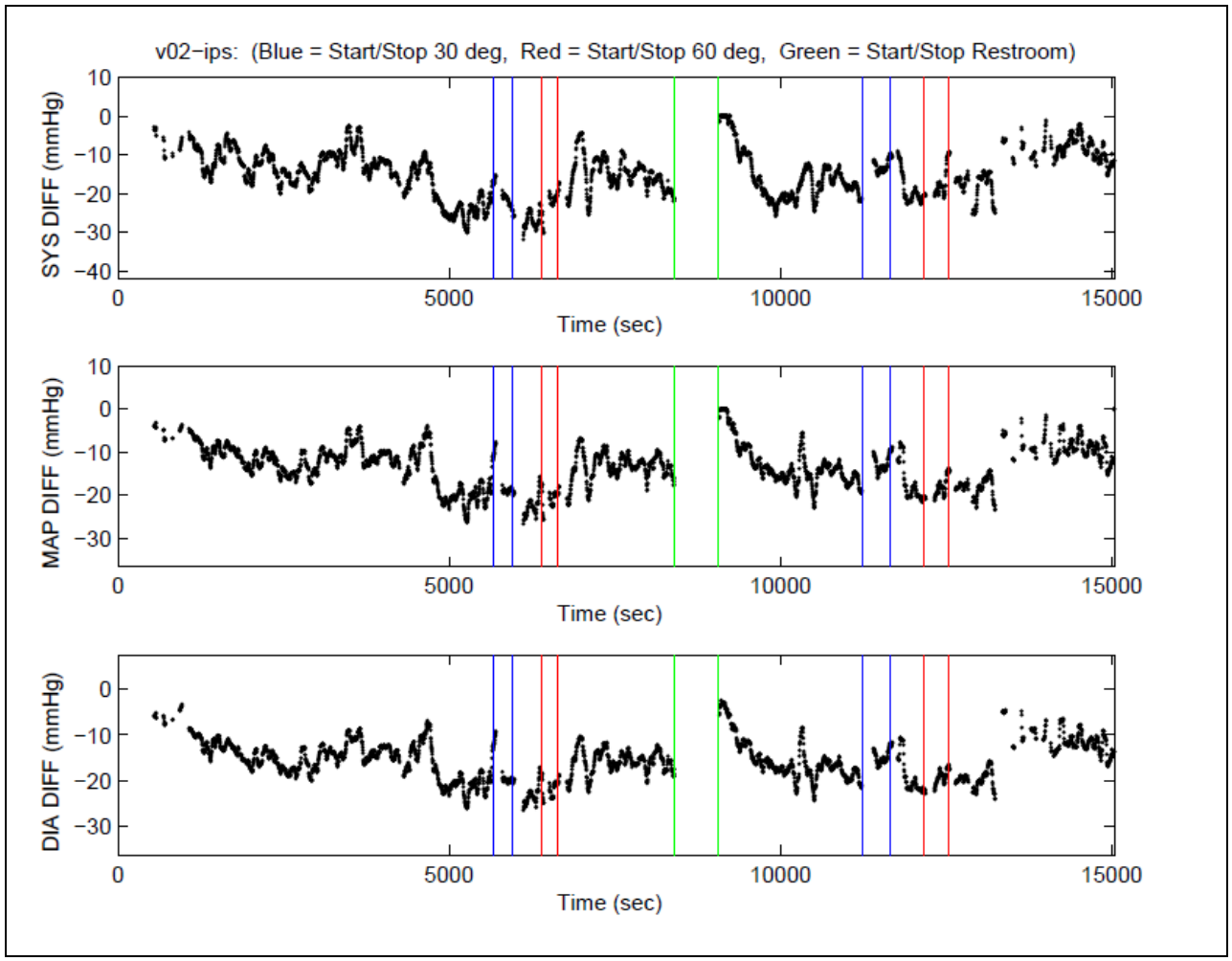


Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v03

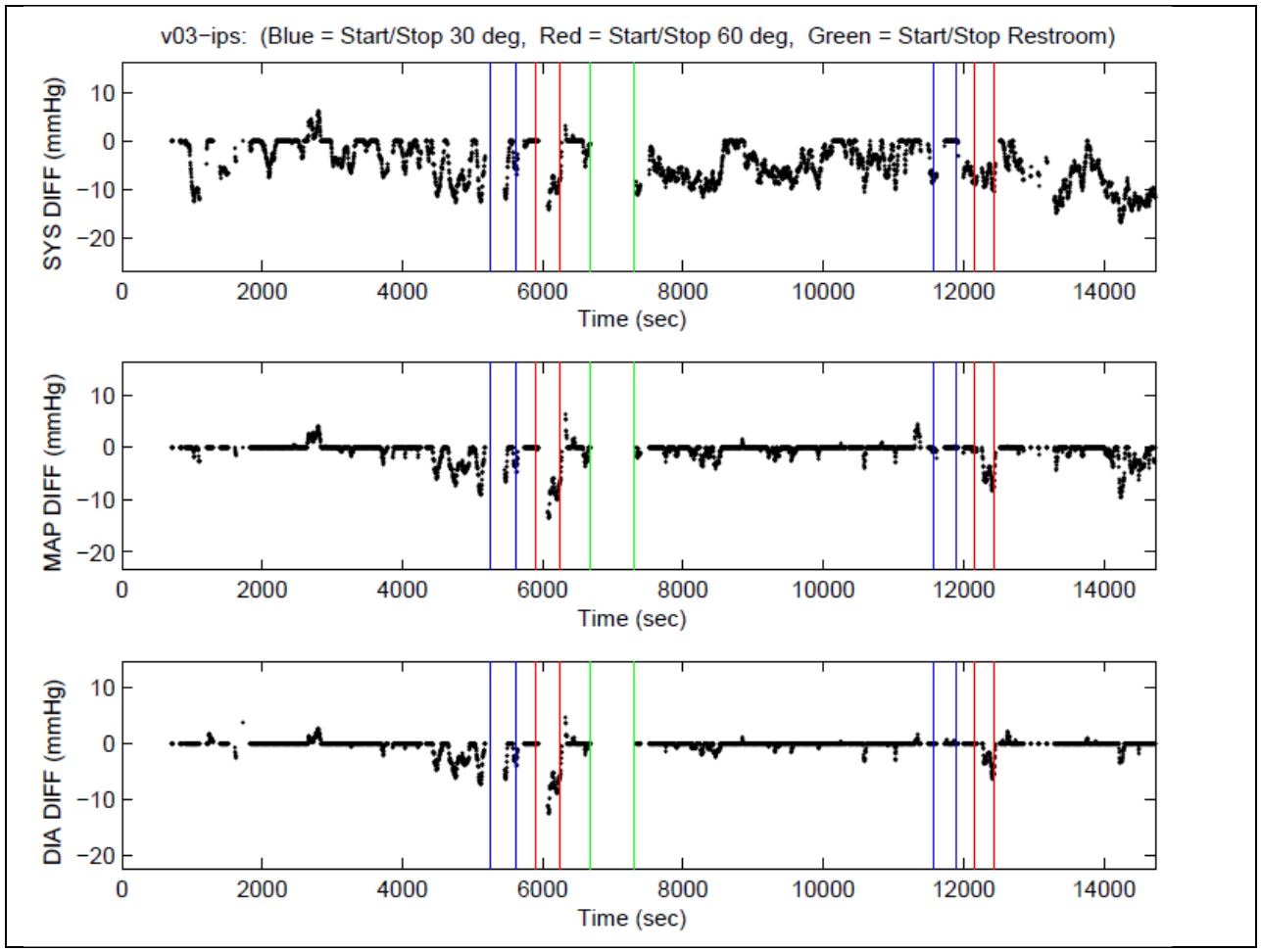


Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v04

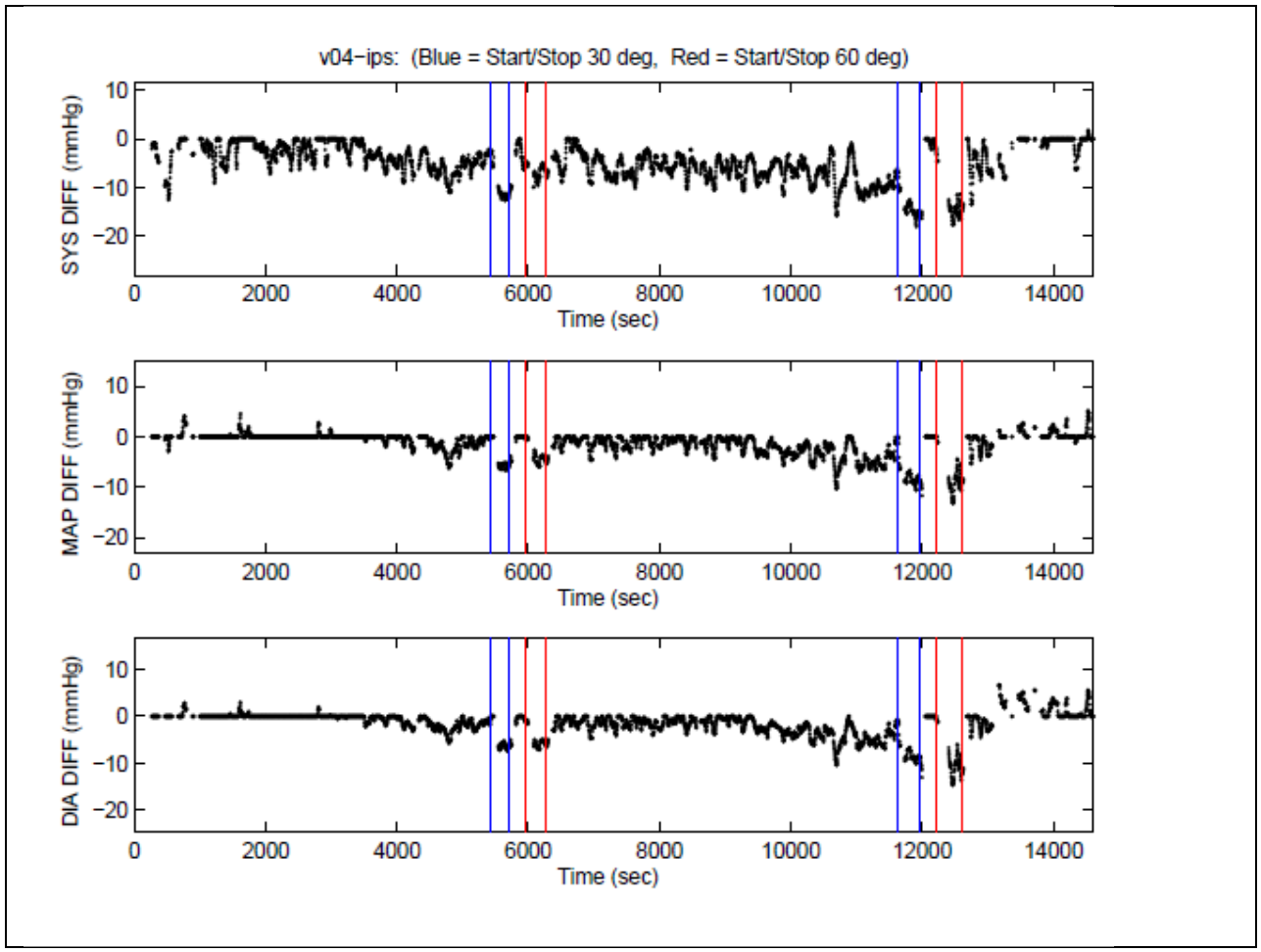


Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v05

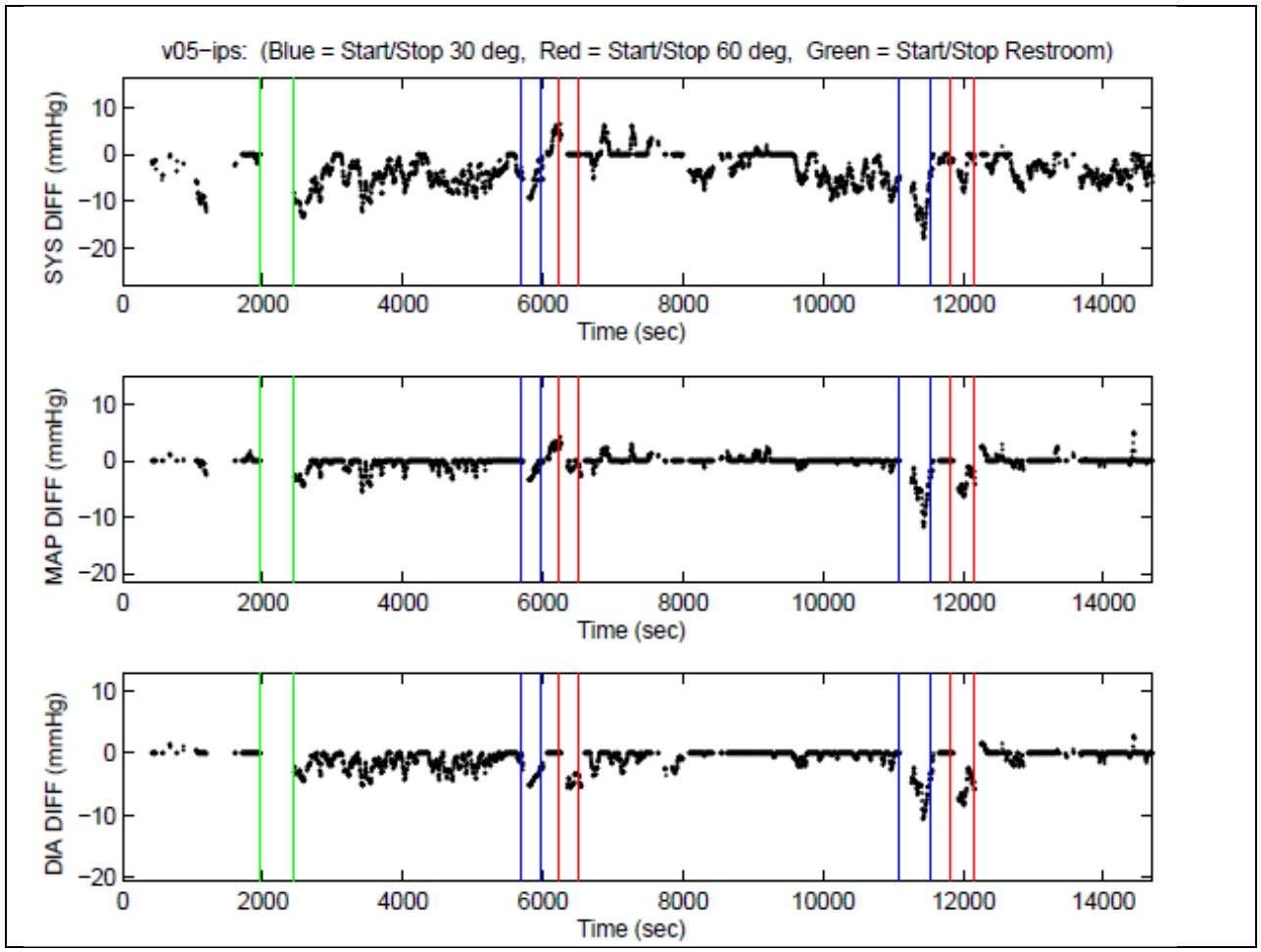


Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v06

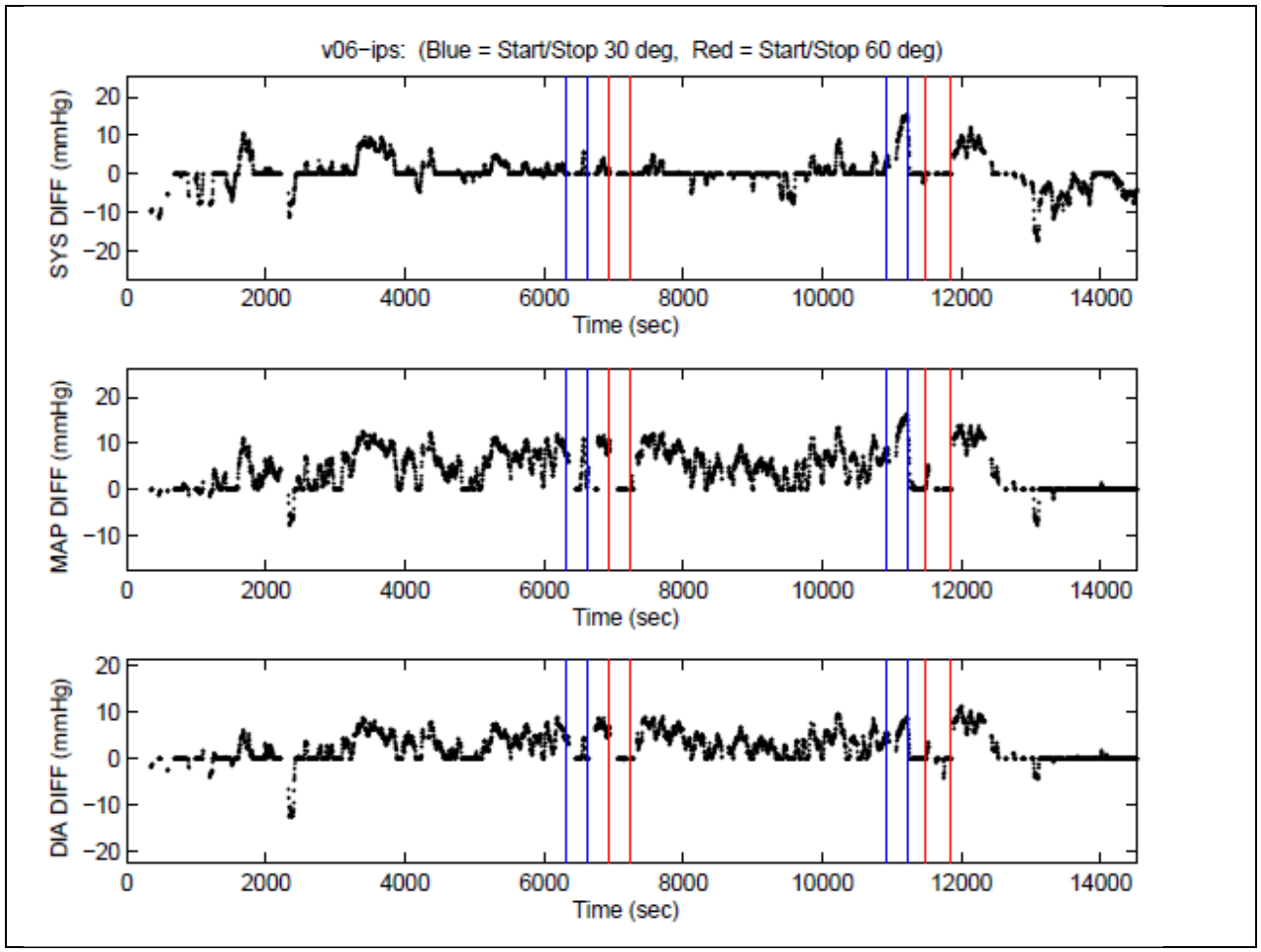


Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

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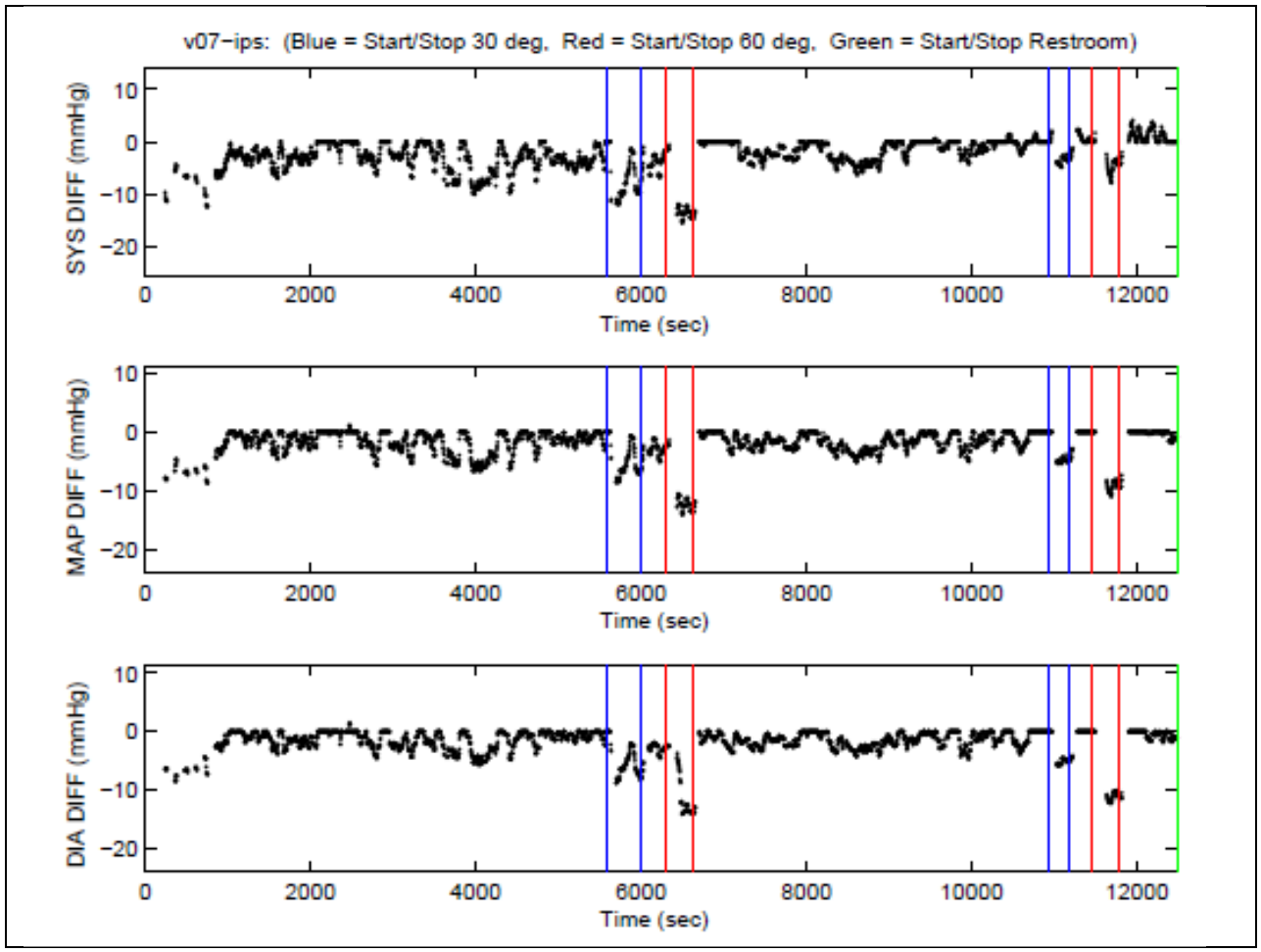

Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

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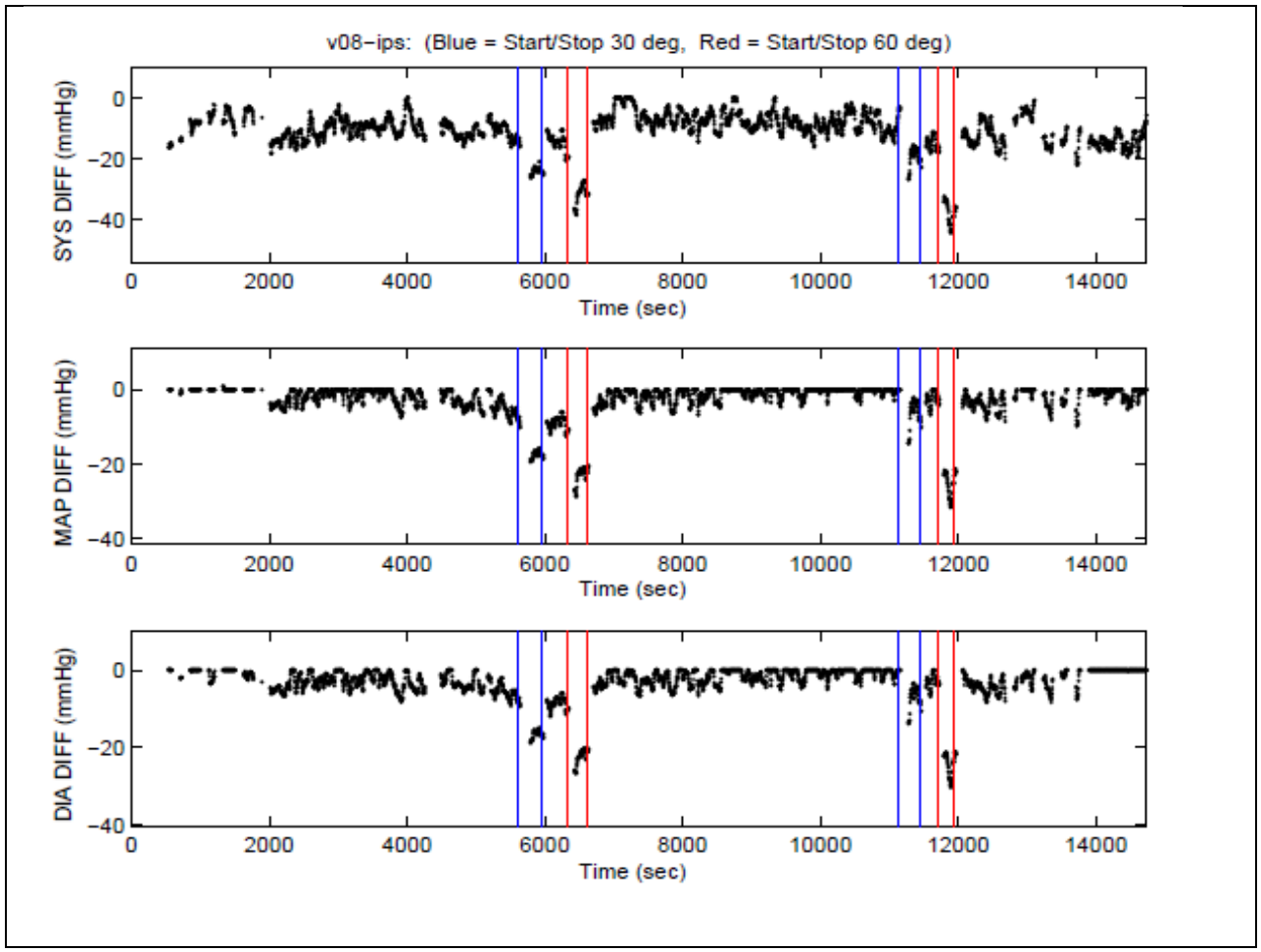

Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

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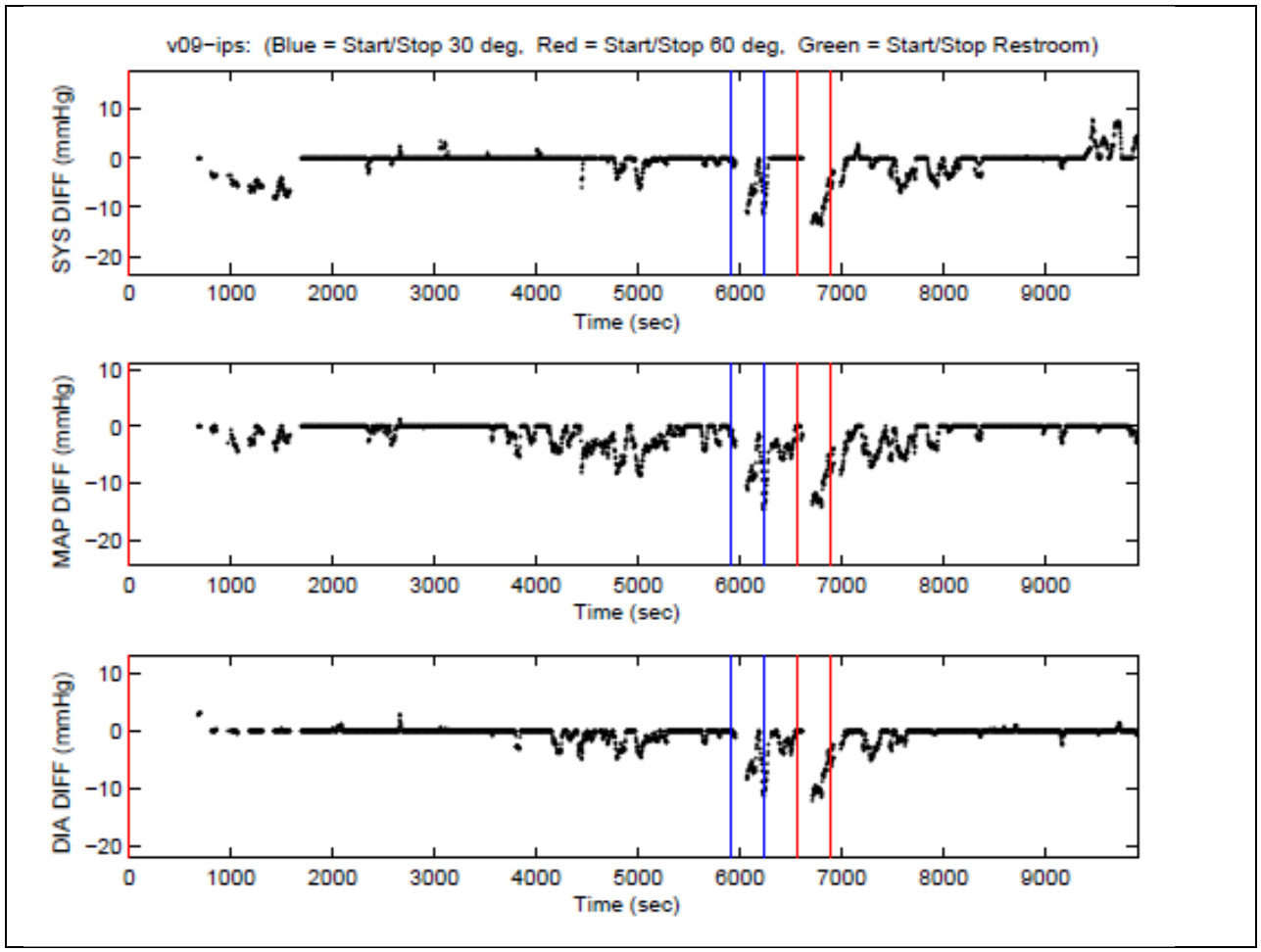

Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

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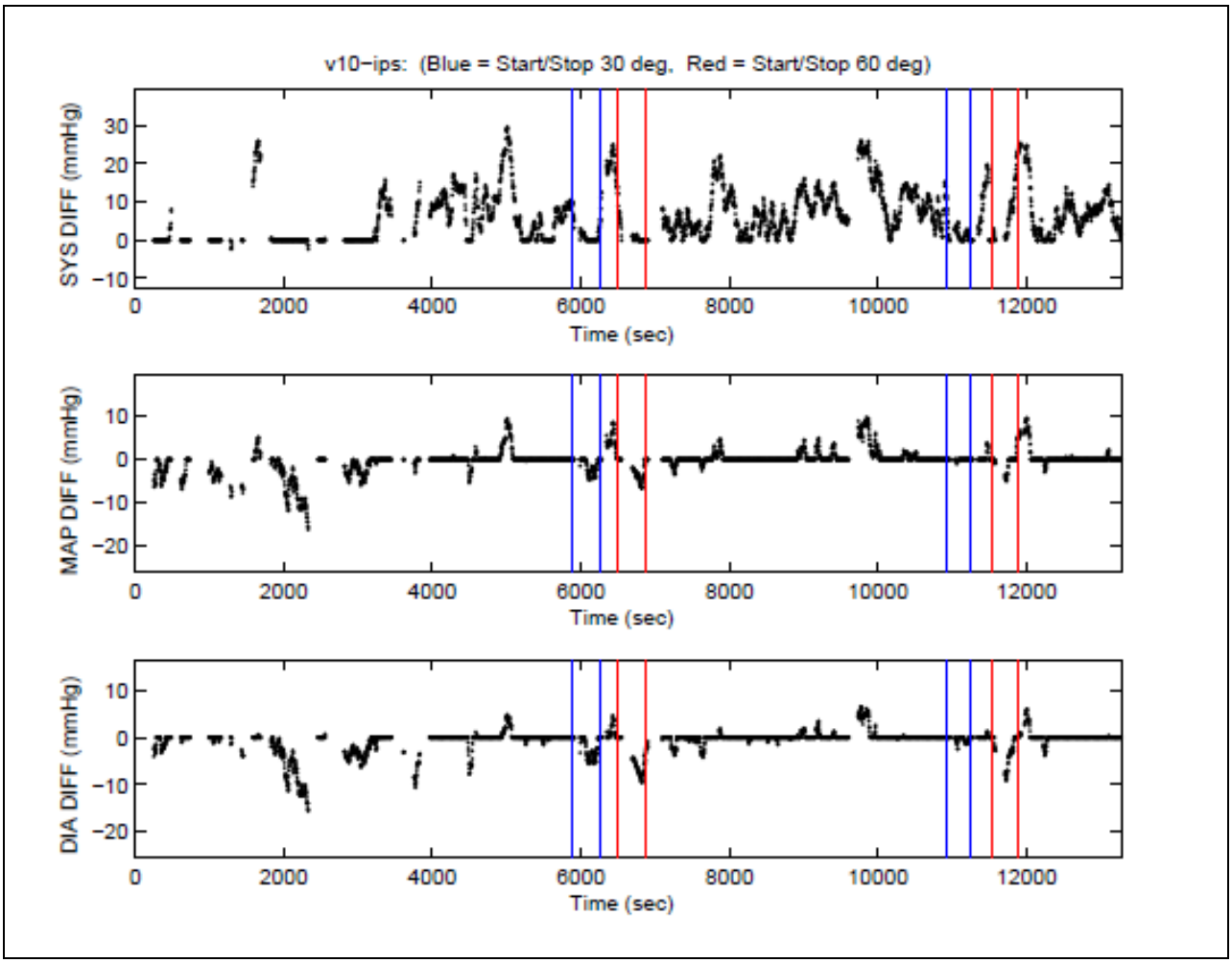

Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v11

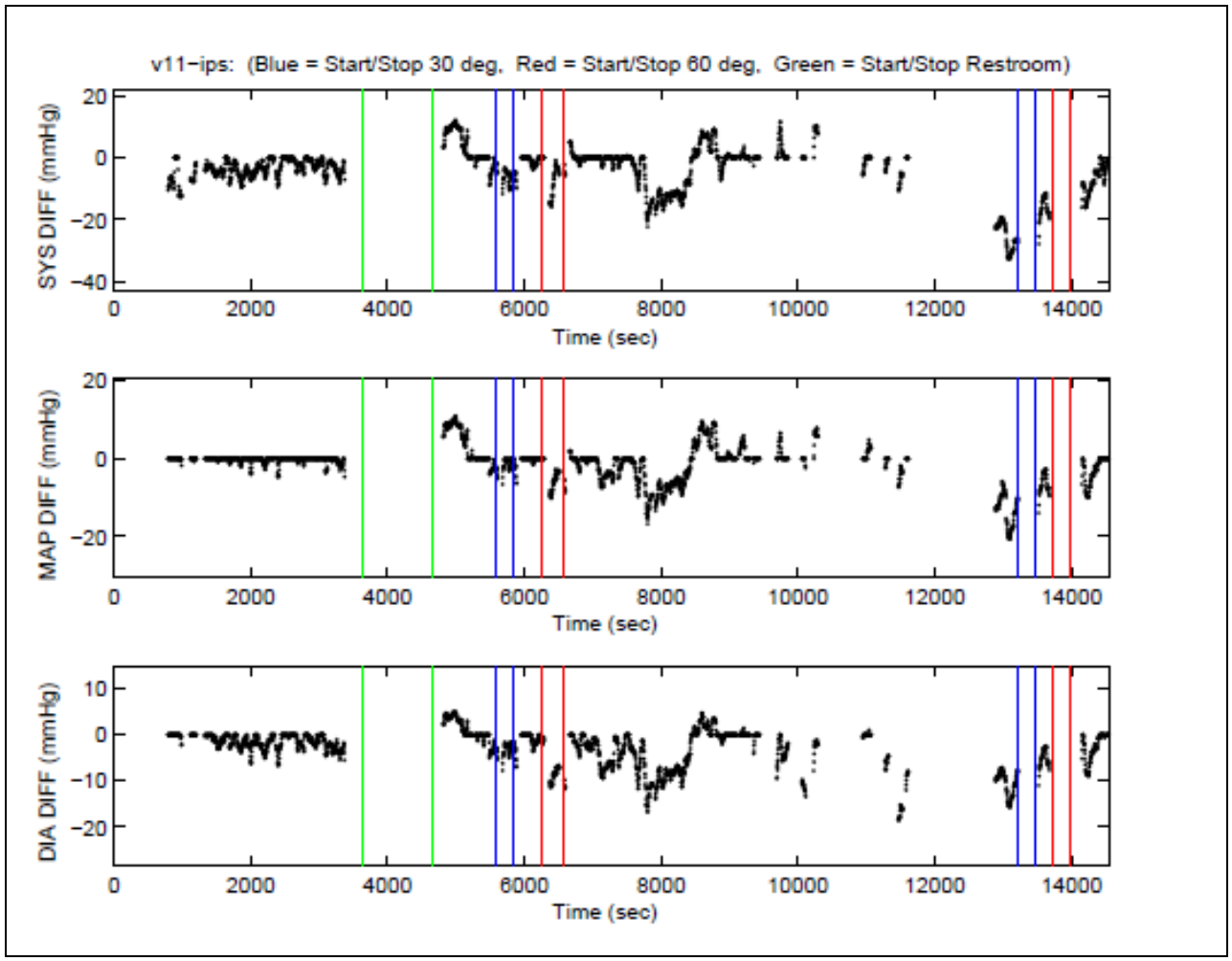

Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v12

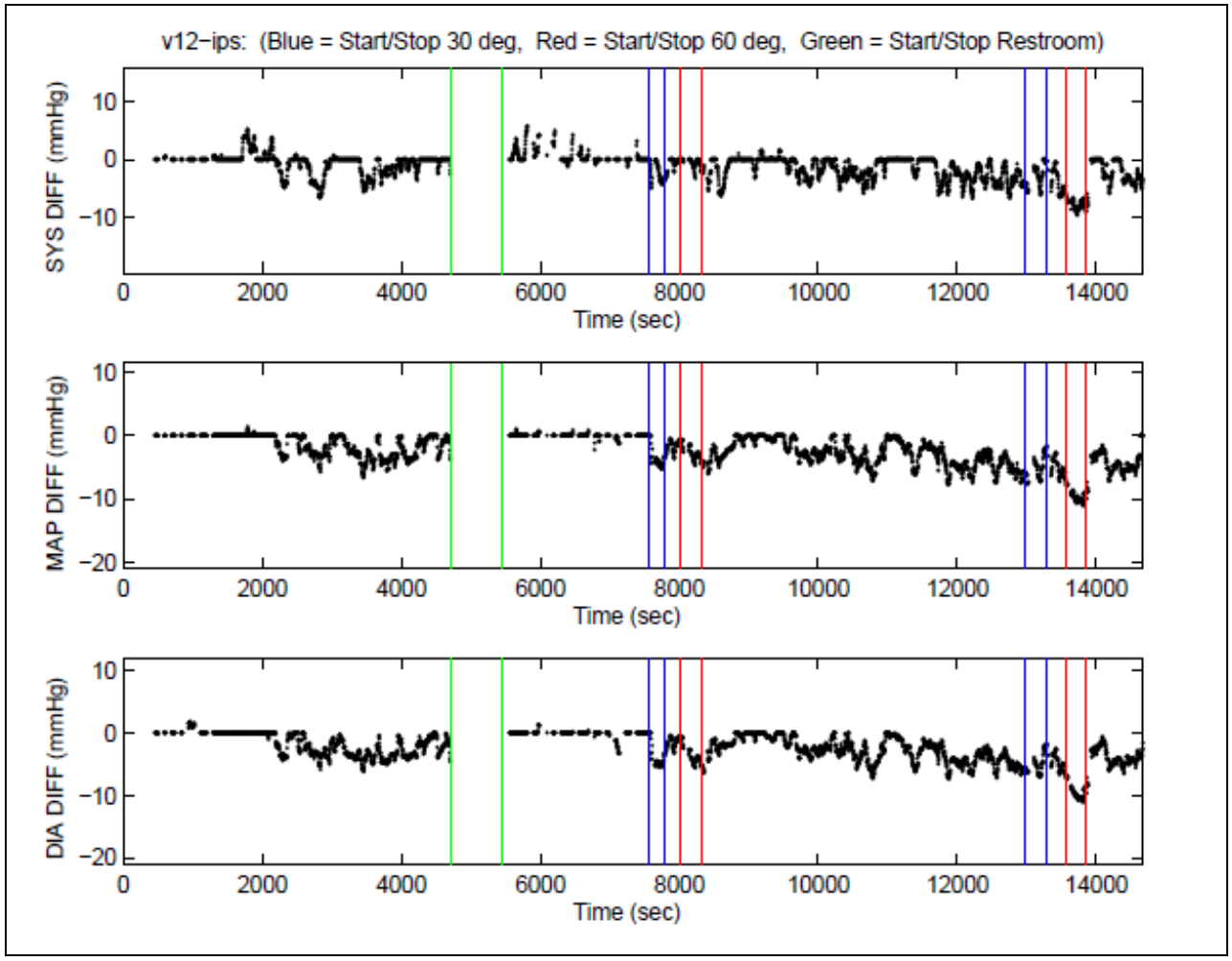

Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v13

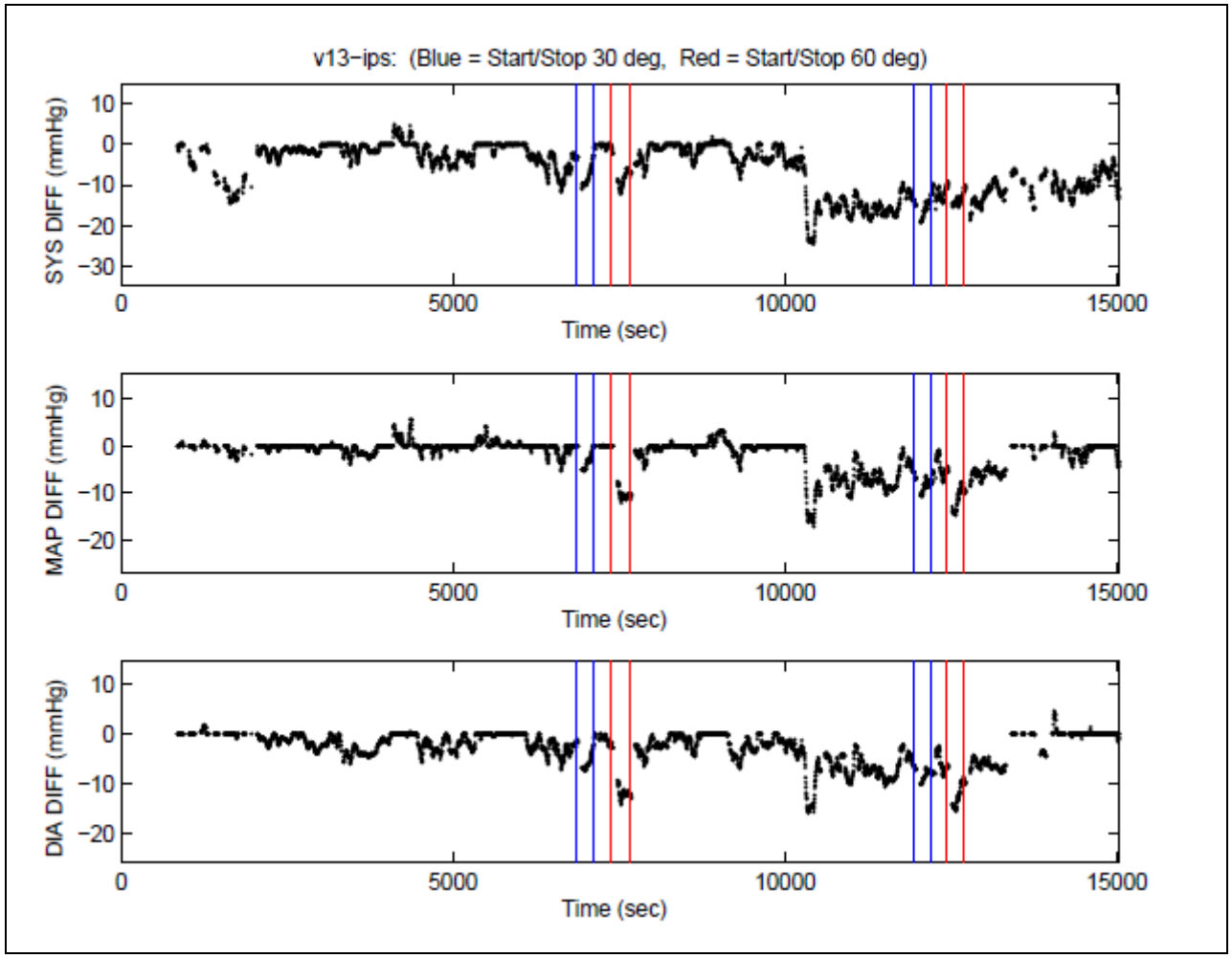

Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

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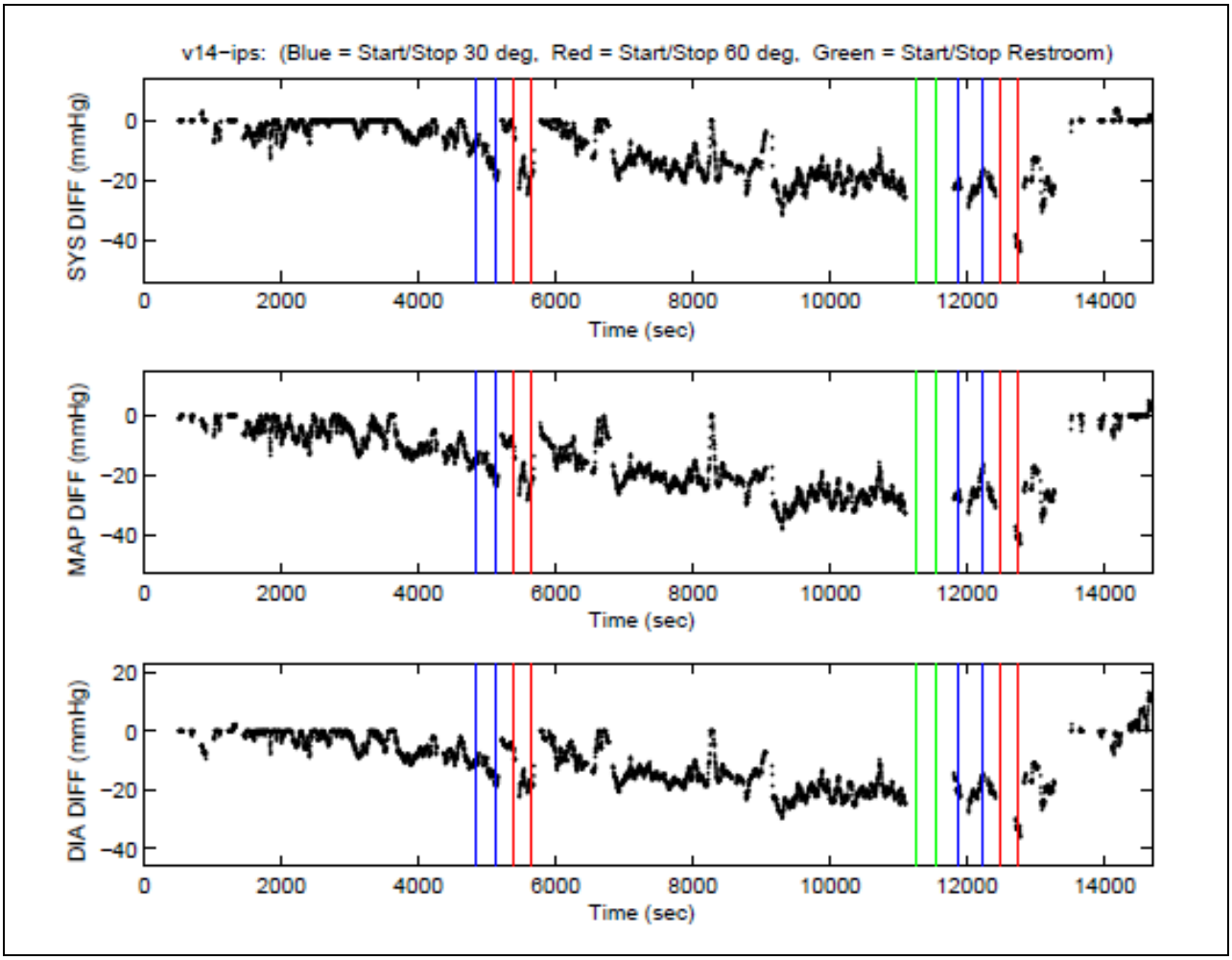

Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

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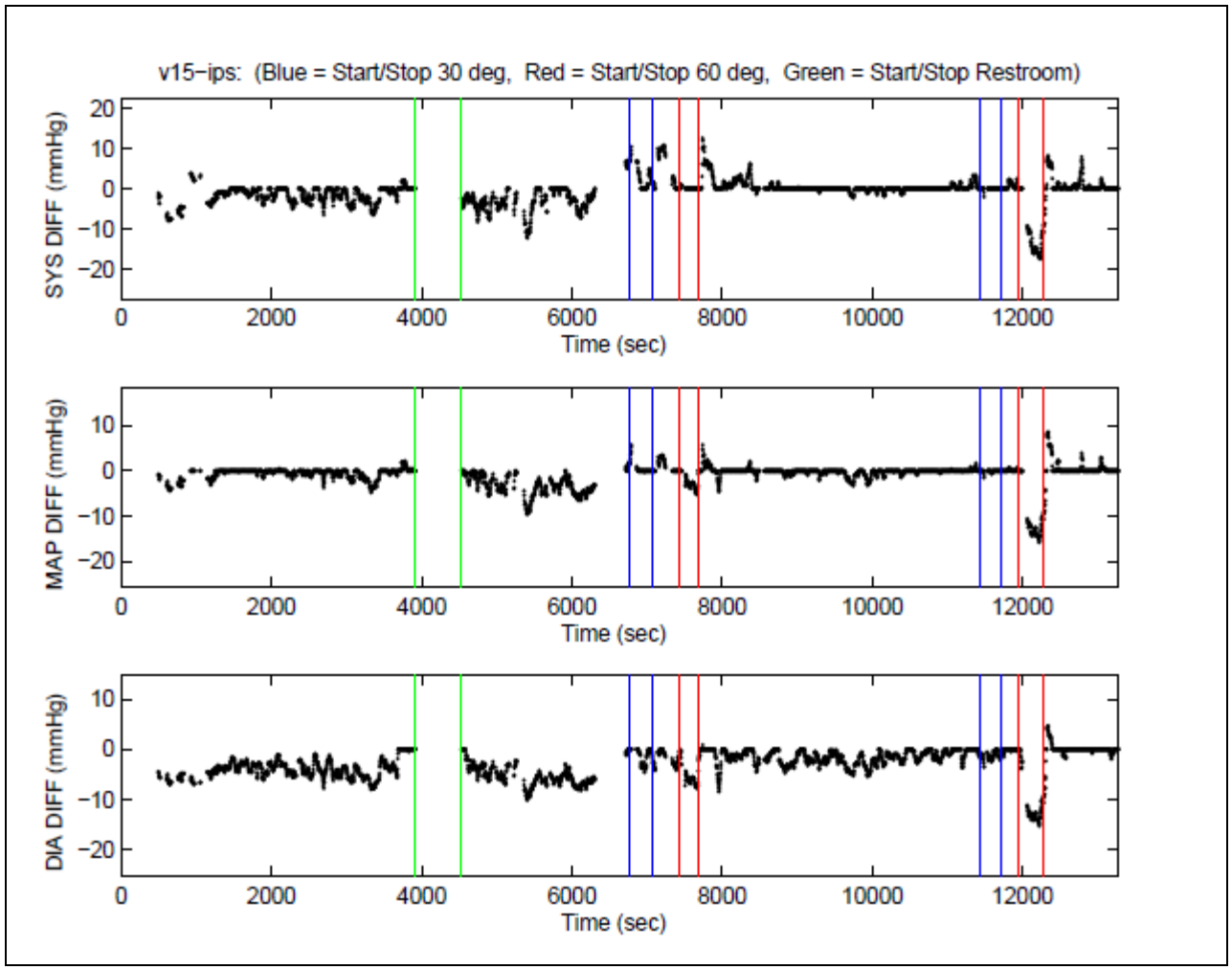


Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v16

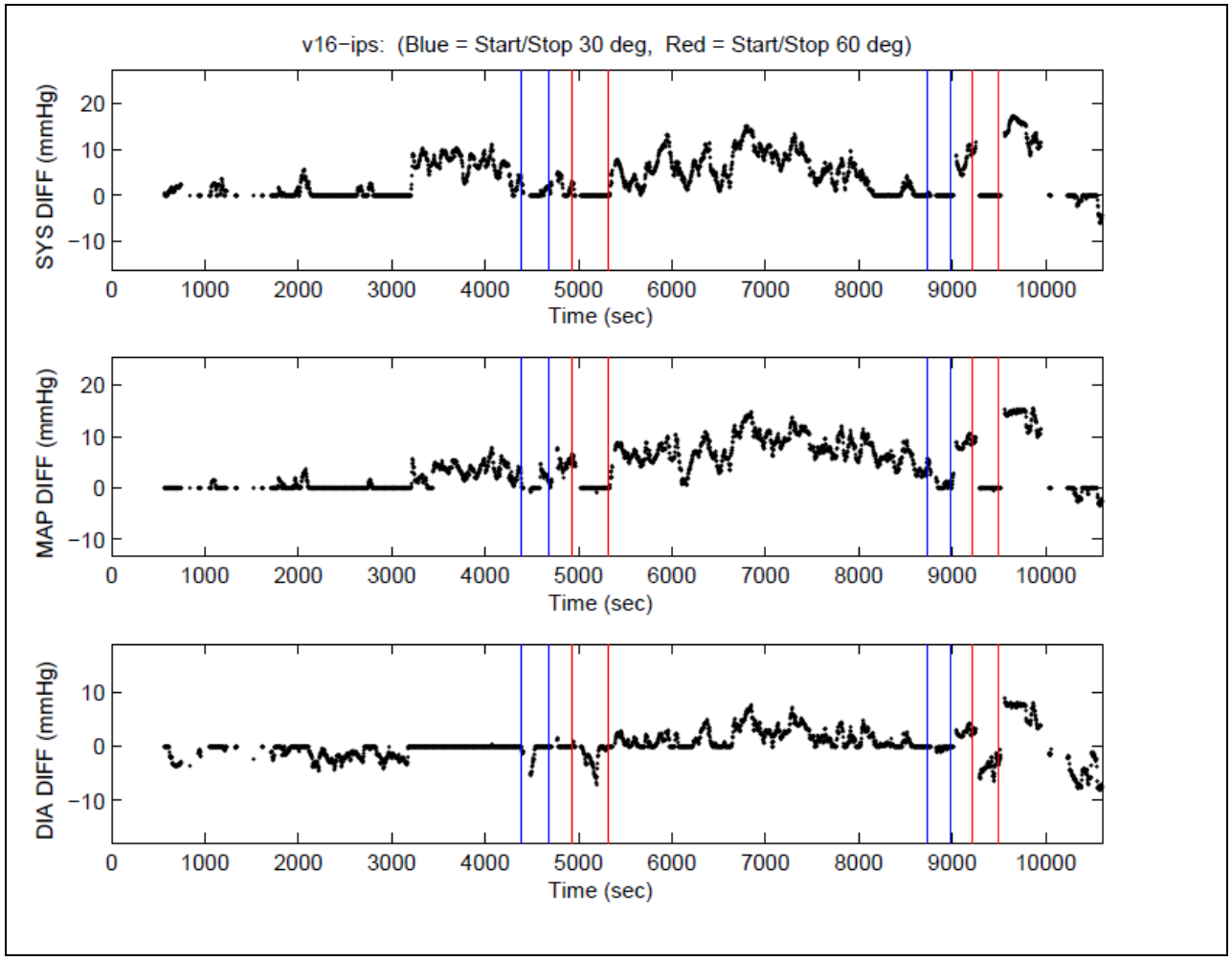
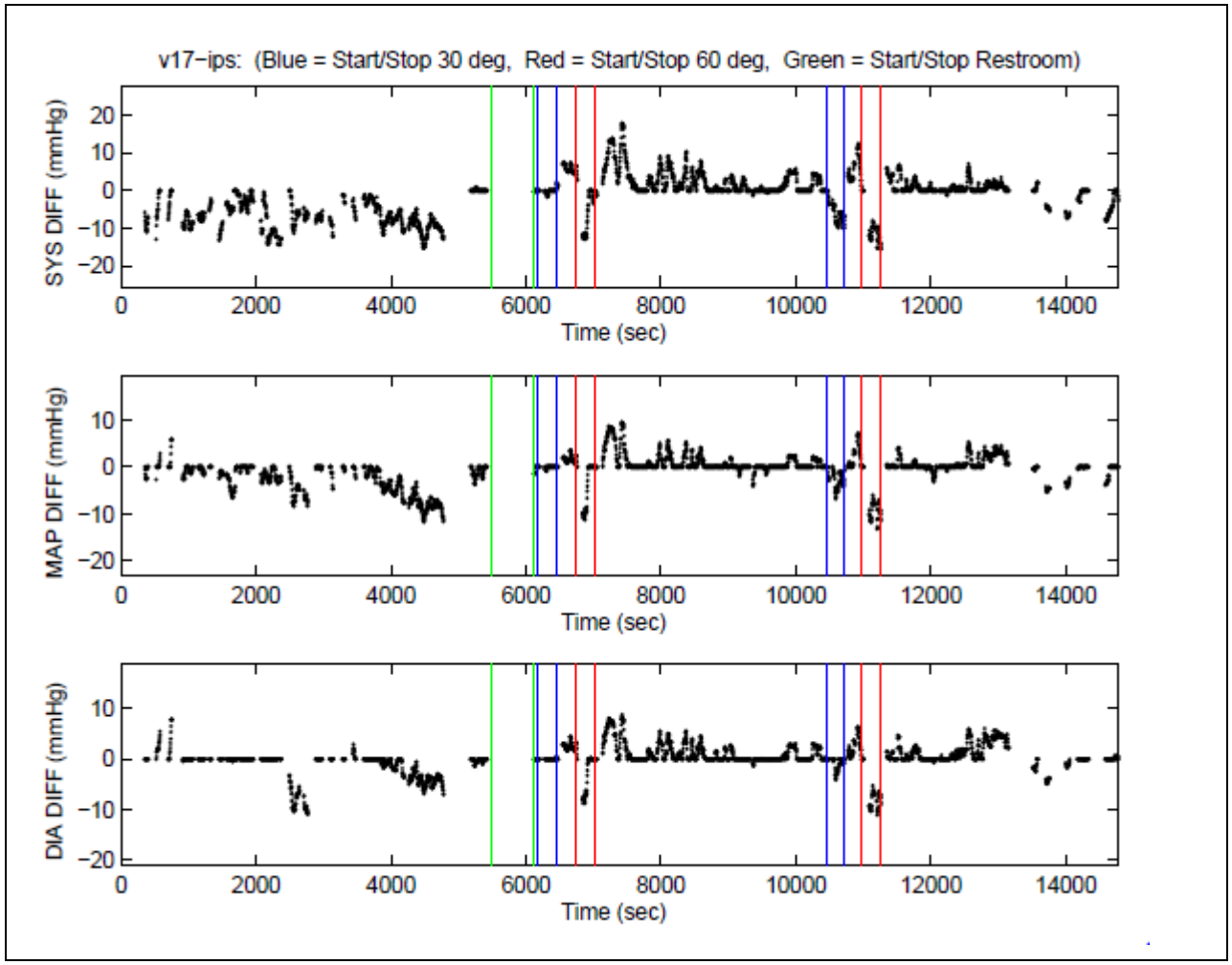


Exhibit 9 – Time Vs. Difference (ViSi - Arterial Reference) [Continued]

Subject: v17



K130709/S3
E-copy

SENT VIA FEDERAL EXPRESS

FDA CDRH DMC
OCT 01 2013
Received

September 30, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Response to Requests for Additional Information
K130709, ViSi Mobile Monitoring System, Model 92-10010

Dear Sir or Madam:

Attached is the formal response to all requests for additional information requested by Dr. Charles Ho, Scientific Reviewer, since the Sotera received the FDA's request for Additional Information (dated July 30, 2013). These questions have arisen in conjunction with the review Sotera Wireless's 510(k) application for our ViSi Mobile Monitoring System.

The response (see Attachment 1) is organized in chronological order according to the date the original question or request for additional was communicated. The same question or request for additional information is stated. The final response that addressed the concern plus any attachments previously submitted are again provided.

We greatly appreciate the thoroughness of your review as we prepared this official response. Also enclosed is a CD-ROM that is an exact copy of this response.

If you have any questions regarding the information contained in this letter, please phone me at 858.373.4841 or write to me at eben.gordon@soterawireless.com.

Sincerely,
SOTERA WIRELESS, INC.

Eben Gordon

Eben Gordon
Senior Director, Regulatory
Official Correspondent

Attachment

14

SENT VIA FEDERAL EXPRESS

September 30, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Response to Requests for Additional Information
K130709, ViSi Mobile Monitoring System, Model 92-10010

Dear Sir or Madam:

Attached is the formal response to all requests for additional information requested by Dr. Charles Ho, Scientific Reviewer, since the Sotera received the FDA's request for Additional Information (dated July 30, 2013). These questions have arisen in conjunction with the review Sotera Wireless's 510(k) application for our ViSi Mobile Monitoring System.

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Sincerely,
SOTERA WIRELESS, INC.

Eben Gordon

Eben Gordon
Senior Director, Regulatory
Official Correspondent

Attachment

ATTACHMENT

The source of the following request for additional information is: FDA deficiency letter dated July 30, 2013. This information was sent in an e-mail to Dr. Charles Ho on 8/8/2013.

1. *In response to our previous Q. 2, you have provided data collected when the subject was 30 and 60 degrees inclined to the horizontal. For the 60 degrees data, we note that the mean error was larger than 5 mmHg for systolic, diastolic and MAP pressures, and thus is not compliant with the AAMI SPI0 requirements. By comparison, the 30 degrees data are compliant with AAMI SP10. Hence, please remove the device's claim of measuring cNIBP when the subject is inclined more than 30 degrees from the horizontal.*

Sotera Wireless agrees with FDA's request to remove the claim of measuring cNIBP when the subject is inclined more 30 degrees from horizontal. The revised wording in the User Manual reads: "The ViSi System accuracy claim (mean error ≤ ± 5 mmHg; standard deviation ≤ ± 8 mmHg) is not met when the subject is inclined more than 30 degrees."

The revised pages 79 (**Exhibit 1**) and 127 (**Exhibit 2**) of the User Manual are provided with the modified text highlighted in yellow.

2. *In response to our previous Q. 16, you have provided a set of rules for requiring recalibration of the subject device's cNIBP function, and also that there was no need for such recalibration during the clinical study. However, using the newly provided rules we have found at least two cases which we believe should have required recalibrations (there may be more cases), as follows:*

   a) *Subject V0l:*

   (Note that we have taken the time 486 seconds after start of study as the time point immediately after calibration, since this is the earliest reported time point for this subject.)

Study Time (sec)	***ViSi Sys (mmHg)***	***ViSi Dia (mmHg)***
486	*106*	*57*
3118	*122*	*55*
4570	*123*	*56*
5425	*125*	*57*

   For subject V01, the ViSi systolic BP at 5425 seconds was 125 mmHg. This is 19 mmHg (= 125-106) larger than the initial systolic BP of 106 mmHg. Thus, when we consider this to be the case for Normotensive patients - due to 125 being smaller than 140 mmHgthe change of 19 mmHg still required a recalibration. Other cases for the same subject that should have triggered recalibrations are found at time 3118 and 4570 seconds.

   b) *Subject V03*

   (Note that we have taken the time 709 seconds after start of study as the time point immediately after calibration, since this is the earliest reported time point for this subject.)

Study Time (sec)	***ViSi Sys (mmHg)***	***ViSi Dia (mmHg)***
709	*129*	*71*
11340	*150*	*86*

For subject V03, the ViSi systolic BP at 11340 seconds was 150 mmHg. This is 21 mmHg (= 150-129) larger than the initial systolic BP of 129 mmHg. Thus, even if we consider this to be the case for Hypertensive patients - due to 150 being larger than 140 mmHg - the change of 21 mmHg still required a recalibration.

The continuous non-invasive blood pressure (cNIBP) measurement is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. The ViSi Mobile Monitor continuously measures cNIBP without further cuff inflations. Recalibration therefore is not related to any set temporal interval.

The response to Q.16 incorrectly stated that recalibration was not performed because the criteria for recalibration were not met. In actuality, recalibration was not performed in the clinical study because the protocol did not provide for it.

The rules for recalibration originate in the ViSi System Risk/Hazard Analysis - cNIBP Module; Document No. 0-000959, Rev. A (**Exhibit 3**). Annunciating an alert for recalibration was implemented as the mitigation for the hazard of incorrect readings when pressure measurement changes exceed defined thresholds. Highlighted in yellow on page 2 of 4 of the risk/hazard analysis are line items of the hazards which are mitigated by the alert message. The threshold or significant change from baseline blood pressure was implemented as: > 15 mmHg for normotensive; > 20 mmHg for hypertensive; and > 10 mmHg for hypotensive readings.

After a significant change in baseline blood pressure, an alert is annunciated instructing the clinician to manually recalibrate the ViSi cNIBP measurement. Since the recalibration is not automatic, it cannot be guaranteed if and when the recalibration by the clinician is to occur. Without recalibration, the true accuracy of the cNIBP measurement principle can be observed. Therefore, the study results represent a reasonable worst case characterization of device performance.

In the intended application of non-ICU settings, nurses routinely check blood pressure on an episodic basis according to physician orders (typically every 4. 6, or 8 hours). When blood pressure changes are noticed under these episodic conditions, the nurse will check blood pressure prior to the administration of prescribed therapy. The User Manual reinforces good clinical practice by notifying the clinician that blood pressure has changed sufficiently to warrant a recalibration. This workflow enhancement feature will notify the nurse in a timelier manner than current periodic episodic blood pressure measurements.

3. *In response to our previous Q. 20, you have clarified that for cNIBP alarms, the alarms are only announced to the patient, not to the central station. Please revise labeling to indicate that the cNIBP alarms are not announced at the central station.*

Sotera Wireless agrees with FDA's request to indicate that cNIBP alarms are not announced at the central station. The revised wording in the User Manual reads: "cNIBP alarms are not announced at the central station."

The revised page 85 of the User Manual is provided in **Exhibit 4** with the modified text highlighted in yellow.

4. *In response to our previous Q. 14, you have provided a labeling revision to indicate a time delay between data collection and display update. However, you have not indicated the magnitude of the delay, as it can be up to 63 seconds at the worst case. Hence, please revise labeling again to indicate the 63 seconds delay as the worst case.*

Sotera Wireless agrees with FDA's request to indicate the worst case time delay between data collection and display update. The revised wording in the User Manual reads: "Due to cNIBP signal averaging, there is a maximum 63 seconds time delay between the instantaneous blood pressure reading and the displayed reading."

The revised page 79 of the User Manual is provided in **Exhibit 1** with the modified text highlighted in yellow.

5. *Please address the following problems with excessive variation in reference device data in the submitted clinical study, in that the specified patients' data should have been removed in accordance with ANSI/AAMI/ISO 81060-2, clause 6.2.4:*

   a. Some of the data show large variations in the reference data (invasive radial catheter). For example, the reference mean systolic BP of subject V01 ranged from 124.01 (located at cell 12303 in the spreadsheet) to 103.51 (located at cell 12680) mmHg during the study. This 20.5 mmHg range is not allowed by ANSI/AAMI/ISO 81060-2, clause 6.2.4, which allows a maximum change in reference systolic BP of20 mmHg and for diastolic BP 12 mmHg. In fact, since you are reporting mean systolic BP recorded during a 60-second period, the actual range of systolic BP data points (without averaging) may be larger. And the recommendation of the standard is that all data from the subject should be removed.

   b. Similarly, the reference mean diastolic BP for subject V01 ranged from 69.70 (located in cell L3369) to 57.30 (located in cell L2680) mmHg, resulting in a range of 12.40 mmHg, which is larger than the 12 mmHg allowed by the same clause of the standard.

   c. Similarly, subject V03 has the same problem of too much variation in the reference systolic and diastolic pressure values.

ISO 81060-2:2009, *Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type,* was adapted as a methodology for validating the ViSi cNIBP measurement. The intent of the standard is so that point-in-time comparisons, like those made by blood pressure cuffs, can be pooled statistically. These measurements are usually collected within 30 minutes or less and care is taken to make certain that the test subject is quiet and undisturbed for several minute prior to the data

collection so that the blood pressure values do not vary much and can be pooled. However, in this study the data is used to show that cNIBP continuously tracks blood pressure.

6. *In response to our previous Q. 5 regarding subject selection you state that" '" the first subjects who met the limb size and/or BP ranges were scheduled for enrollment." The wording "scheduled for enrollment" is unclear. Please indicate if these subjects were enrolled or if additional later concerns caused them to be dropped (excluding subjects v02 and v14 for whom you have provided explanations).*

As stated in the response to Q.5, possible "test subjects were selected from a group of subjects in the Clinimark physiology lab database, who in the past had met the limb size and blood pressure distribution ranges required by ISO 81060-2". Approximately 3 weeks before the study, biceps were measured and NIBP blood pressures were assessed using a manual mercury manometer. The first subjects who met the limb size and or blood pressure ranges were scheduled for study enrollment.

The wording "scheduled for enrollment" means that the subject was scheduled for a final screen on the day of the study to determine if the subject still met the inclusion criteria (sometimes blood pressures measured 3 weeks earlier would change). If the subject still had the blood pressure needed to meet the specific ranges required by ISO 81060-2, they were "enrolled" at that immediate time and the study was conducted.

7. *You state in response to our previous Q. 7 that subject v02 was excluded because he/she had BMI > 35 (=35.5). Of concern is the fact that this subject was not initially excluded (all data were collected for the subject) but was excluded later. Additionally there are large differences between the ViSi device and the clinical reference standard (arterial reference measurement). Furthermore, it does not seem reasonable that a change in BMI of 0.5 should be so problematic for device measurements (the subject appears to have met other inclusion/exclusion criteria). This raises concerns of potential selection bias. Please explain why the subject was not excluded after the baseline assessment when BMl was found to be over the limit.*

The data rejection criteria specified in the study protocol (reference original K130709 submission, Exhibit 14, "*Accuracy Study of ViSi*…", page 61) included subjects with "BMI >35, conical shaped biceps and bias of >5 mmHg between the arterial reference reading and a currently marketed NIBP cuff reading." The > 5 mmHg difference can only be discovered after subject enrollment and placement of the radial arterial line. The study protocol specified this data rejection criteria because oscillometric blood pressure measurements, the basis for the cNIBP calibration, are known to be inaccurate among this subject group. The data exclusion rationale was included in the study protocol (reference original K130709 submission, Exhibit 14, "*Accuracy Study of ViSi*…", pages 66-67 of 68).

As stated in the response to Q.7, page 79 of the User Manual has been updated to caution the user that the cNIBP measurement should not be relied upon in patients with BMI >35.

8. *In response to our previous Q. 10 you have provided plots of differences in blood pressures (systolic, diastolic and mean arterial pressures) between investigative device and the arterial-line. Please address the following:*

a. Please clarify whether these plots use differences as explained in response to our previous Q. 6, l., i.e., you are looking at difference between upper/lower ROVs of arterial reference lines for each 60-second average as opposed to looking at differences between the average reference value and the reported cNIBP value. Interpretation of the analysis results would differ depending on the definition used.

The former interpretation is correct: the plots evaluated the difference between upper/lower ROVs of the arterial reference for each 60-second average as specified in clause 6.2.4 of ISO 81060-2.

b. These plots indicate that in several instances the differences between the arterial line and your device exceed 10 mmHg, and are as high as 30-40 mmHg in some cases. Differences of this magnitude are of concern, since there would likely he differences in treatment recommendations. The magnitude is of even greater concern if the differences you reported are calculated based on upper/lower ROV values, and thus under-estimate the difference between reported ViSi cNIBP value and the average arterial line reference. Please provide an adequate justification for why these differences are acceptable

The large differences between the arterial line and the cNIBP measurement occurred when the posture changed. Arterial Blood pressure can vary with posture changes, transient transducer off-sets, and motion artifact. No attempt was made to redact this data during analysis. Despite these artifacts, the mean error of ≤ ± 5 mmHg and standard deviation of ≤ 8 mmHg was met over the approximately 4 hour data collection period.

Separate [i.e. individual subject] supine error plots for both ipsilateral and contralateral data are provided in *TimeSeries_Supine.pdf* (**Exhibit 5)** and the data line listing in *Supine_data.zip* (Excel spreadsheet; CD attached).

9. *In response to our previous Q.10 you have provided results from a mixed model that models differences between your device measurements and the arterial reference modeled as a function of random subject effects, You also discuss (but do not appear to have provided result" for) a model that includes a fixed time effect. The model provided is deficient in the following respects: it models differences without accounting for "baseline effects" - a model of device measurements as a function of the arterial measurement would be preferable for this purpose. In addition, exclusion of the time effect results in loss of useful information. The absence of such accounting for the time effect is also the deficiency of the Bland-Altman repeated measures approach. Please provide results (statistical program code and output would be appreciated) for the modified model that accounts for baseline and time effects.*

A mixed-effects model that has the differences between test and reference device as the response variable and fixed time effects and random subject effects was fit to the data. The SAS code used was as follows:

```
proc mixed data=ipssub_all method=reml;
class subnum;
model sys_diff= time/s;
random subnum;
run;
```

The variable subnum identified each subject and was defined as a random effect, the systolic BP differences were stored in the variable sys_diff, and time measured the time from the start of the experiment. Similar code was used for diastolic and MAP BP differences. SAS output is attached (**Exhibit 6**) and the results are summarized below:

Parameter	Systolic		Diastolic		MAP	
	Mix-Eff	Mix-Eff w. time	Mix-Eff	Mix-Eff w. time	Mix-Eff	Mix-Eff w. time
Ipsilateral arm						
Mean at 0 hours	-1.61	-1.15	-1.33	-1.64	-0.33	-0.31
Mean at 4 hours	-1.61	-2.01	-1.33	-1.00	-0.33	-0.36
Between subject SD	3.93	3.90	2.00	2.00	2.08	2.08
Within subject SD	4.14	4.13	2.39	2.38	2.66	2.66
Total SD	5.70	5.68	3.11	3.11	3.38	3.38
Contralateral arm						
Mean at 0 hours	-1.55	-1.33	-1.11	-0.67	-0.54	-0.34
Mean at 4 hours	-1.55	-1.76	-1.11	-1.53	-0.54	-0.78
Between subject SD	2.65	2.64	3.20	3.20	2.62	2.61
Within subject SD	3.68	3.68	2.91	2.90	2.90	2.90
Total SD	4.53	4.53	4.33	4.32	3.90	3.90

Additionally, a model was run using the absolute value of baseline differences as an explanatory variable. This model revealed that this variable was not statistically significant for any of the variables. It is likely that the random subject effects already accounts for some of the baseline effects. It is unclear how a model with a baseline effect can be used to determine if the device meets the accuracy requirements of the ISO standard, as the baseline values vary over subjects. Also, the addition of another explanatory variable in the model should reduce the estimated variances and improve the estimated accuracy of the test device.

We have used the differences between the test and reference devices as the response variable because the differences measure the closeness of the test device to the reference measurements (i.e. the accuracy) and because the ISO standard requirements are stated in terms of the differences of the measurements. Using the test device measurements as the response and the reference measurements as an explanatory variable yields estimates of the correlation of the device and reference measurements. Correlation has been shown to be problematic for determining the accuracy between the test and reference devices (as explained in Bland and Altman (Lancet 1986)).

10. *You state that your device can be used for arm circumferences ranging from 20~ 46 cm, but, as your demographic data in response to our previous Q. 13 indicate, your study includes subjects with circumferences ranging from only 21 to 36 cm. Furthermore, the single subject (v02) who had circumference of 37 cm and was excluded since s/he had a BMI of35.5 (since it exceeded 35) showed large differences between device and clinical reference standard measurements. Please explain why you believe your study data are generalizable for circumferences that are larger than those studied.*

The range for arm circumferences indicated in the demographics spreadsheet is 21-38 cm (v10), not 21 cm – 36 cm. The 38 cm arm circumference subject was not excluded. Study data are generalizable for circumferences that are larger than those studied since the subjects met the size range criteria specified in the ISO standard based on the formula 1/ 2 x n. Table 3 of the clinical study report (reference original K130709 submission, Exhibit 14, "*Accuracy Study of ViSi…*", page 22 of 68) has been updated to indicate which subjects fall within each cuff size and the recommended arm circumference for each cuff size.

Table 3 Cuff Size Distribution
ISO Requirements – 1/(2n) for each cuff size
Requirement: A minimum of 2 subjects is needed for each cuff size

Cuff Size	Number of Subjects Tested	Meets Requirement	Recommended arm circumference	Subjects
Small Adult	4	Yes	20-26 cm	v01, v12, v13, v16
Adult	4[a]	Yes	25-34 cm	v03, v04, v07, v15
Adult Long	3	Yes	25-34 cm	v05, v06, v09
Large Adult	2[b]	Yes	32-43 cm	v10, v17
Large Adult Long	2	Yes	32-43 cm	v11, v08

[a] Does not include subject v14 who was dropped for obstructed arterial line
[b] Does not include subject v02 who was excluded for BMI >35 & > 5 mmHg difference between arterial line and cuff NIBP

The User Manual has been revised to indicate that arm circumference range tested in the validation study was 21–38 cm. The revised page 127 is provided in **Exhibit 2.**

The source of the following request for additional information is: FDA-Sotera Conference call, 8/12/2013. This information was sent in an e-mail to Dr. Charles Ho dated 8/13/2013.

Provide an analysis of the mean bias and standard deviation data in 30-minute intervals.

The following tables provide the analyses requested. All supine data in each 30-minute interval is considered. The analyses demonstrate that all time intervals met the mean bias ≤ ± 5 mmHg and standard deviation ≤ 8 mmHg requirements.

Ipsilateral

Interval (min)	**0 to 30**	**30 to 60**	**60 to 90**	**90 to 120**	**120 to 180**	**150 to 180**	**180 to 210**	**210 to 240**
# subjects	15	15	15	15	15	15	13	12
data points	5891	7859	6431	4783	8078	6981	3662	3877
SYS Bias (mmHg)	-2.34	-1.63	-1.60	-0.17	-1.00	-1.06	-3.68	-3.86
SYS Std Dev (mmHg)	4.36	4.49	5.92	5.36	4.75	6.97	7.69	6.00
DIA Bias (mmHg)	-1.17	-1.89	-1.63	-1.11	-0.90	-1.68	-2.04	-0.57
DIA Std Dev (mmHg)	2.60	3.01	2.87	3.85	2.87	3.80	4.01	1.94
MAP Bias (mmHg)	-0.60	-0.58	-0.53	0.23	0.36	-0.23	-1.49	-0.95
MAP Std Dev (mmHg)	2.00	2.75	3.74	4.59	2.95	3.86	4.49	2.06

Contralateral

Interval (min)	**0 to 30**	**30 to 60**	**60 to 90**	**90 to 120**	**120 to 180**	**150 to 180**	**180 to 210**	**210 to 240**
# subjects	15	15	15	15	15	15	13	12
data points	6344	7662	5931	5160	7985	6317	4107	3365
SYS Bias (mmHg)	-2.28	-1.12	-1.47	-1.15	-0.80	-1.55	-1.80	-2.88
SYS Std Dev (mmHg)	3.78	3.79	3.88	4.52	4.24	5.97	5.59	4.46
DIA Bias (mmHg)	-1.37	-0.86	-0.88	-0.57	-0.51	-1.73	-2.00	-1.99
DIA Std Dev (mmHg)	3.53	3.70	3.86	4.08	4.84	5.12	5.65	3.90
MAP Bias (mmHg)	-1.10	-0.35	-0.29	-0.20	0.23	-0.84	-0.99	-1.46
MAP Std Dev (mmHg)	3.45	3.09	3.30	3.38	4.26	4.86	5.46	3.41

In addition, Jim Welch sent an e-mail after Monday's conference call further clarifying in the labeling that: 1) recalibration is required when any of the conditions stated in section To recalibrate cNIBP on page 80 are met; and 2) that whenever the ViSi device detects a change in blood pressure that requires recalibration, a technical alarm is displayed. The revised text is highlighted on pages 79-81 of the User Manual (**Exhibit 1).**

The source of the following request for additional information is: e-mail from Dr. Charles Ho, dated 8/14/2013. This information was sent in an e-mail to Dr. Ho on 8/18/2013.

a. *The labeling change is good.*

Thanks

b. *The new analysis of data show some issues:*

i) *The data seem to be grouped into intervals of 30 minutes each, as shown by the large number of data points in each interval. However, please re-group the data into time points at 30 minutes after calibration, at 60 minutes after calibration, at 90 minutes after calibration, etc. At each time point, plus or minus 60 seconds, please collect 10 data point for the subject device and for the arterial reference, centered around the intended time point, in order to generate 10 data points of differences. (As you can see, I am trying to follow SP10's method for data collection when an invasive reference is used.) Thus, the number of data points for each subject at each time point should be at most 10. Afterwards, please re-do the bias and standard deviation calculations for these data.*

Sotera Response: The spreadsheet [for reviewer ease, the table is provided below] provides the analysis requested. The 30-minute time intervals sometimes coincided with periods of posture change or with trips to the bathroom. Since the analysis was to be applied only to the supine data, it was necessary to expand the ± 60 second time period for some time intervals in order to obtain the ten data points required for the analysis. The time period was expanded about the predefined interval in fixed increments (60s, 120s, 240s, and 480s) to the minimum window size that provided the 10 values.

Ipsilateral

Interval (min)	**30**	**60**	**90**	**120**	**150**	**180**	**210**	**240**
# subjects	15	15	15	15	15	13	12	10
data points	150	150	150	150	150	130	120	100
SYS Bias (mmHg)	-1.34	-0.37	-0.92	-0.07	-0.37	-1.87	-3.66	-3.73
SYS Std Dev (mmHg)	2.7	3.9	3.5	3.8	3.8	4.2	7.5	4.7
DIA Bias (mmHg)	-1.14	-1.65	-1.09	-0.94	-0.76	-1.51	-2.03	-0.28
DIA Std Dev (mmHg)	2.8	3.4	3.4	2.8	2.0	3.1	3.2	1.6
MAP Bias (mmHg)	-0.40	0.39	0.07	0.64	0.38	-0.80	-1.42	-0.35
MAP Std Dev (mmHg)	1.7	2.9	3.8	3.1	1.3	2.9	3.2	2.1

Contralateral

Interval (min)	30	60	90	120	150	180	210	240
# subjects	15	15	15	15	15	13	12	10
data points	150	150	150	150	150	130	120	100
SYS Bias (mmHg)	-1.04	-0.78	-0.67	-1.25	-1.41	-2.53	-2.24	-2.64
SYS Std Dev (mmHg)	1.4	2.6	1.3	3.6	2.6	4.7	4.0	3.7
DIA Bias (mmHg)	-0.90	-1.04	-0.38	-0.63	-0.57	-2.33	-2.66	-2.19
DIA Std Dev (mmHg)	2.6	3.3	3.6	4.3	4.3	4.7	4.2	4.6
MAP Bias (mmHg)	-0.52	-0.11	-0.02	-0.10	0.12	-1.57	-1.51	-1.42
MAP Std Dev (mmHg)	1.8	2.7	3.4	3.1	3.4	4.1	3.4	3.9

ii) *Since the minimum number of subjects at each time point should be 15, the data collected 180 minutes after calibration (and later data) are not sufficient to support the device's claim of longevity of each calibration lasting longer than 3 hours. Hence, please revise labeling to require a recalibration after 3 hours, regardless of other factors.*

Sotera Response: Sotera has investigated the calibration requirements for the predicate device and similar continuous non-invasive blood pressure monitors cleared by the FDA. The predicate device for the submission, the CNAP Monitor (K082599), does not have a specified recalibration interval but does have a notification for recalibration at baseline pressure changes of > 25 mmHg (similar to ViSi). The following table summarizes the recalibration requirements for monitors for which the labeling was available:

Continuous NIBP monitor	Recalibration Requirement
CNSystems K082599 CNAP 500	No recalibration requirement Recalibration notification for blood pressure change of > 25 mmHg
Tensys K121141 TL-200	No recalibration requirement
Finapres K023723 Finometer	No recalibration requirement

Sotera understands FDA's position that the number of subjects at each time point in our study should have been 15 to support the device's claim of longevity and the labeling we have proposed. We fully intend to rectify this by repeating this study, and plans are underway to do so immediately. In the meanwhile, we propose to modify the language to ensure the testing conditions under which the ViSi cNIBP accuracy and precision information were collected are fully disclosed. We believe this language is consistent with the predicate and similar devices and reflects ViSi performance. To this end, the specifications section of the User Manual has been revised as follows:

"The accuracy and precision of the cNIBP measurement met ISO 81060-2 requirements for the first 2.5 hours of testing."

Page 127 of the User Manual with the highlighted text is attached **(Exhibit 2).** This information is provided in addition to the recalibration requirement when any of the conditions stated on page 80 of the User Manual are met:

- Blood pressure changes >10 mmHg for hypotensive patients
- Blood pressure changes > 15 mmHg for normotensive patients
- Blood pressure changes > 20 mmHg for hypertensive patients

The source of the following request for additional information is: FDA-Sotera conference call, 8/21/2013. This information was sent in an e-mail to Dr. Charles Ho on 8/25/2013.

1) *Provide Bland-Altman plots showing the differences between cNIBP and the mean arterial reference values without using the ROV methodology. [Dr. Gomatam]*

Attached please find Bland-Altman plots using the methodology for multiple observations per individual[1]. Each plot is presented in two ways: 1) All data points plotted individually [Exhibits 9, 11]; and 2) on a per subject basis [Exhibits 8, 10]. The limits of agreement for all plots are based on ±1.96 standard deviations of the mean differences between the ViSi and the reference arterial line measurements. Contralateral ("CON") and ipsilateral ("IPS") data are presented in separate exhibits. Contralateral data precludes the possible interference of the reference radial arterial line.

- Exhibit_8_Supine-CON-cNIBP_BlandAltman.docx
- Exhibit_9_Supine-CON-cNIBP_BlandAltman-AllData.docx
- Exhibit_10_Supine-IPS-cNIBP_BlandAltman.docx
- Exhibit_11_Supine-IPS-cNIBP_BlandAltman-AllData.docx

2) *Provide worked examples of how bias was calculated from the raw data using ROV. [Dr. Charles Ho]*

Summarized below is the methodology used for the treatment of ViSi and reference radial-line data to determine differences at 30, 60, 90, 120, 150, 180, 210, and 240 minute intervals:

1. The step-by-step analysis described in this section refers to the cells in the Excel spreadsheet titled "*FDA_ErrorCalcualtionExample.zip*" on the accompanying CD. This numeric example was performed on subject "v01" using data collected from the contralateral arm.
2. The first cNIBP measurement for this subject was recorded at time 466.973 seconds. Time zero was established as the time that the ViSi monitor on the ipsilateral arm connected to the patient data server. The time of the first cNIBP measurement was considered the start time for this patient (cell B4). All of the time intervals in the analysis are given relative to this start time as shown in cells B5-B12.

[1] Bland, J.M., Altman, D.G. (2007). Agreement between methods of measurement with multiple observations per individual. *Journal of Biopharmaceutical Statistics*. 17: 571-582.

3. The numeric example in the spreadsheet was performed at the 30-minute mark (2266.973 seconds).
4. An interval of ±60 seconds was defined around the 30-minute mark. The times that mark the start and stop of the data analysis interval are given in cells B17 and B18.
5. All of the cNIBP measurements for systolic, diastolic and MAP that were measured during this interval are provided in cells B23-B62, C23-C62, and D23-D62 along with the time of the measurements.
6. All of the beat-to-beat systolic, diastolic, and mean pressure values that were measured from the radial line during the time interval and for 60 seconds prior to the start of the time interval are given in cells B67-B240, C67-C240, and D67-C240 along with the time of the measurement.
7. The average systolic, diastolic, and mean radial-line pressures that correspond to each of the cNIBP measurements are given in cells F23-F62, G23-G62, and H23-H62. The average values corresponding to each cNIBP measurement were calculated as the mean value of the beat-to-beat radial line data that were measured in the 60 seconds prior to the cNIBP measurement. The formulas given in each of the cells indicate the range of beat-to-beat radial line values used to calculate the averages.
8. The standard deviation of the systolic, diastolic, and mean radial-line pressures that correspond to each of the cNIBP measurements are given in cells I23-I62, J23-J62, and K23-K62. The standard deviation values corresponding to each cNIBP measurement were calculated as the standard deviation of the beat-to-beat radial line data that were measured in the 60 seconds prior to the cNIBP measurement. The formulas given in each of the cells indicate the range of beat-to-beat radial line values used to calculate the standard deviations.
9. A difference between the device-under-test or ViSi and the radial-line reference was calculated for each cNIBP systolic, diastolic, and mean value in the 120-second interval. The differences were calculated using the upper and lower range of variation (ROV). The differences for systolic, diastolic and mean pressure are given in cells N23-N62, O23-O62, and P23-P62.
10. Ten values were selected for subject v01 from the 40 difference values contained in the 120-second interval for use in the statistical error analysis at the 30-minute mark. The ten sets of differences (SYS, DIA, and MAP) for the subject were selected by creating and ordered list of the absolute values of the systolic differences in ascending order and selecting the first ten sets of differences in the ordered list.
11. The ten difference values from subject v01 were combined with ten difference values from each of the other 14 subjects to calculate the mean difference and standard deviation of the differences that were presented in the statistical analysis. The difference values for the other subjects were calculated in a manner identical to the example presented in the spreadsheet.

This information was sent in an e-mail to Dr. Charles Ho on 8/27/2013.

Last evening, it was noticed that the first plot Bland-Altman plot in Exhibit 2 was incorrectly labeled "Systolic" while it is actually the "MAP" plot (as noted in the sub-heading). The correct "Systolic" Bland-Altman plot has been copied into a revised Exhibit 2. The correct plot is attached (**Exhibit 12**): *Exhibit_12_REVISED_Supine-CON-cNIBP_Bland-Altman-AllData.pdf*. Sorry for the mix-up.

The source of the following request for additional information is: FDA-Sotera conference call, 9/4/2013. This information was sent in an e-mail to Dr. Charles Ho on 9/5/2013.

1. *Please group the data into time points at 30 minutes after calibration, at 60 minutes after calibration, at 90 minutes after calibration, etc. At each time point, collect the preceding 10 paired data points for the subject device and for the arterial reference, in order to generate 10 data points of differences. Thus, the number of data points for each subject at each time point should be 10. Afterwards, please re-do the bias and standard deviation calculations for these data.*

The following tables present the revised interval analysis requested.

Contralateral

Interval (min)	**30**	**60**	**90**	**120**	**150**	**180**	**210**	**240**
# subjects	15	15	15	15	15	13	12	10
data points	150	150	150	150	150	130	120	100
SYS Bias (mmHg)	-1.9	-1.2	-1.5	-0.1	-1.6	-4.1	-3.9	-3.8
SYS Std Dev (mmHg)	3.7	3.6	2.9	3.8	3.6	6.4	5.4	4.7
DIA Bias (mmHg)	-1.0	-1.2	-0.8	-0.7	-0.5	-2.6	-3.6	-2.4
DIA Std Dev (mmHg)	3.7	3.7	3.5	4.4	4.8	6.5	4.7	4.9
MAP Bias (mmHg)	-0.7	-0.4	-0.3	0.1	0.3	-1.9	-2.1	-1.6
MAP Std Dev (mmHg)	3.0	3.0	3.4	2.7	4.1	6.2	3.4	4.3

Ipsilateral

Interval (min)	**30**	**60**	**90**	**120**	**150**	**180**	**210**	**240**
# subjects	15	15	15	15	15	13	12	10
data points	150	150	150	150	150	130	120	100
SYS Bias (mmHg)	-0.1	-0.7	-1.6	0.8	-0.4	-2.1	-2.8	-6.3
SYS Std Dev (mmHg)	7.3	5.3	4.0	3.6	5.0	6.3	7.1	5.4
DIA Bias (mmHg)	-1.2	-1.4	-1.3	-0.8	-0.7	-2.1	-2.6	-0.8
DIA Std Dev (mmHg)	3.0	3.1	3.2	3.2	1.9	3.9	4.1	1.7
MAP Bias (mmHg)	-0.2	0.1	-0.1	0.9	0.5	-0.7	-1.2	-1.5
MAP Std Dev (mmHg)	2.4	3.3	3.5	3.5	1.6	4.3	3.2	2.0

2. *Please provide subject level Bland-Altman plots*

Individual Bland-Altman plots are provided for all 15 subjects (i.e. v01, v03, v04, v05, v06, v07, v08, v09, v10, v11, v12, v13, v15, v16, and v17). A set of systolic, MAP, diastolic plots are provided for the data analyzed from contralateral and ipsilateral arms in the attached file: *IndividualBlandAltmanPlots.pdf.* **(Exhibit 13).**

3. *What model statements were used in the response to Question 9 (August 8, 2013 e-mail)?*

The model statements used for the SAS outputs were:

proc mixed data=ipssub_all method=reml;
class subnum;
model sys_diff= time/s;
random subnum;
run;
	proc mixed data=ipssub_all method=reml;
	class subnum;
	model sys_diff= /s;
	random subnum;
	run;

proc mixed data=consub_all method=reml;
class subnum;
model sys_diff= /s;
random subnum;
run;
	proc mixed data=ipssub_all method=reml;
	class subnum;
	model dia_diff= /s;
	random subnum;
	run;

proc mixed data=consub_all method=reml;
class subnum;
model dia_diff= /s;
random subnum;
run;
	proc mixed data=ipssub_all method=reml;
	class subnum;
	model map_diff= /s;
	random subnum;
	run;

proc mixed data=consub_all method=reml;
class subnum;
model map_diff= /s;
random subnum;
run;
	proc mixed data=ipssub_all method=reml;
	class subnum;
	model sys_diff= time/s;
	random subnum;
	run;

proc mixed data=consub_all method=reml;
class subnum;
model sys_diff= time/s;
random subnum;
run;
	proc mixed data=ipssub_all method=reml;
	class subnum;
	model dia_diff= time/s;
	random subnum;
	run;

proc mixed data=consub_all method=reml;
class subnum;
model dia_diff= time/s;
random subnum;
run;
	proc mixed data=ipssub_all method=reml;
	class subnum;
	model map_diff= time/s;
	random subnum;
	run;

proc mixed data=consub_all method=reml;
class subnum;
model map_diff= time/s;
random subnum;
run;
	proc mixed data=ipssub_all method=reml;
	class subnum;
	model sys_diff= time base_sys/s;
	random subnum;
	run;

proc mixed data=consub_all method=reml;
class subnum;
model sys_diff= time base_sys/s;
random subnum;
run;
	proc mixed data=ipssub_all method=reml;
	class subnum;
	model dia_diff= time base_dia/s;
	random subnum;
	run;

proc mixed data=consub_all method=reml;
class subnum;
model dia_diff= time base_dia/s;
random subnum;
run;
	proc mixed data=ipssub_all method=reml;
	class subnum;
	model map_diff= time base_map/s;
	random subnum;
	run;

proc mixed data=consub_all method=reml;
class subnum;
model map_diff= time base_map/s;
random subnum;
run;	

4. *How is "baseline" defined in the response?*

Baseline was defined as the first paired BP measurement, at time 0.

5. *Can you explain the variability of the intercepts from model to model?*

The difference between the intercepts in the mixed-effects models with and without time reflects the small time effect estimated. For example with systolic BP, we see a small change over time toward larger negative differences. Specifically, the mean difference at time 0 hours is -1.15 mmHg and the mean difference at time 4 hours is -2.01 mmHg. The model without time has an intercept equal to approximately the average of the previously stated means or -1.61 mmHg. In all cases, the time effect from 0 to 4 hours is less than 1 mmHg.

The source of the following request for additional information is: e-mail from Dr. Charles Ho dated 9/11/2013. This information was sent in an e-mail dated 9/15/2013 to Dr. Ho.

1) *Can you explain the downward trend in the differences with increasing value of blood pressure in the graphs in your IndividualBlandAltmanPlots.pdf? (PS: I note that the X-axis plots the Clinical reference standard (CRS) measurement, not the average of the device and CRS – this may have been the result of a miscommunication during our previous telecon, if so we apologize).*

The downward trend is expected with the reference as the X-axis and test - reference as the Y-axis. This is because the correlation of the reference and (test - reference) is negative, specifically: Corr(X, Y-X) = Corr(X,Y) - 1 < 0 (if the variance of the test and reference values are the same). This is why Bland-Altman suggests plotting the differences against the sum, because Corr(X +Y, Y-X) = 0 (if the variance of the test and reference values are the same).

The Bland-Altman data is stratified into diagonal lines because the resolution of the ViSi cNIBP measurements are ±1 mmHg. These stratifications appear when a large number of data points are used in the plot.

Individual Bland-Altman plots using the average of the ViSi device and the CRS on the X-axis are provided *IndividualBlandAltmanPlots_AvgCRS+Device.pdf*. (**Exhibit 14**). The downward trend is now less evident.

2) *In the plots in Exhibit 5 (provided in August) there are gaps in the data other than for posture changes and bathroom breaks. Can you identify the major reasons for these gaps? (for example, what percentage were due periods of motion etc.)*

The ViSi monitor displays "XX" for systolic, diastolic, and mean arterial pressure when unable to calculate cNIBP values. The majority of the cNIBP data missing from the time series error plots were periods in which the ViSi monitor was displaying "XX". The cNIBP numeric value was updated every 3 seconds. If the device displayed "XX" a value of -1 was recorded in the electronic data files to indicate this condition. The attached plot, *v11-visi-ips.pdf* (**Exhibit 15**), shows all of the cNIBP values recorded in the electronic data file for subject v11 on the ipsilateral arm. The "XX" values were excluded from the time series error plots depicting the differences between the DUT and arterial line reference.

In order to calculate a blood pressure value the cNIBP algorithm requires a minimum of 25 pulse arrival time (PAT) measurements in the previous 60 seconds. There are four main reasons why the algorithm failed to add enough PAT values to the 60-second buffer. In general, all are caused by poor quality ECG and/or PPG signals:

1) The algorithm used to identify pulse onsets in the photoplethysmogram (PPG) failed to detect the pulse. This can occur when the PPG signal-to-noise ratio is low due to corruption by artifact.

2) The algorithm used to identify QRS peaks in the ECG failed to detect the beat. This can occur when the ECG signal-to-noise ratio is low due to corruption by artifact.

3) A PAT value is calculated but discarded from the 60-second buffer because the quality of the PPG signal is classified as poor or the PAT value does not fall within a pre-specified timing range.

4) The PAT value is classified as an outlier when compared to adjacent values and removed from the 60-second buffer.

A small amount of missing cNIBP data was caused by a loss of the wireless radio connection used to collect the electronic data. The table below summarizes the percentage of time which the ViSi Monitor displayed ("XX").

Table: Percentage of cNIBP measurements in which device displayed "XX" (Supine data)

Subject	cNIBP Measurements Displaying "XX" (%)	
	Contralateral data	Ipsilateral data
v01	0.56	0.44
v03	0.36	1.54
v04	0.38	0.31
v05	0.66	0.93
v06	0.47	1.60
v07	0.55	0.19
v08	0.34	1.14
v09	3.21	0.24
v10	0.52	0.78
v11	0.54	18.85
v12	1.07	0.56
v13	7.59	0.58
v15	0.38	8.28
v16	4.31	0.41
v17	6.18	3.14

3) *When we look at the plot from Exhibit 5 for V17 ipsilateral for instance and compare with the associated plot in IndividualBlandAltmanPlots.pdf, it appears that the data in the two are not consistent. For instance, there are no differences that are below -20 in the Exhibit 5 plots, whereas there are some in the IndividualBlandAltmanPlots.pdf plot. Were the same data used for the two plots?*

The time series error plots provided in Exhibit 5 depicted the differences that were calculated using the arterial line range of variation as a reference. As requested by Dr Gomatam in our teleconference, the individual Bland-Altman plots did not use the range of variation method to determine the difference but rather the differences shown in the plots were calculated between the ViSi measurement and the mean arterial line value determined from the same time interval used to calculate the ViSi cNIBP.

Time series error plots calculated using the difference between the ViSi measurement and the mean arterial line value for both ipsilateral and contralateral data are provided in *TimeSeriesRevised_Supine.pdf* (**Exhibit 16**). Using this bias calculation method, there is agreement between the individual time series error plots and Bland-Altman plots.

5.2.8 Continuous NIBP Monitoring

Sotera's continuous blood pressure monitor (cNIBP) is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every three seconds. Recalibration will be required when any of the conditions stated in section *To recalibrate cNIBP on page 80* are met.

The accuracy of cNIBP is dependent on the initial cuff calibration. Use good clinical practice to confirm cNIBP accuracy before initiating or treating a patient.

The accuracy of the cNIBP measurement cannot be relied upon in patients with a BMI greater than 35.

Due to cNIBP signal averaging, there is a maximum 63 second time delay between the instantaneous blood pressure reading and the displayed reading.

The ViSi Mobile Monitoring System accuracy claim (mean error of ≤ ±5 mmHg and a std. dev. of ≤ 8 mmHg) is not met when the subject is inclined more than 30 degrees from horizontal.

Note: Continuous NIBP monitoring is an optional feature that requires an additional license key.

To calibrate cNIBP

Chest Sensor, Thumb Sensor and Cuff Module connected | **NIBP Reading In Progress** | **Spot-Check Reading** | **cNIBP Calibrated**

1. Connect the ViSi Mobile Chest Sensor, Thumb Sensor and Cuff Module and navigate to the **Vitals Signs** screen.

The Start Cuff button *will change to the Calibrate cNIBP button.*

2. Touch **Calibrate cNIBP** on the **Vital Signs** screen.

   The Cuff will start to inflate, indicating the calibration process has started. After a single NIBP measurement has been taken, the ViSi Mobile Monitor will calibrate cNIBP. The NIBP measurement will be displayed in white during the calibration process.

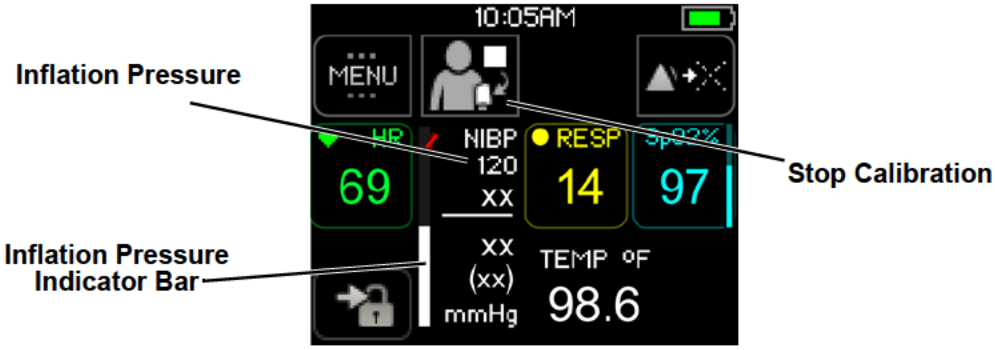
   Once cNIBP has been calibrated, Systolic, Diastolic and MAP measurements will be displayed in red. The displayed measurement will be refreshed every 3 seconds.

Note: The calibration process will take approximately 1 to 2 minutes to complete.

Note: If the first calibration is not successful, a second calibration attempt will automatically occur. A failure to calibrate will be indicated by a "Calibration Failed" alert and the Cuff will inflate for again.

To stop the cNIBP calibration

A cNIBP calibration currently in progress may be stopped at any time.



Touch **Stop NIBP** to stop the cuff inflation and NIBP measurement.

The cuff will deflate.

To recalibrate cNIBP

Note: Whenever a device detects a change in continuous blood pressure that requires a recalibration, the technical alert Calibrate cNIBP is displayed.

To manually recalibrate cNIBP, following the steps outlined in section *To calibrate cNIBP on page 79*.

There are several reasons why cNIBP will require recalibration:

- A vasoactive drug is administered to the patient.
- Any of the cNIBP measurements exceed the upper or lower alarm limits.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 15mmHg for a normotensive patient over a period longer than 60 seconds.

- Either the systolic or diastolic measurement indicates a change since calibration by more than 20mmHg when in a hypertensive range (systolic above 140mmHg or diastolic above 90mmHg) over a period longer than 60 seconds.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 10mmHg when in a hypotensive range (systolic below 90mmHg or diastolic below 60mmHg) over a period longer than 60 seconds.
- An unexpected interruption of monitoring occurred, such as all sensors being disconnected. If the interruption is less than 30 seconds, no recalibration is required. *See section All Sensors Disconnected on page 84.*

Note: When a recalibration event is detected and the Cuff Module is connected, the ViSi Mobile Monitor will automatically recalibrate cNIBP.

Note: When a recalibration event is detected and the Cuff Module is not connected, the ViSi Mobile Monitor will display the Calibrate cNIBP alert. Connect the Cuff Module and recalibrate manually.

You should manually recalibrate cNIBP after any drug administration.

9.2.5 Continuous Non-Invasive Blood Pressure (cNIBP)

Continuous Non-Invasive Blood Pressure (cNIBP)	
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.
Principle of Operation	cNIBP is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location.
Display Update	Continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every 3 seconds.
Systolic	Range: 60 to 240 mmHg Accuracy[a,b]: Mean error of ≤ ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Diastolic	Range: 40 to 160 mmHg Accuracy[a,b]: Mean error of ≤ ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Mean Arterial Pressure (MAP)	Range: 50 to 185 mmHg Accuracy[a,b]: Mean error of ≤ ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Validation Study	Invasive blood pressure (radial artery) reference Number of subjects: 15 Subject age range: 19-48 years Arm circumference range tested: 21-38 cm

a. *ViSi Mobile Monitoring System accuracy claim is not met when the subject is inclined more than 30 degrees from horizontal.*
b. *The accuracy and precision of the cNIBP measurement met ISO 81060-2 requirements for the first 2.5 hours of testing.*

cNIBP Clinical Study Results
Sotera ViSi cNIBP vs. Reference Invasive Radial Artery Transducer (n=15 subjects)

Subject Position		**Supine**	**30º**	**60º**	**Overall**
Systolic	Bias	-1.61	-4.77	-7.36	-1.88
	Std. Dev.	5.69	7.87	9.97	6.17
Diastolic	Bias	-1.33	-3.97	-8.31	-1.65
	Std. Dev.	3.16	4.49	6.07	3.62
MAP	Bias	-0.33	-3.01	-7.23	-0.67
	Std. Dev.	3.36	5.37	6.67	3.86
Data Points		47,572	1,774	1,724	54,179

ViSi System Risk /Hazard Analysis - cNIBP Module

Document No.: 0-000959	Revision: A
CO #: 01799	Release Date: 31 JAN 2013

Product Description	This Hazards Analysis applies to the optional cNIBP feature of the ViSi Mobile Monitoring System
Scope	This Hazards Analysis applies to the cNIBP feature only of the ViSi Mobile Monitoring System. It includes system-level and software risks. There are no hardware changes made from the already released ViSi Mobile product. The remaining aspects of the ViSi System are addressed in Hazard Analysis 0-000020, and 0-000082

Risk Management Team

Name	Title	Role
S. Tsadok	Prin Eng, Pt Safety and Clinical Performance	Risk Management Team Leader
E. Gordon	Sr. Director, Regulatory Affairs	Risk Management Team member
C. DiBattista	Mgr, Application Design	Risk Management Team member
J. Welch	VP, RA/QA/ Clinical Engineering	Risk Management Team member
D. McCombie	Dir, Science	Risk Management Team member
D. Walker	Mgr, Embedded SW Engineering	Risk Management Team member
J. Moon	CTO	Risk Management Team member

Revision History

Author	Revision	Date	Description
S. Tsadok	A	1/31/2013	Initial release

Hazard Category: cNIBP

Entry ID	Hazard	Potential Harm	Applies To	Potential Cause	Intial Severity	Intial Probability	Intial Risk Eval.	Mitigation Description	Mitigation RM ID	Residual Severity	Residual Probability	Residual Risk Eval.	Notes/Comments
10	Wrong / harmful intervention based on incorrect BP reading	1) delay in treatment 2) incorrect treatment	P	Incorrect calibration as a result of incorrect NIBP measurement due to:									
				- incorrect cuff size	3	2	A	Provide mutliple cuff sizes	02000	3	2	A	MMEA - IFU
				- incorrect cuff placement	3	3	A	Labeling / training	02001	3	2	A	MMEA - IFU
				- calibration algorithm error	3	4	I	Use of default calibration curves	02002	3	1	BA	SW: requires verification of algorithmic calculations
								Evaluation of calibration using change in PAT, goodness of fit, number of PAT values	02003				SW: requires verification of algorithmic calculations
								Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold	02004				MMEA - IFU
								Clinical/pivotal trials	01075				Pivotal trials
				- motion artifact	3	4	I	Labeling / training to keep patient still	02005	3	2	A	MMEA - IFU
								PPG noise tracking	02006				SW: requires verification of algorithmic calculations
			P	Incorrect PAT due to:									
				- Change in PEP, VTT due to change in load caused by:									
				- change in medication	3	4	I	labeling to recalibrate with changes in care	02007	3	3	A	MMEA - IFU
				- change in cardiovascular blood volume	3	4	I	labeling to recalibrate with changes in patient condition	02008	3	3	A	MMEA - IFU
				- change in body position / posture	3	4	I	Measure and correct for torso and arm posture changes	02009	3	2	A	SW: requires verification test
				- change of PEP, VTT due to change in contractility due to changes in medication	3	4	I	labeling to recalibrate with changes in care	02007	3	3	A	MMEA - IFU
								Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold	02004				MMEA - IFU, requires verification test
			P	Algorithm issues due to:									
				- inaccurate fiducial point, PPG, ECG	3	4	I	Outlier rejection	02010	3	2	A	SW: requires verification test
								Use of averaging	02011				SW: requires verification test
				- bad ECG lead placement	3	4	I	Labeling, training on correct electrode placement	02012	3	3	A	MMEA - IFU
				- poor skin to electrode conductivity	3	4	I	PAT measurement qualifications and rejection criteria	02013	3	2	A	SW: requires verification test
				- motion	3	4	I	Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold	02004	3	3	A	MMEA - IFU
				- difficulties with the patient's waveform morphology	3	4	I	Clinical evalution of algorithm per ISO 9919	01075	3	2	A	clinical pivotal trials report
				- incorrect beat picking	3	4	I	Testing against accepted beat databases	02014	3	2	A	SW: requires verification test
				- inaccurate pleth readings	3	4	I	PAT measurement qualifications and rejection criteria	02013	3	2	A	SW: requires verification test
				- incorrect arm position or change in arm position relative to heart	3	4	I	Measure and correct for torso and arm posture changes	02009	3	2	A	SW: requires verification test
								Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold	02004				MMEA - IFU

Mitigation								
RM ID	Summary Description	Description	Type	Device(s)	H/W	S/W	Process	Labeling
00000	None required	No mitigation is necessary						
01075	cNIBP clinical validation	Validate cNIBP accuracy clinically against change in NIBP baseline.	PROD	System				
02000	NIBP calibraton measurement	Provide mutliple cuff sizes	PROD	NIBP	X			
02001	NIBP calibraton measurement	Labeling / training	INFO	System				X
02002	NIBP calibraton measurement	Use of default cal bration curves	PROD	WT		X		
02003	NIBP calibraton measurement	Evaluation of calibration using change in PAT, goodness of fit, number of PAT values	PROD	WT		X		
02004	NIBP calibraton measurement	Alert to the clinician to retake an NIBP measurement to recalibrate if there is a change in the cNIBP that exceeds a threshold	PROD	WT		X		X
02005	NIBP calibraton measurement	Labeling / training to keep patient still	INFO	System				X
02006	NIBP calibraton measurement	PPG noise tracking	PROD	WT		X		
02007	PAT calculation	labeling to recalibrate with changes in care	INFO	System				X
02008	PAT calculation	labeling to recalibrate with changes in patient condition	INFO	System				X
02009	PAT calculation	Measure and correct for torso and arm posture changes	PROD	WT		X		
02010	cNIBP algorithm	Outlier rejection	PROD	WT		X		
02011	cNIBP algorithm	Use of averaging	PROD	WT		X		
02012	cNIBP algorithm	Labeling, training on correct electrode placement	INFO	System				X
02013	cNIBP algorithm	PAT measurement qualifications and rejection criteria	PROD	WT		X		
02014	cNIBP algorithm	Testing against accepted beat databases	PROC	ECG			X	

Risk Evaluation Lookup Table		Severity				
		1	2	3	4	5
Probability	1	BA	BA	BA	A	A
	2	BA	BA	A	A	I
	3	BA	A	A	I	I
	4	A	A	I	I	I
	5	A	A	I	I	I

BA Broadly acceptable
A As low as reasonably practicable
I Intolerable

"Applies to" codes

P Patient
U User
B Bystander
S Service
F Facility
E Environment

Severity

0	None	No health impact, no limitation
1	Nuisance	No health impact. Awkward use. Limitation.
2	Minor	Short term discomfort, minor injury with low or no impact on activities of daily living
3	Serious	Small injury requiring minor medical intervention (cuts, bruises, etc.)
4	Critical	Injury requiring immediate medical attention. Result in failure to rescue. Damage to property/environment exceeding $1,000,000
5	Catastrophic	Direct permanent serious injury, disability, death, damage to property/environment exceeding $10,000,000

Probability

0	Never	Will never occur during the expected service life
1	Remote	Extremely rare occurrance during the expected service life
2	Seldom	Not likely to occur during the expected service life
3	Sometimes	Possible to occur during expected service life
4	Likely	Probable to occur several times during the expected service life
5	Definite	Will occur during the expected service life

6. Alarms and Alerts

6.1 Introduction

The ViSi Mobile Monitoring System provides a comprehensive alarm system that alarms on changes to the patient's physiologic status. The system provides default alarm limits or the clinician can manage the alarm limits per patient to provide individualized care. Equipment alerts are provided to alert the clinician of situations that may impede the ability to monitor your patient.

6.2 Managing Alarms and Alerts

A responsible clinician must be within audible range of the assigned patient wearing the ViSi Mobile Monitor at all times.

cNIBP alarms are not announced at the central station.

6.2.1 Turning Alarms On/Off

Alarm limits for each vital sign parameter are predefined and turned on automatically whenever a sensor is connected to the patient and to the Monitor. Sometimes it is desirable to adjust the alarm limits to meet a patient's monitoring requirements.

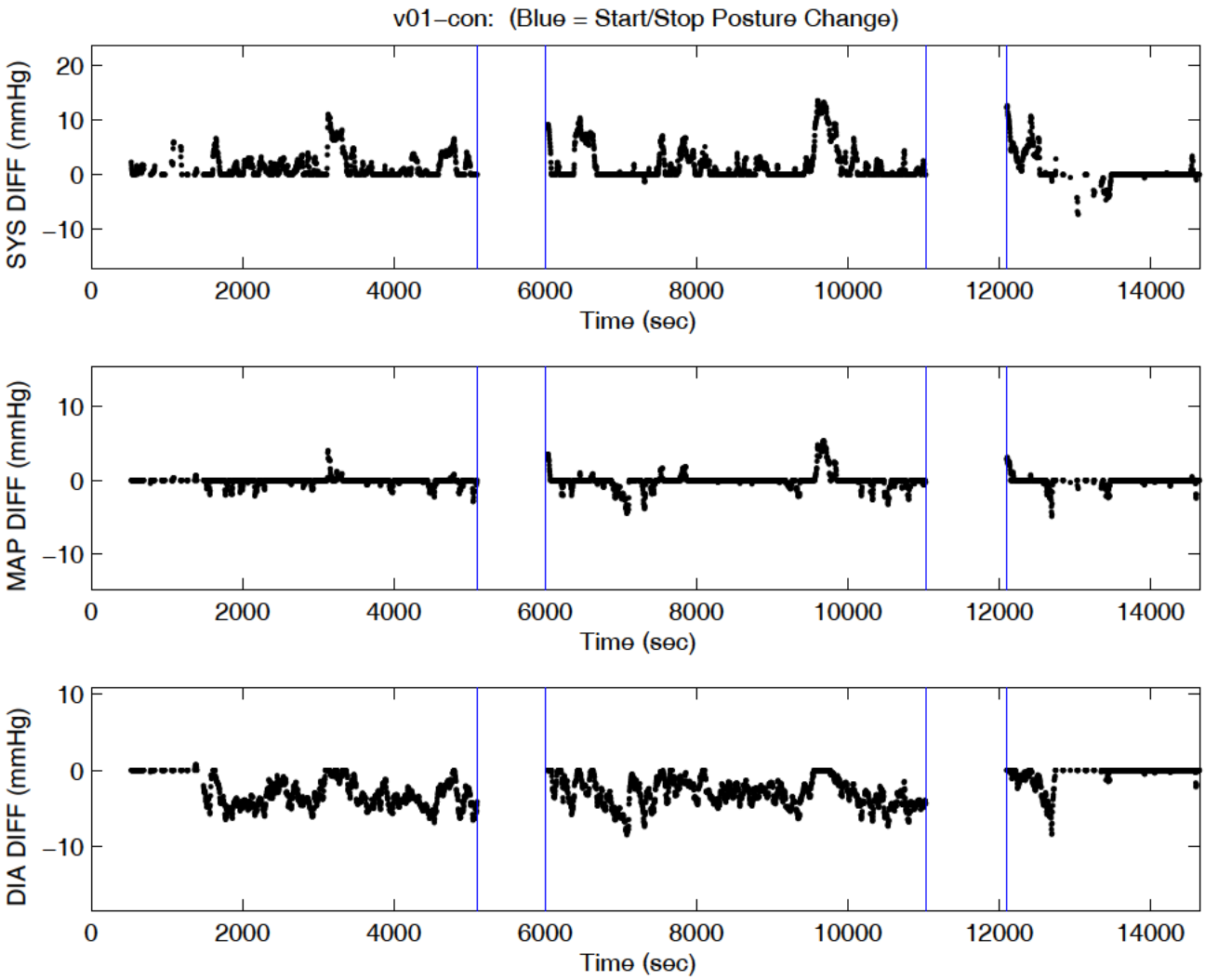
When alarms are turned OFF, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarms are turned OFF.

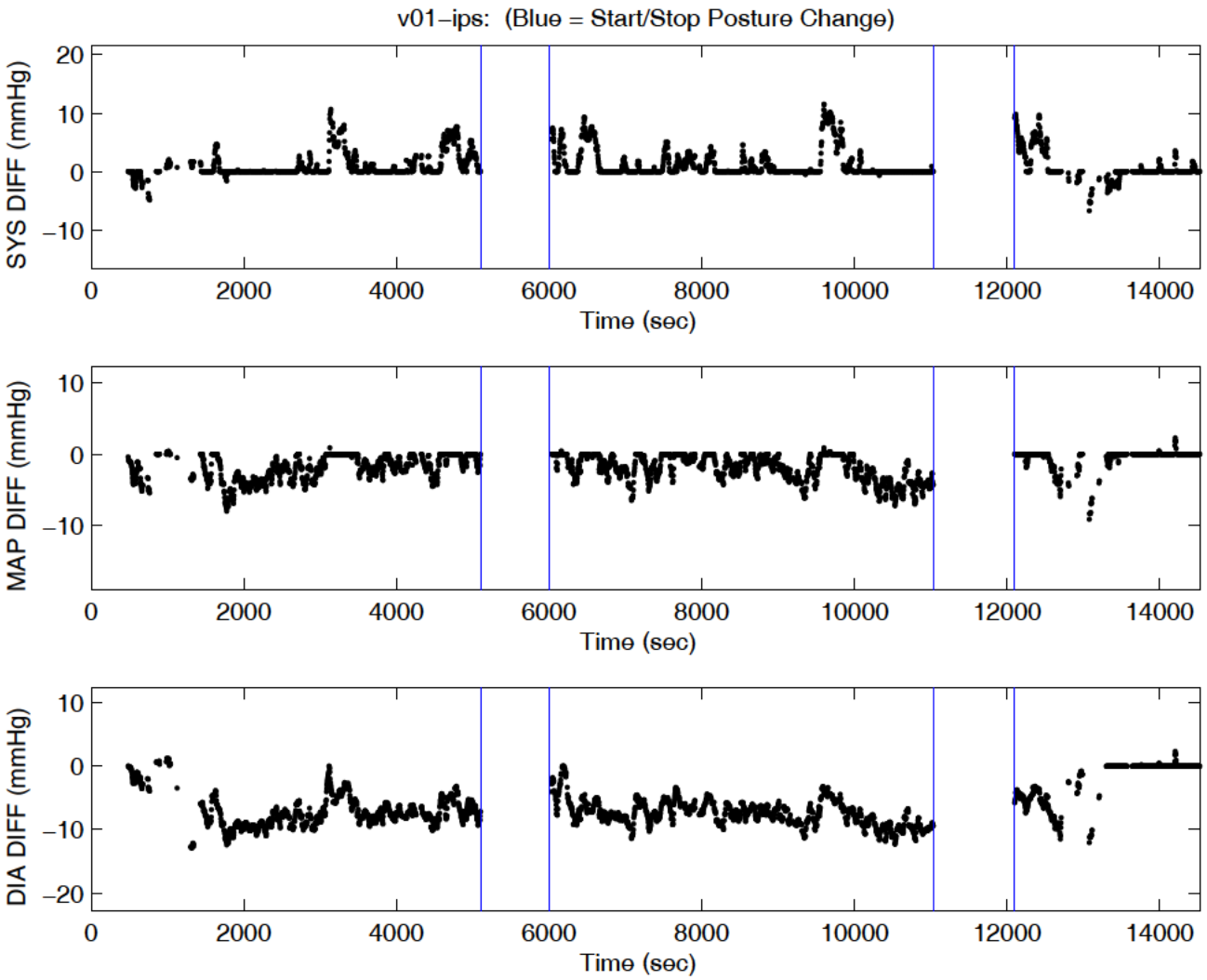
To turn all alarms off

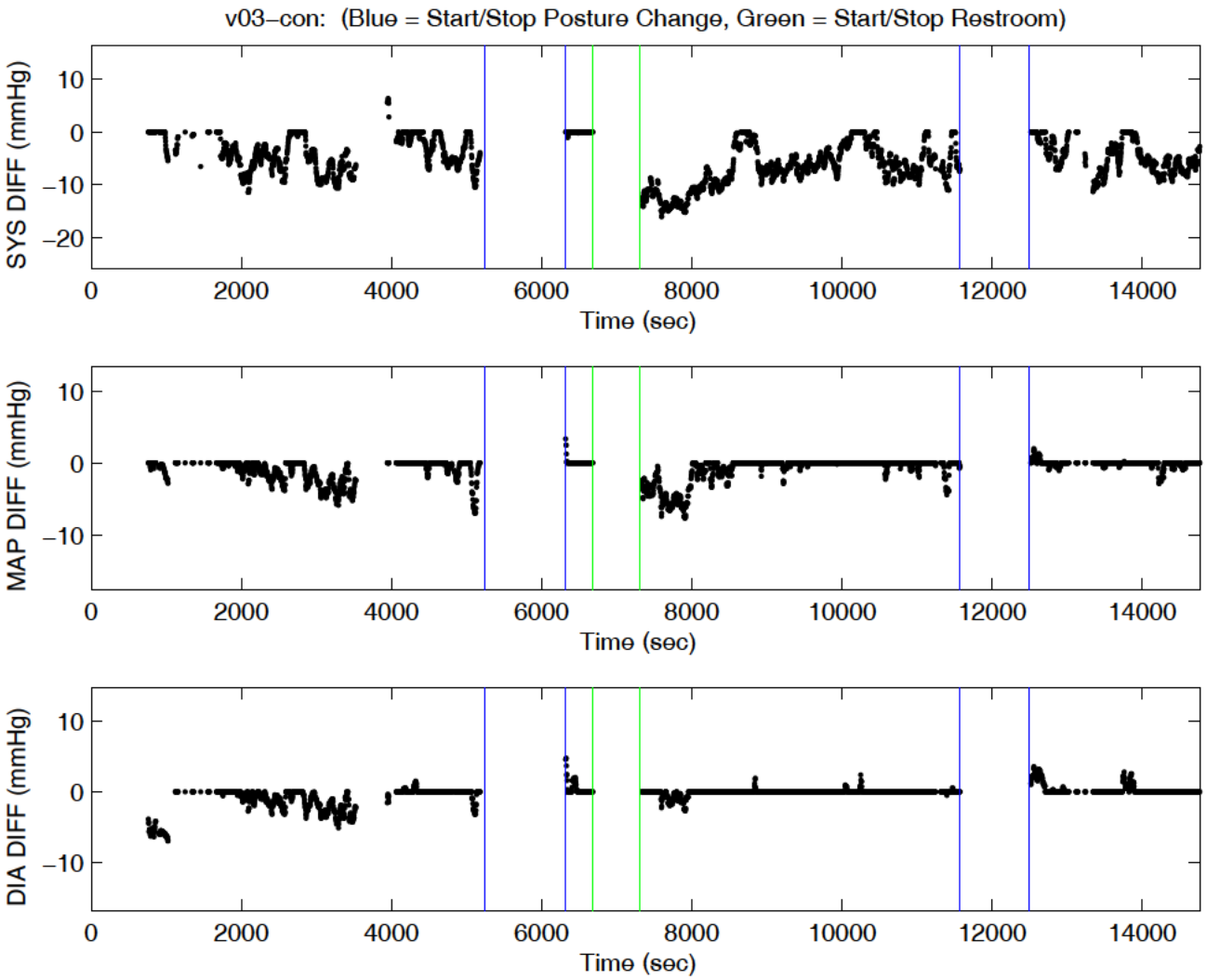
1. Touch **Menu** on the **Vital Signs** screen.

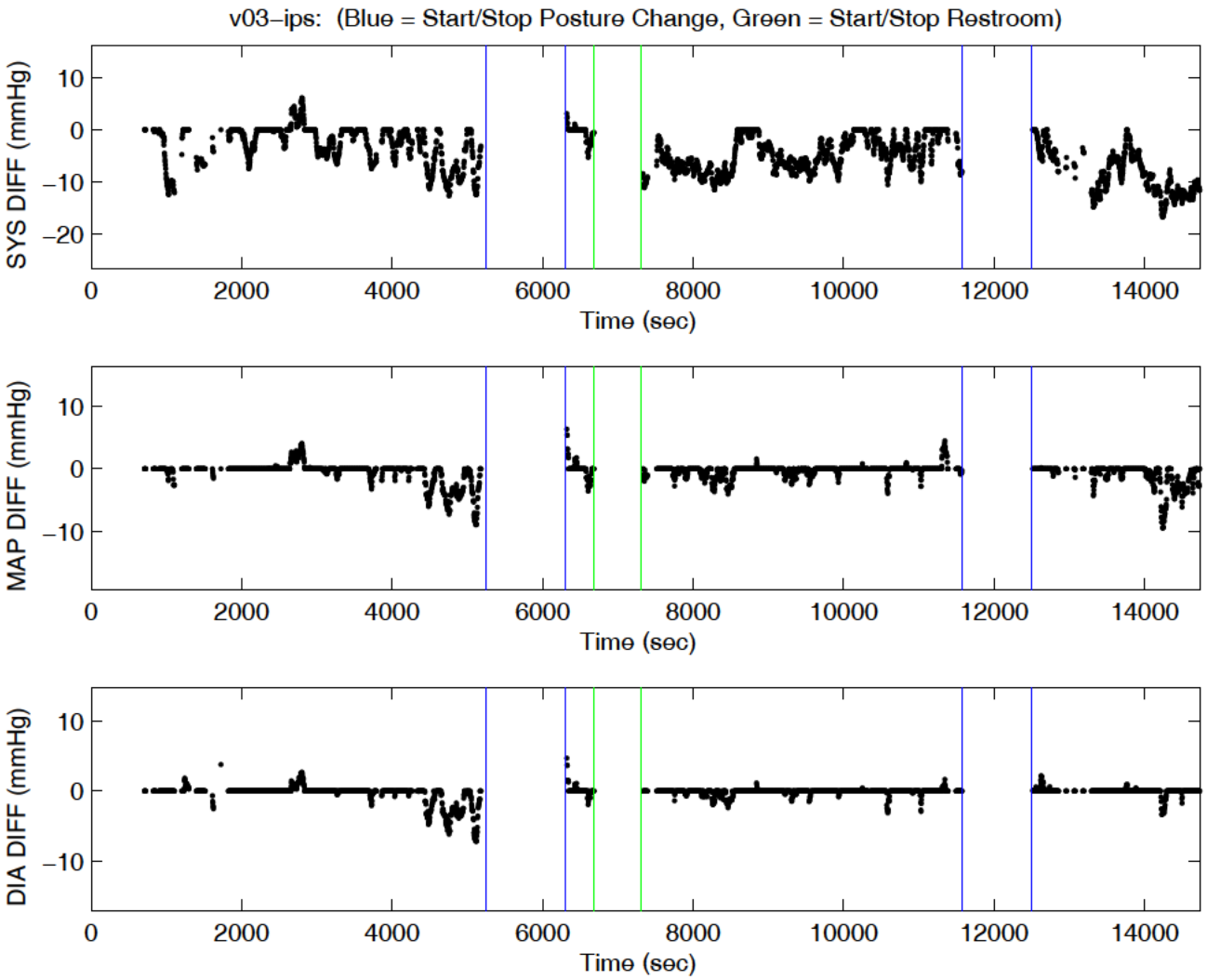
   The Menu screen appears.

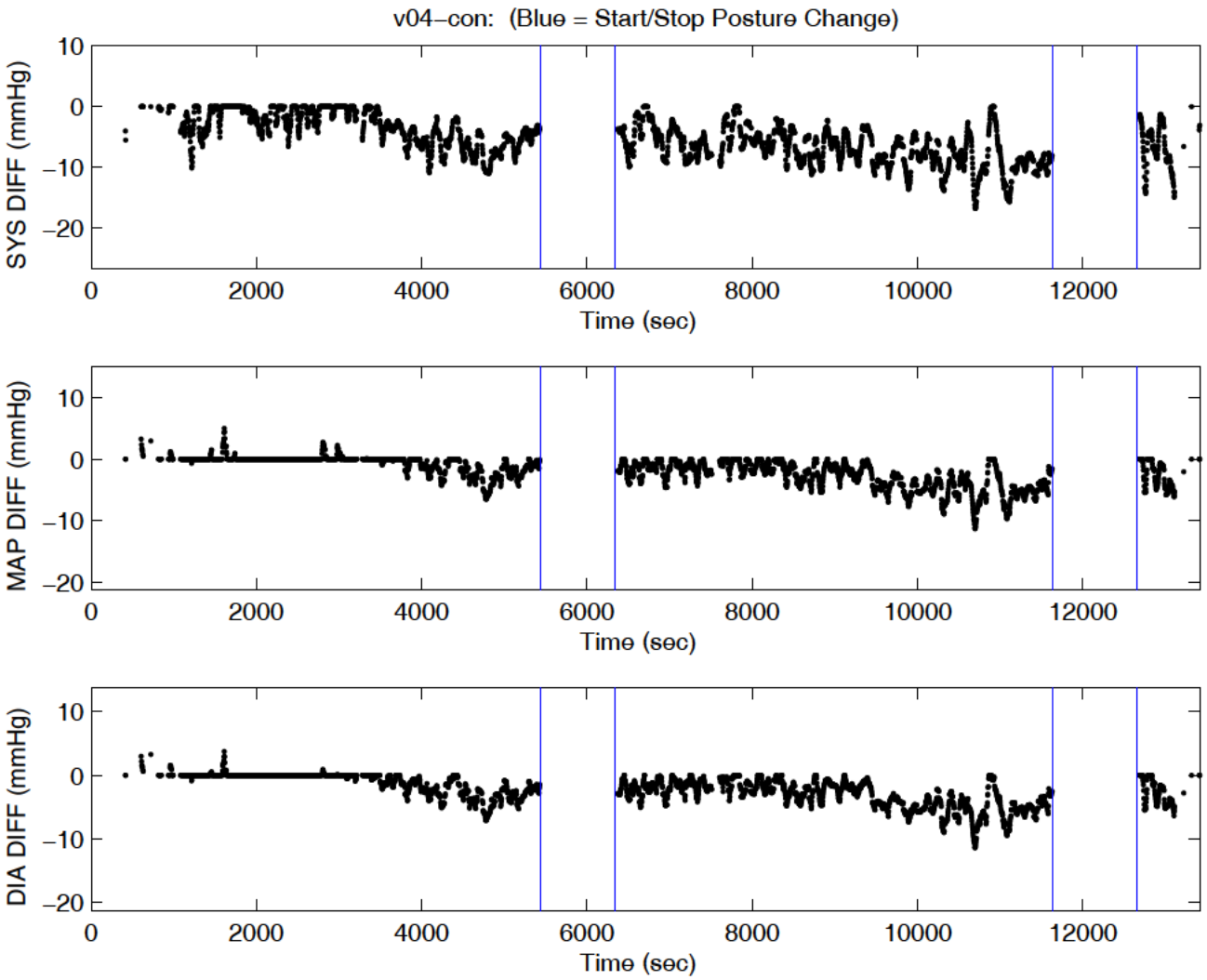
2. Touch **Alarms Settings.**

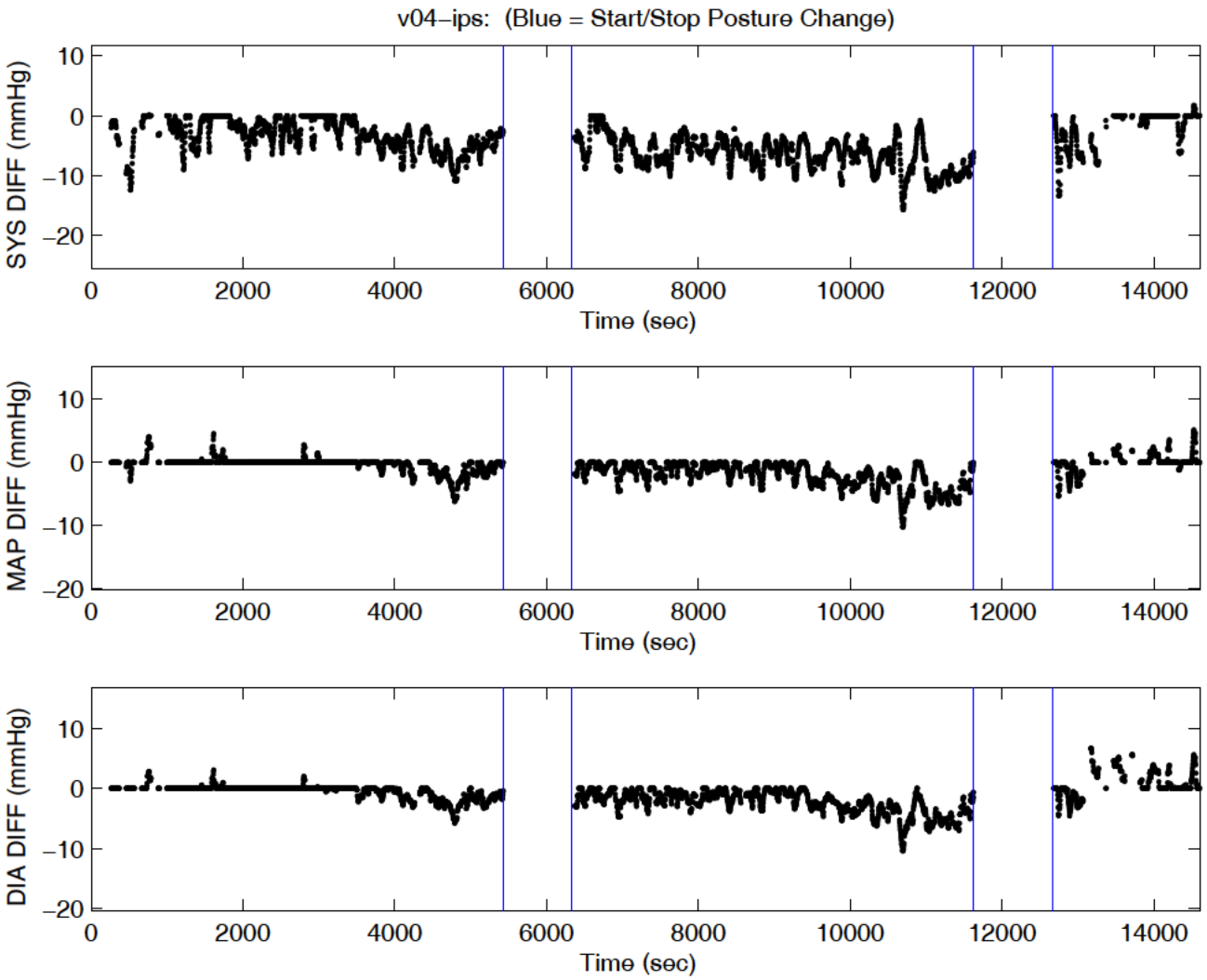

v01−con: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
20
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
MAP DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
DIA DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)

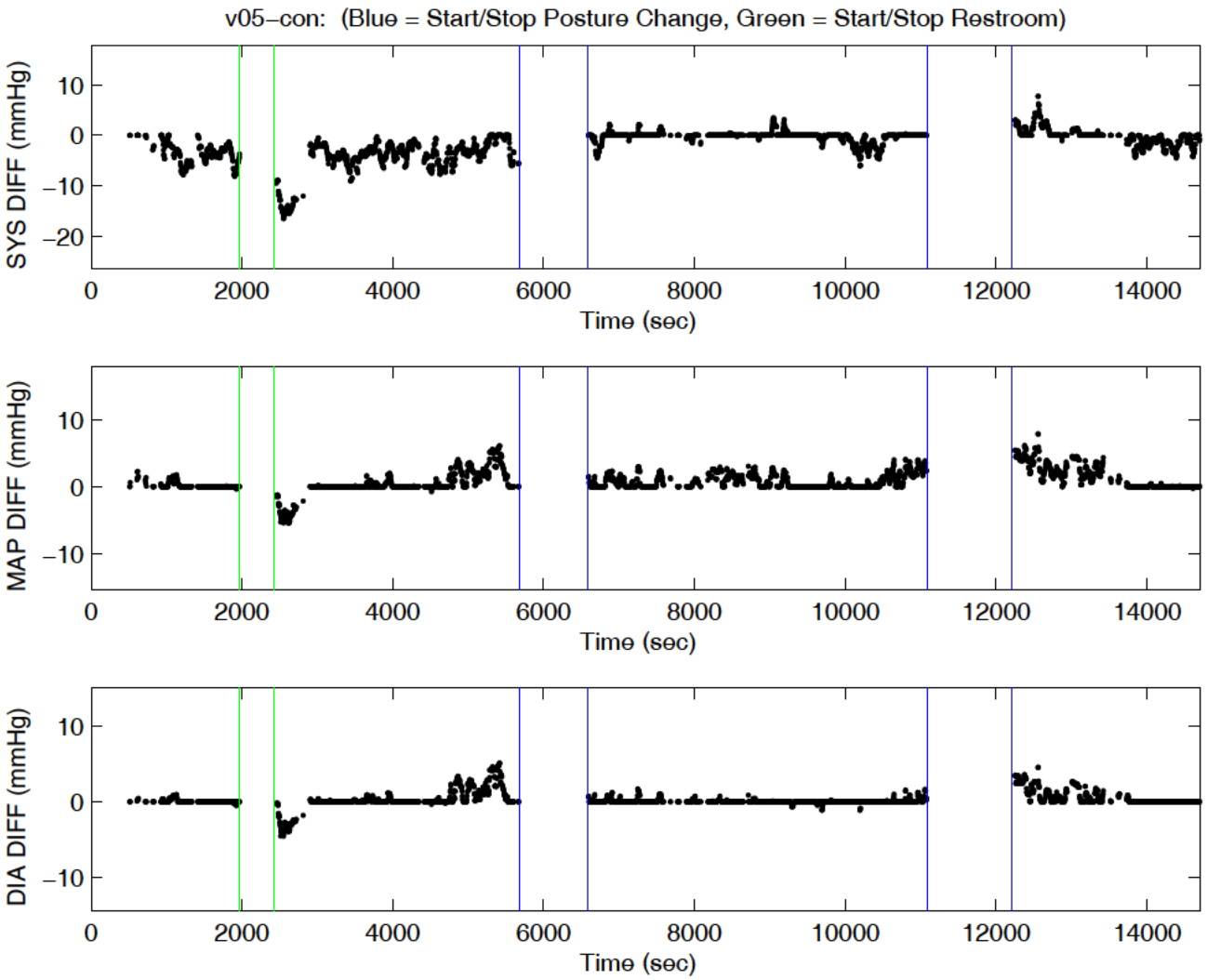

v01−ips: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
20
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
MAP DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
DIA DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)

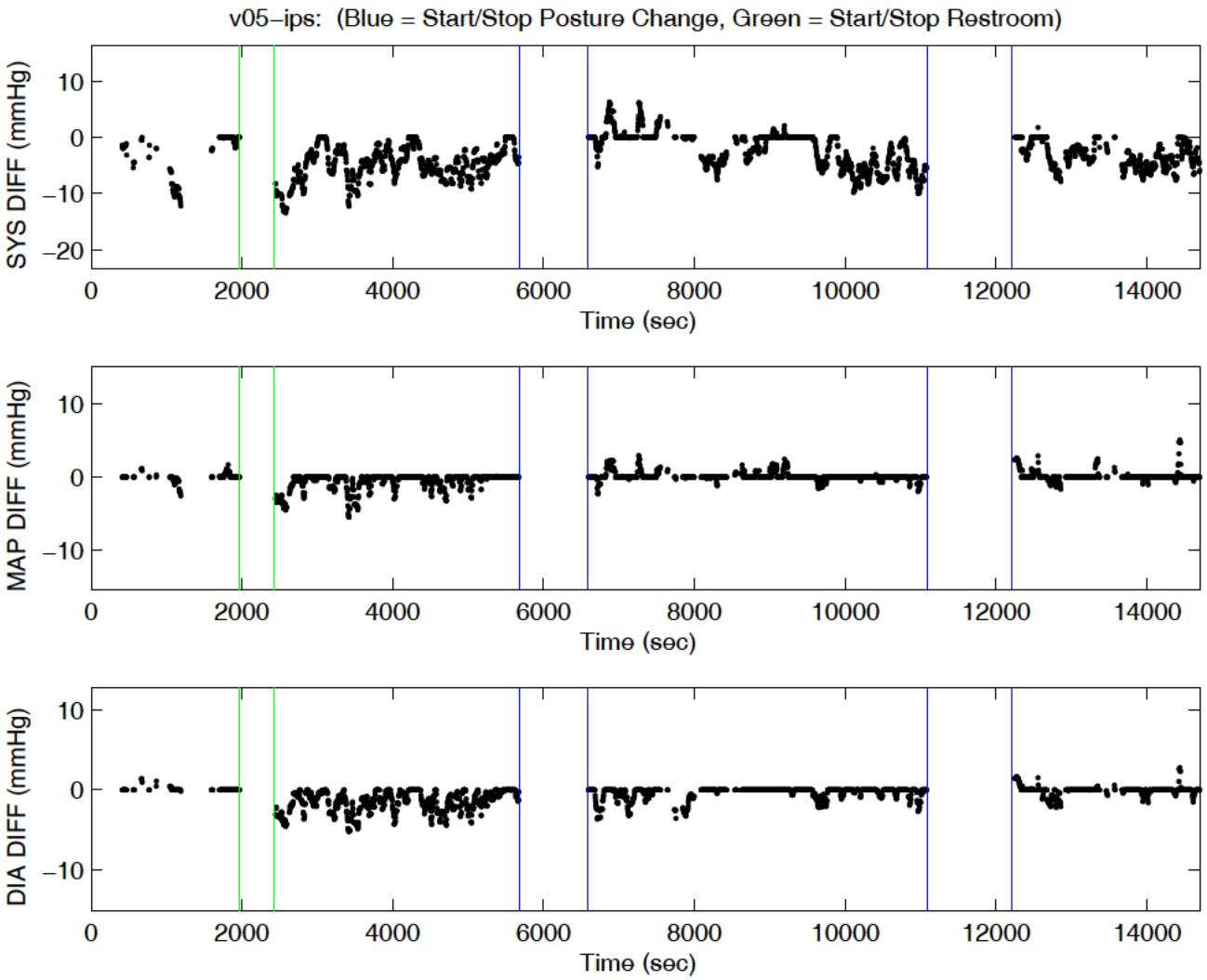

v03−con: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000

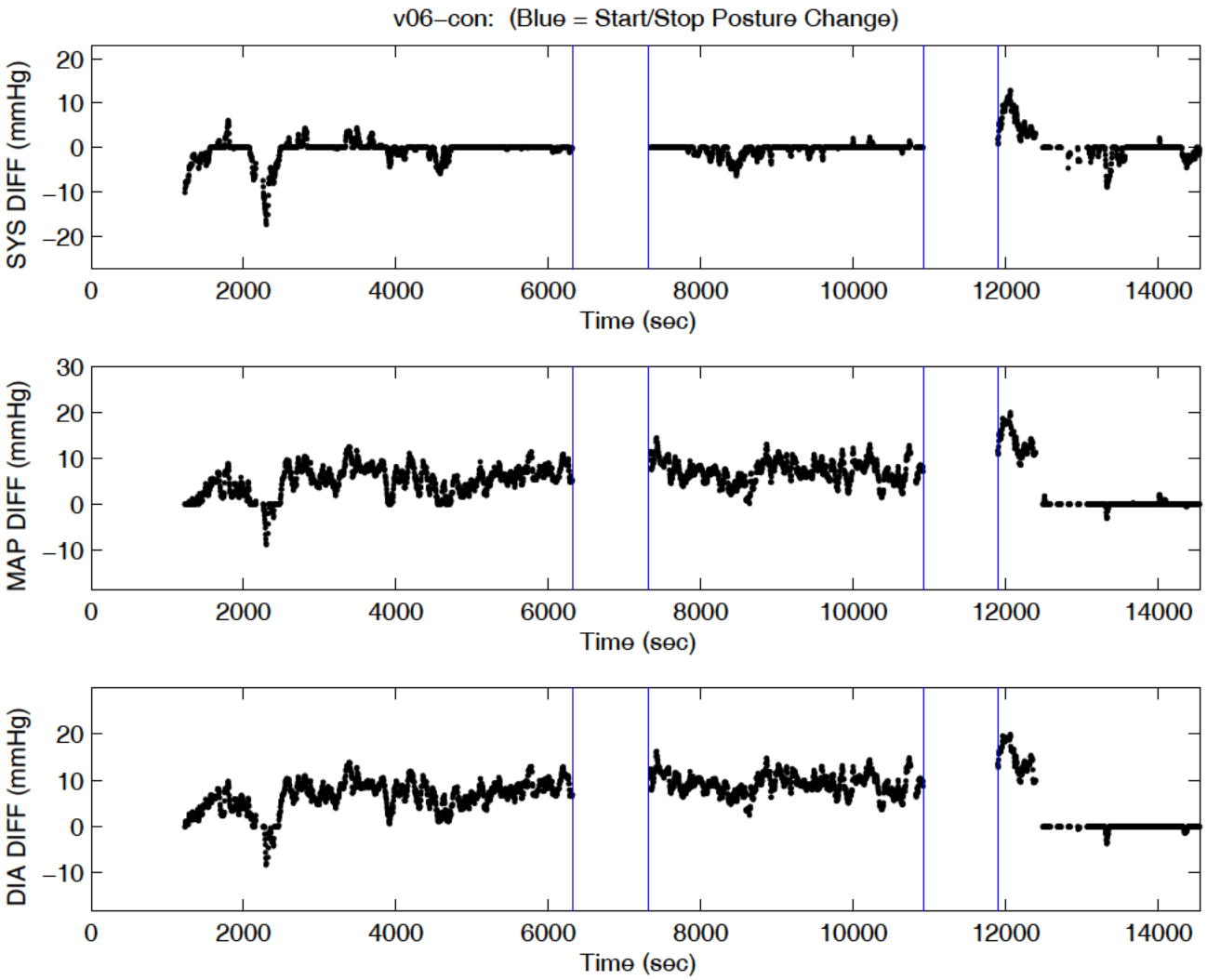

v03–ips: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
MAP DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
DIA DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)

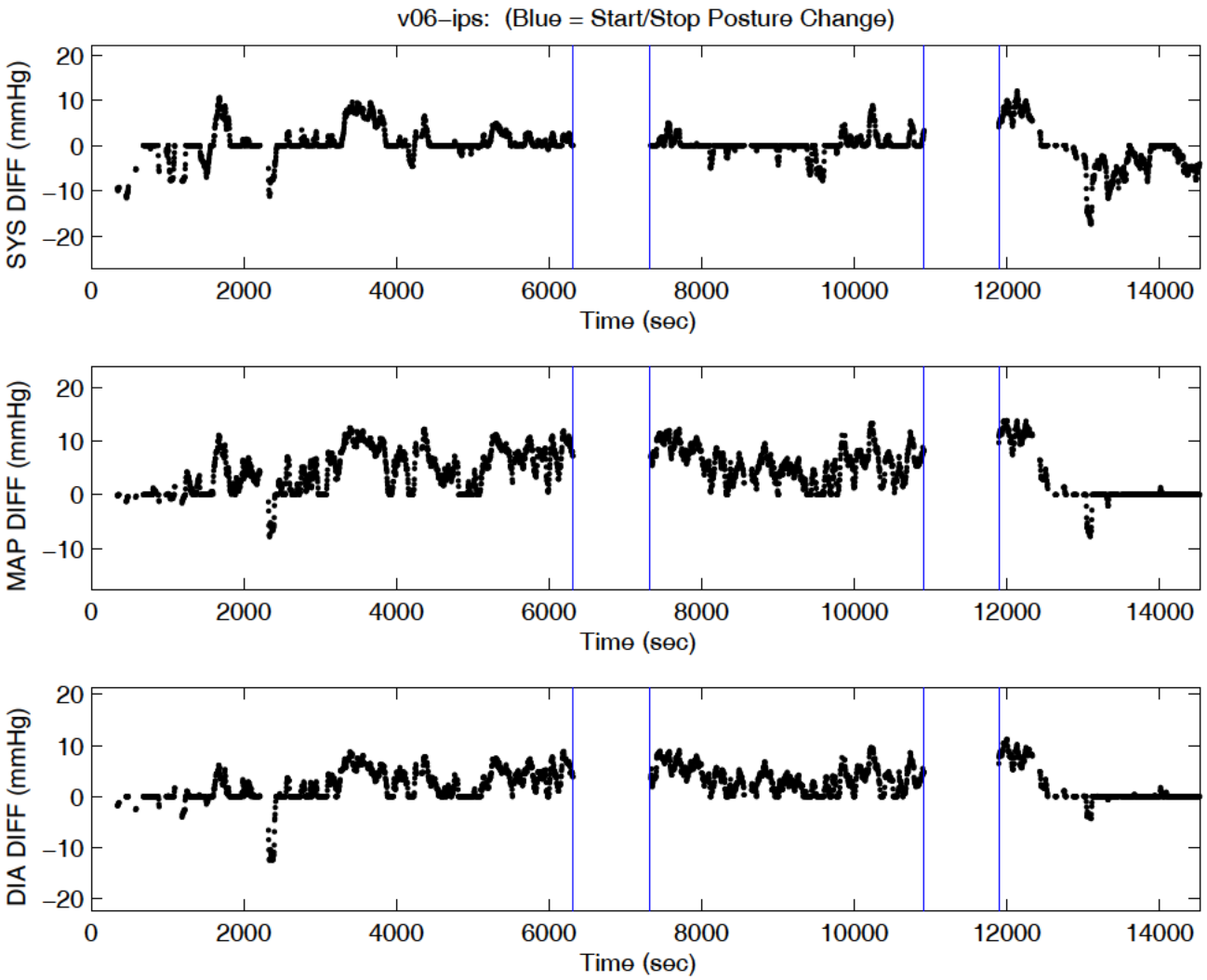

v04−con: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
Time (sec)

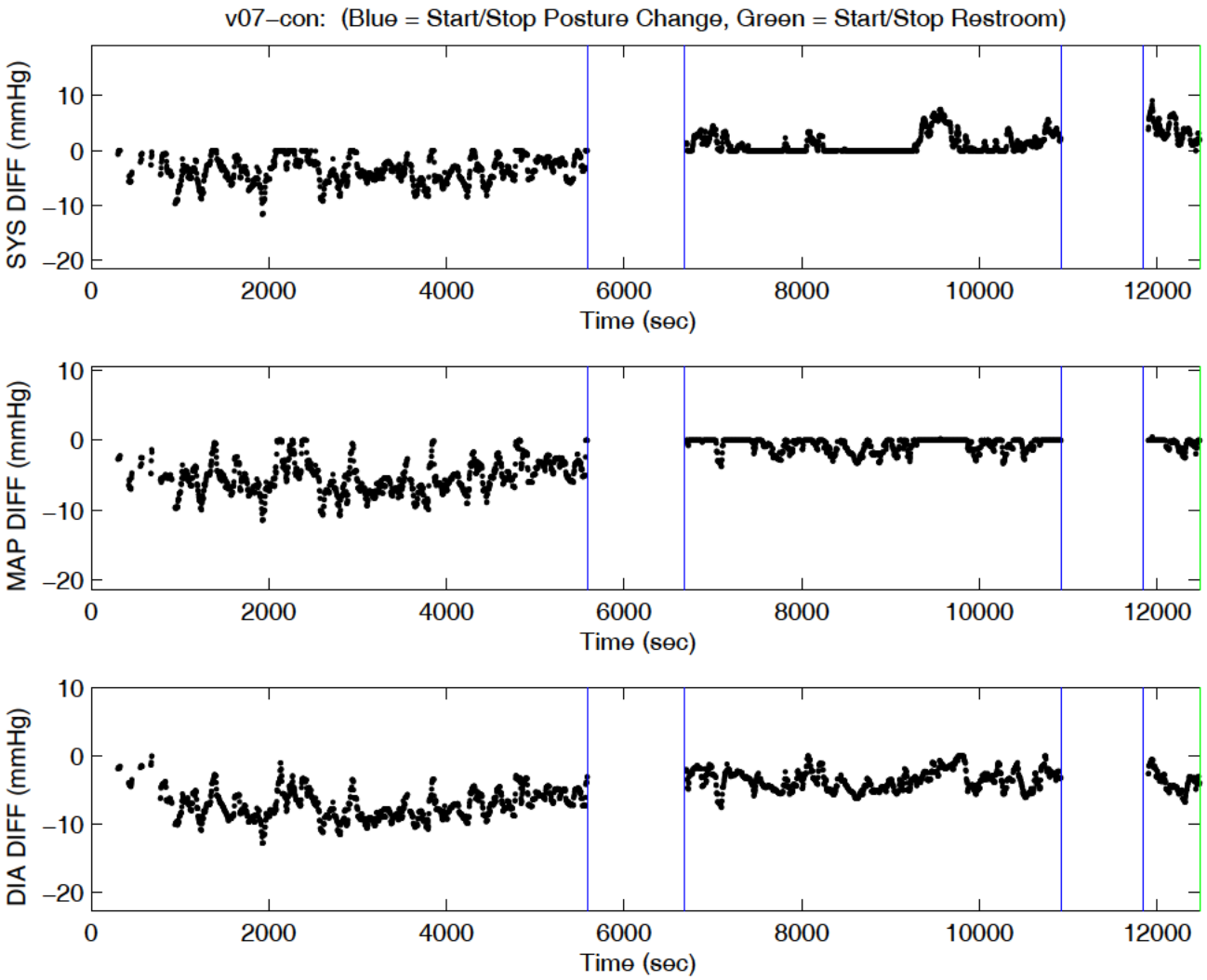

v04–ips: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)

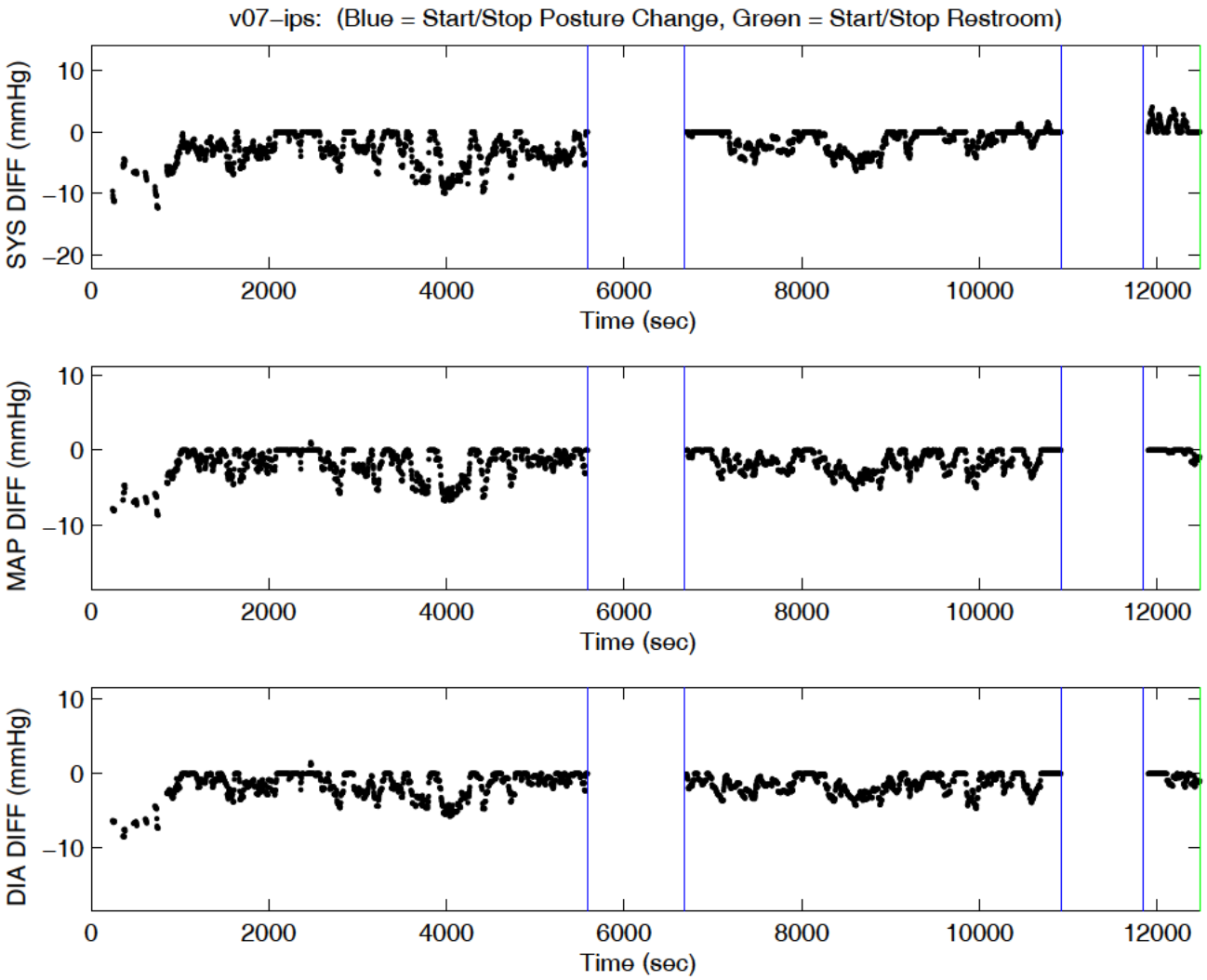

v05−con: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
MAP DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
DIA DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)

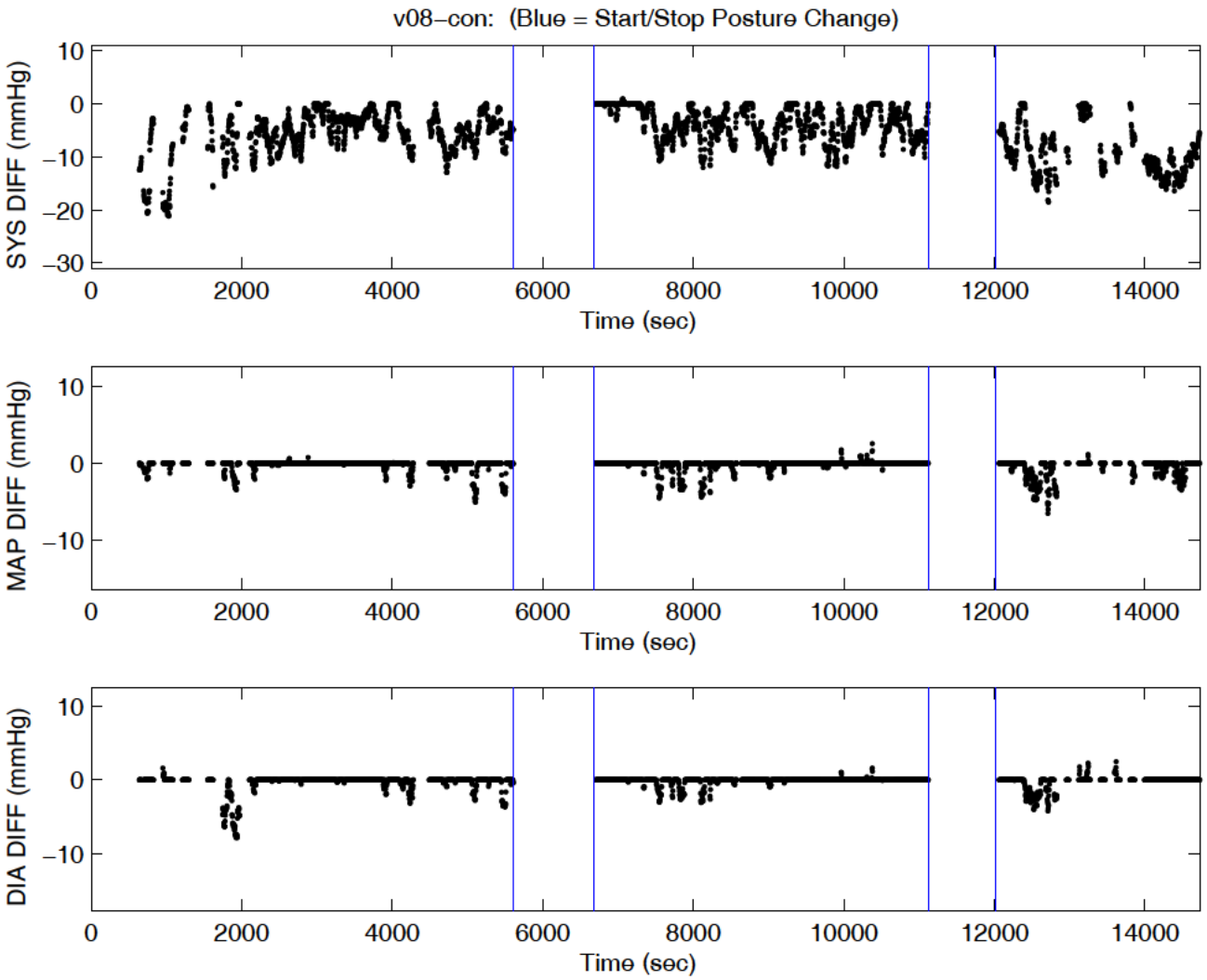

v05–ips: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000

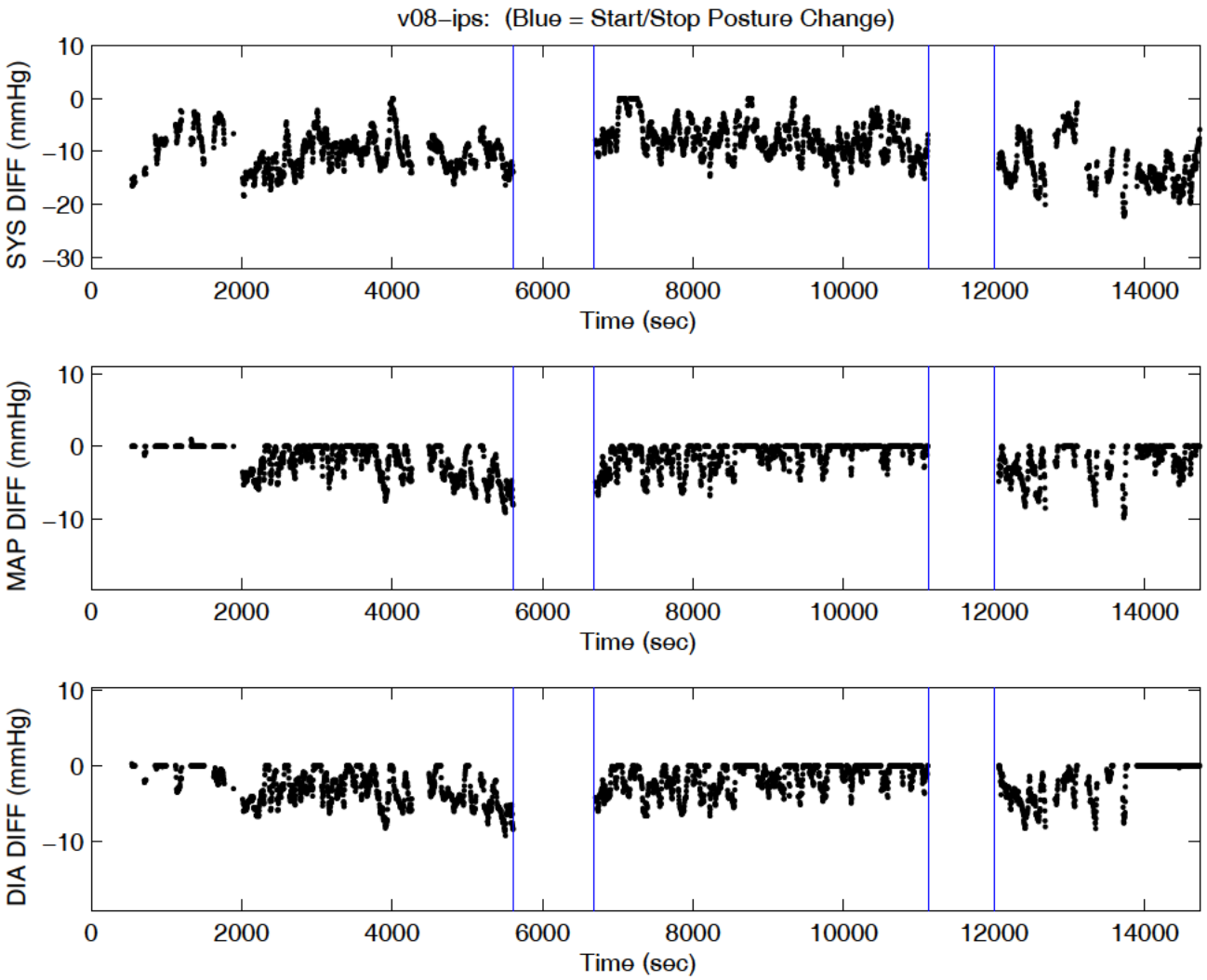

v06−con: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
0
2000
4000
6000
8000
10000
12000
14000

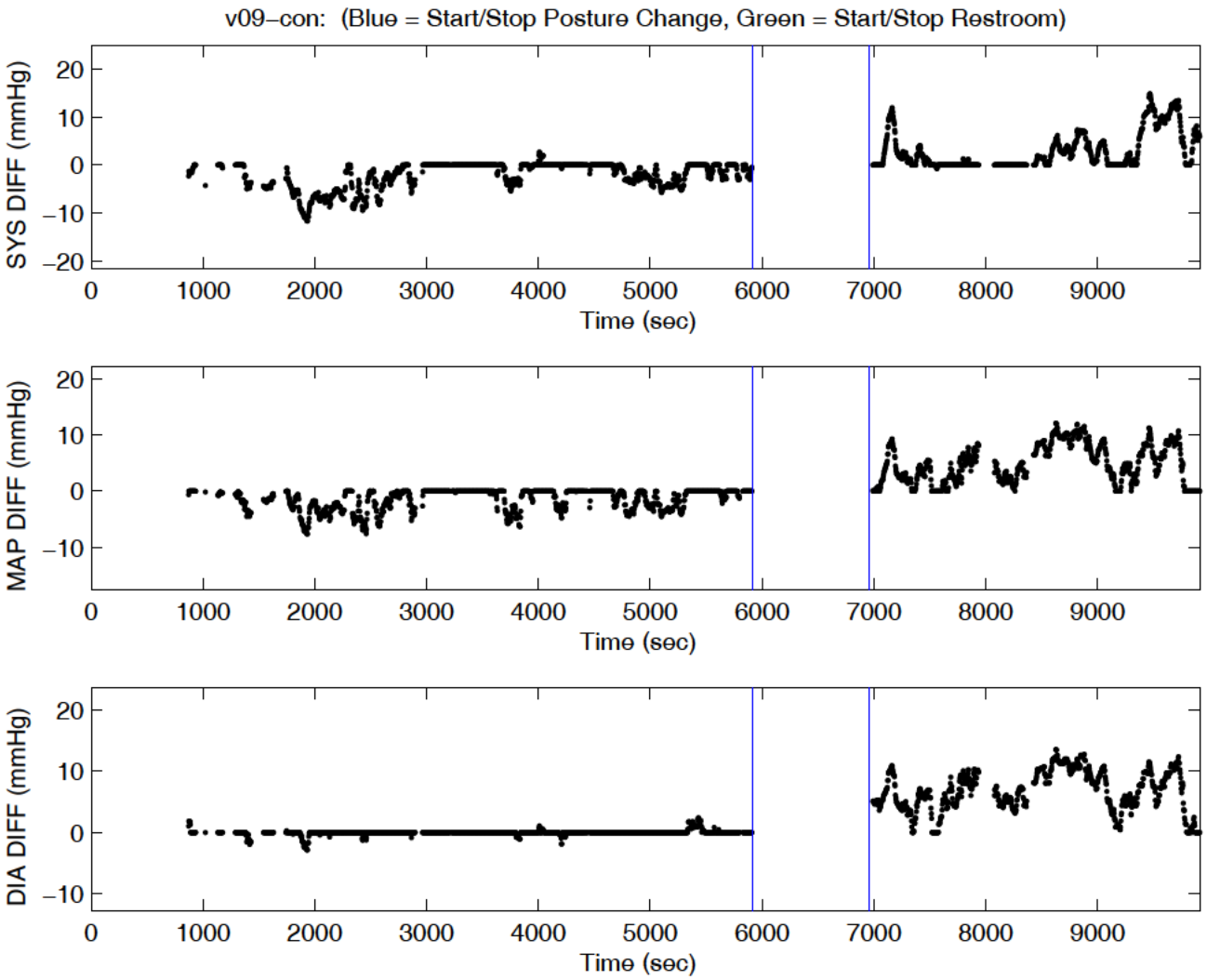

v06–ips: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
20
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000

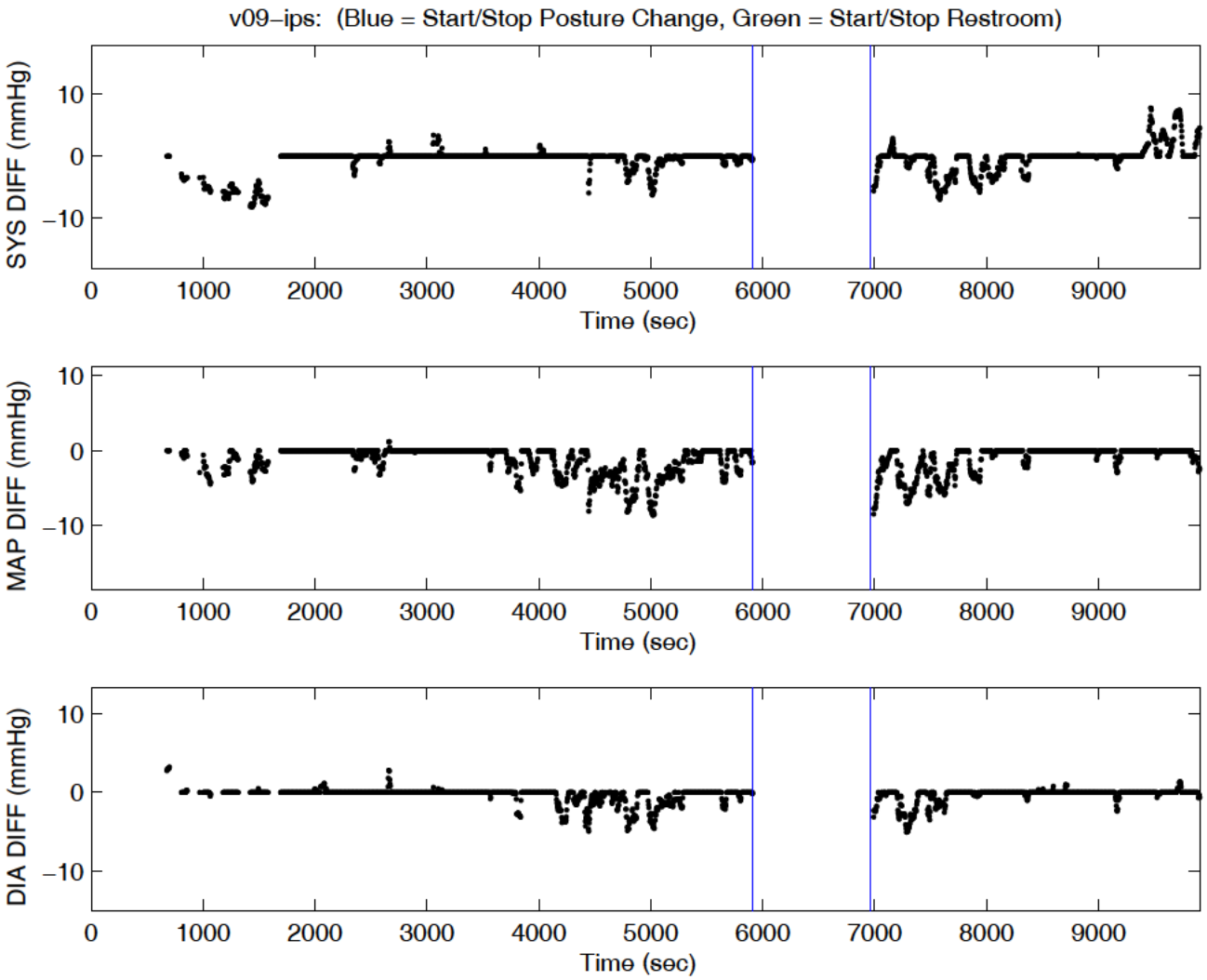

v07−con: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
Time (sec)

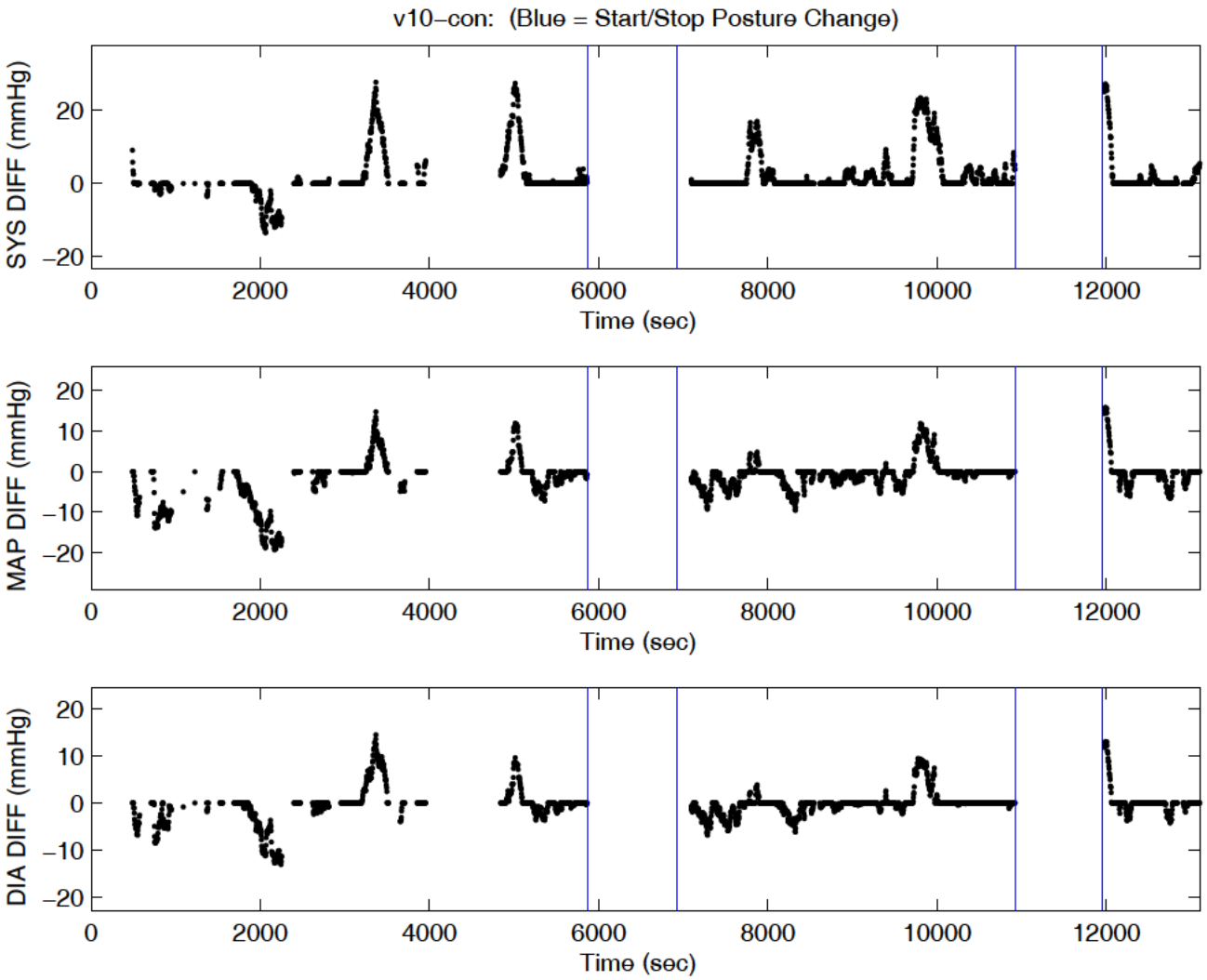

v07–ips: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000

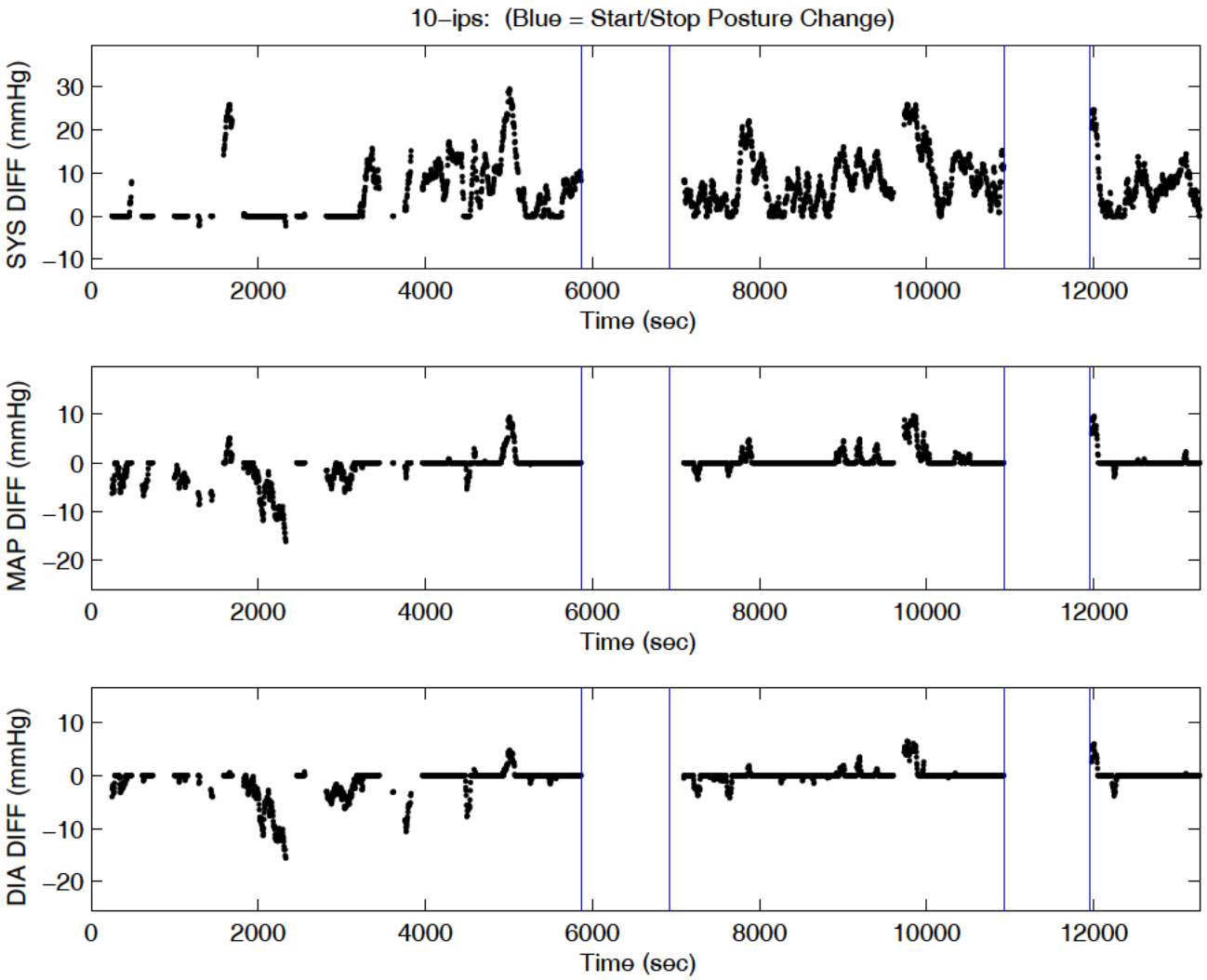

v08−con: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
10
0
−10
−20
−30
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
MAP DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
DIA DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)

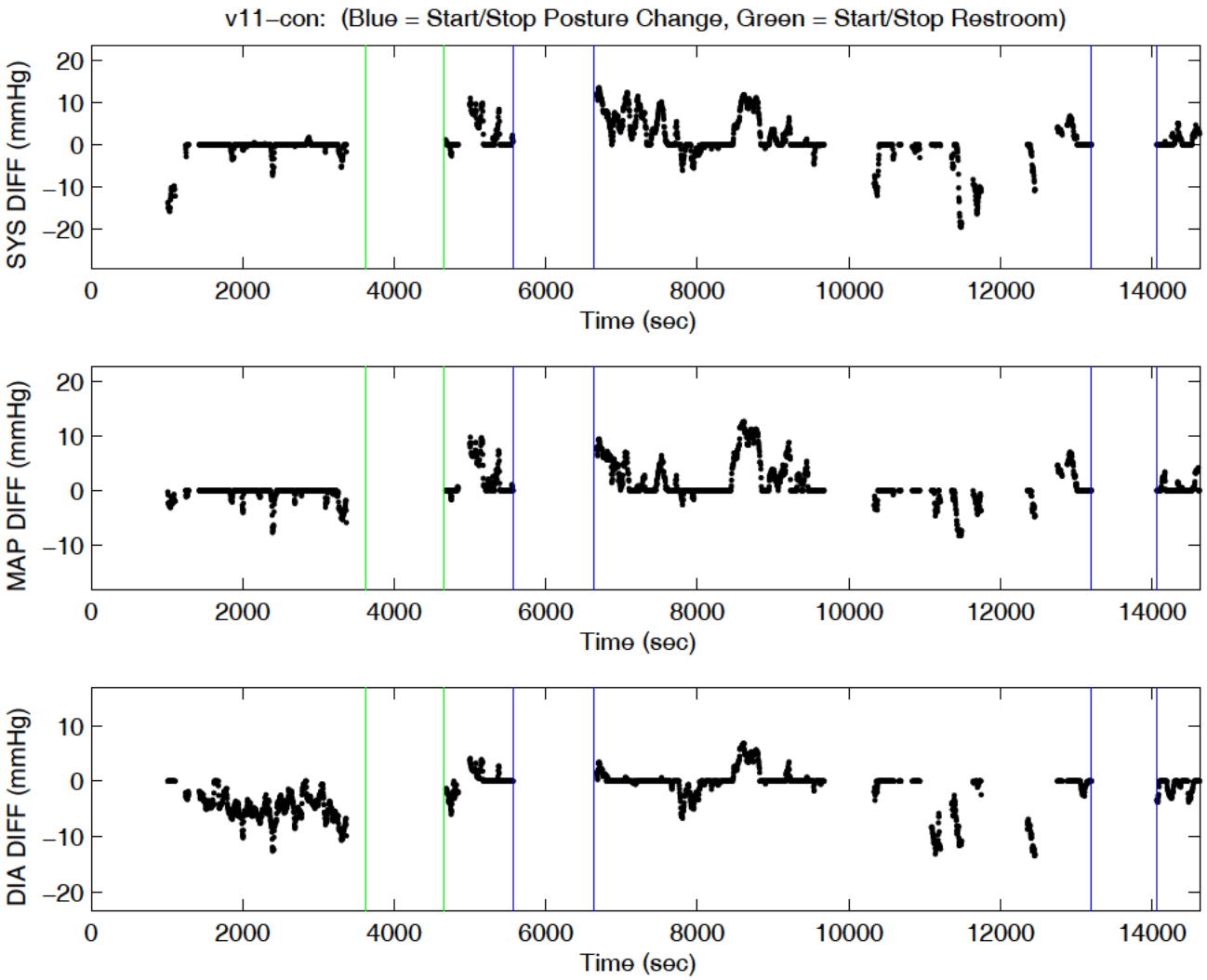

v08–ips: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
10
0
−10
−20
−30
0
2000
4000
6000
8000
10000
12000
14000

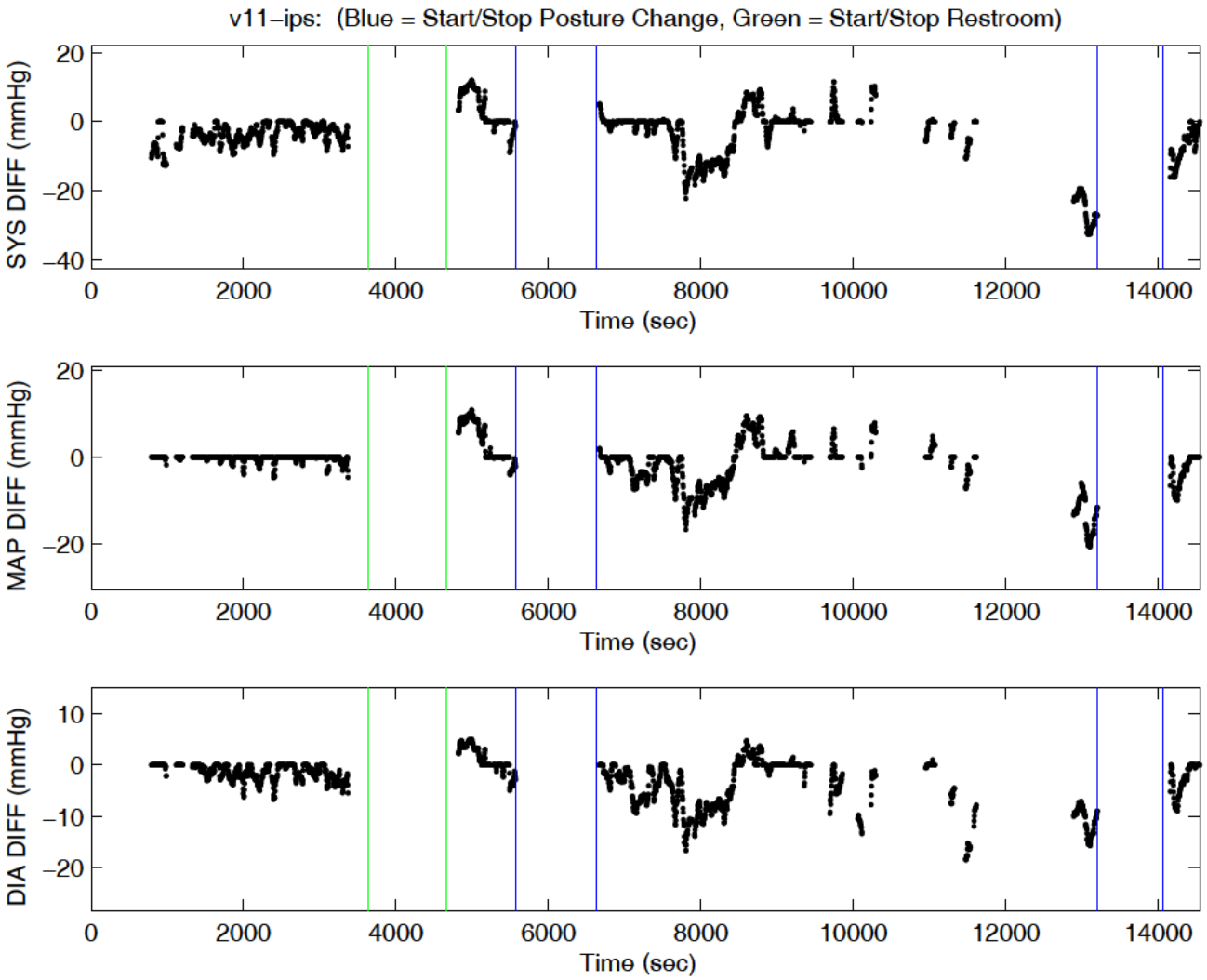

v09−con: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
20
10
0
−10
−20
0
1000
2000
3000
4000
5000
6000
7000
8000
9000

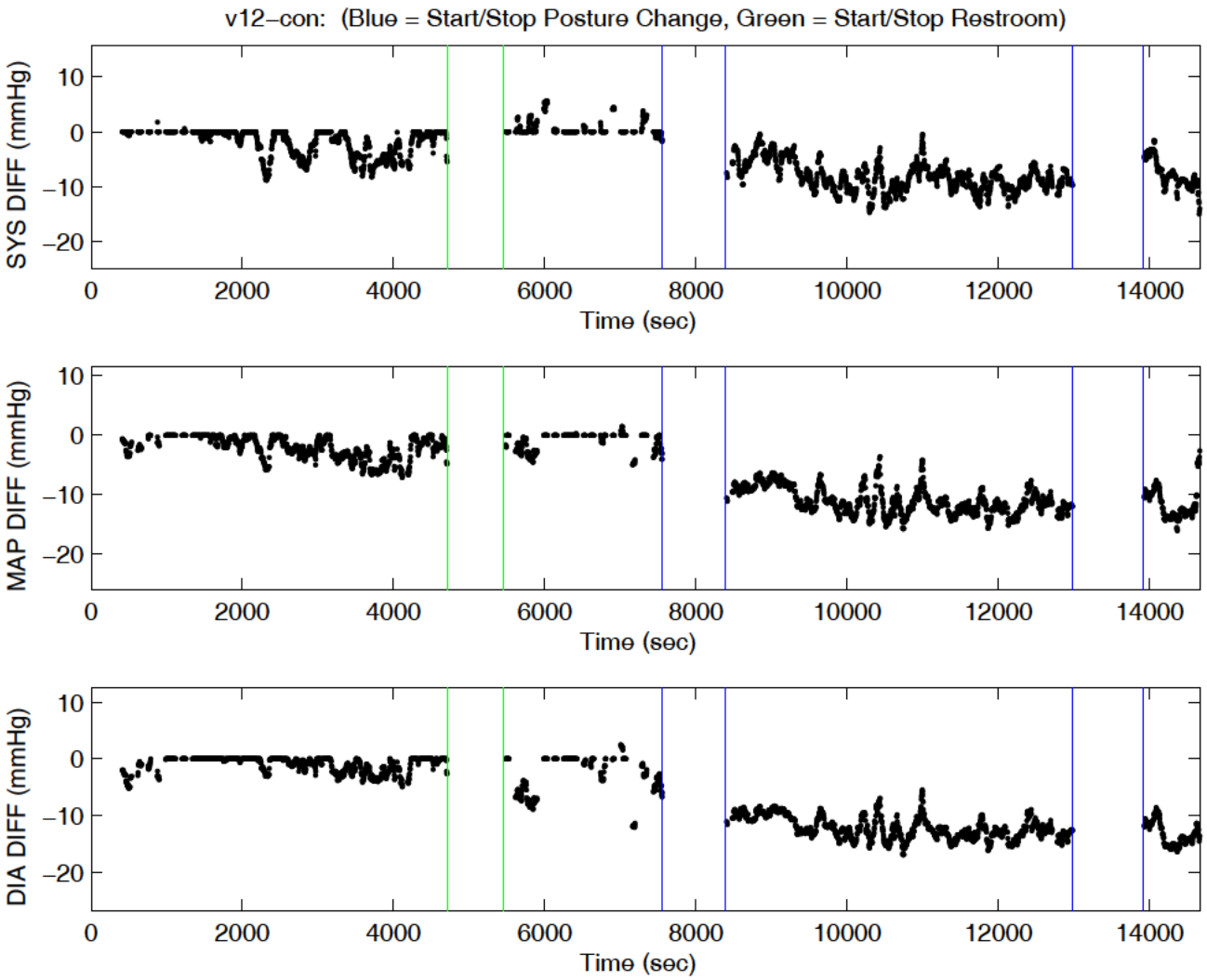

v09–ips: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
10
0
−10
0
1000
2000
3000
4000
5000
6000
7000
8000
9000
Time (sec)

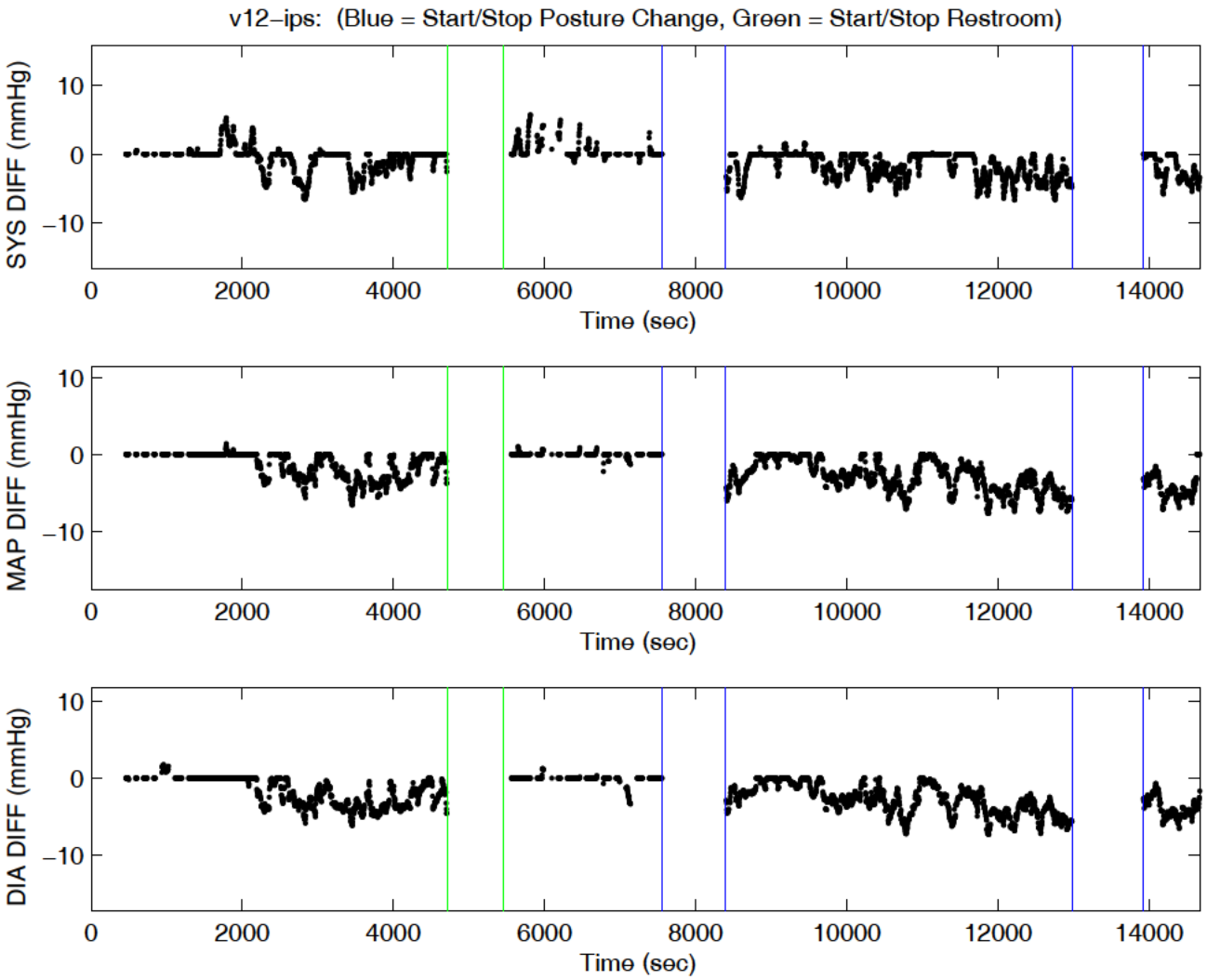

v10−con: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
0
2000
4000
6000
8000
10000
12000
20
10
0
−10
−20

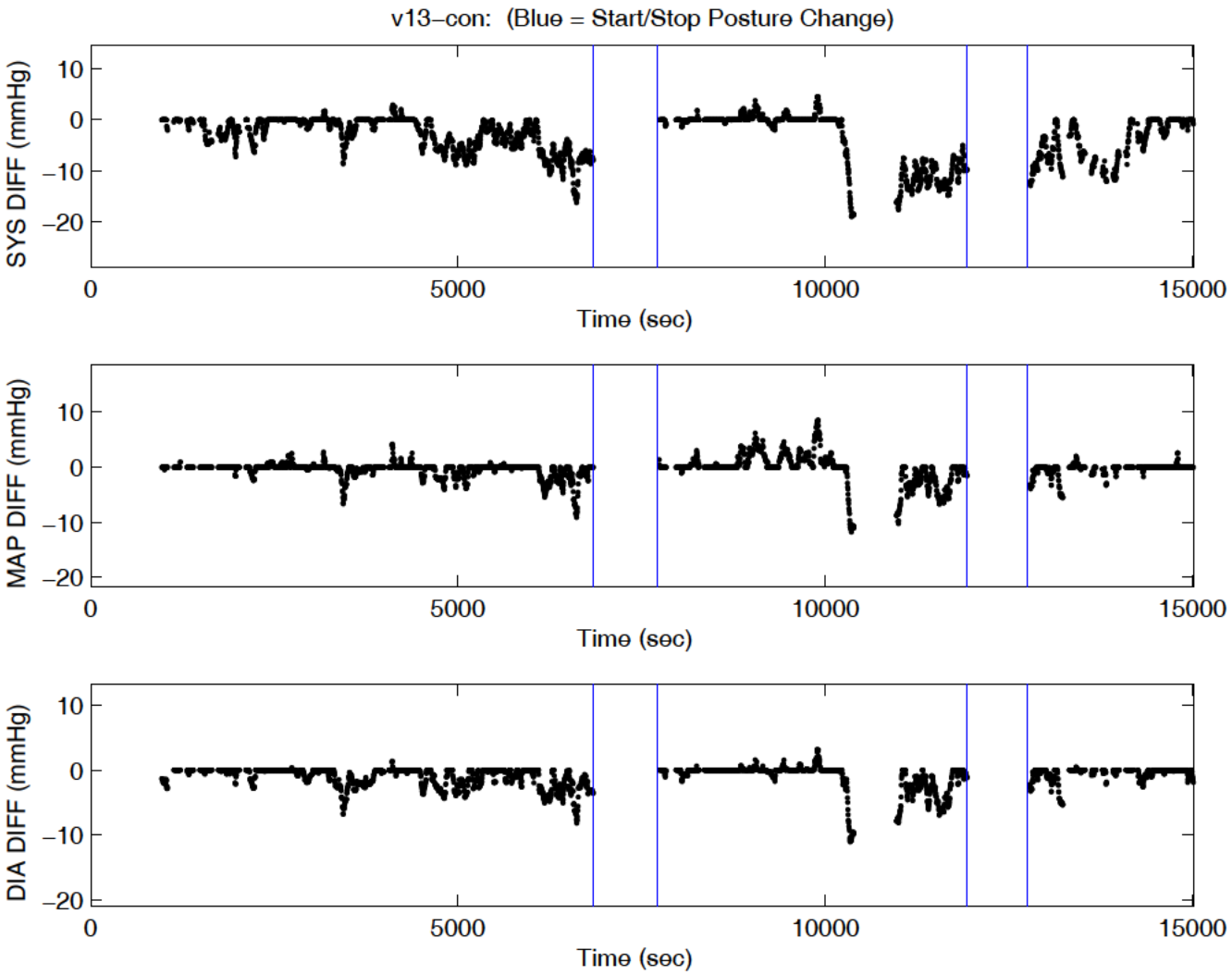

10–ips: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
30
20
10
0
−10
0
2000
4000
6000
8000
10000
12000
Time (sec)
MAP DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
Time (sec)
DIA DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
Time (sec)

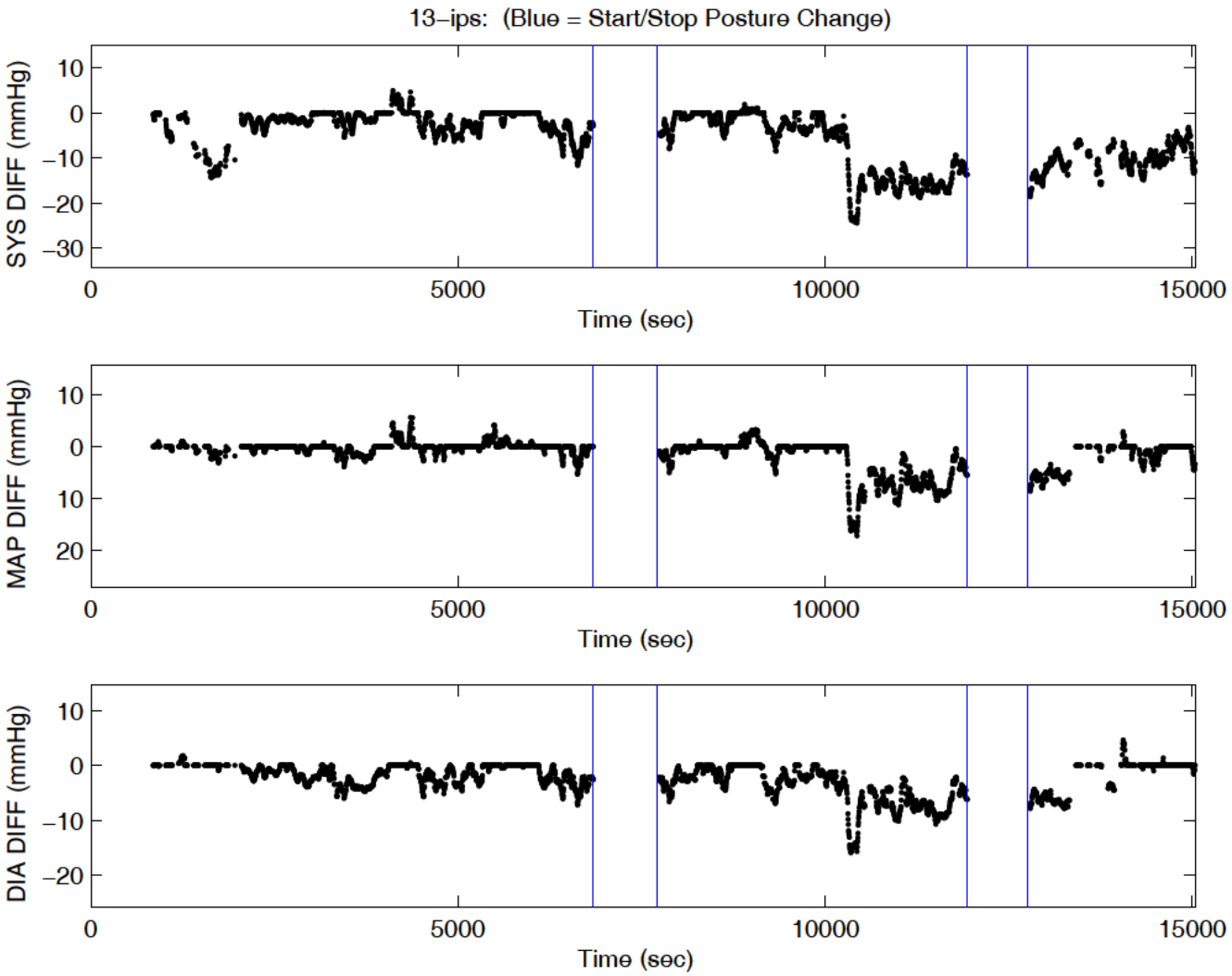

v11−con: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
0
2000
4000
6000
8000
10000
12000
14000
20
10
0
−10
−20

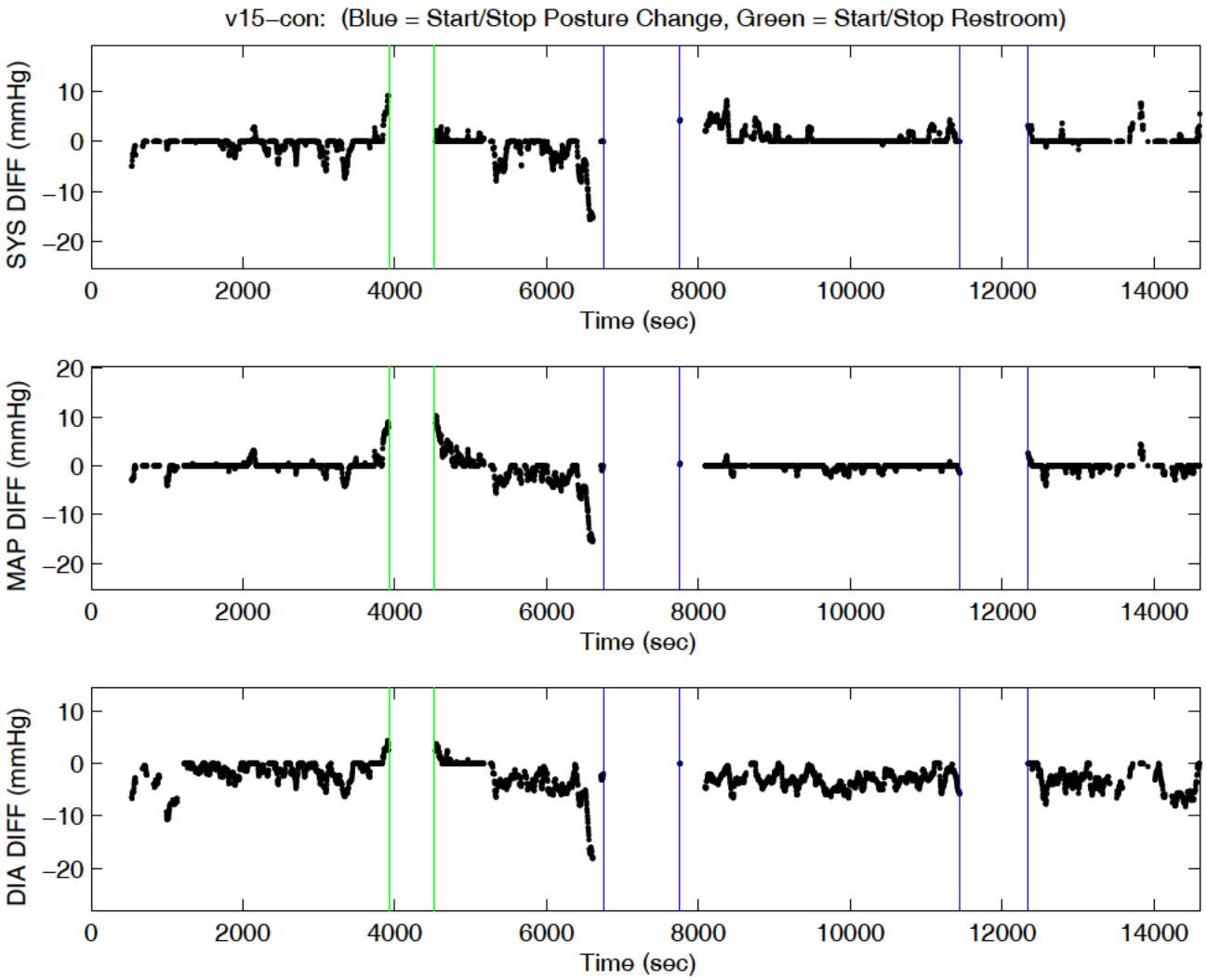

v11–ips: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
0
2000
4000
6000
8000
10000
12000
14000

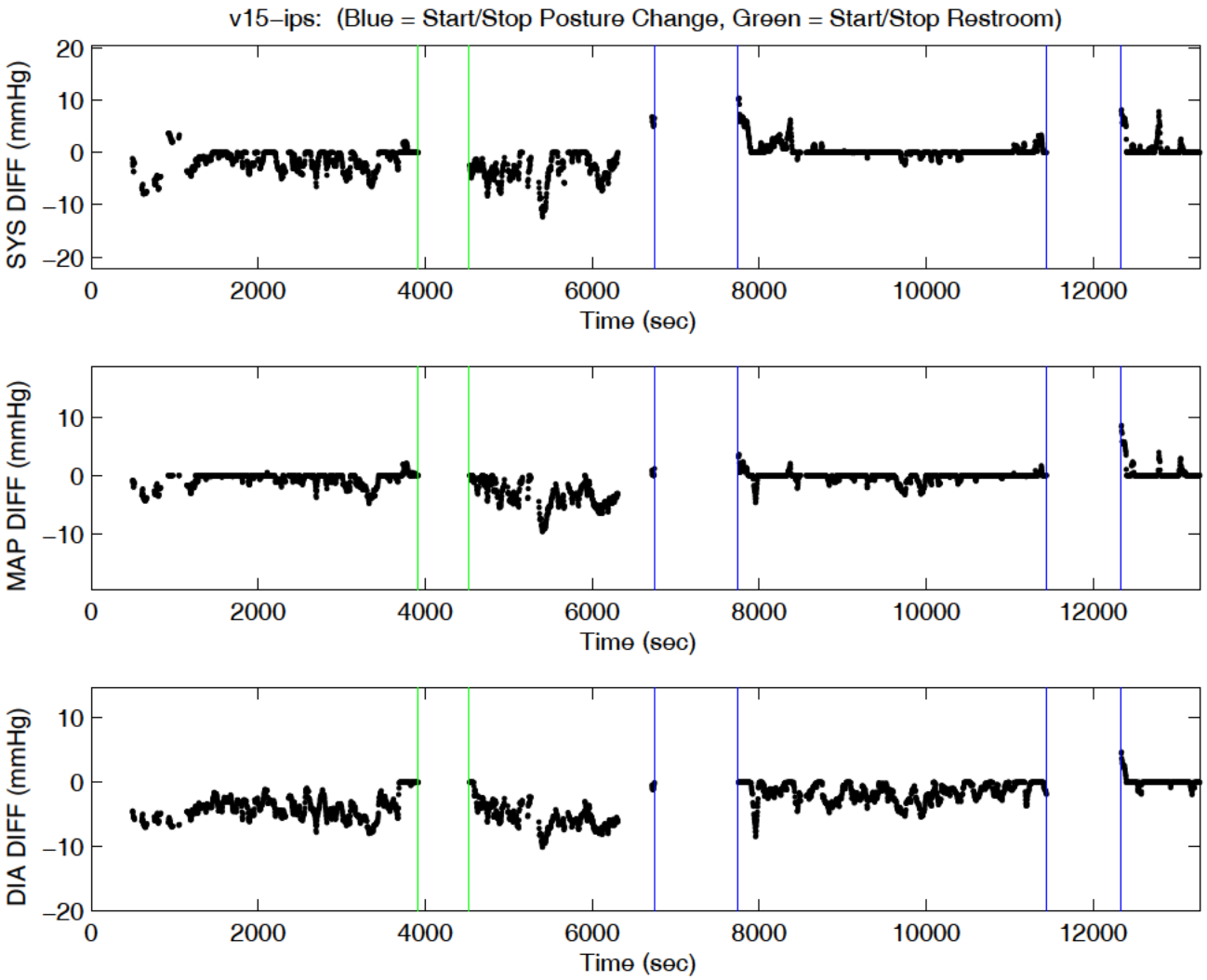

v12−con: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)

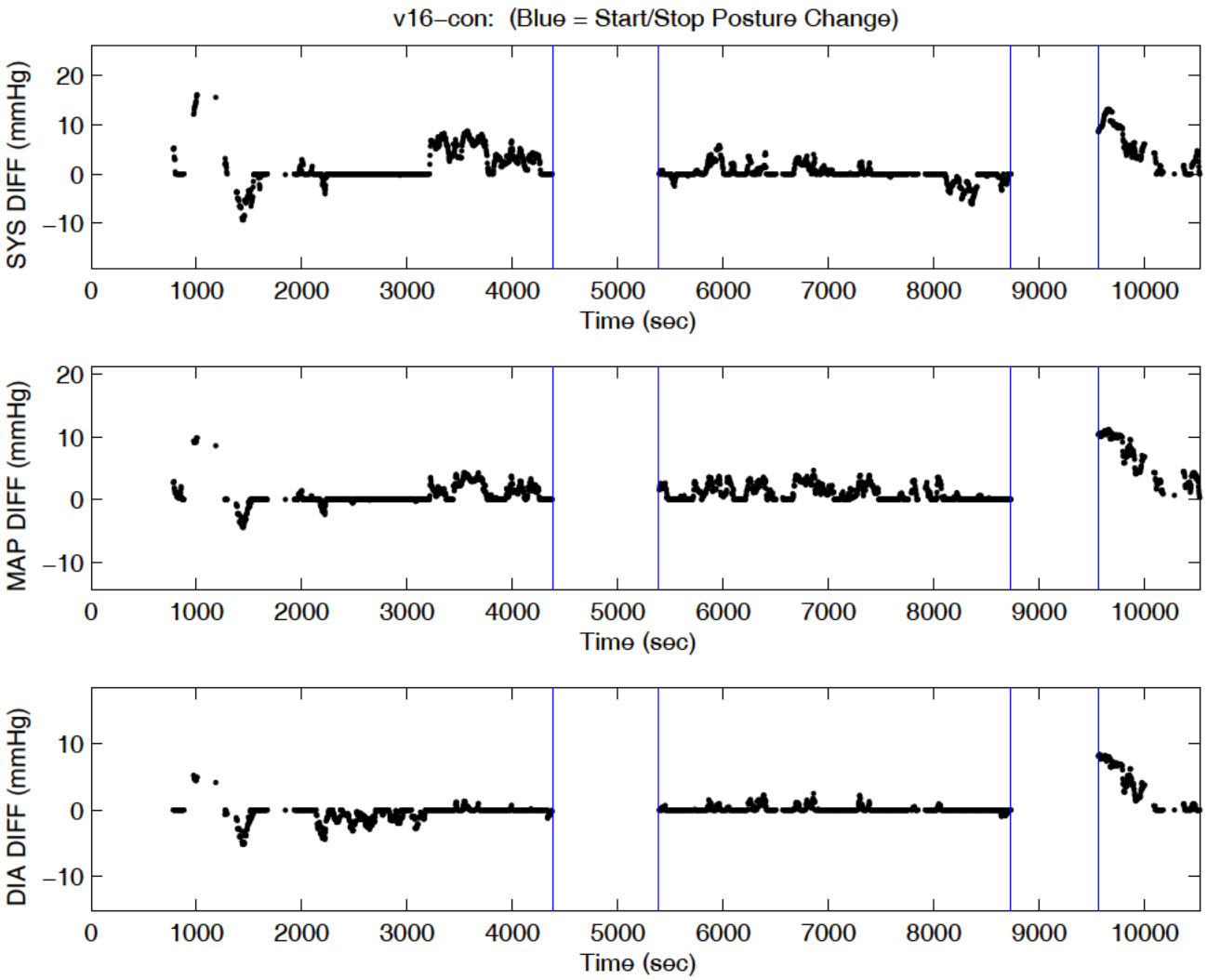

v12–ips: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
10
0
−10
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)

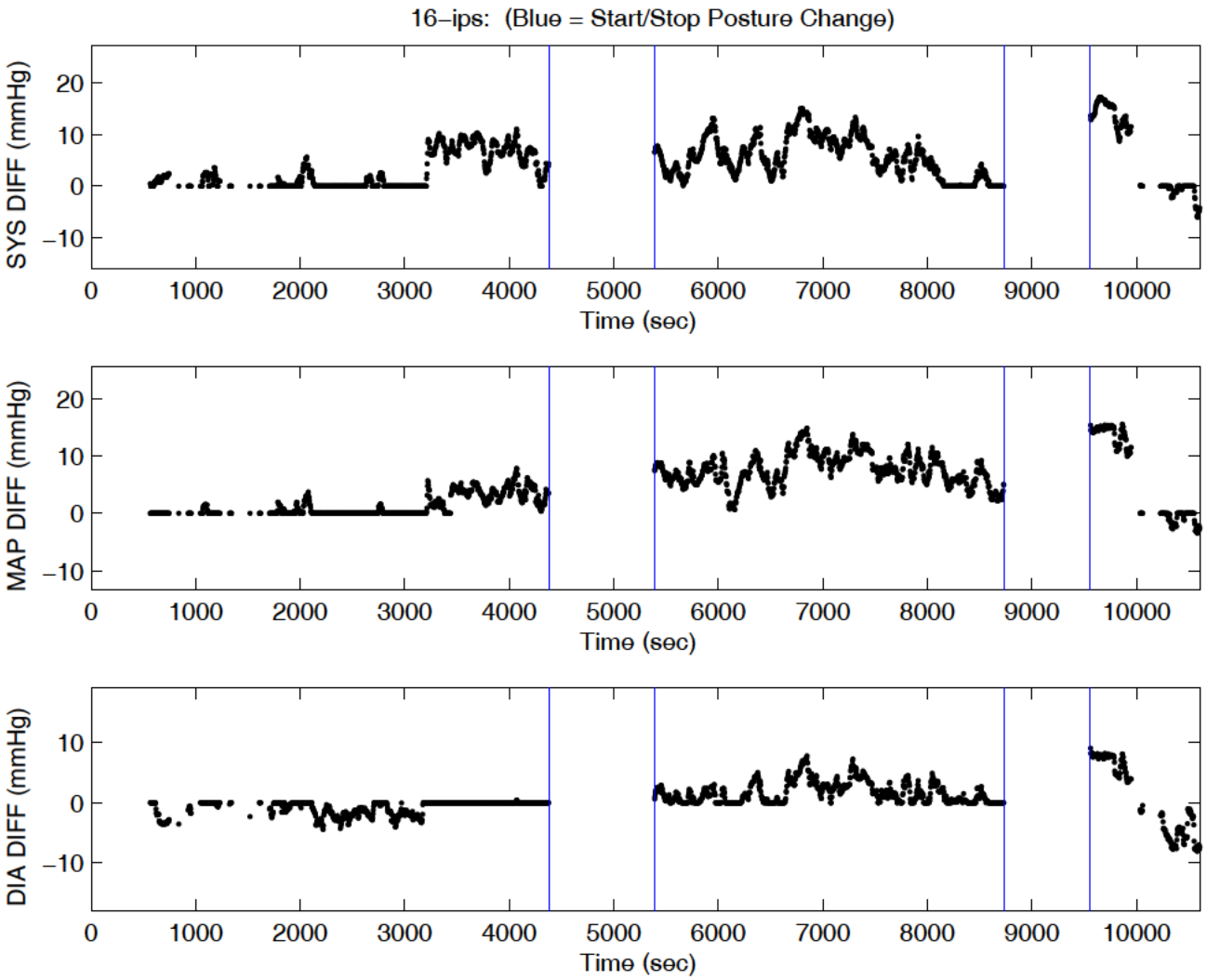

v13–con: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
0
5000
10000
15000
Time (sec)

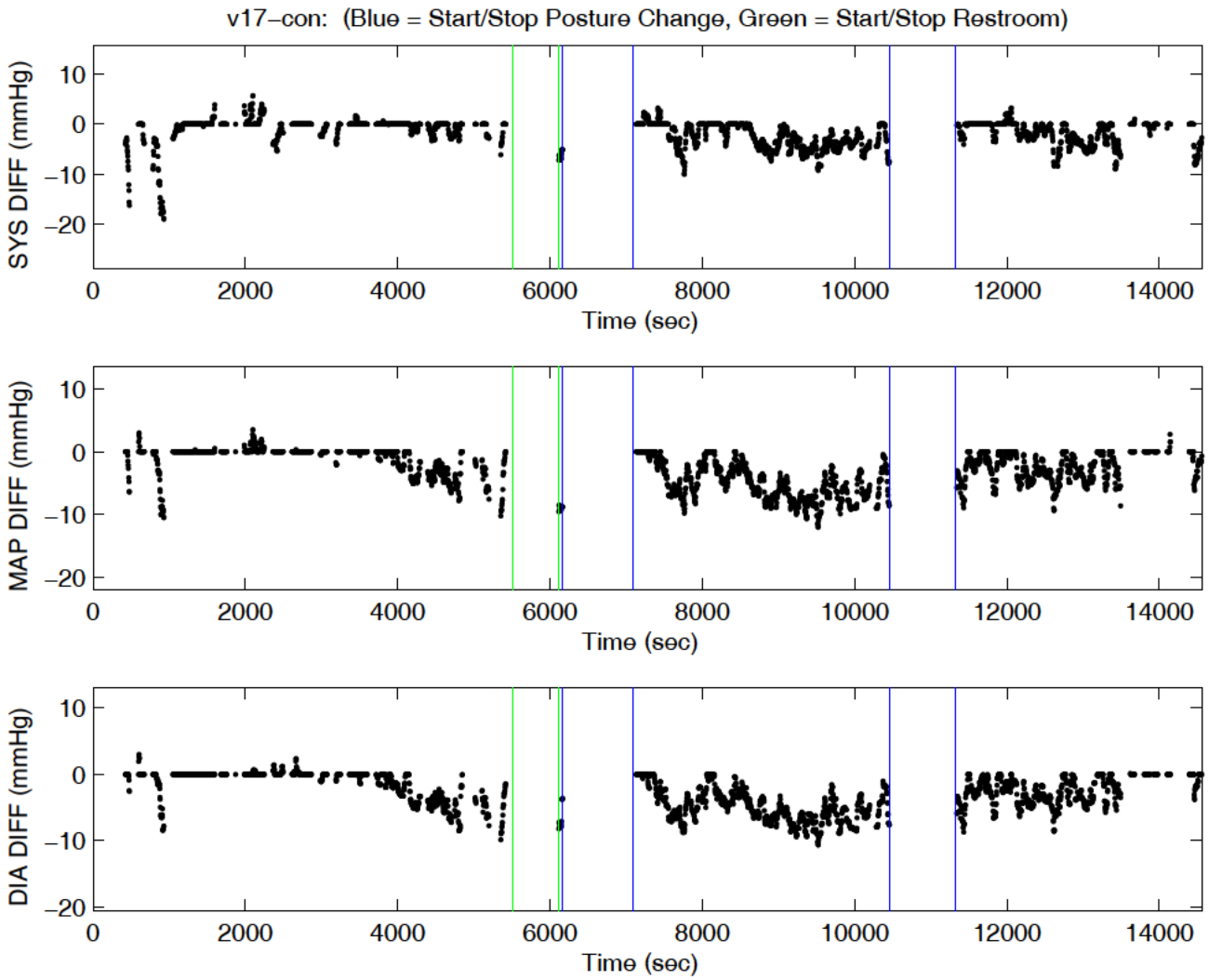

13–ips: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
10
0
−10
−20
−30
0
5000
10000
15000
Time (sec)
MAP DIFF (mmHg)
10
0
10
20
0
5000
10000
15000
Time (sec)
DIA DIFF (mmHg)
10
0
−10
−20
0
5000
10000
15000
Time (sec)

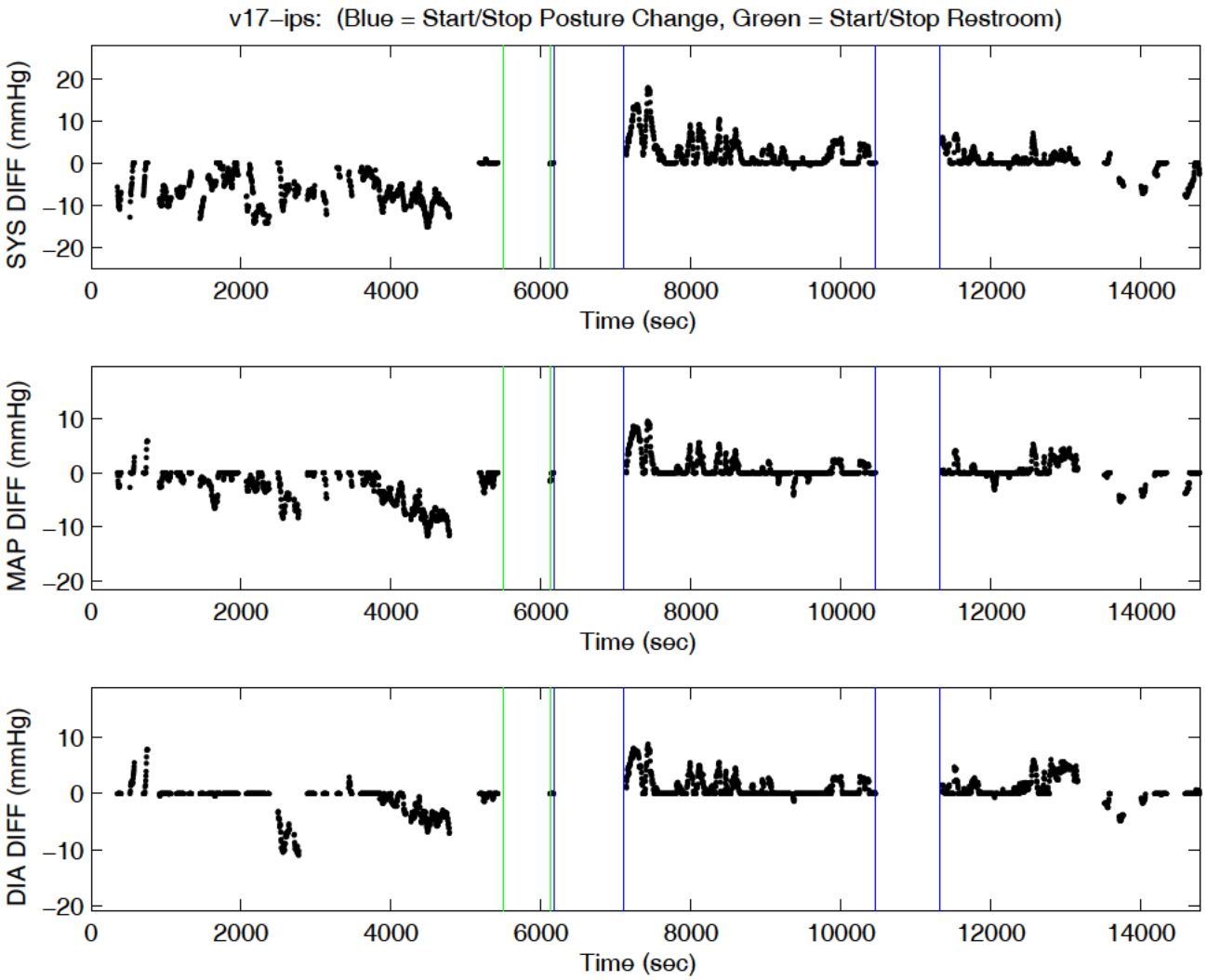

v15−con: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
0
2000
4000
6000
8000
10000
12000
14000
10
0
−10
−20
20


v15–ips: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
0
2000
4000
6000
8000
10000
12000
20
10
0
−10
−20


v16−con: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
0
1000
2000
3000
4000
5000
6000
7000
8000
9000
10000
20
10
0
−10


16–ips: (Blue = Start/Stop Posture Change)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
0
1000
2000
3000
4000
5000
6000
7000
8000
9000
10000
20
10
0
−10


v17−con: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)


v17–ips: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYS DIFF (mmHg)
MAP DIFF (mmHg)
DIA DIFF (mmHg)
Time (sec)
20
10
0
−10
−20
0
2000
4000
6000
8000
10000
12000
14000

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.IPSSUB_ALL
Dependent Variable	sys_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	1
Columns in Z	15
Subjects	1
Max Obs Per Subject	47572

Number of Observations	
Number of Observations Read	47572
Number of Observations Used	47572
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	298867.26493064	
1	2	270187.39246202	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	15.4198
Residual	17.1025

Fit Statistics	
-2 Res Log Likelihood	270187.4
AIC (smaller is better)	270191.4
AICC (smaller is better)	270191.4
BIC (smaller is better)	270192.8

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-1.6073	1.0141	14	-1.59	0.1353

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.IPSSUB_ALL
Dependent Variable	dia_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	1
Columns in Z	15
Subjects	1
Max Obs Per Subject	47572

Number of Observations	
Number of Observations Read	47572
Number of Observations Used	47572
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	243095.86990752	
1	3	217969.13132807	0.00000108
2	1	217969.05332259	0.00000004
3	1	217969.05096157	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	3.9922
Residual	5.7065

Fit Statistics	
-2 Res Log Likelihood	217969.1
AIC (smaller is better)	217973.1
AICC (smaller is better)	217973.1
BIC (smaller is better)	217974.5

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-1.3269	0.5160	14	-2.57	0.0222

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.IPSSUB_ALL
Dependent Variable	map_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	1
Columns in Z	15
Subjects	1
Max Obs Per Subject	47572

Number of Observations	
Number of Observations Read	47572
Number of Observations Used	47572
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	249088.81171647	
1	2	228209.97243941	0.00000001

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	4.3298
Residual	7.0775

Fit Statistics	
-2 Res Log Likelihood	228210.0
AIC (smaller is better)	228214.0
AICC (smaller is better)	228214.0
BIC (smaller is better)	228215.4

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-0.3347	0.5374	14	-0.62	0.5434

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.IPSSUB_ALL
Dependent Variable	sys_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	2
Columns in Z	15
Subjects	1
Max Obs Per Subject	47572

Number of Observations	
Number of Observations Read	47572
Number of Observations Used	47572
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	298458.19860773	
1	2	270040.97889548	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	15.2358
Residual	17.0422

Fit Statistics	
-2 Res Log Likelihood	270041.0
AIC (smaller is better)	270045.0
AICC (smaller is better)	270045.0
BIC (smaller is better)	270046.4

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-1.1516	1.0086	14	-1.14	0.2727
time	-0.00006	4.955E-6	48E3	-13.01	<.0001

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	48E3	169.30	<.0001

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.IPSSUB_ALL
Dependent Variable	dia_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	2
Columns in Z	15
Subjects	1
Max Obs Per Subject	47572

Number of Observations	
Number of Observations Read	47572
Number of Observations Used	47572
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	243052.62341734	
1	3	217760.26164129	0.00000114
2	1	217760.17970929	0.00000004
3	1	217760.17712475	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	4.0136
Residual	5.6788

Fit Statistics	
-2 Res Log Likelihood	217760.2
AIC (smaller is better)	217764.2
AICC (smaller is better)	217764.2
BIC (smaller is better)	217765.6

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-1.6356	0.5178	14	-3.16	0.0070
time	0.000044	2.86E-6	48E3	15.27	<.0001

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	48E3	233.13	<.0001

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.IPSSUB_ALL
Dependent Variable	map_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	2
Columns in Z	15
Subjects	1
Max Obs Per Subject	47572

Number of Observations	
Number of Observations Read	47572
Number of Observations Used	47572
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	249057.80489824	
1	2	228231.89863387	0.00000001

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	4.3265
Residual	7.0774

Fit Statistics	
-2 Res Log Likelihood	228231.9
AIC (smaller is better)	228235.9
AICC (smaller is better)	228235.9
BIC (smaller is better)	228237.3

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-0.3067	0.5377	14	-0.57	0.5775
time	-3.97E-6	3.193E-6	48E3	-1.24	0.2139

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	48E3	1.55	0.2139

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.IPSSUB_ALL
Dependent Variable	sys_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	3
Columns in Z	15
Subjects	1
Max Obs Per Subject	47572

Number of Observations	
Number of Observations Read	47572
Number of Observations Used	47572
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	293944.93246792	
1	2	270038.99797863	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	12.8169
Residual	17.0422

Fit Statistics	
-2 Res Log Likelihood	270039.0
AIC (smaller is better)	270043.0
AICC (smaller is better)	270043.0
BIC (smaller is better)	270044.4

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	0.2063	1.1636	14	0.18	0.8618
time	-0.00006	4.955E-6	48E3	-13.01	<.0001
base_sys	-0.3649	0.1896	48E3	-1.92	0.0543

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	48E3	169.33	<.0001
base_sys	1	48E3	3.70	0.0543

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.IPSSUB_ALL
Dependent Variable	dia_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	3
Columns in Z	15
Subjects	1
Max Obs Per Subject	47572

Number of Observations	
Number of Observations Read	47572
Number of Observations Used	47572
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	242837.23147982	
1	3	217760.98013739	0.00000070
2	1	217760.93069286	0.00000002
3	1	217760.92961230	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	4.2909
Residual	5.6788

Fit Statistics	
-2 Res Log Likelihood	217760.9
AIC (smaller is better)	217764.9
AICC (smaller is better)	217764.9
BIC (smaller is better)	217766.3

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-1.7452	0.6371	13	-2.74	0.0169
time	0.000044	2.86E-6	48E3	15.27	<.0001
base_dia	0.08389	0.2643	48E3	0.32	0.7510

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	48E3	233.15	<.0001
base_dia	1	48E3	0.10	0.7510

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.IPSSUB_ALL
Dependent Variable	map_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	3
Columns in Z	15
Subjects	1
Max Obs Per Subject	47572

Number of Observations	
Number of Observations Read	47572
Number of Observations Used	47572
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	248789.29143215	
1	2	228232.75388628	0.00000001

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	4.5774
Residual	7.0774

Fit Statistics	
-2 Res Log Likelihood	228232.8
AIC (smaller is better)	228236.8
AICC (smaller is better)	228236.8
BIC (smaller is better)	228238.2

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-0.1920	0.6020	14	-0.32	0.7545
time	-3.97E-6	3.193E-6	48E3	-1.24	0.2138
base_map	-0.1125	0.2335	48E3	-0.48	0.6297

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	48E3	1.55	0.2138
base_map	1	48E3	0.23	0.6297

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.CONSUB_ALL
Dependent Variable	sys_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	1
Columns in Z	15
Subjects	1
Max Obs Per Subject	46871

Number of Observations	
Number of Observations Read	46871
Number of Observations Used	46871
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	273585.48318814	
1	2	255315.74775059	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	7.0021
Residual	13.5584

Fit Statistics	
-2 Res Log Likelihood	255315.7
AIC (smaller is better)	255319.7
AICC (smaller is better)	255319.7
BIC (smaller is better)	255321.2

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-1.5535	0.6835	14	-2.27	0.0393

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.CONSUB_ALL
Dependent Variable	dia_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	1
Columns in Z	15
Subjects	1
Max Obs Per Subject	46871

Number of Observations	
Number of Observations Read	46871
Number of Observations Used	46871
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	269990.29479630	
1	3	233259.29108768	0.00000070
2	1	233259.23496399	0.00000002
3	1	233259.23368062	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	10.2527
Residual	8.4669

Fit Statistics	
-2 Res Log Likelihood	233259.2
AIC (smaller is better)	233263.2
AICC (smaller is better)	233263.2
BIC (smaller is better)	233264.6

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-1.1113	0.8269	14	-1.34	0.2003

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.CONSUB_ALL
Dependent Variable	map_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	1
Columns in Z	15
Subjects	1
Max Obs Per Subject	46871

Number of Observations	
Number of Observations Read	46871
Number of Observations Used	46871
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	260488.03794171	
1	3	232853.82725691	0.00000029
2	1	232853.80455946	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	6.8417
Residual	8.3950

Fit Statistics	
-2 Res Log Likelihood	232853.8
AIC (smaller is better)	232857.8
AICC (smaller is better)	232857.8
BIC (smaller is better)	232859.2

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-0.5401	0.6755	14	-0.80	0.4374

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.CONSUB_ALL
Dependent Variable	sys_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	2
Columns in Z	15
Subjects	1
Max Obs Per Subject	46871

Number of Observations	
Number of Observations Read	46871
Number of Observations Used	46871
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	273456.09626703	
1	2	255289.67510591	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	6.9602
Residual	13.5446

Fit Statistics	
-2 Res Log Likelihood	255289.7
AIC (smaller is better)	255293.7
AICC (smaller is better)	255293.7
BIC (smaller is better)	255295.1

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-1.3309	0.6821	14	-1.95	0.0714
time	-0.00003	4.459E-6	47E3	-6.99	<.0001

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	47E3	48.90	<.0001

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.CONSUB_ALL
Dependent Variable	dia_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	2
Columns in Z	15
Subjects	1
Max Obs Per Subject	46871

Number of Observations	
Number of Observations Read	46871
Number of Observations Used	46871
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	269866.99776401	
1	3	232969.03241415	0.00000099
2	1	232968.95222282	0.00000003
3	1	232968.94973847	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	10.2254
Residual	8.4106

Fit Statistics	
-2 Res Log Likelihood	232968.9
AIC (smaller is better)	232972.9
AICC (smaller is better)	232972.9
BIC (smaller is better)	232974.4

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-0.6663	0.8261	14	-0.81	0.4334
time	-0.00006	3.514E-6	47E3	-17.74	<.0001

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	47E3	314.61	<.0001

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.CONSUB_ALL
Dependent Variable	map_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	2
Columns in Z	15
Subjects	1
Max Obs Per Subject	46871

Number of Observations	
Number of Observations Read	46871
Number of Observations Used	46871
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	260460.25775839	
1	3	232815.38885176	0.00000038
2	1	232815.35930058	0.00000001

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	6.8182
Residual	8.3841

Fit Statistics	
-2 Res Log Likelihood	232815.4
AIC (smaller is better)	232819.4
AICC (smaller is better)	232819.4
BIC (smaller is better)	232820.8

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-0.3432	0.6748	14	-0.51	0.6189
time	-0.00003	3.508E-6	47E3	-7.86	<.0001

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	47E3	61.77	<.0001

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.CONSUB_ALL
Dependent Variable	sys_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	3
Columns in Z	15
Subjects	1
Max Obs Per Subject	46871

Number of Observations	
Number of Observations Read	46871
Number of Observations Used	46871
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	272589.03917900	
1	2	255290.54142056	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	6.8809
Residual	13.5446

Fit Statistics	
-2 Res Log Likelihood	255290.5
AIC (smaller is better)	255294.5
AICC (smaller is better)	255294.5
BIC (smaller is better)	255296.0

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-2.0501	0.9643	14	-2.13	0.0518
time	-0.00003	4.459E-6	47E3	-6.99	<.0001
base_sys	0.1566	0.1493	47E3	1.05	0.2941

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	47E3	48.91	<.0001
base_sys	1	47E3	1.10	0.2941

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.CONSUB_ALL
Dependent Variable	dia_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	3
Columns in Z	15
Subjects	1
Max Obs Per Subject	46871

Number of Observations	
Number of Observations Read	46871
Number of Observations Used	46871
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	267805.05391184	
1	3	232967.65996532	0.00000092
2	1	232967.58487050	0.00000003
3	1	232967.58252745	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	10.1672
Residual	8.4106

Fit Statistics	
-2 Res Log Likelihood	232967.6
AIC (smaller is better)	232971.6
AICC (smaller is better)	232971.6
BIC (smaller is better)	232973.0

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-0.1372	0.9683	13	-0.14	0.8895
time	-0.00006	3.514E-6	47E3	-17.74	<.0001
base_dia	-0.4787	0.4604	47E3	-1.04	0.2985

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	47E3	314.59	<.0001
base_dia	1	47E3	1.08	0.2985

The SAS System

The Mixed Procedure

Model Information	
Data Set	WORK.CONSUB_ALL
Dependent Variable	map_diff
Covariance Structure	Variance Components
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Containment

Class Level Information		
Class	**Levels**	**Values**
subnum	15	01 03 04 05 06 07 08 09 10 11 12 13 15 16 17

Dimensions	
Covariance Parameters	2
Columns in X	3
Columns in Z	15
Subjects	1
Max Obs Per Subject	46871

Number of Observations	
Number of Observations Read	46871
Number of Observations Used	46871
Number of Observations Not Used	0

Iteration History			
Iteration	**Evaluations**	**-2 Res Log Like**	**Criterion**
0	1	260147.00183007	
1	3	232814.33440112	0.00000015
2	1	232814.32305540	0.00000000

Convergence criteria met.

The SAS System

The Mixed Procedure

Covariance Parameter Estimates	
Cov Parm	**Estimate**
subnum	7.3280
Residual	8.3841

Fit Statistics	
-2 Res Log Likelihood	232814.3
AIC (smaller is better)	232818.3
AICC (smaller is better)	232818.3
BIC (smaller is better)	232819.7

Solution for Fixed Effects					
Effect	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Intercept	-0.2224	0.8175	13	-0.27	0.7898
time	-0.00003	3.508E-6	47E3	-7.86	<.0001
base_map	-0.1862	0.6522	47E3	-0.29	0.7752

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
time	1	47E3	61.78	<.0001
base_map	1	47E3	0.08	0.7752

5.2.8 Continuous NIBP Monitoring

Sotera's continuous blood pressure monitor (cNIBP) is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location. Pulse Arrival Time (PAT) is measured from the time an ECG R-Wave is detected to its arrival at the SpO2 thumb sensor. The shorter the time, the higher the blood pressure. Calibration of PAT for an individual patient requires an initial NIBP cuff measurement. Once this measurement is made, continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every three seconds. Recalibration will be required when any of the conditions stated in section *To recalibrate cNIBP on page 80* are met.

The accuracy of cNIBP is dependent on the initial cuff calibration. Use good clinical practice to confirm cNIBP accuracy before initiating or treating a patient.

The accuracy of the cNIBP measurement cannot be relied upon in patients with a BMI greater than 35.

Due to cNIBP signal averaging, there is a maximum 63 second time delay between the instantaneous blood pressure reading and the displayed reading.

The ViSi Mobile Monitoring System accuracy claim (mean error of ≤ ±5 mmHg and a std. dev. of ≤ 8 mmHg) is not met when the subject is inclined more than 30 degrees from horizontal.

Note: Continuous NIBP monitoring is an optional feature that requires an additional license key.

To calibrate cNIBP

Chest Sensor, Thumb Sensor and Cuff Module connected | **NIBP Reading In Progress** | **Spot-Check Reading** | **cNIBP Calibrated**

1. Connect the ViSi Mobile Chest Sensor, Thumb Sensor and Cuff Module and navigate to the **Vitals Signs** screen.

The Start Cuff button *will change to the Calibrate cNIBP button.*

2. Touch **Calibrate cNIBP** on the **Vital Signs** screen.

   The Cuff will start to inflate, indicating the calibration process has started. After a single NIBP measurement has been taken, the ViSi Mobile Monitor will calibrate cNIBP. The NIBP measurement will be displayed in white during the calibration process.

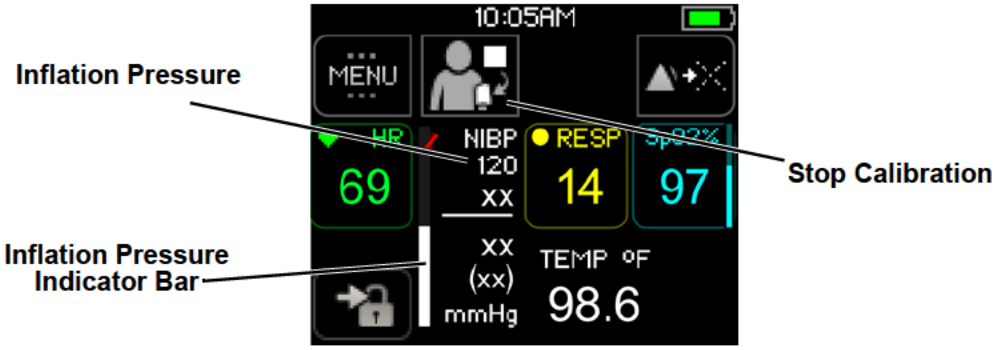
   Once cNIBP has been calibrated, Systolic, Diastolic and MAP measurements will be displayed in red. The displayed measurement will be refreshed every 3 seconds.

Note: The calibration process will take approximately 1 to 2 minutes to complete.

Note: If the first calibration is not successful, a second calibration attempt will automatically occur. A failure to calibrate will be indicated by a "Calibration Failed" alert and the Cuff will inflate for again.

To stop the cNIBP calibration

A cNIBP calibration currently in progress may be stopped at any time.



Touch **Stop NIBP** to stop the cuff inflation and NIBP measurement.

The cuff will deflate.

To recalibrate cNIBP

Note: Whenever a device detects a change in continuous blood pressure that requires a recalibration, the technical alert Calibrate cNIBP is displayed.

To manually recalibrate cNIBP, following the steps outlined in section *To calibrate cNIBP on page 79*.

There are several reasons why cNIBP will require recalibration:

- A vasoactive drug is administered to the patient.
- Any of the cNIBP measurements exceed the upper or lower alarm limits.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 15mmHg for a normotensive patient over a period longer than 60 seconds.

- Either the systolic or diastolic measurement indicates a change since calibration by more than 20mmHg when in a hypertensive range (systolic above 140mmHg or diastolic above 90mmHg) over a period longer than 60 seconds.
- Either the systolic or diastolic measurement indicates a change since calibration by more than 10mmHg when in a hypotensive range (systolic below 90mmHg or diastolic below 60mmHg) over a period longer than 60 seconds.
- An unexpected interruption of monitoring occurred, such as all sensors being disconnected. If the interruption is less than 30 seconds, no recalibration is required. *See section All Sensors Disconnected on page 84.*

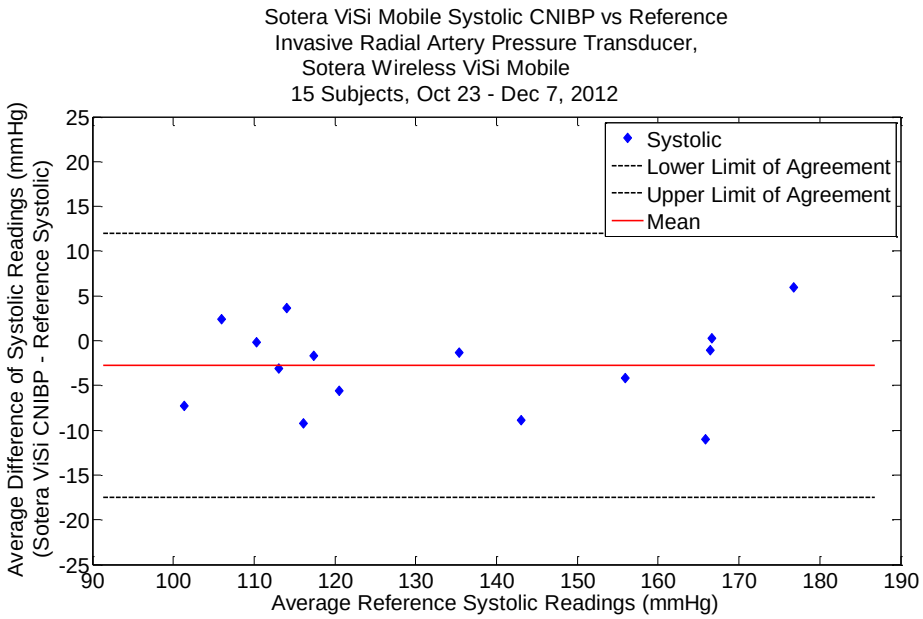
Note: When a recalibration event is detected and the Cuff Module is connected, the ViSi Mobile Monitor will automatically recalibrate cNIBP.

Note: When a recalibration event is detected and the Cuff Module is not connected, the ViSi Mobile Monitor will display the Calibrate cNIBP alert. Connect the Cuff Module and recalibrate manually.

You should manually recalibrate cNIBP after any drug administration.

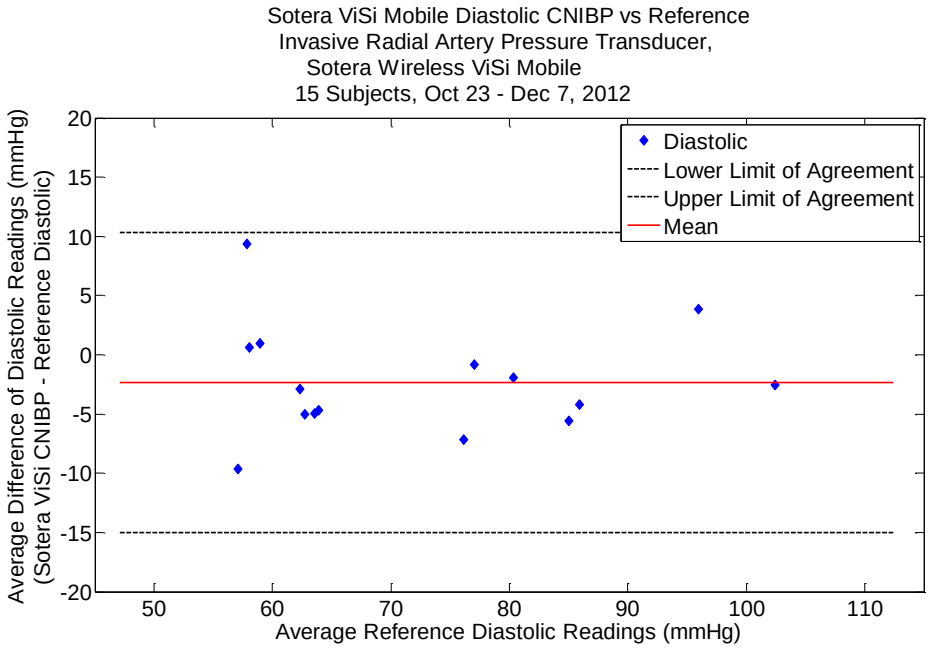
Exhibit_8_Supine-CON-cNIBP-BlandAltman.docx

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Contralateral Arm, Supine – Systolic Blood Pressure



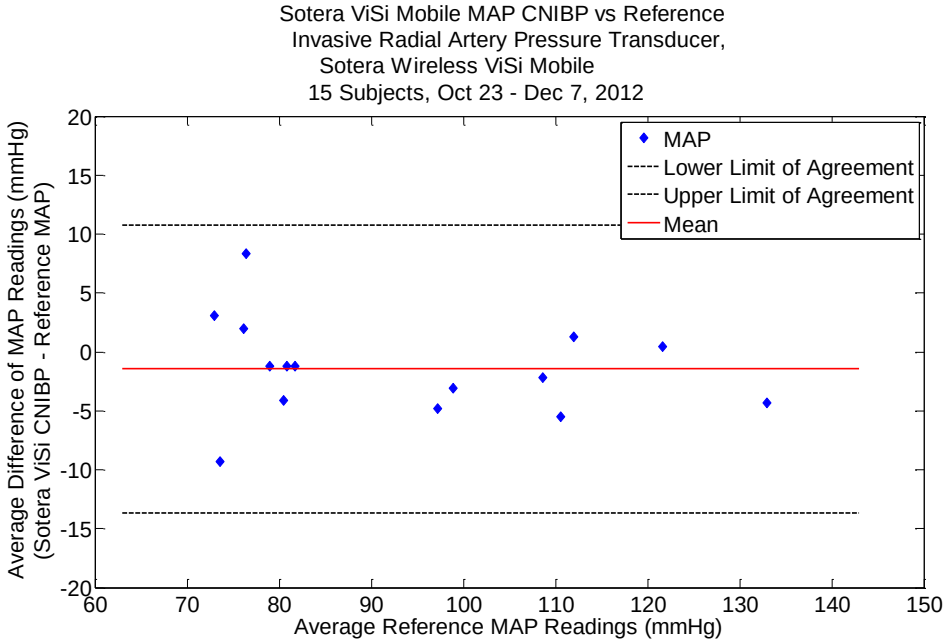
Sample Size: 46,871 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Contralateral Arm, Supine – Diastolic Blood Pressure



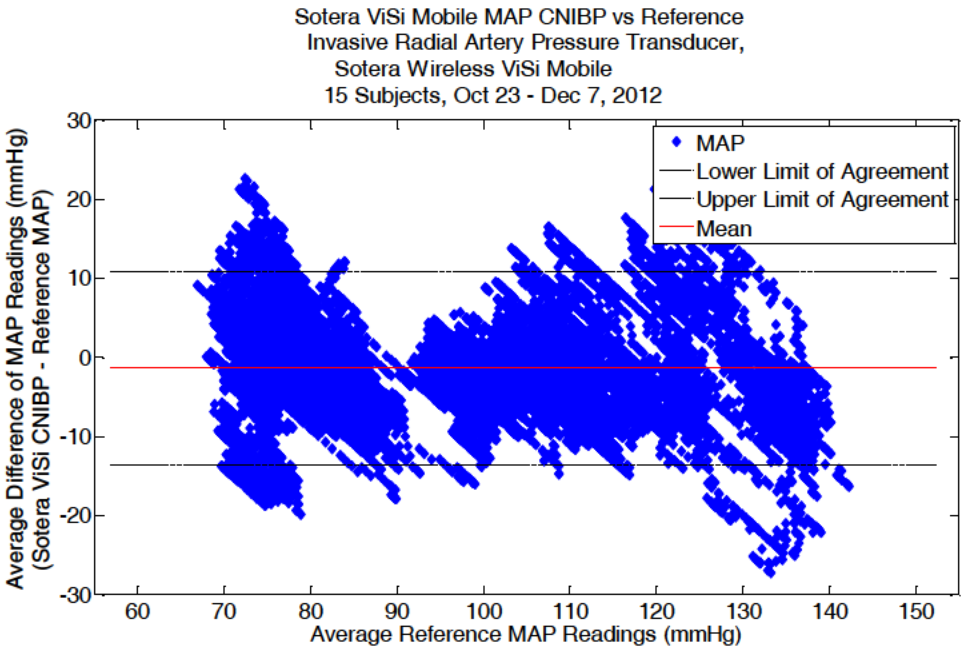
Sample Size: 46,871 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Contralateral Arm, Supine – MAP Blood Pressure



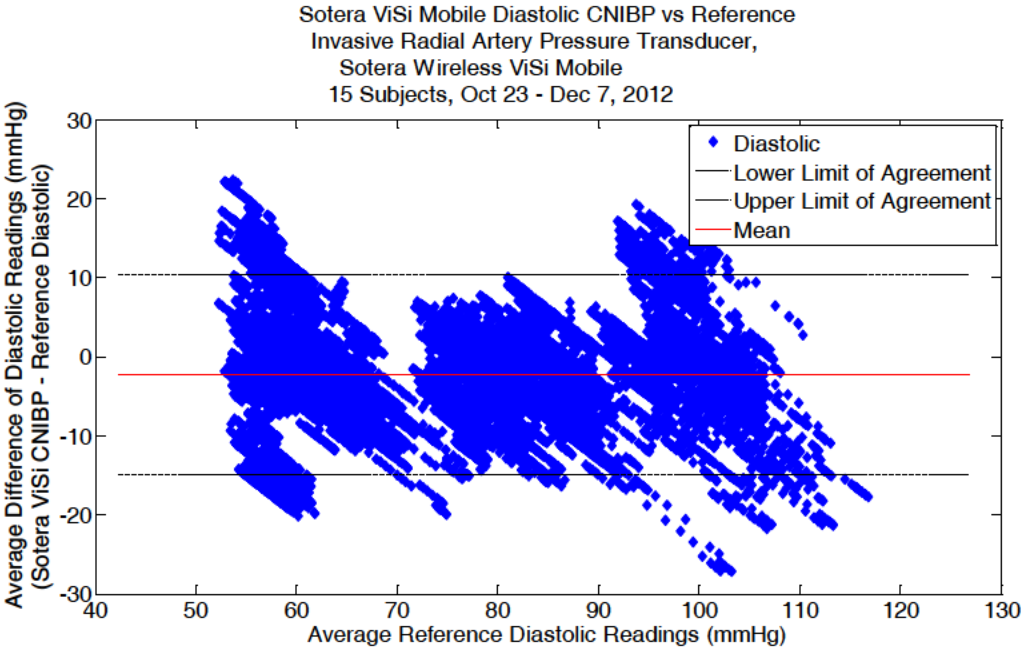
Sample Size: 46,871 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Contralateral Arm, Supine – Systolic Blood Pressure



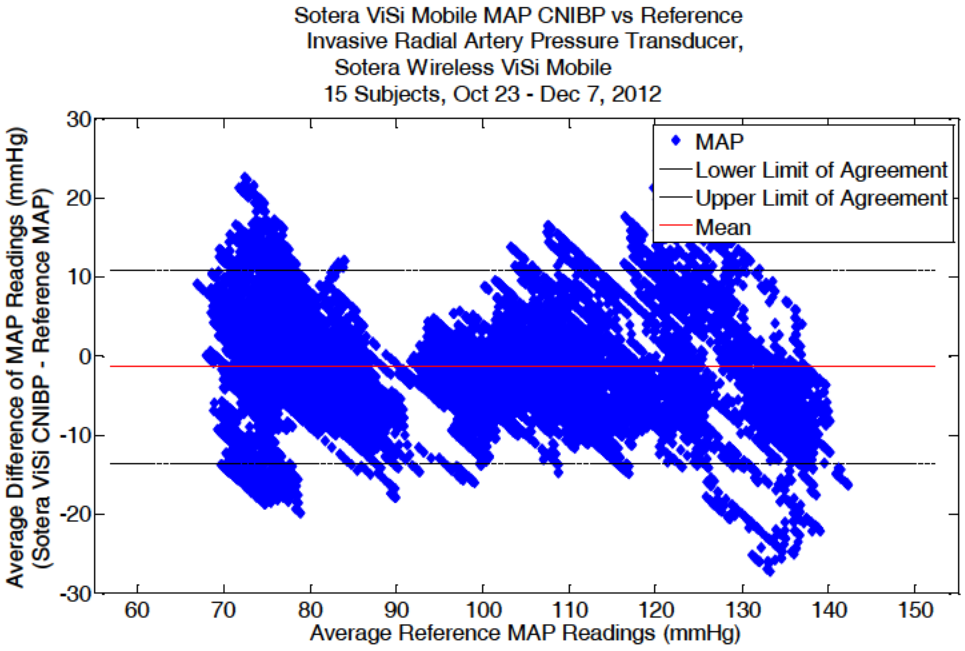
Sample Size: 46,871 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Contralateral Arm, Supine – Diastolic Blood Pressure



Sample Size: 46,871 pts

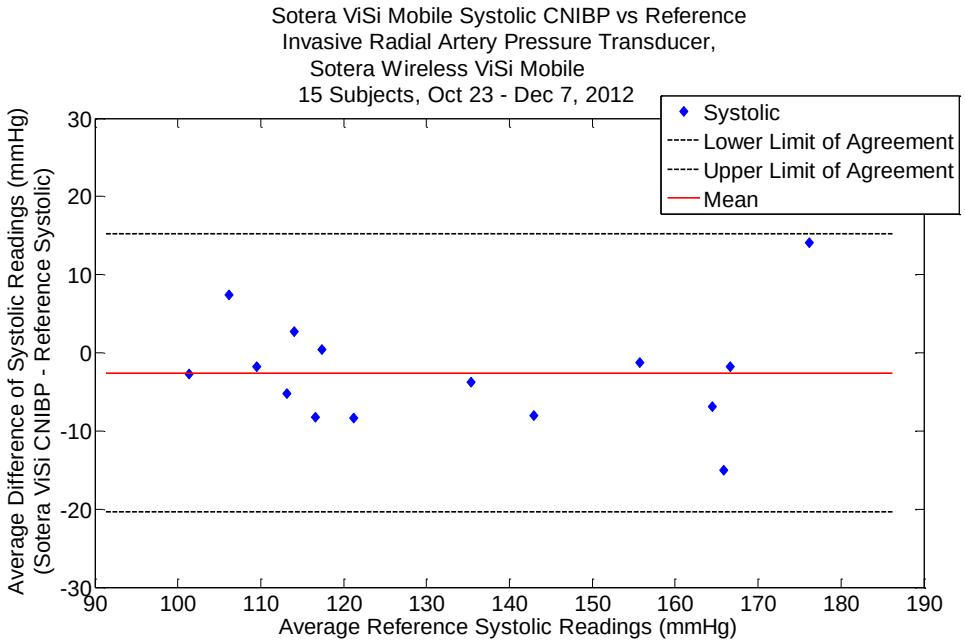
Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Contralateral Arm, Supine – MAP Blood Pressure



Sample Size: 46,871 pts

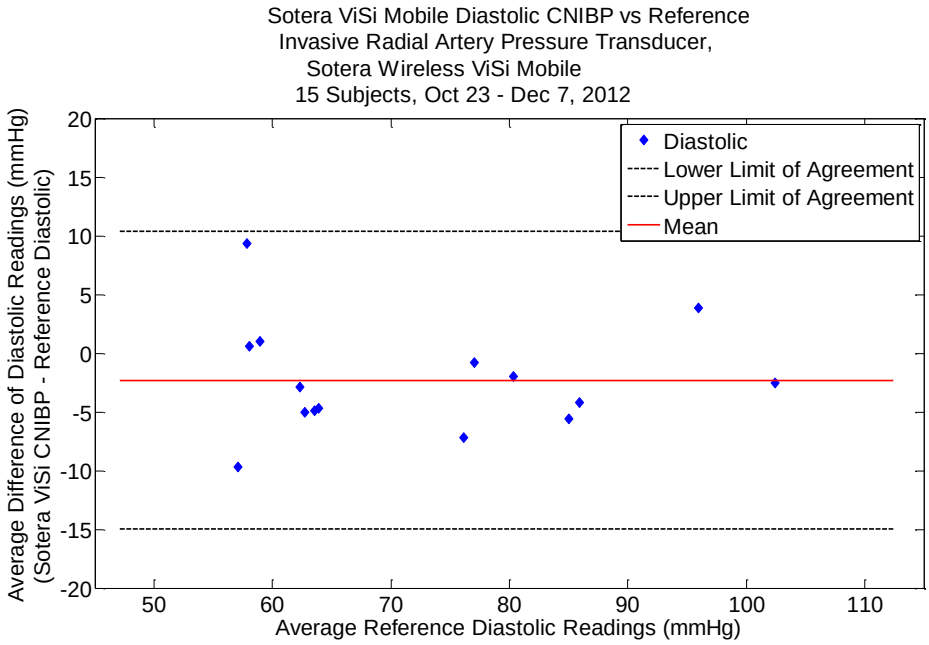
Exhibit_10_Supine-IPS-cNIBP-BlandAltman.docx

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Ipsilateral Arm, Supine – Systolic Blood Pressure



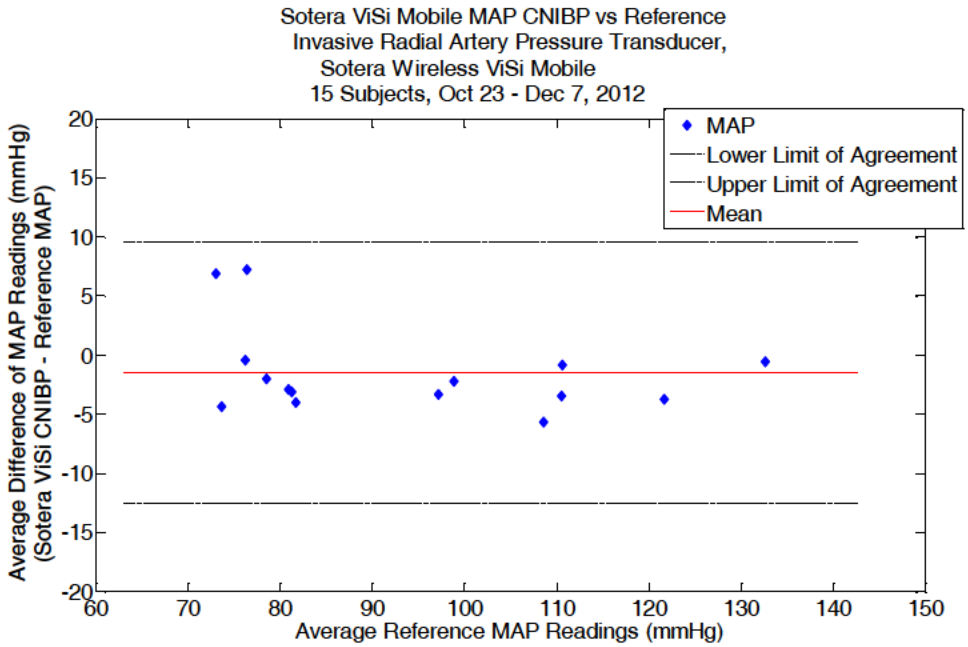
Sample Size: 47,572 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Ipsilateral Arm, Supine – Diastolic Blood Pressure



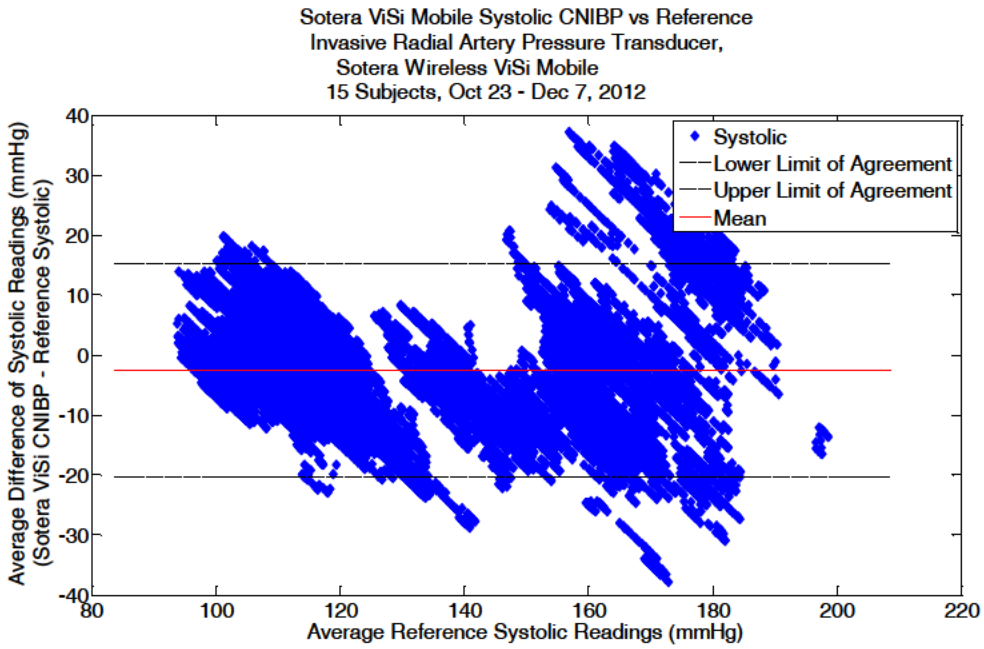
Sample Size: 47,572 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Ipsilateral Arm, Supine – MAP Blood Pressure



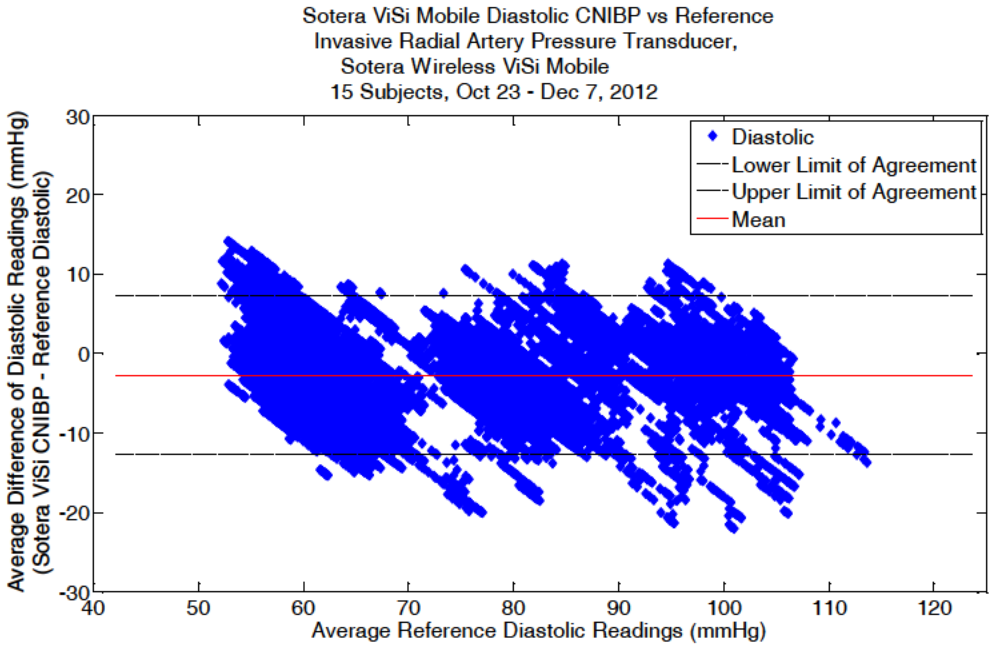
Sample Size: 47,572 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Ipsilateral Arm, Supine – Systolic Blood Pressure



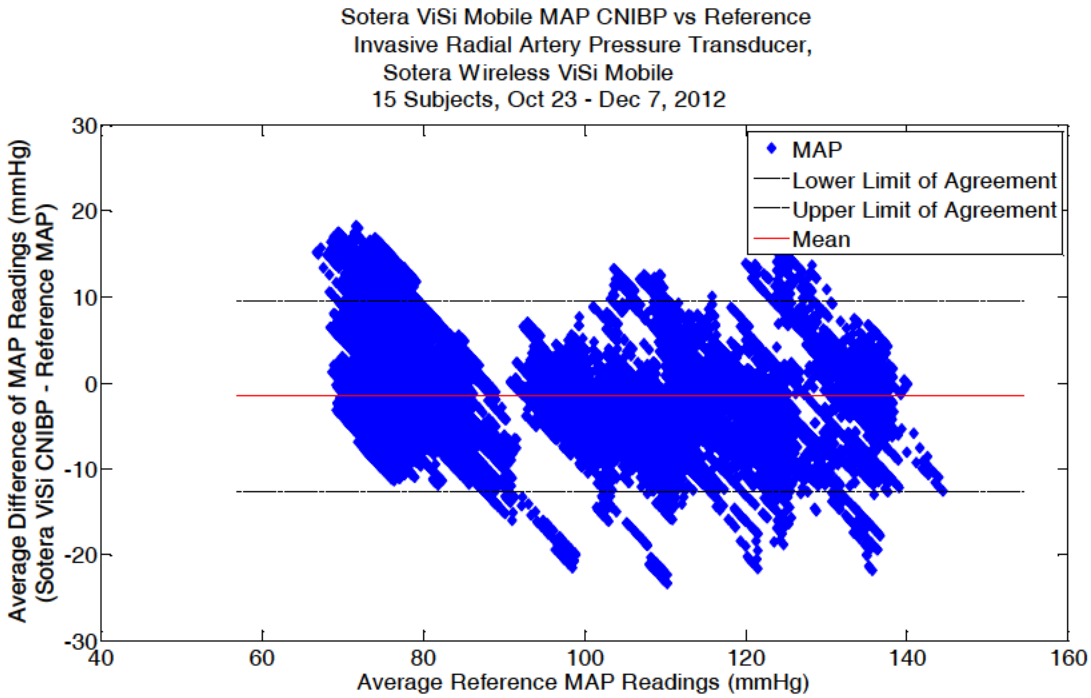
Sample Size: 47,572 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Ipsilateral Arm, Supine – Diastolic Blood Pressure



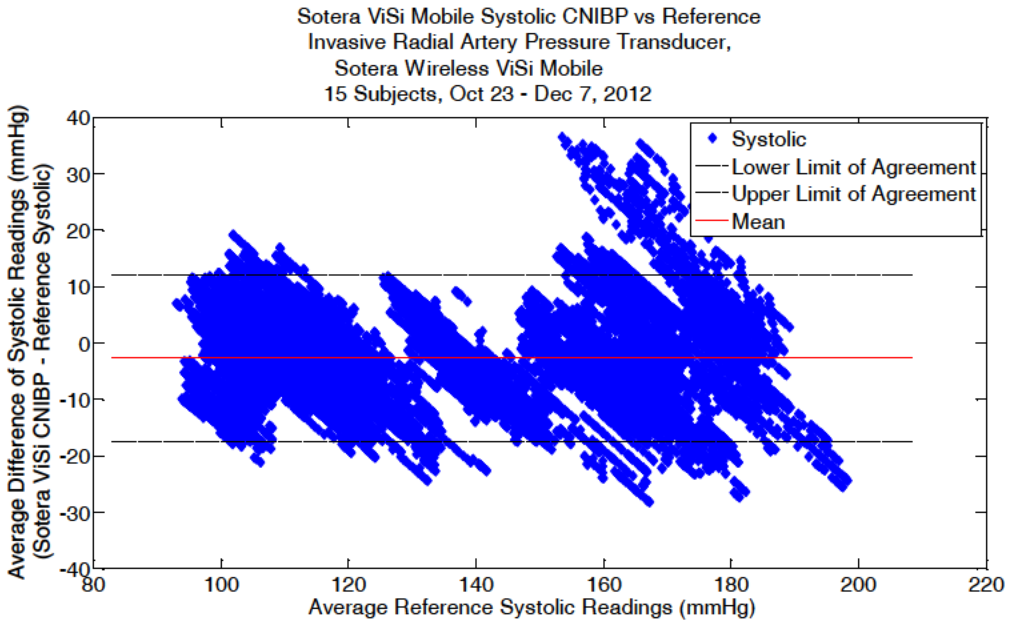
Sample Size: 47,572 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Ipsilateral Arm, Supine – MAP Blood Pressure



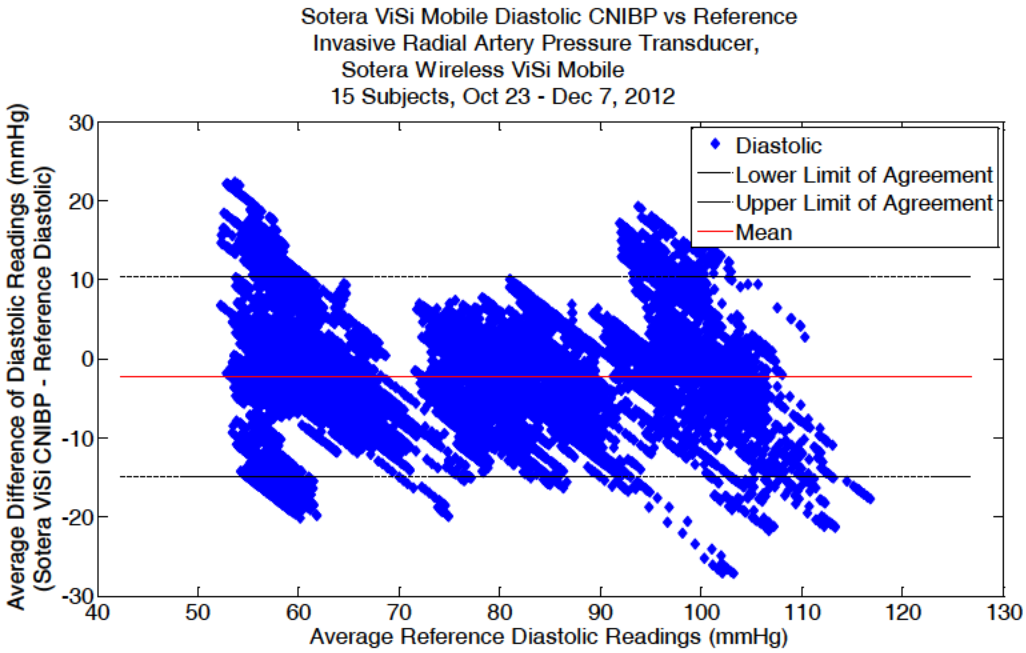
Sample Size: 47,572 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Contralateral Arm, Supine – Systolic Blood Pressure



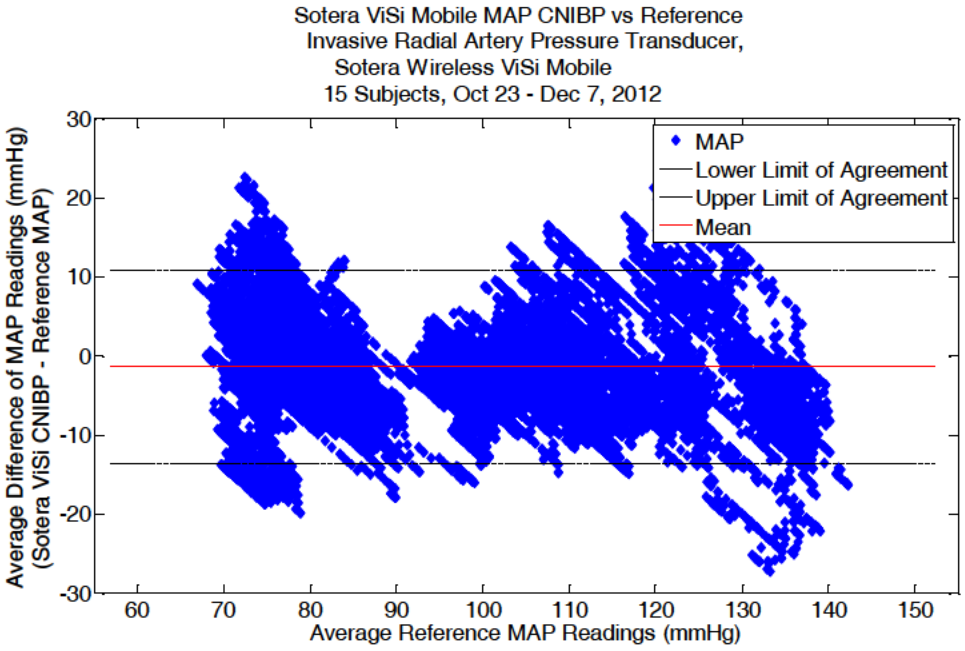
Sample Size: 46,871 pts

Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Contralateral Arm, Supine – Diastolic Blood Pressure

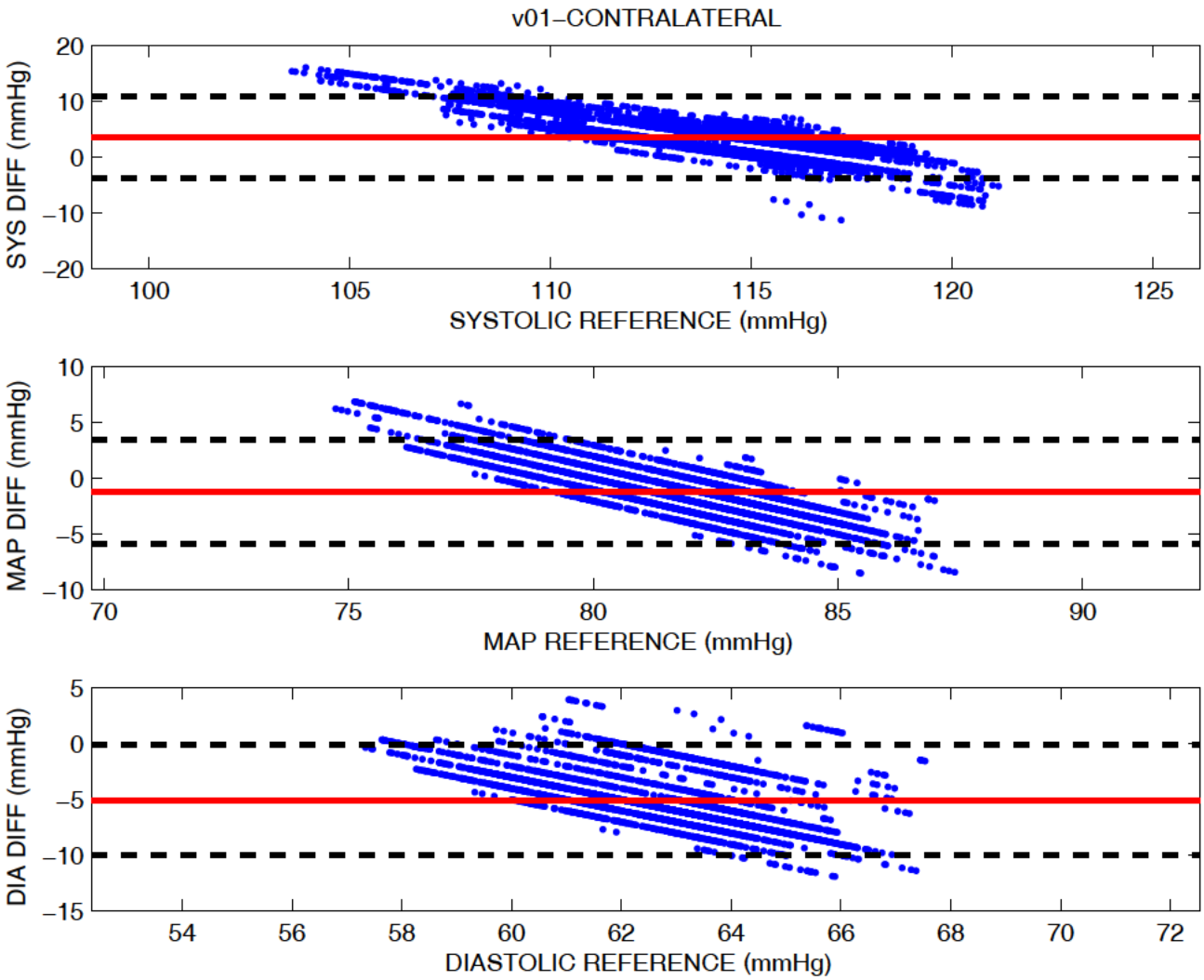


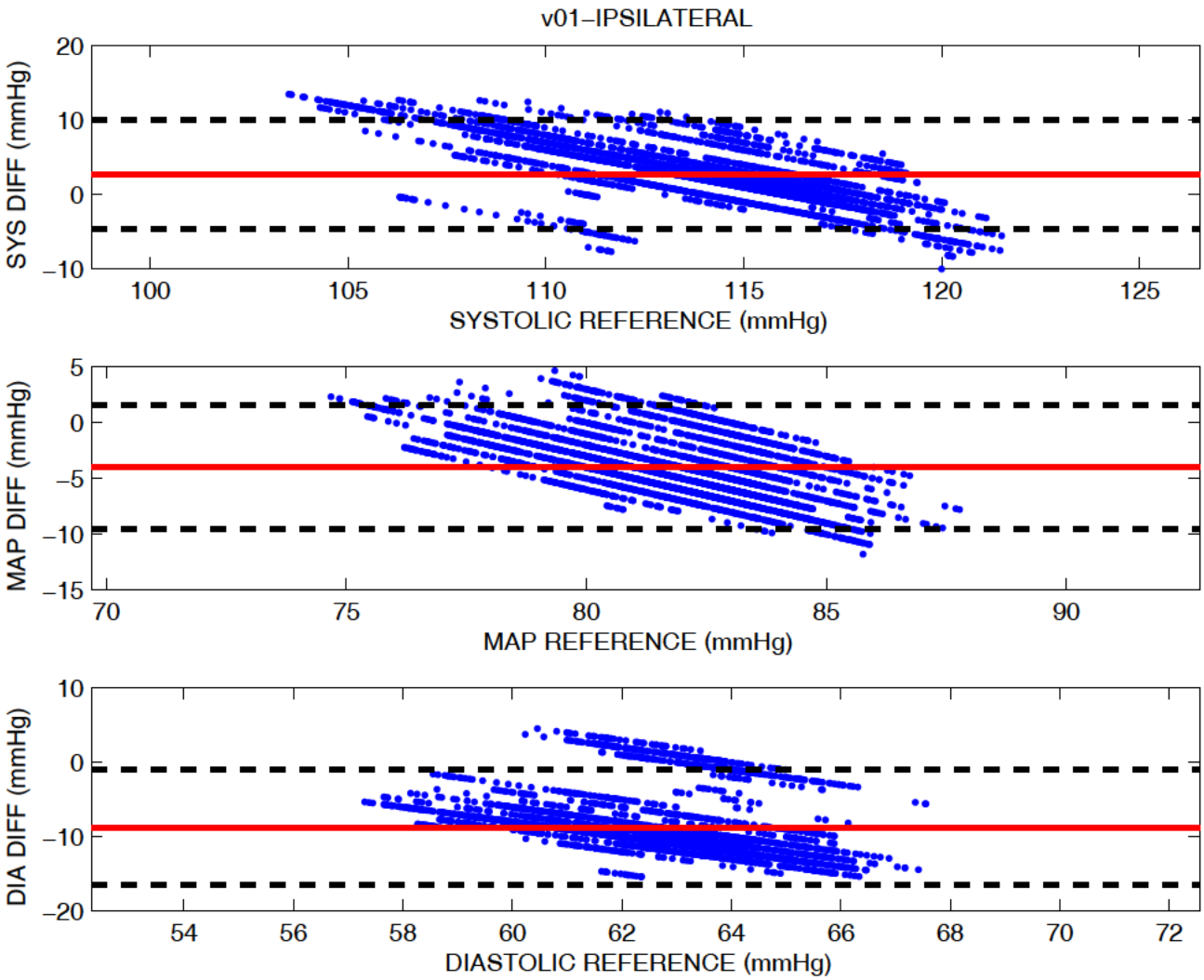
Sample Size: 46,871 pts

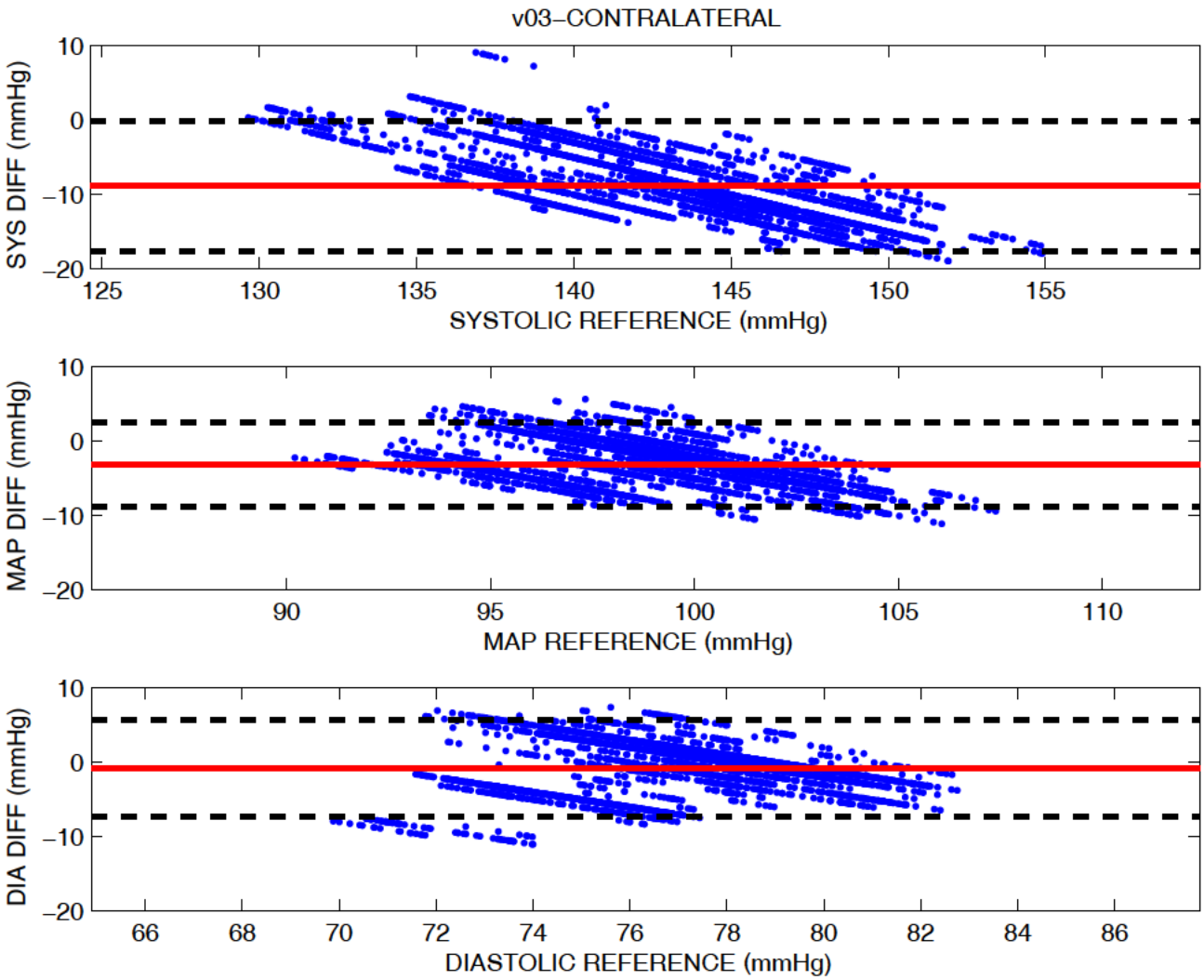
Bland-Altman: Sotera Wireless ViSi Mobile cNIBP, Contralateral Arm, Supine – MAP Blood Pressure

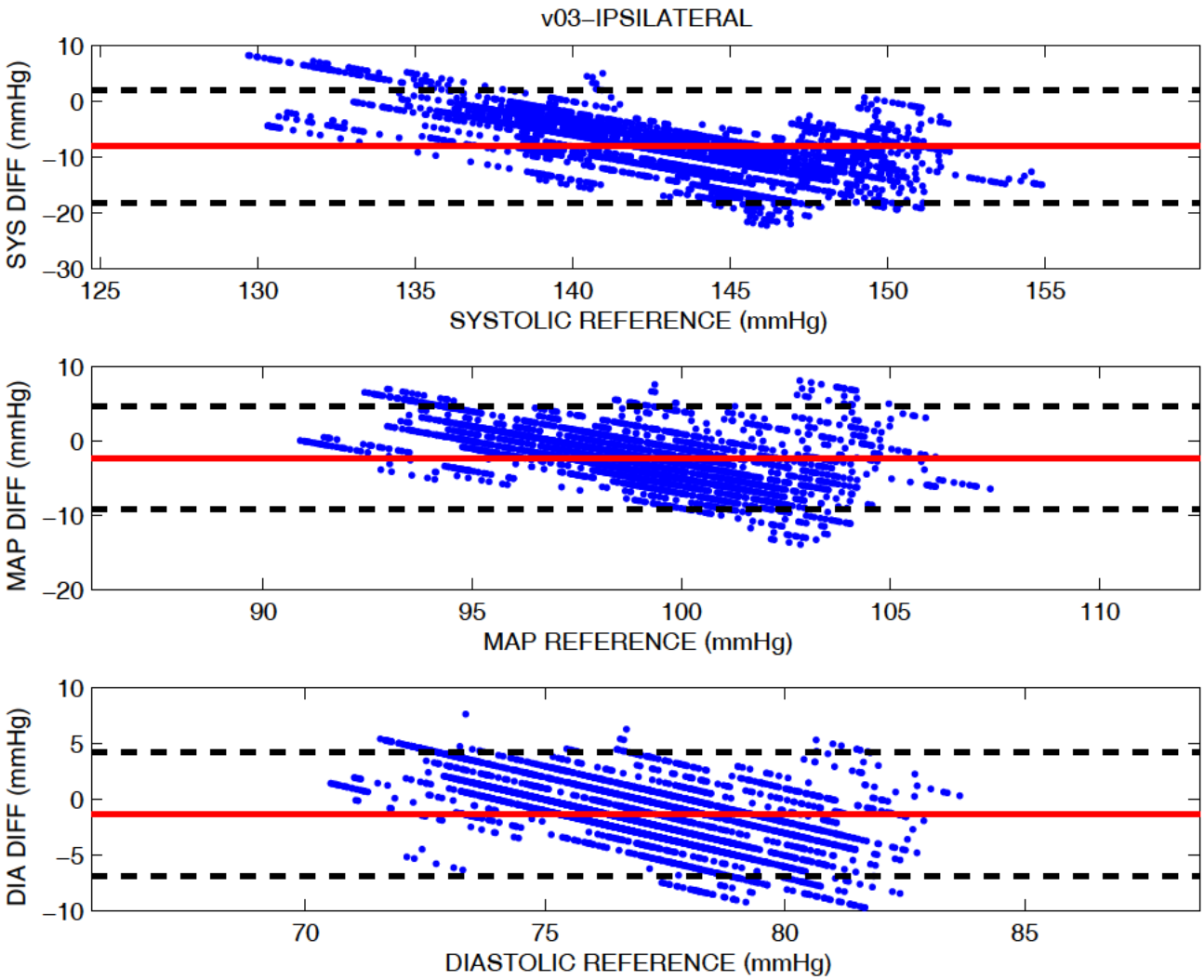


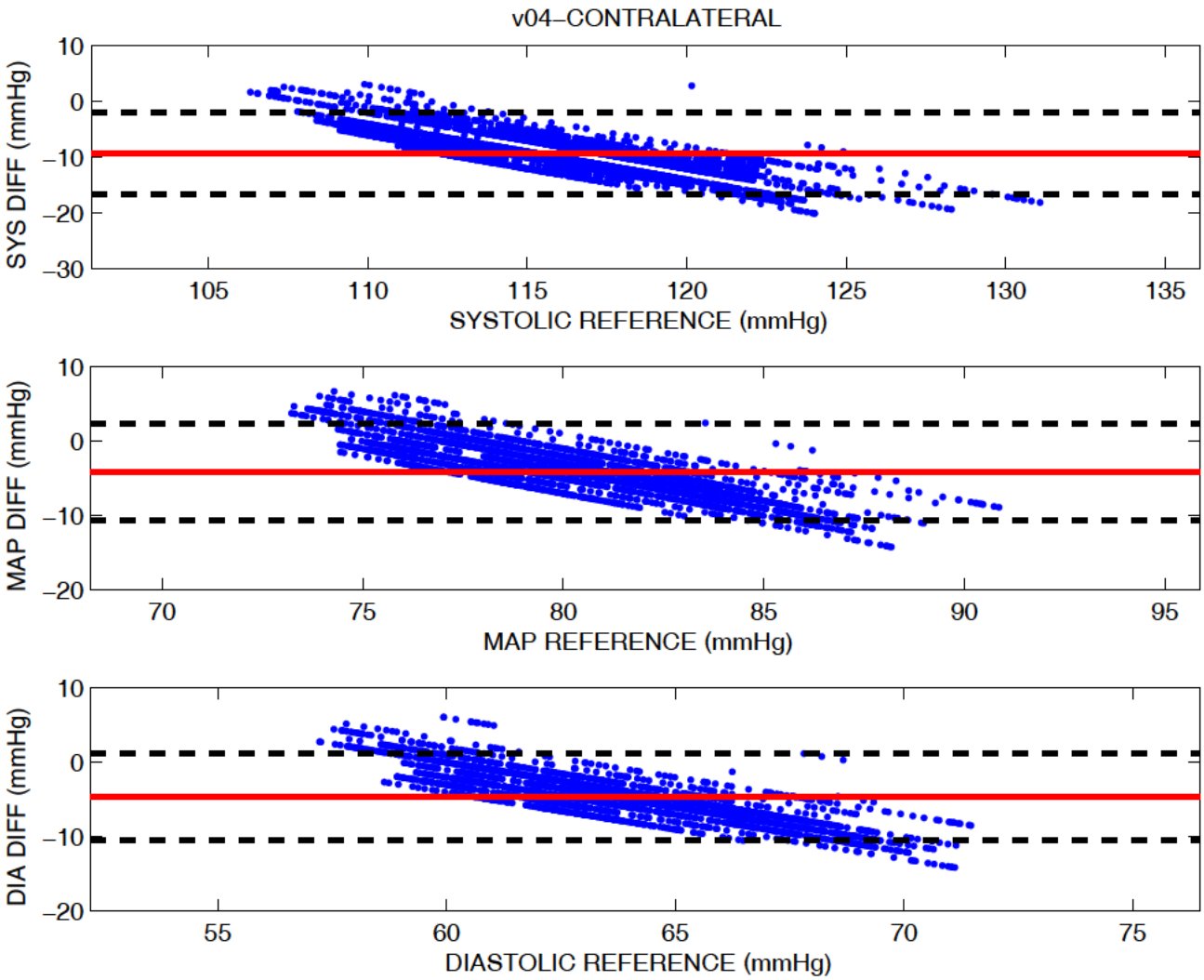
Sample Size: 46,871 pts

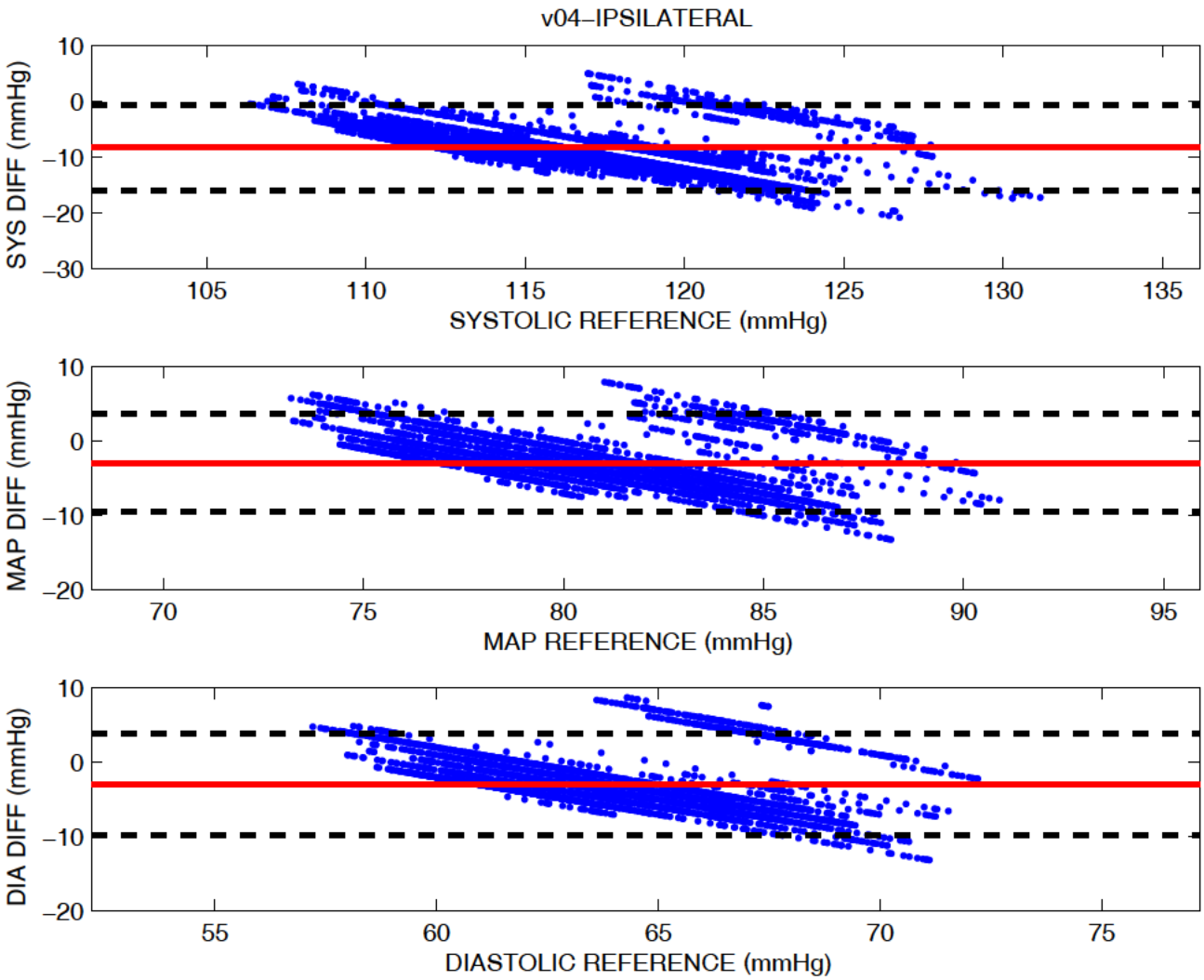

v01–CONTRALATERAL
SYS DIFF (mmHg)
20
10
0
−10
−20
100
105
110
115
120
125
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
5
0
−5
−10
70
75
80
85
90
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
5
0
−5
−10
−15
54
56
58
60
62
64
66
68
70
72
DIASTOLIC REFERENCE (mmHg)

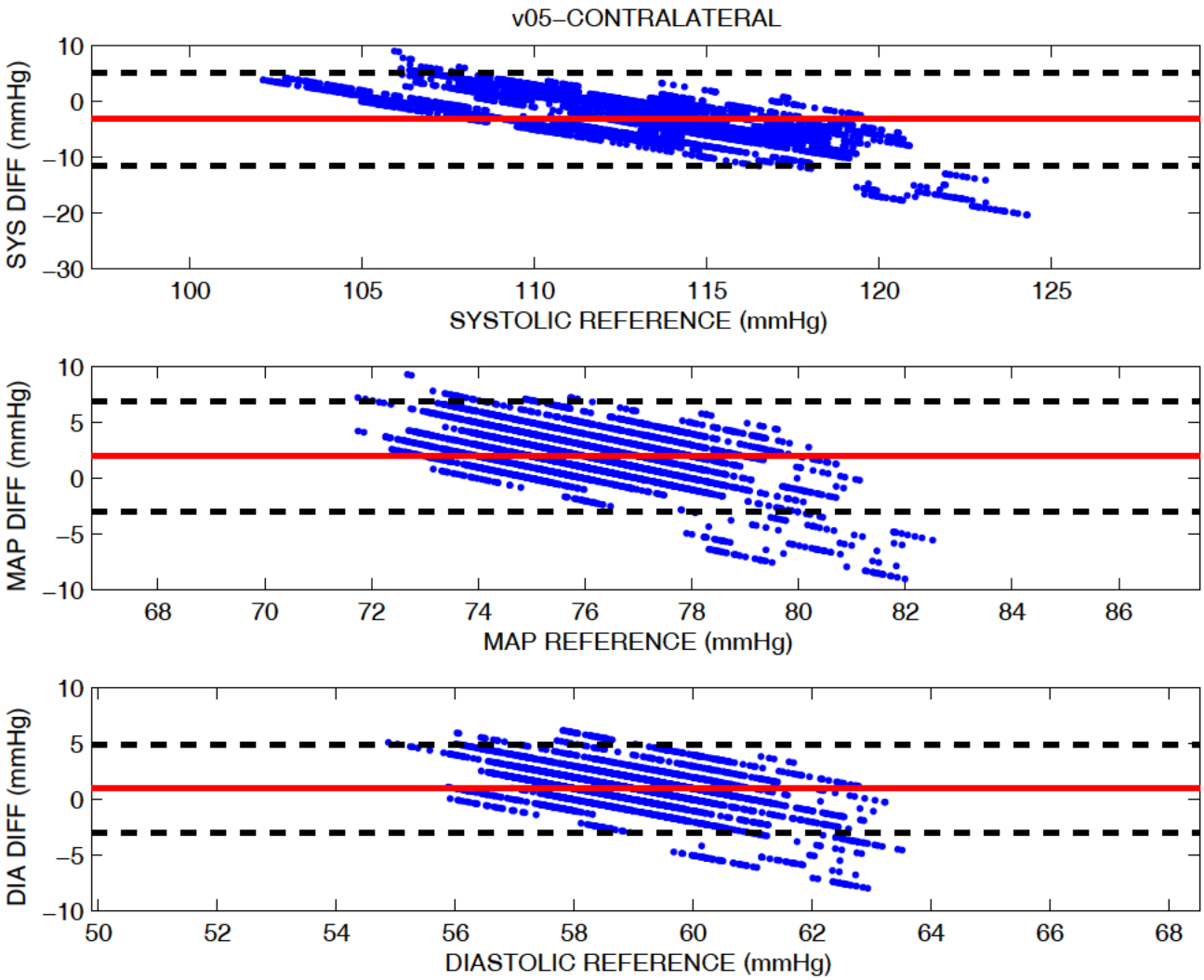

v01–IPSILATERAL
SYS DIFF (mmHg)
20
10
0
−10
100
105
110
115
120
125
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
5
0
−5
−10
−15
70
75
80
85
90
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
54
56
58
60
62
64
66
68
70
72
DIASTOLIC REFERENCE (mmHg)

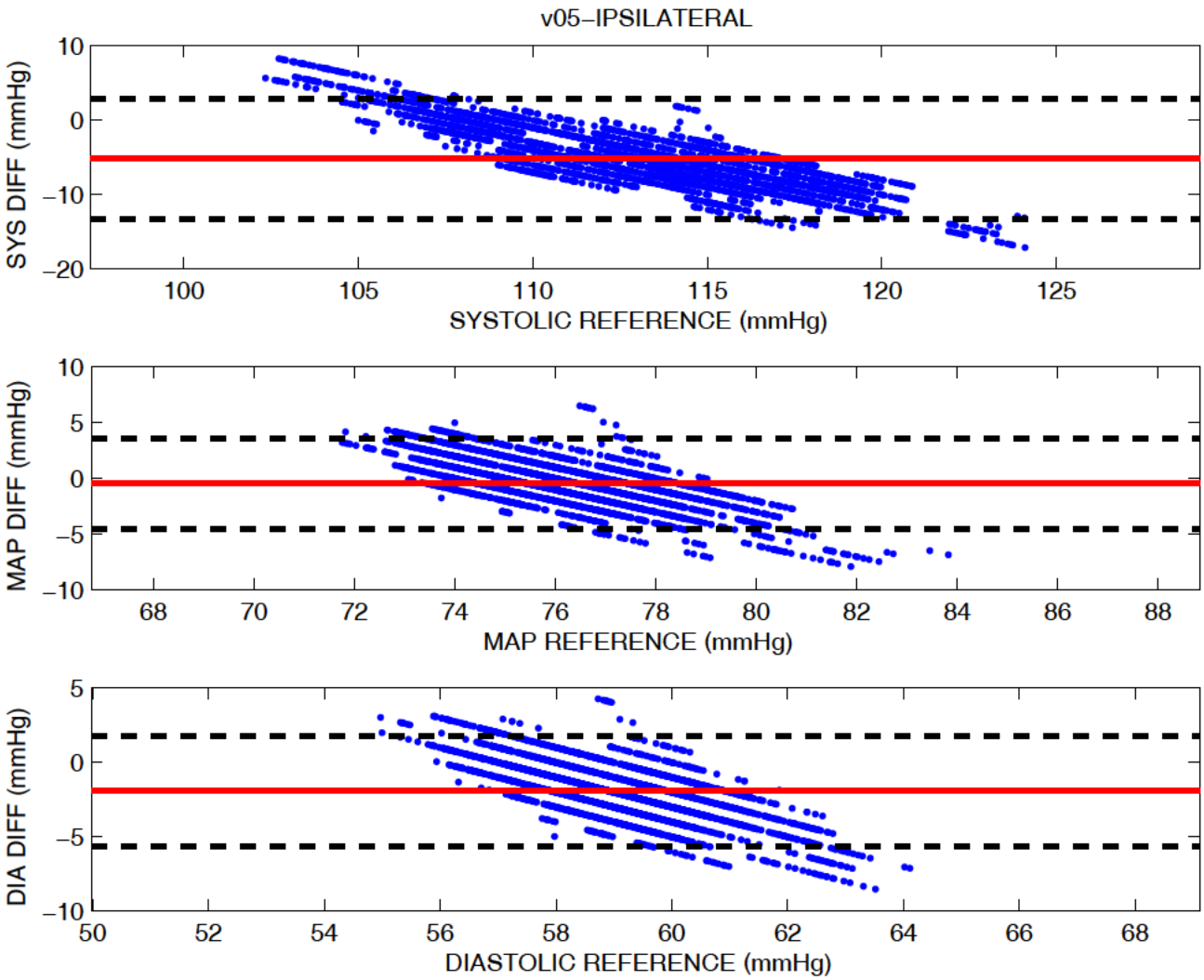

v03–CONTRALATERAL
SYS DIFF (mmHg)
10
0
−10
−20
125
130
135
140
145
150
155
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
0
−10
−20
90
95
100
105
110
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
66
68
70
72
74
76
78
80
82
84
86
DIASTOLIC REFERENCE (mmHg)

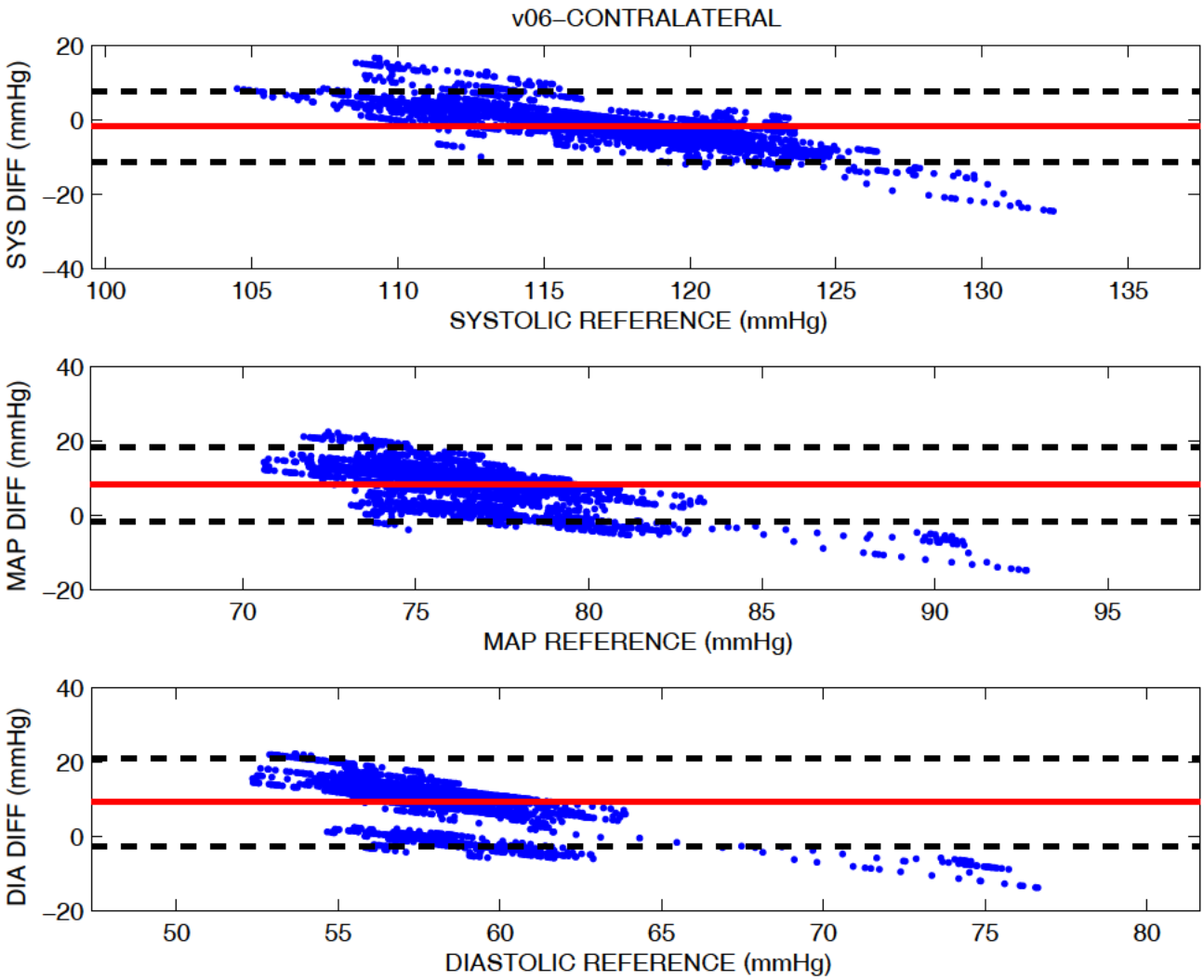

v03–IPSILATERAL
SYS DIFF (mmHg)
10
0
−10
−20
−30
125
130
135
140
145
150
155
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
0
−10
−20
90
95
100
105
110
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
5
0
−5
−10
70
75
80
85
DIASTOLIC REFERENCE (mmHg)

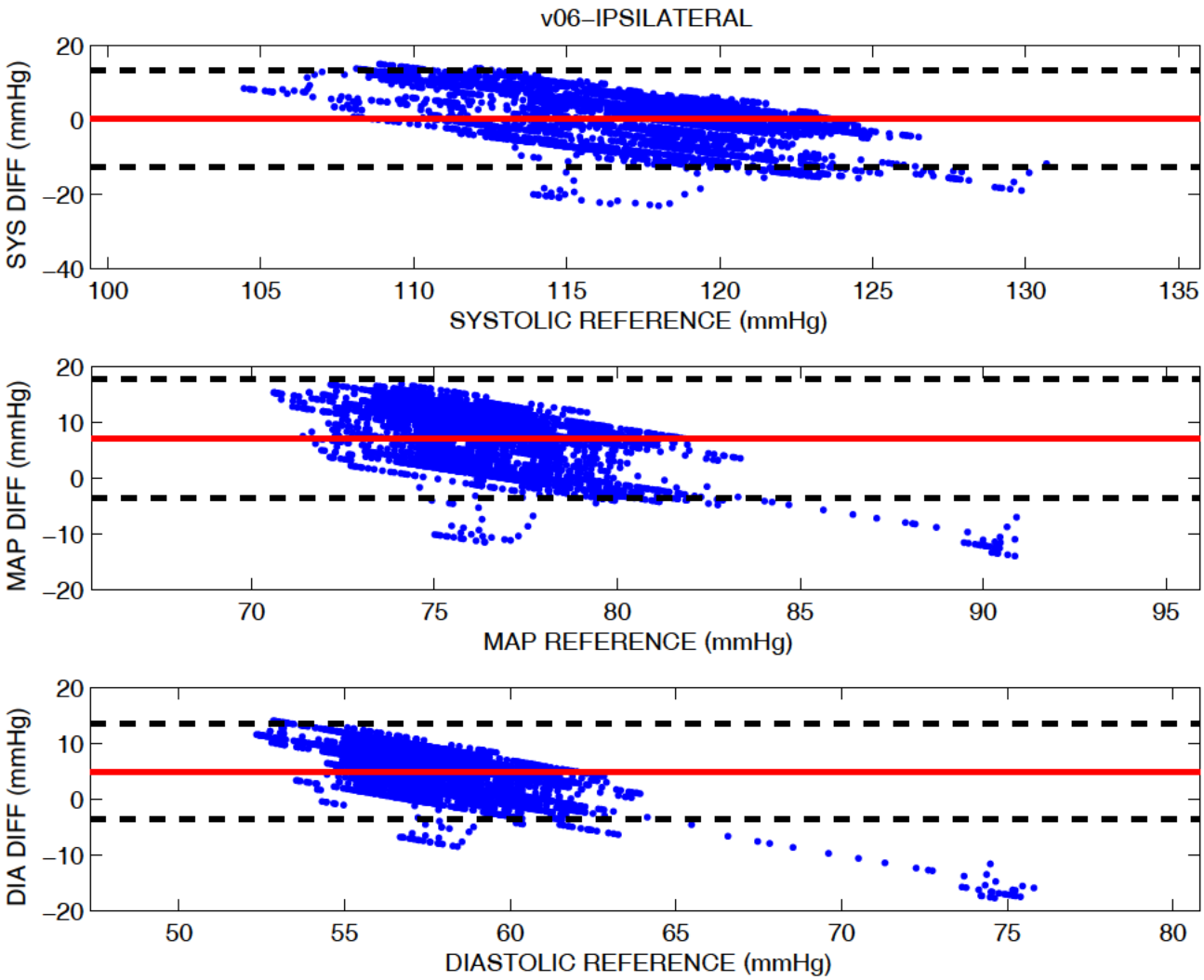

v04–CONTRALATERAL
SYS DIFF (mmHg)
10
0
−10
−20
−30
105
110
115
120
125
130
135
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
0
−10
−20
70
75
80
85
90
95
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
55
60
65
70
75
DIASTOLIC REFERENCE (mmHg)

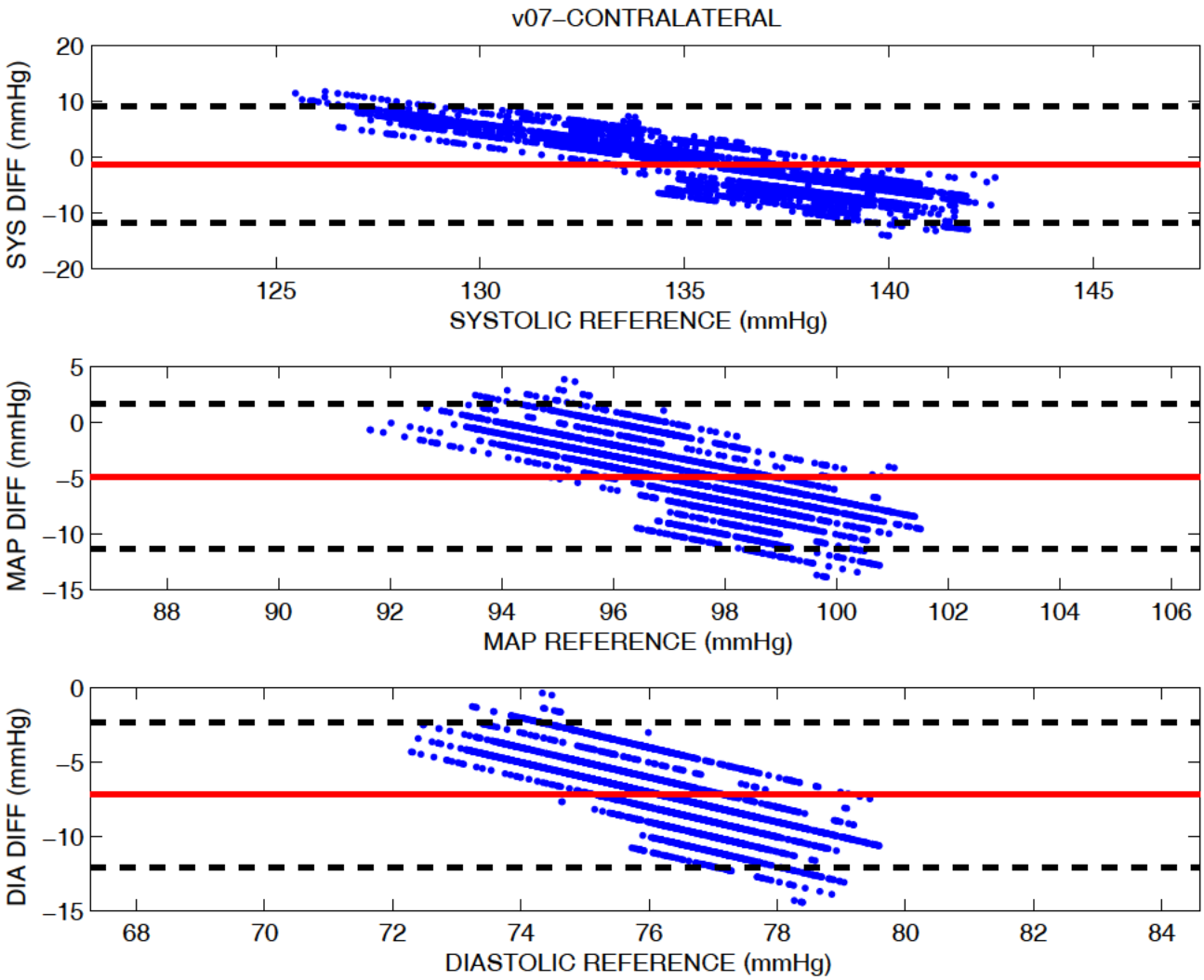

v04–IPSILATERAL
SYS DIFF (mmHg)
10
0
−10
−20
−30
105
110
115
120
125
130
135
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
0
−10
−20
70
75
80
85
90
95
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
55
60
65
70
75
DIASTOLIC REFERENCE (mmHg)

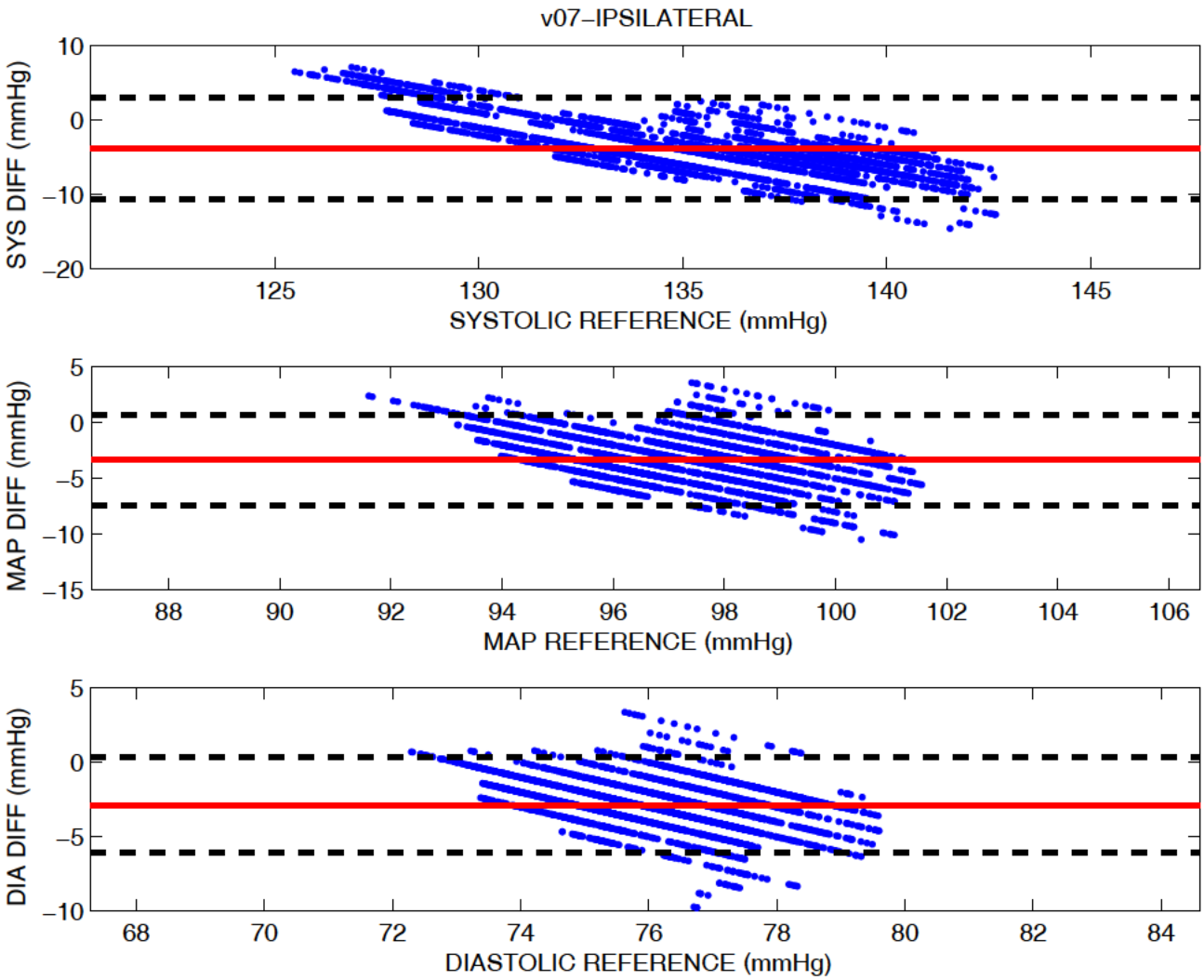

v05–CONTRALATERAL
SYS DIFF (mmHg)
10
0
−10
−20
−30
100
105
110
115
120
125
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
5
0
−5
−10
68
70
72
74
76
78
80
82
84
86
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
5
0
−5
−10
50
52
54
56
58
60
62
64
66
68
DIASTOLIC REFERENCE (mmHg)

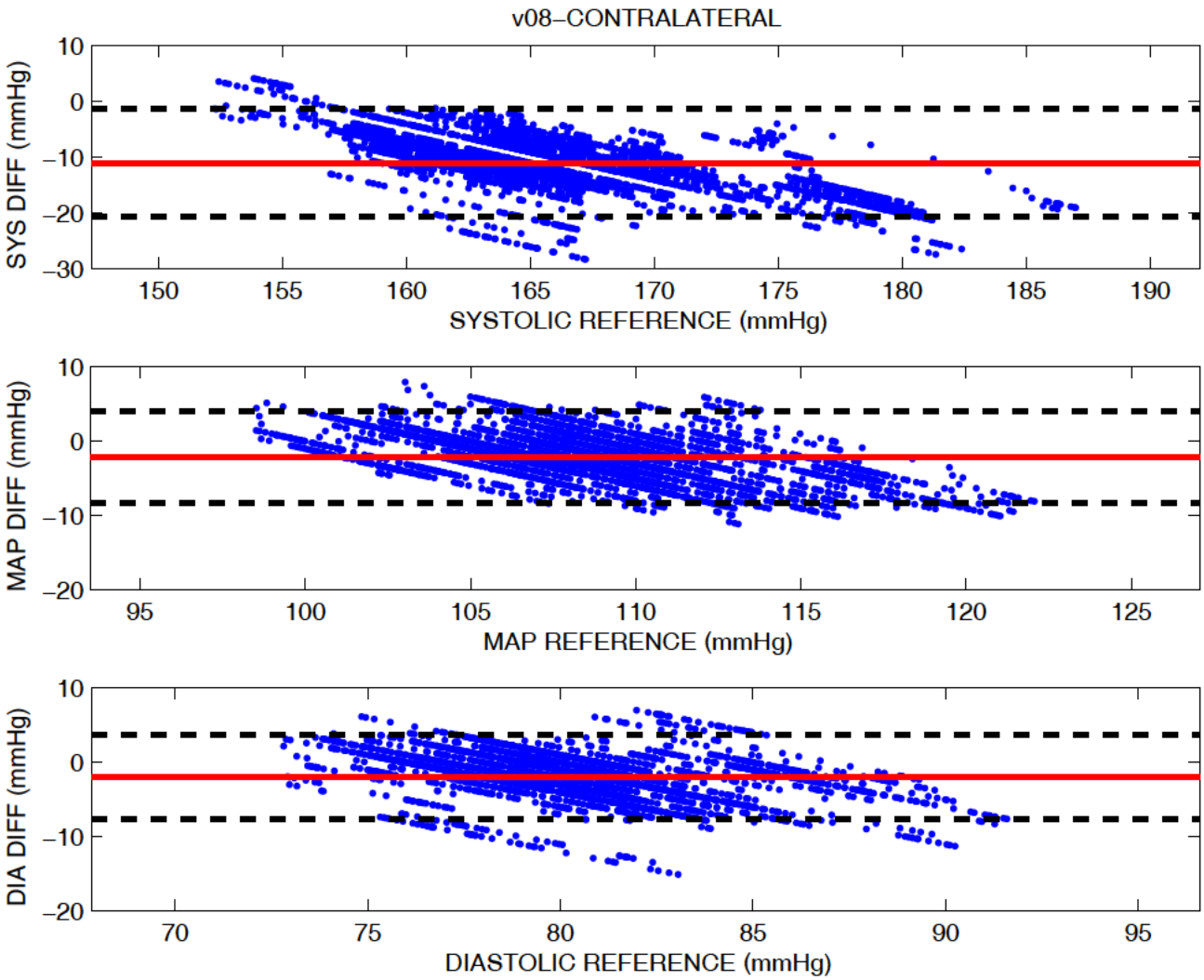

v05–IPSILATERAL
SYS DIFF (mmHg)
10
0
−10
−20
100
105
110
115
120
125
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
5
0
−5
−10
68
70
72
74
76
78
80
82
84
86
88
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
5
0
−5
−10
50
52
54
56
58
60
62
64
66
68
DIASTOLIC REFERENCE (mmHg)

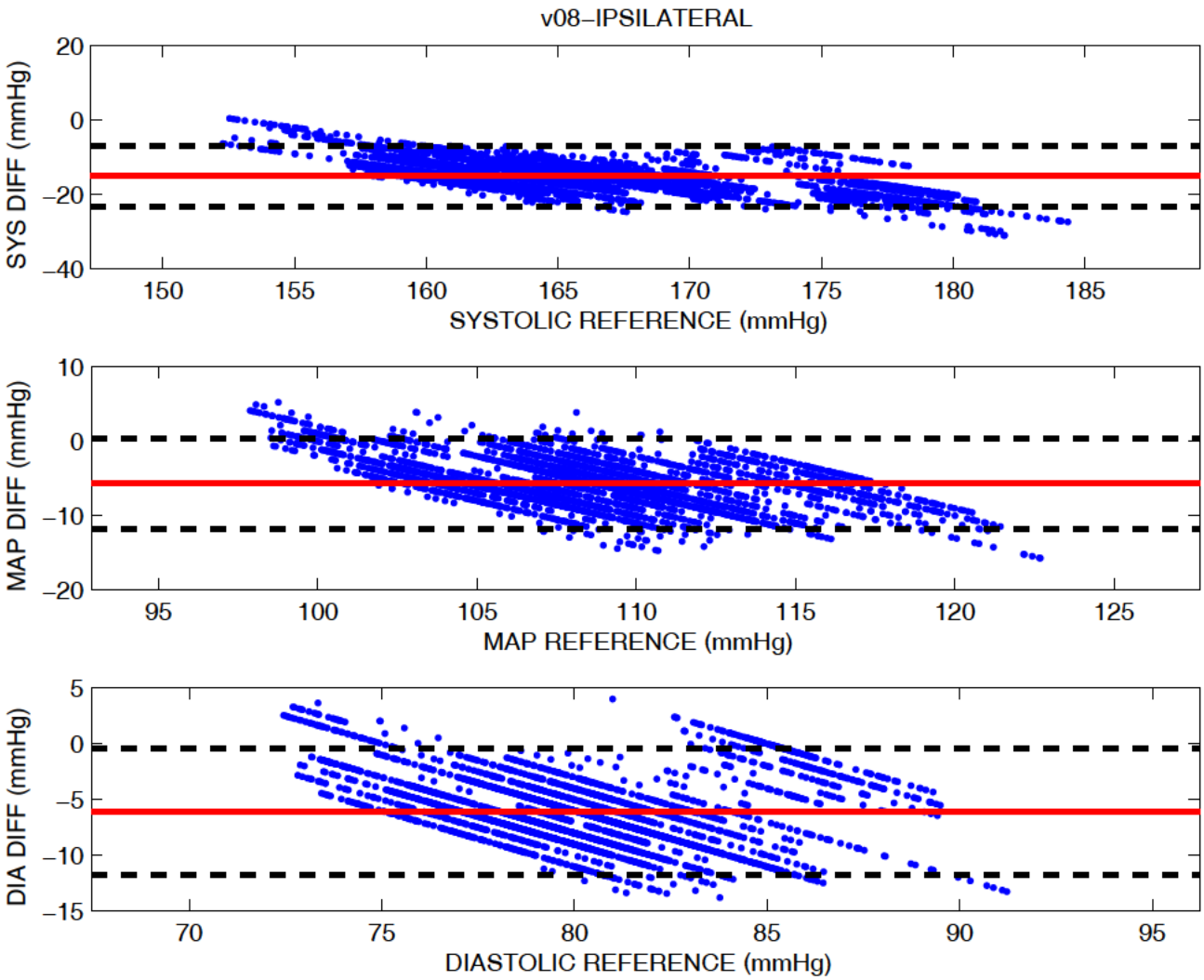

v06–CONTRALATERAL
SYS DIFF (mmHg)
20
0
−20
−40
100
105
110
115
120
125
130
135
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
40
20
0
−20
70
75
80
85
90
95
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
40
20
0
−20
50
55
60
65
70
75
80
DIASTOLIC REFERENCE (mmHg)

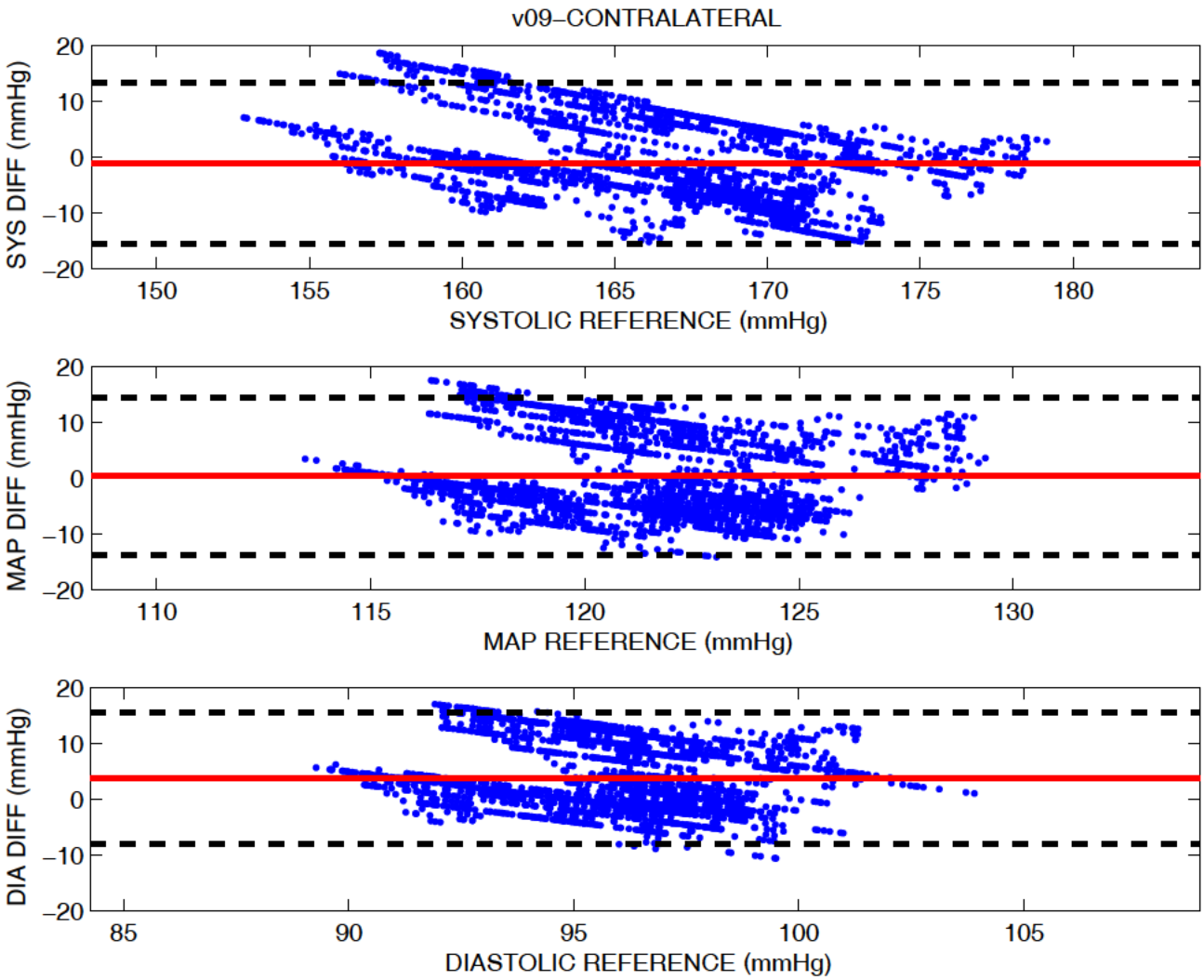

v06–IPSILATERAL
SYS DIFF (mmHg)
20
0
−20
−40
100
105
110
115
120
125
130
135
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
10
0
−10
−20
70
75
80
85
90
95
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
20
10
0
−10
−20
50
55
60
65
70
75
80
DIASTOLIC REFERENCE (mmHg)

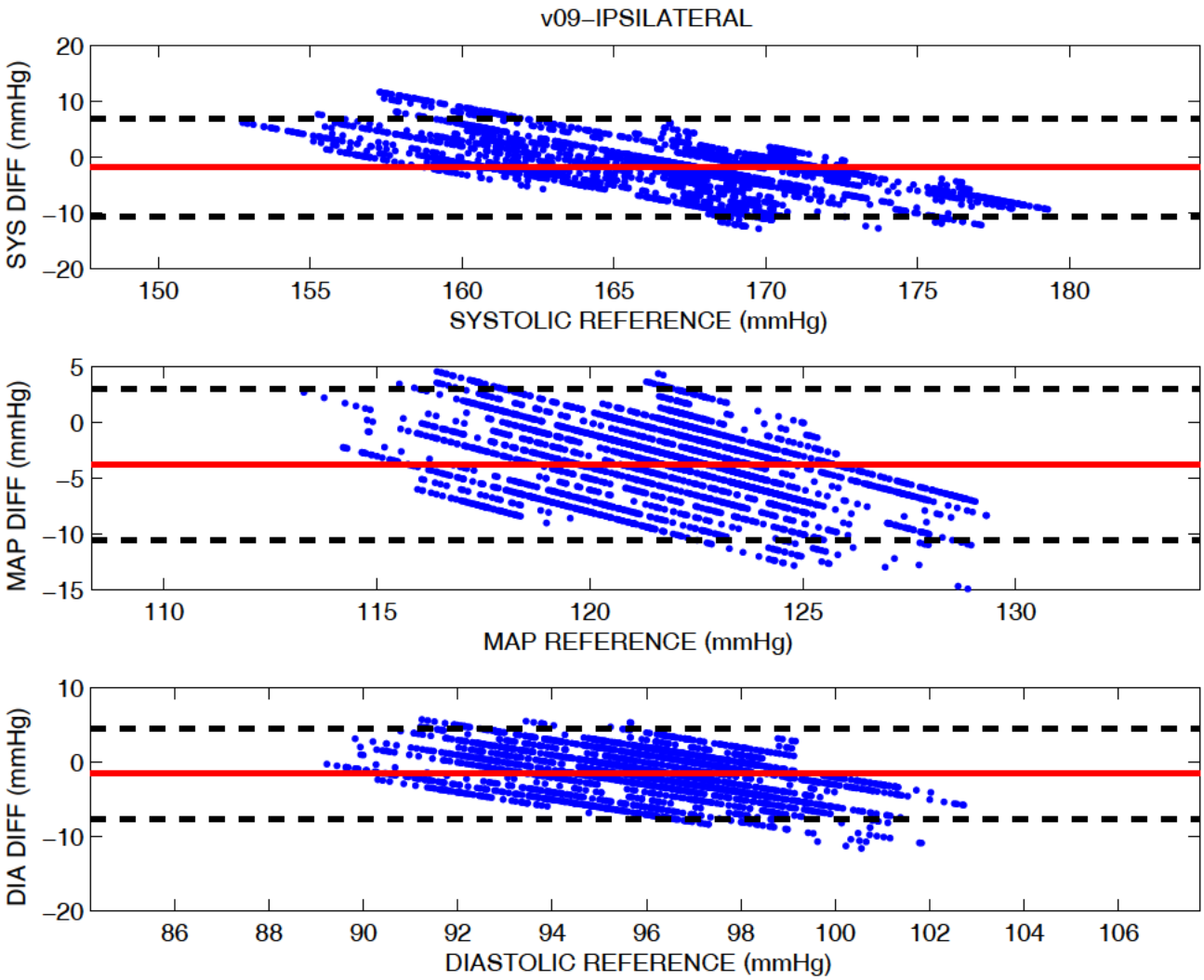

v07–CONTRALATERAL
SYS DIFF (mmHg)
20
10
0
−10
−20
125
130
135
140
145
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
5
0
−5
−10
−15
88
90
92
94
96
98
100
102
104
106
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
0
−5
−10
−15
68
70
72
74
76
78
80
82
84
DIASTOLIC REFERENCE (mmHg)

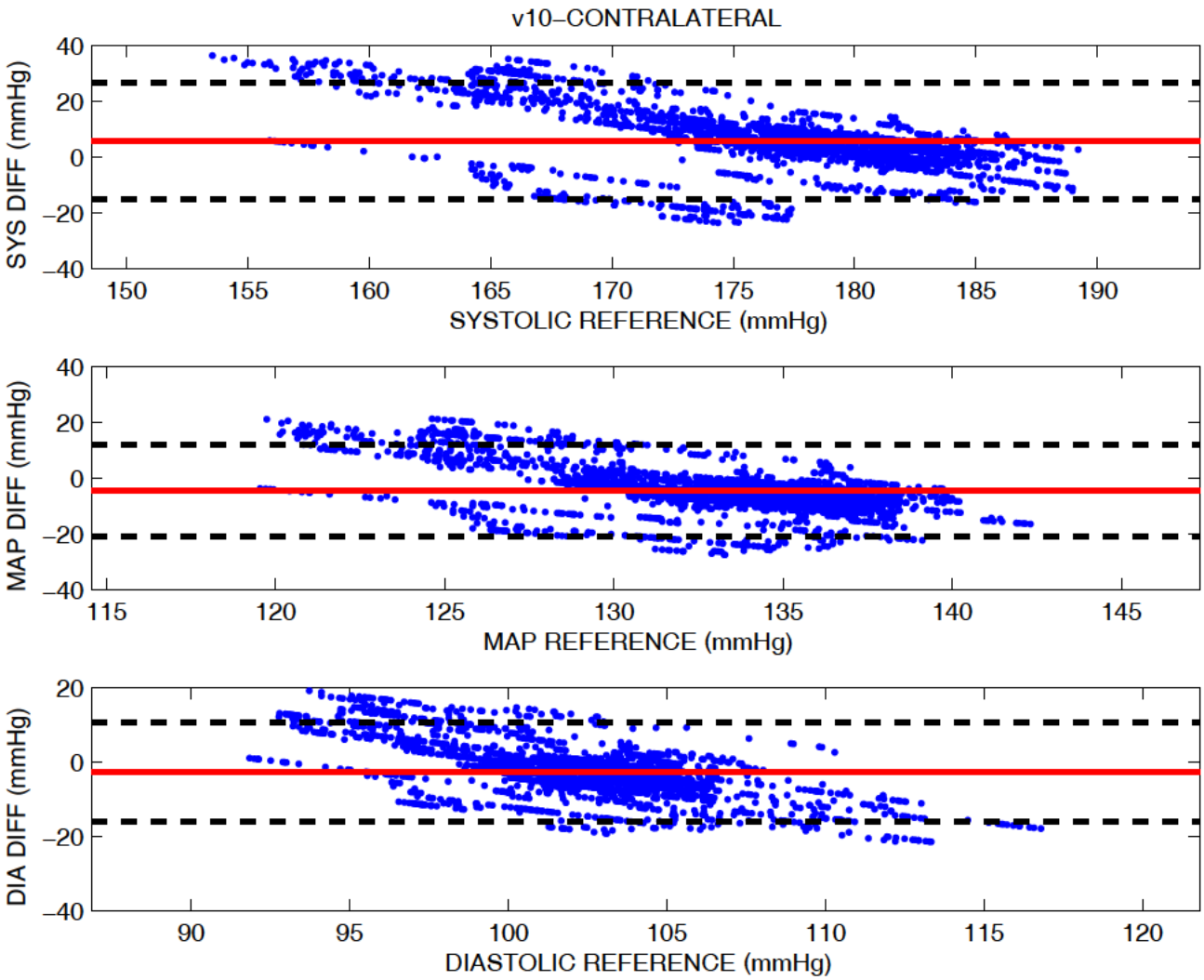

v07–IPSILATERAL
SYS DIFF (mmHg)
10
0
−10
−20
125
130
135
140
145
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
5
0
−5
−10
−15
88
90
92
94
96
98
100
102
104
106
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
5
0
−5
−10
68
70
72
74
76
78
80
82
84
DIASTOLIC REFERENCE (mmHg)

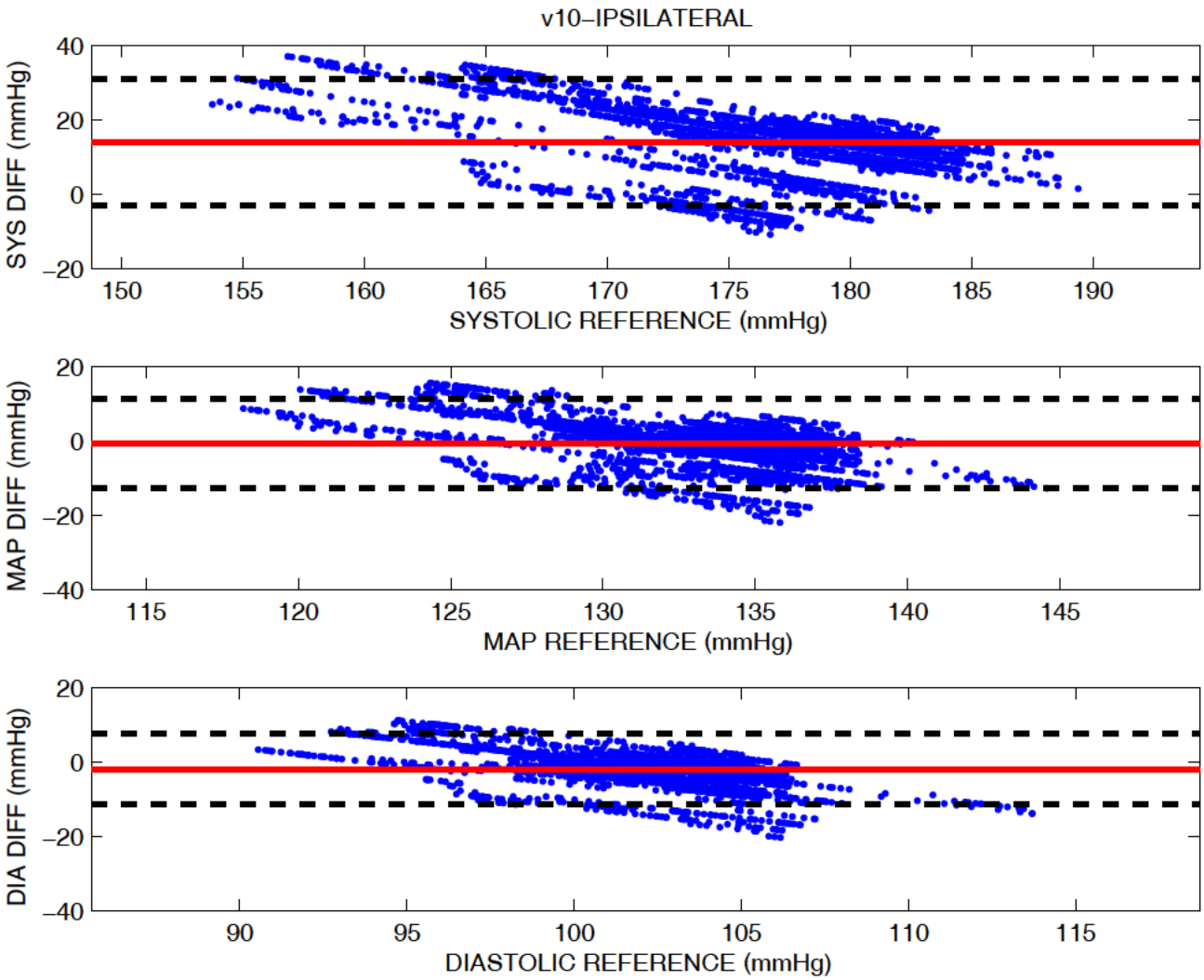

v08–CONTRALATERAL
SYS DIFF (mmHg)
10
0
−10
−20
−30
150
155
160
165
170
175
180
185
190
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
0
−10
−20
95
100
105
110
115
120
125
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
70
75
80
85
90
95
DIASTOLIC REFERENCE (mmHg)

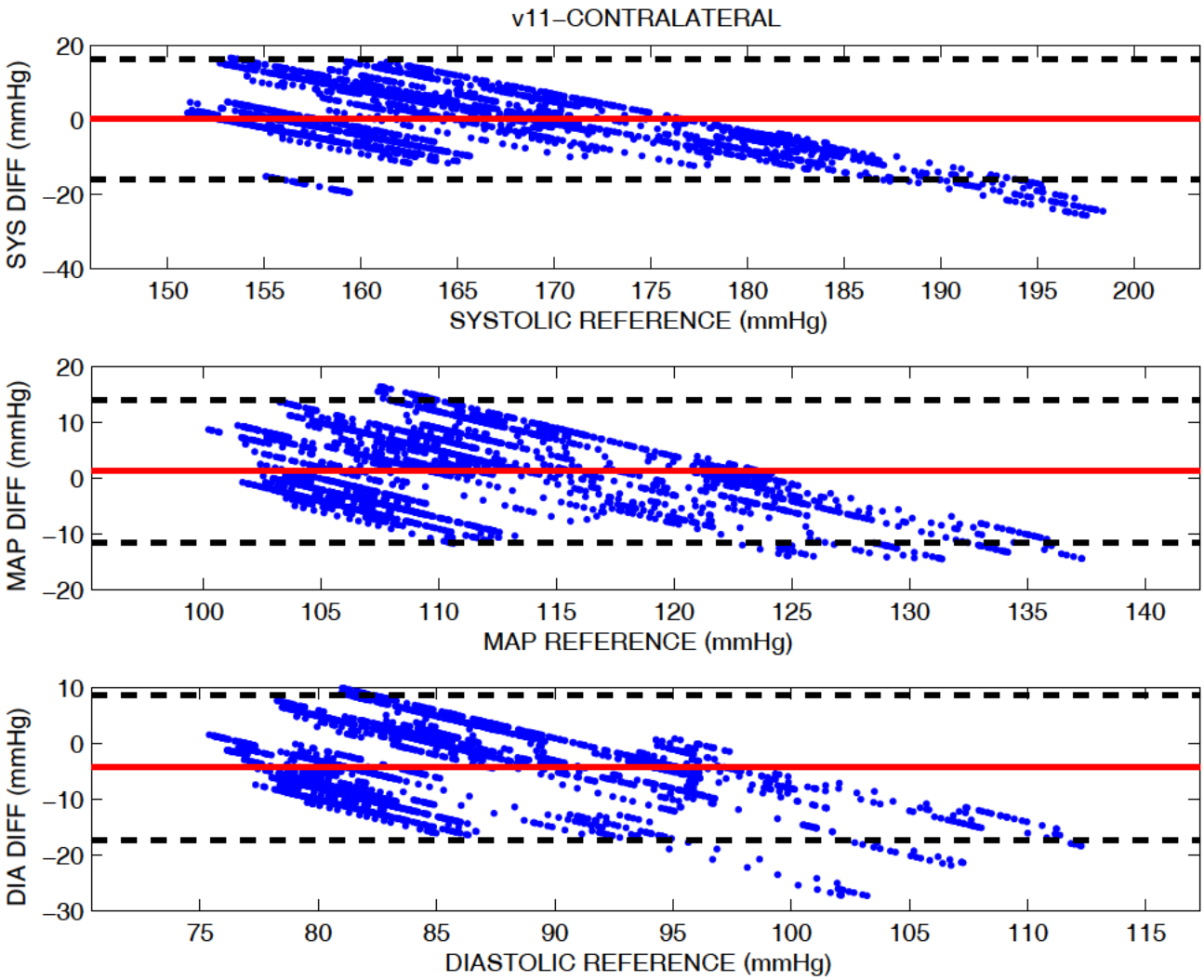

v08–IPSILATERAL
SYS DIFF (mmHg)
20
0
−20
−40
150
155
160
165
170
175
180
185
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
0
−10
−20
95
100
105
110
115
120
125
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
5
0
−5
−10
−15
70
75
80
85
90
95
DIASTOLIC REFERENCE (mmHg)

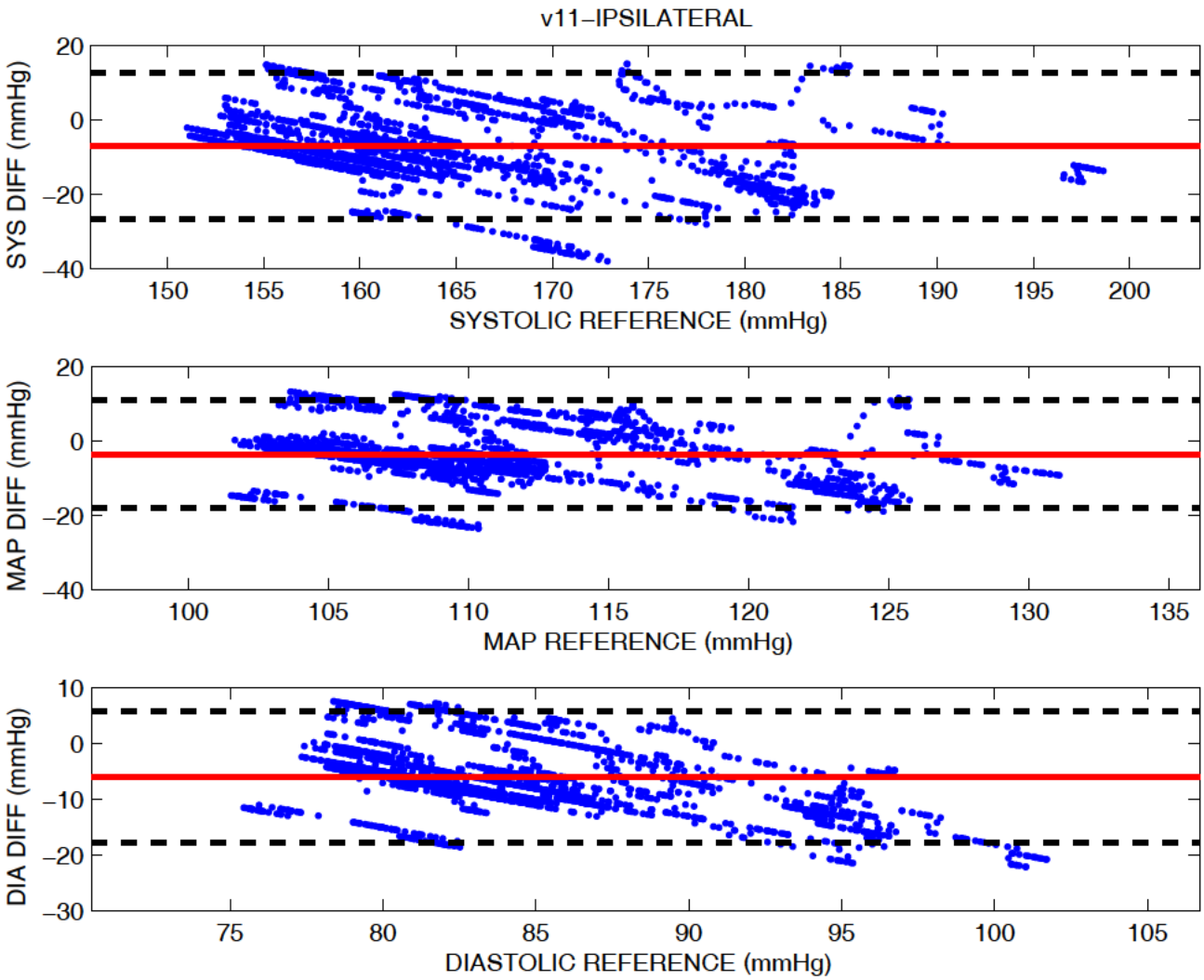

v09–CONTRALATERAL
SYS DIFF (mmHg)
20
10
0
−10
−20
150
155
160
165
170
175
180
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
10
0
−10
−20
110
115
120
125
130
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
20
10
0
−10
−20
85
90
95
100
105
DIASTOLIC REFERENCE (mmHg)

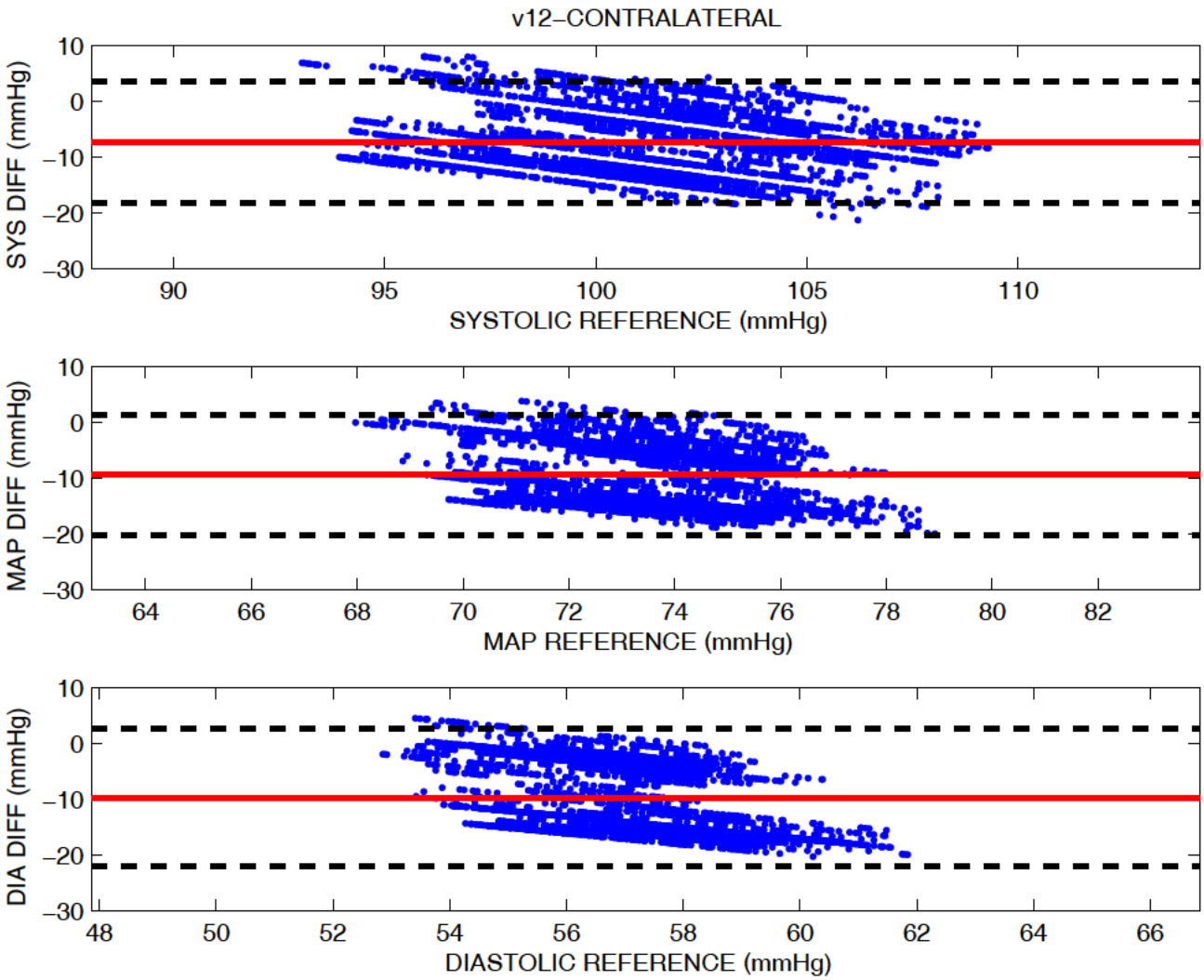

v09–IPSILATERAL
SYS DIFF (mmHg)
20
10
0
−10
−20
150
155
160
165
170
175
180
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
5
0
−5
−10
−15
110
115
120
125
130
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
86
88
90
92
94
96
98
100
102
104
106
DIASTOLIC REFERENCE (mmHg)

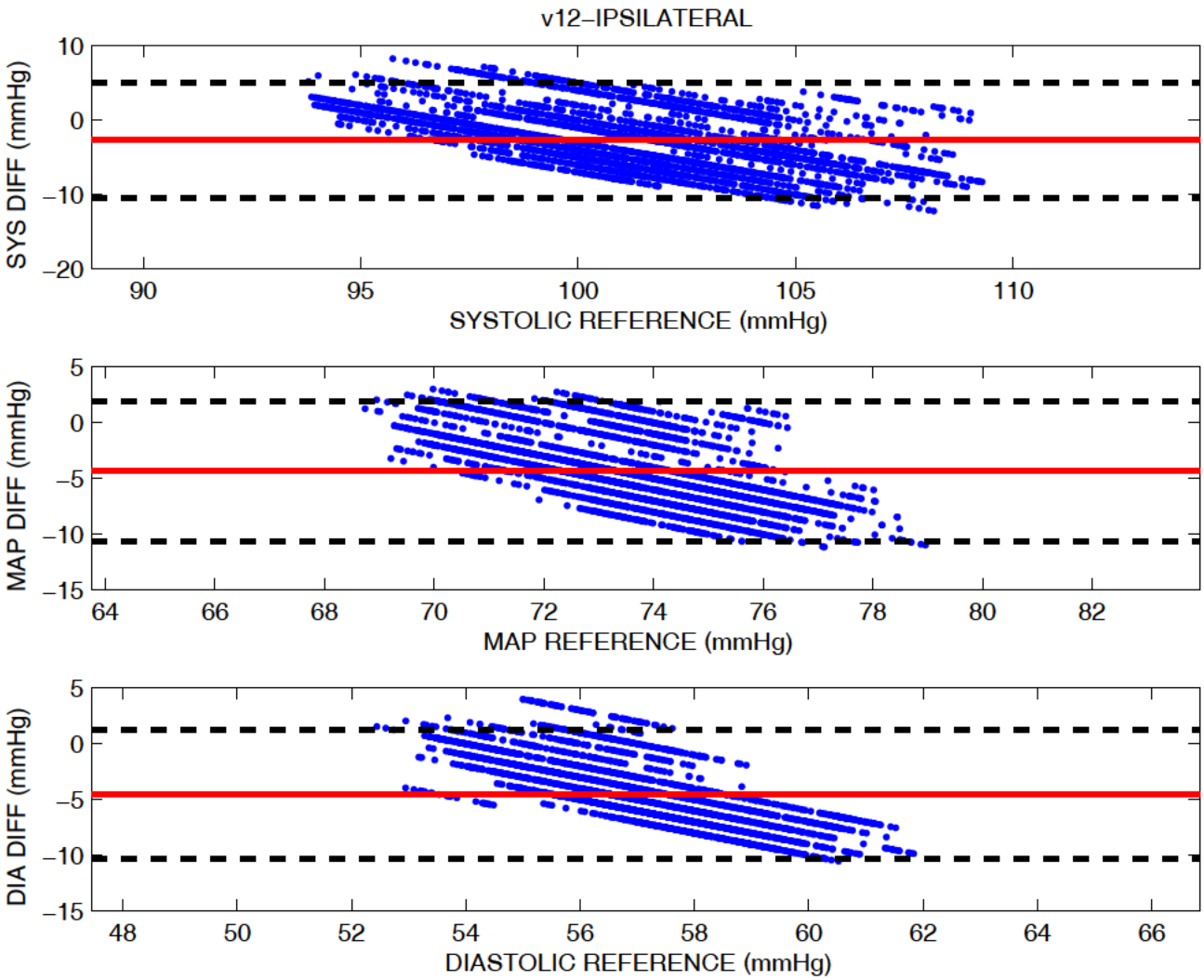

v10–CONTRALATERAL
SYS DIFF (mmHg)
40
20
0
−20
−40
150
155
160
165
170
175
180
185
190
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
40
20
0
−20
−40
115
120
125
130
135
140
145
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
20
0
−20
−40
90
95
100
105
110
115
120
DIASTOLIC REFERENCE (mmHg)

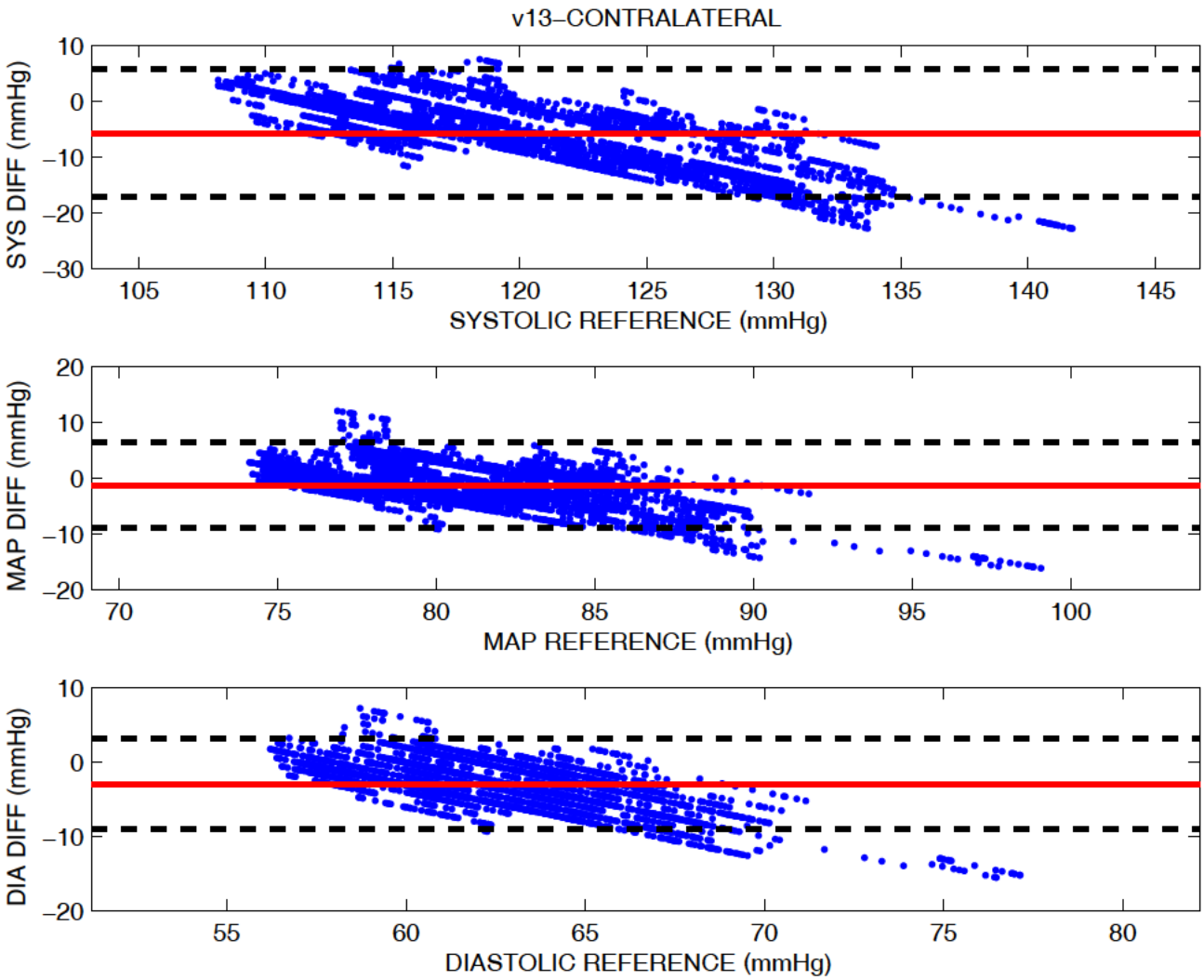

v10–IPSILATERAL
SYS DIFF (mmHg)
40
20
0
−20
150
155
160
165
170
175
180
185
190
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
0
−20
−40
115
120
125
130
135
140
145
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
20
0
−20
−40
90
95
100
105
110
115
DIASTOLIC REFERENCE (mmHg)

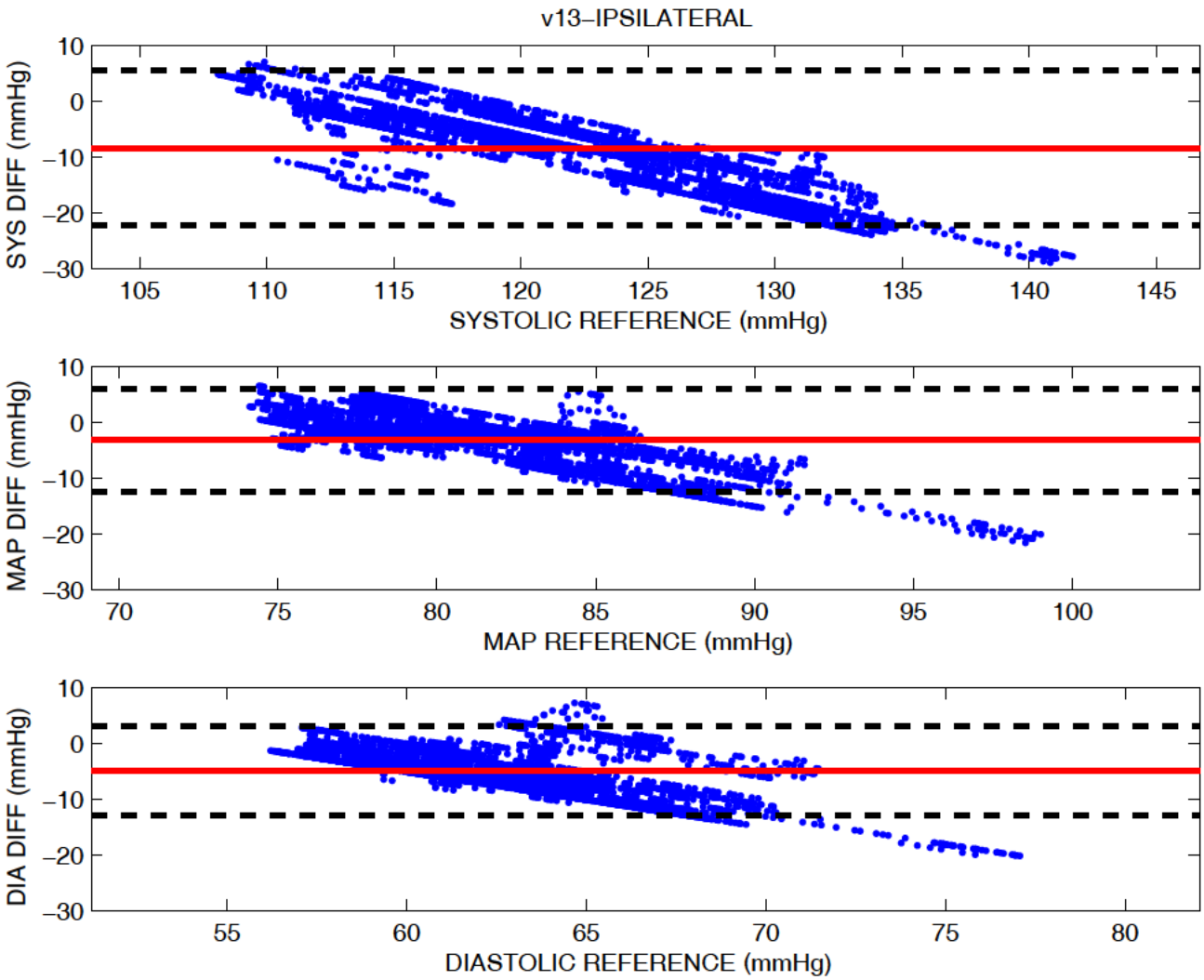

v11–CONTRALATERAL
SYS DIFF (mmHg)
20
0
–20
–40
150
155
160
165
170
175
180
185
190
195
200
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
10
0
–10
–20
100
105
110
115
120
125
130
135
140
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
–10
–20
–30
75
80
85
90
95
100
105
110
115
DIASTOLIC REFERENCE (mmHg)

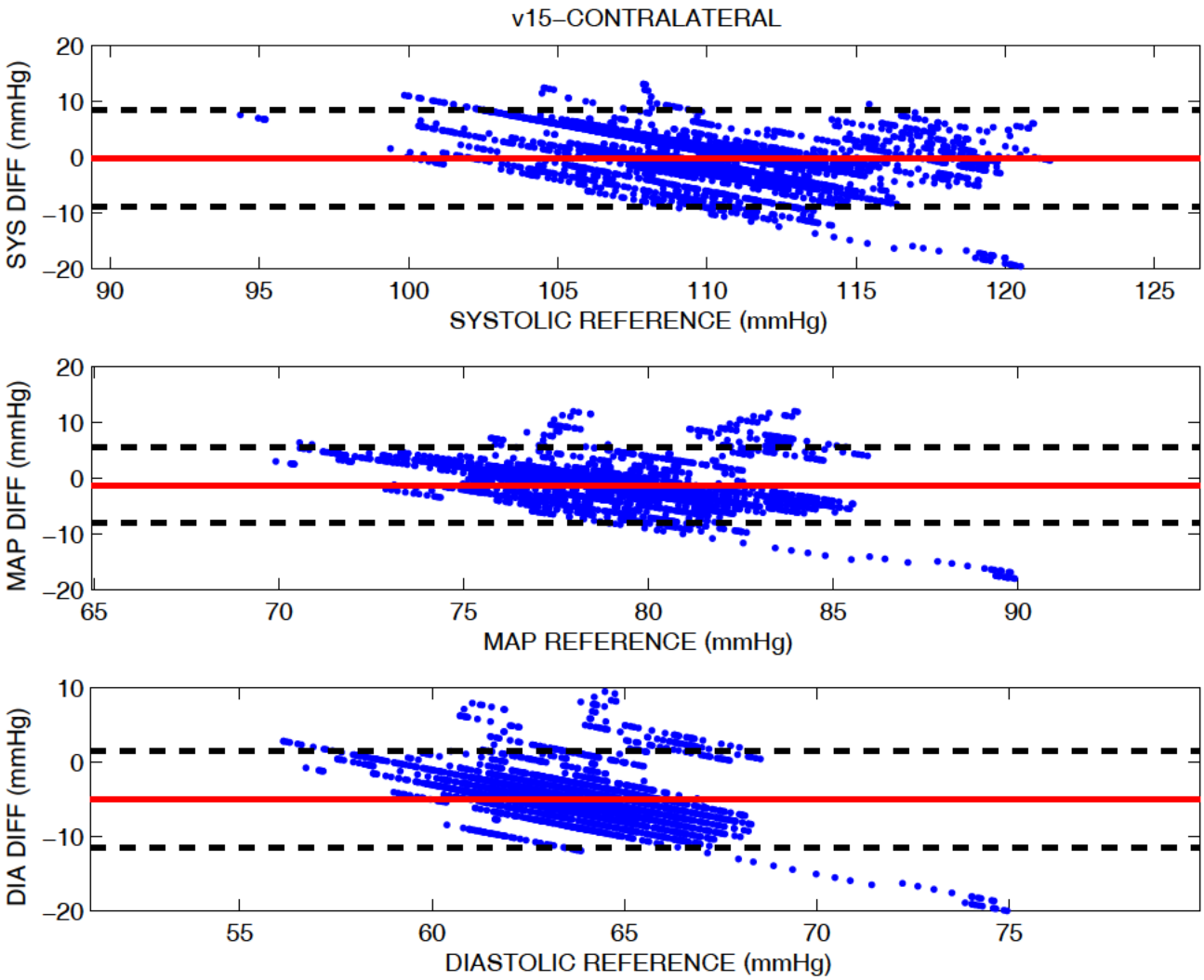

v11–IPSILATERAL
SYS DIFF (mmHg)
20
0
−20
−40
150
155
160
165
170
175
180
185
190
195
200
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
0
−20
−40
100
105
110
115
120
125
130
135
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
−30
75
80
85
90
95
100
105
DIASTOLIC REFERENCE (mmHg)

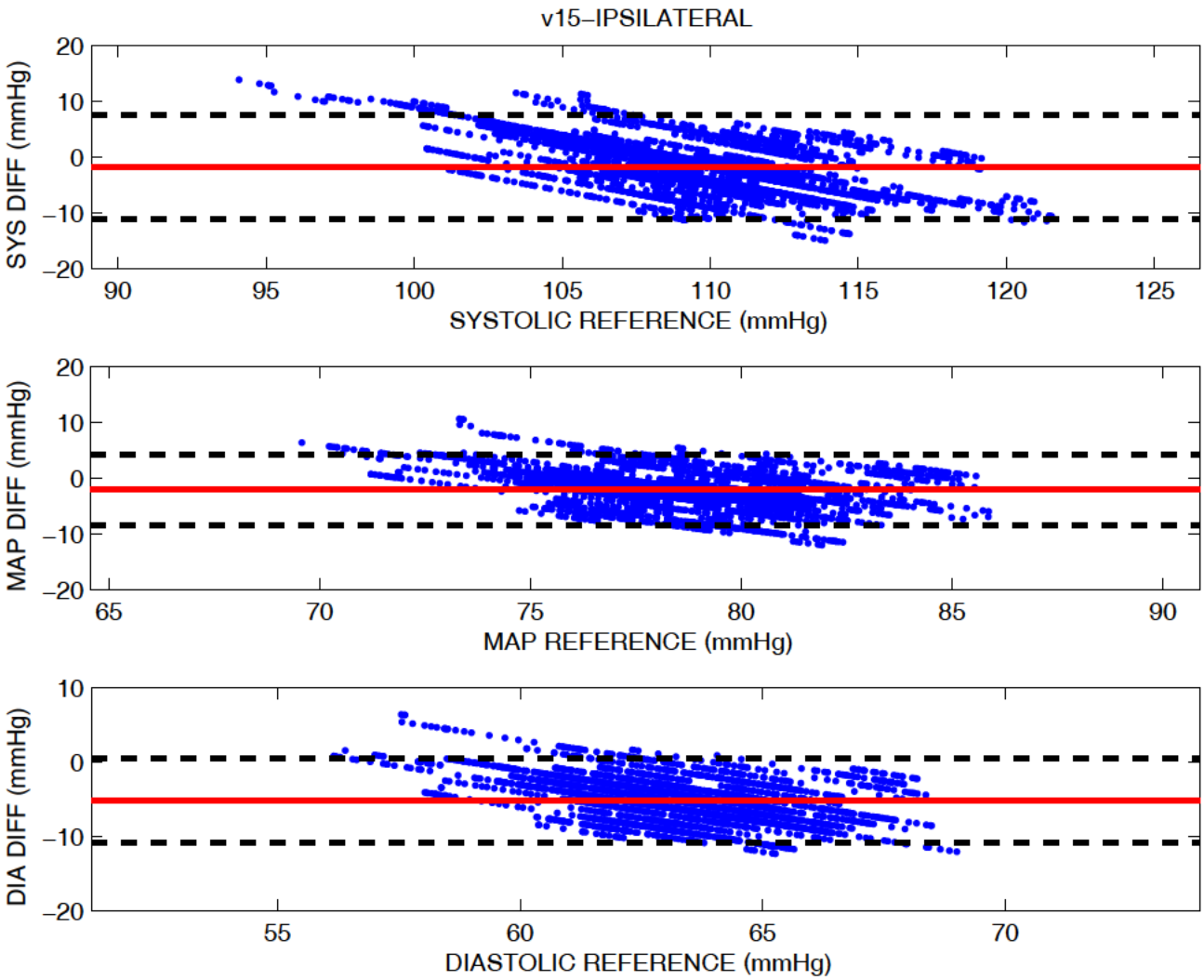

v12–CONTRALATERAL
SYS DIFF (mmHg)
10
0
−10
−20
−30
90
95
100
105
110
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
0
−10
−20
−30
64
66
68
70
72
74
76
78
80
82
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
−30
48
50
52
54
56
58
60
62
64
66
DIASTOLIC REFERENCE (mmHg)

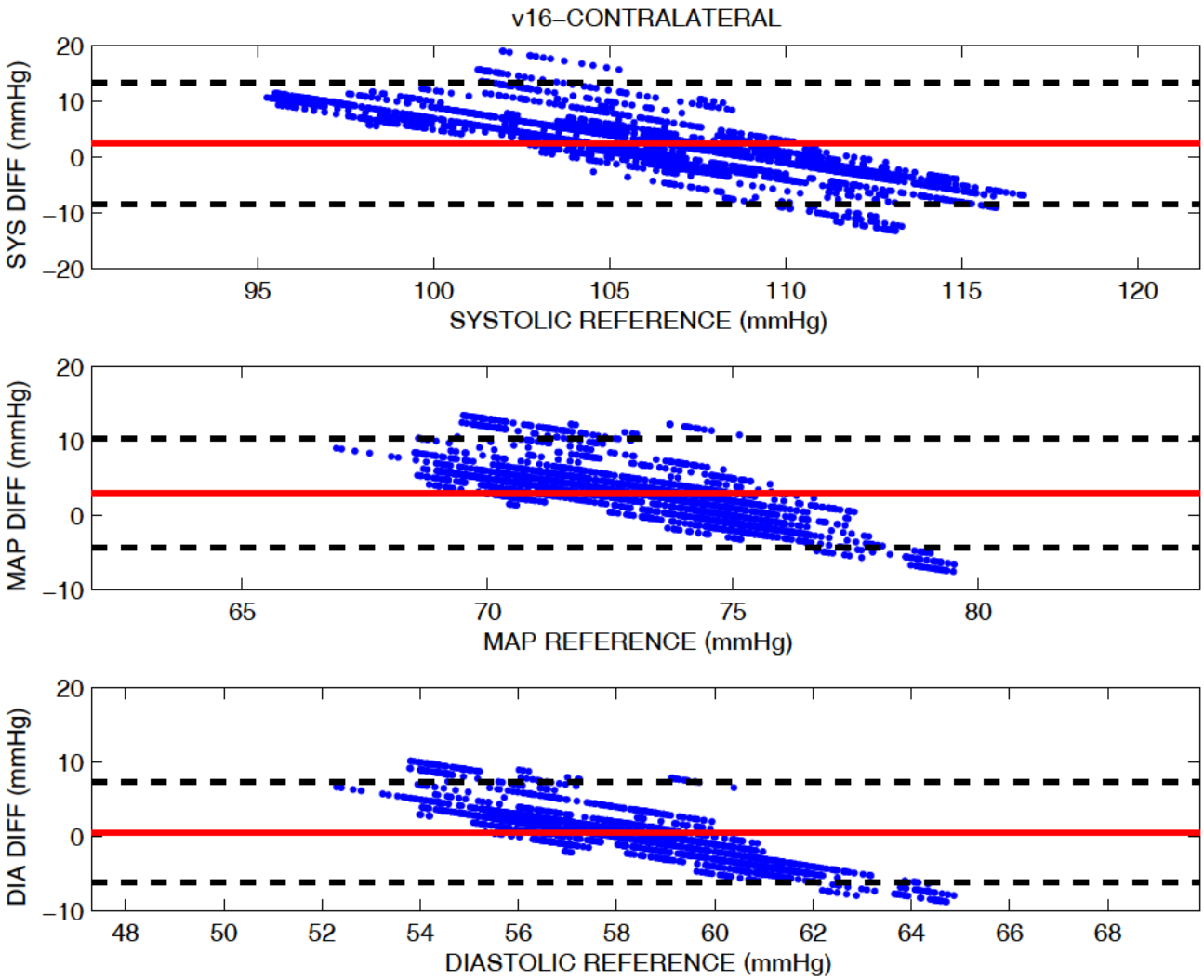

v12–IPSILATERAL
SYS DIFF (mmHg)
10
0
−10
−20
90
95
100
105
110
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
5
0
−5
−10
−15
64
66
68
70
72
74
76
78
80
82
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
5
0
−5
−10
−15
48
50
52
54
56
58
60
62
64
66
DIASTOLIC REFERENCE (mmHg)

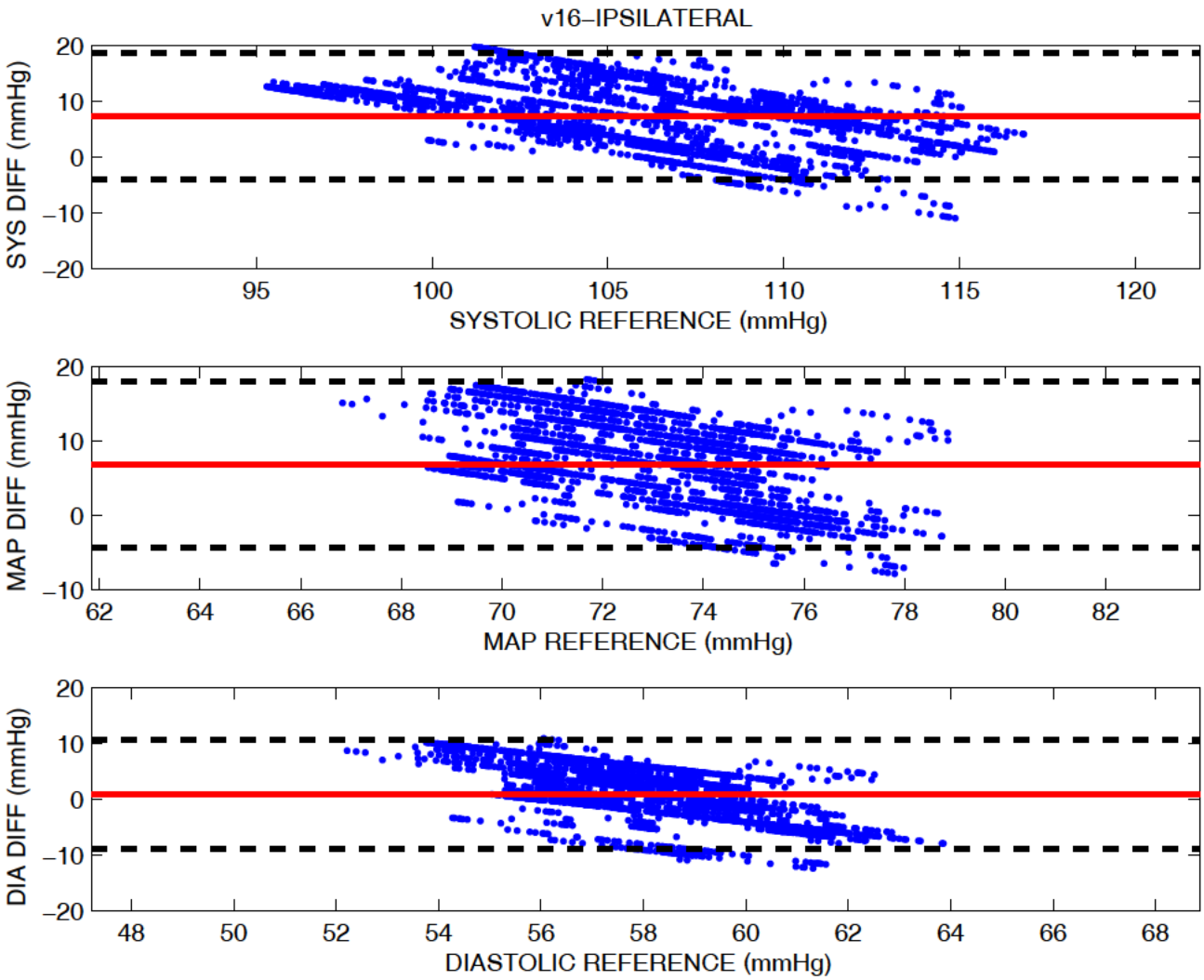

v13–CONTRALATERAL
SYS DIFF (mmHg)
10
0
−10
−20
−30
105
110
115
120
125
130
135
140
145
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
10
0
−10
−20
70
75
80
85
90
95
100
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
55
60
65
70
75
80
DIASTOLIC REFERENCE (mmHg)

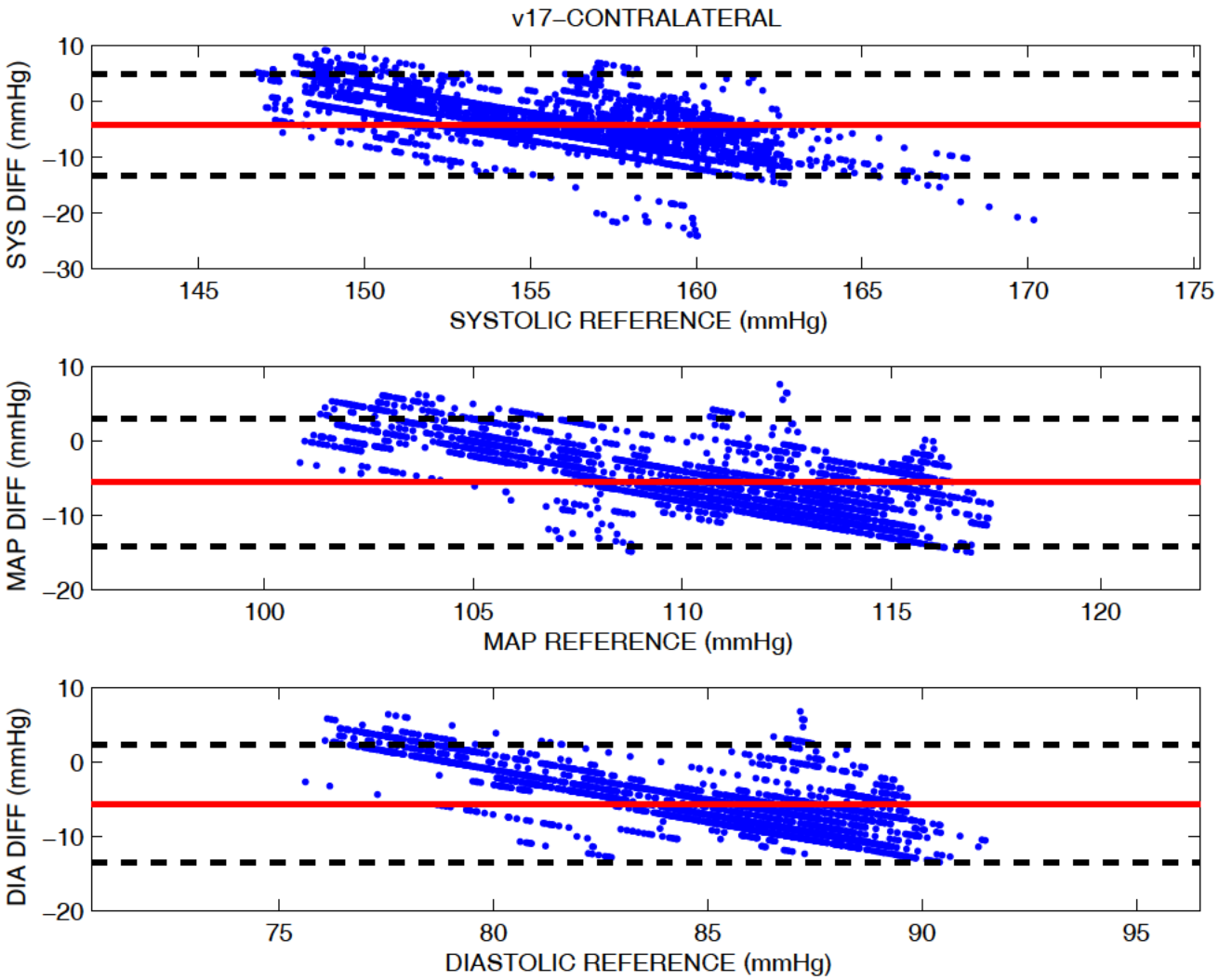

v13–IPSILATERAL
SYS DIFF (mmHg)
10
0
−10
−20
−30
105
110
115
120
125
130
135
140
145
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
0
−10
−20
−30
70
75
80
85
90
95
100
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
−30
55
60
65
70
75
80
DIASTOLIC REFERENCE (mmHg)


v15–CONTRALATERAL
SYS DIFF (mmHg)
20
10
0
−10
−20
90
95
100
105
110
115
120
125
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
10
0
−10
−20
65
70
75
80
85
90
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
55
60
65
70
75
DIASTOLIC REFERENCE (mmHg)


v15–IPSILATERAL
SYS DIFF (mmHg)
20
10
0
−10
−20
90
95
100
105
110
115
120
125
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
10
0
−10
−20
65
70
75
80
85
90
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
55
60
65
70
DIASTOLIC REFERENCE (mmHg)


v16–CONTRALATERAL
SYS DIFF (mmHg)
20
10
0
−10
−20
95
100
105
110
115
120
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
10
0
−10
65
70
75
80
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
20
10
0
−10
48
50
52
54
56
58
60
62
64
66
68
DIASTOLIC REFERENCE (mmHg)


v16–IPSILATERAL
SYS DIFF (mmHg)
20
10
0
−10
−20
95
100
105
110
115
120
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
10
0
−10
62
64
66
68
70
72
74
76
78
80
82
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
20
10
0
−10
−20
48
50
52
54
56
58
60
62
64
66
68
DIASTOLIC REFERENCE (mmHg)


v17–CONTRALATERAL
SYS DIFF (mmHg)
10
0
−10
−20
−30
145
150
155
160
165
170
175
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
10
0
−10
−20
100
105
110
115
120
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
10
0
−10
−20
75
80
85
90
95
DIASTOLIC REFERENCE (mmHg)

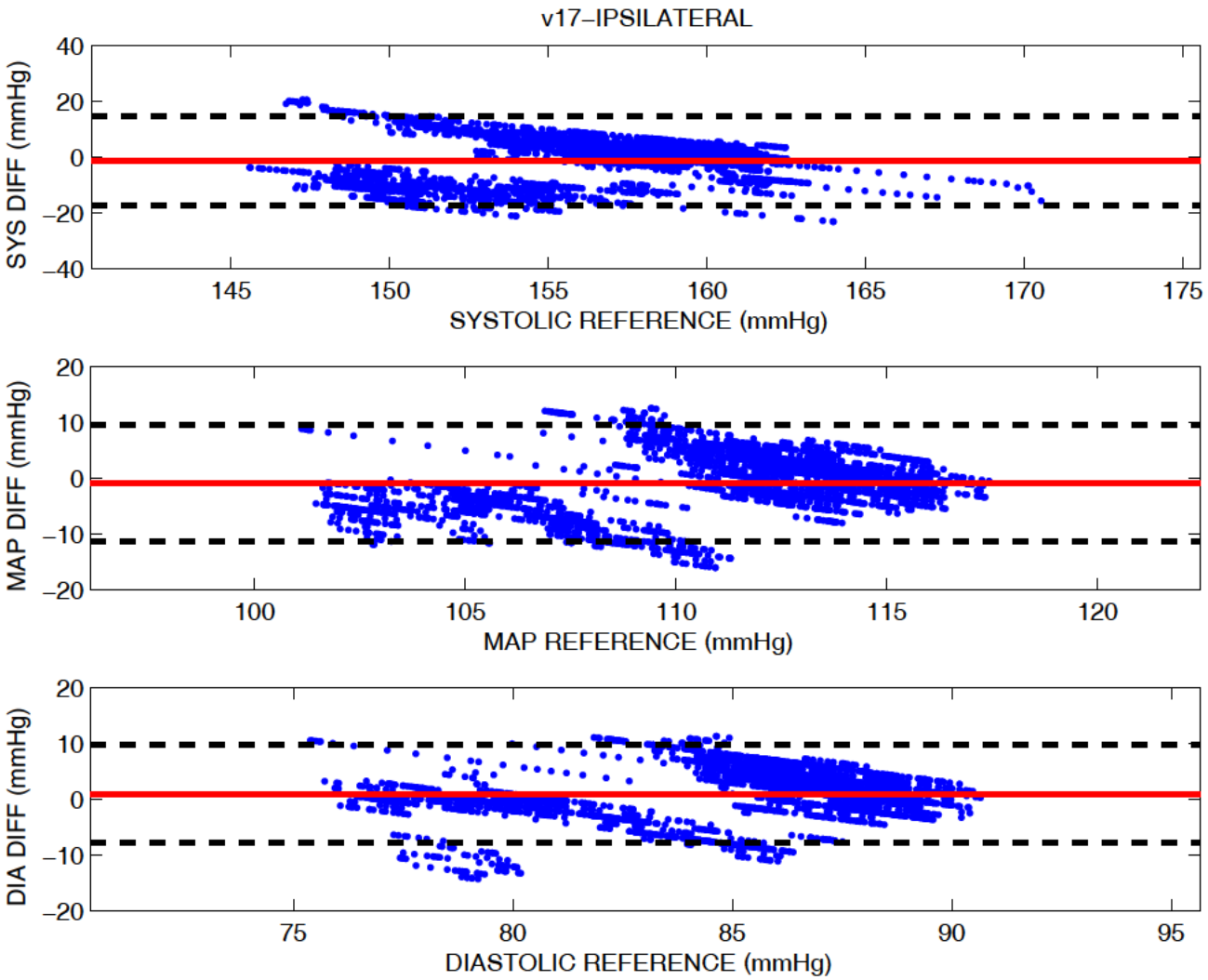

v17–IPSILATERAL
SYS DIFF (mmHg)
40
20
0
−20
−40
145
150
155
160
165
170
175
SYSTOLIC REFERENCE (mmHg)
MAP DIFF (mmHg)
20
10
0
−10
−20
100
105
110
115
120
MAP REFERENCE (mmHg)
DIA DIFF (mmHg)
20
10
0
−10
−20
75
80
85
90
95
DIASTOLIC REFERENCE (mmHg)

Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

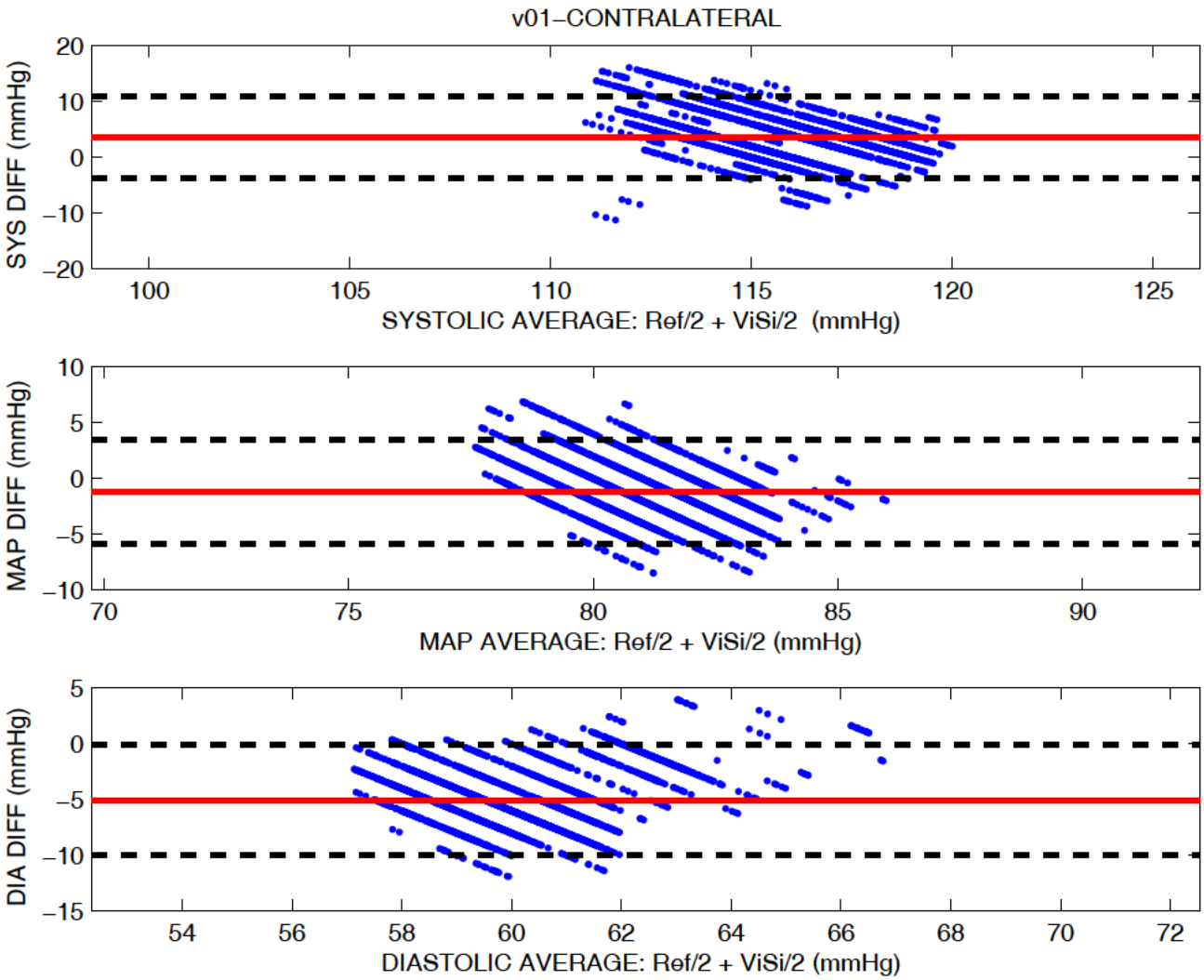


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

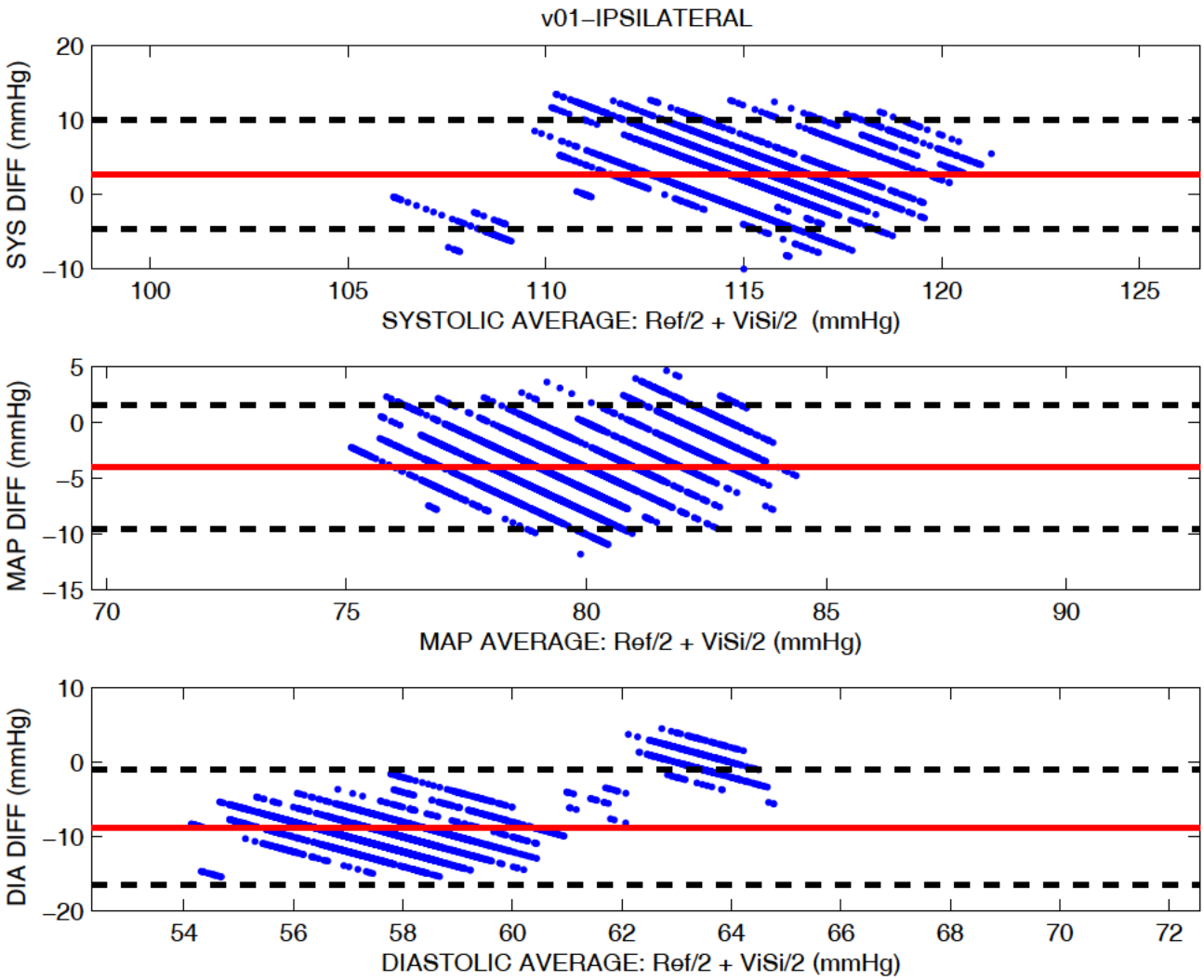


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

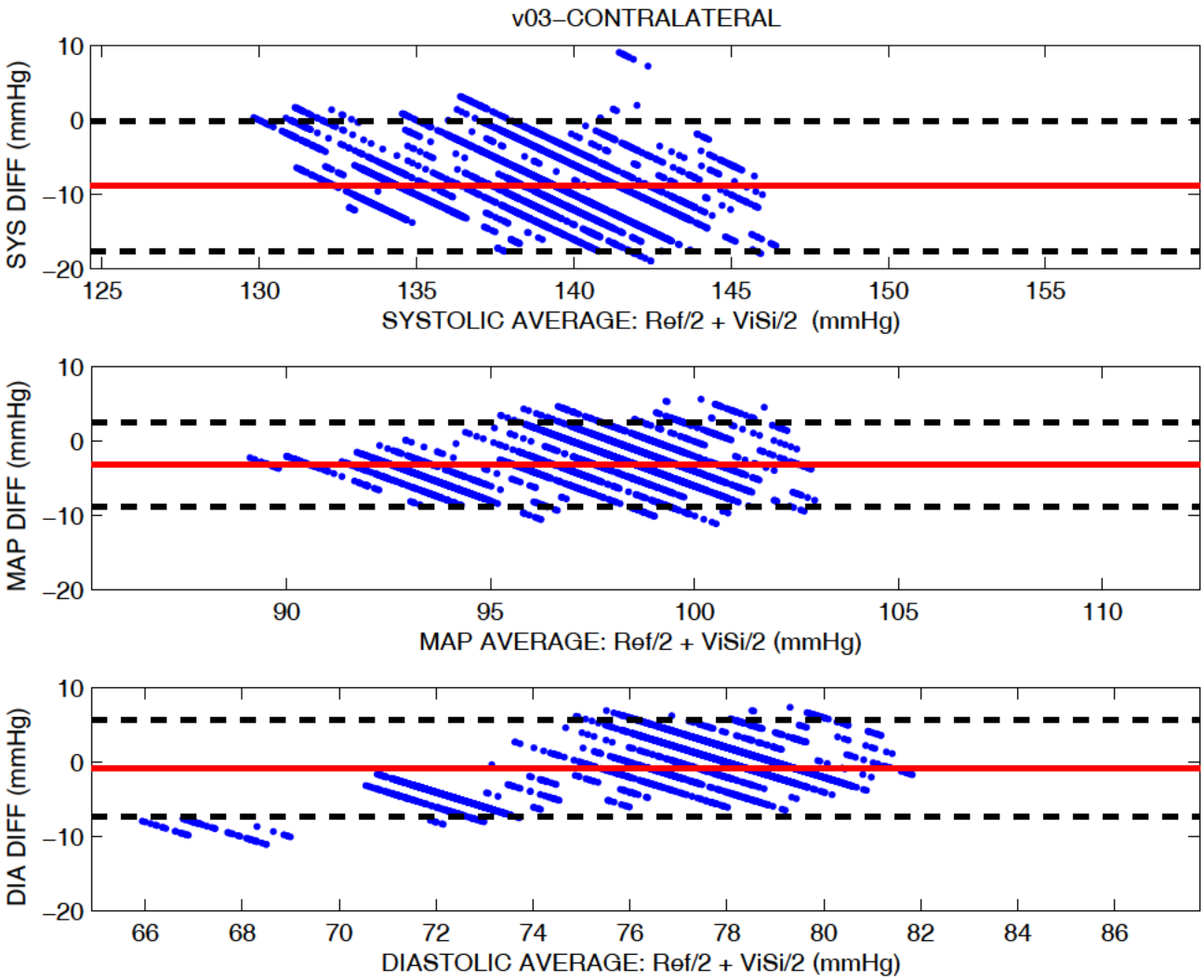


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

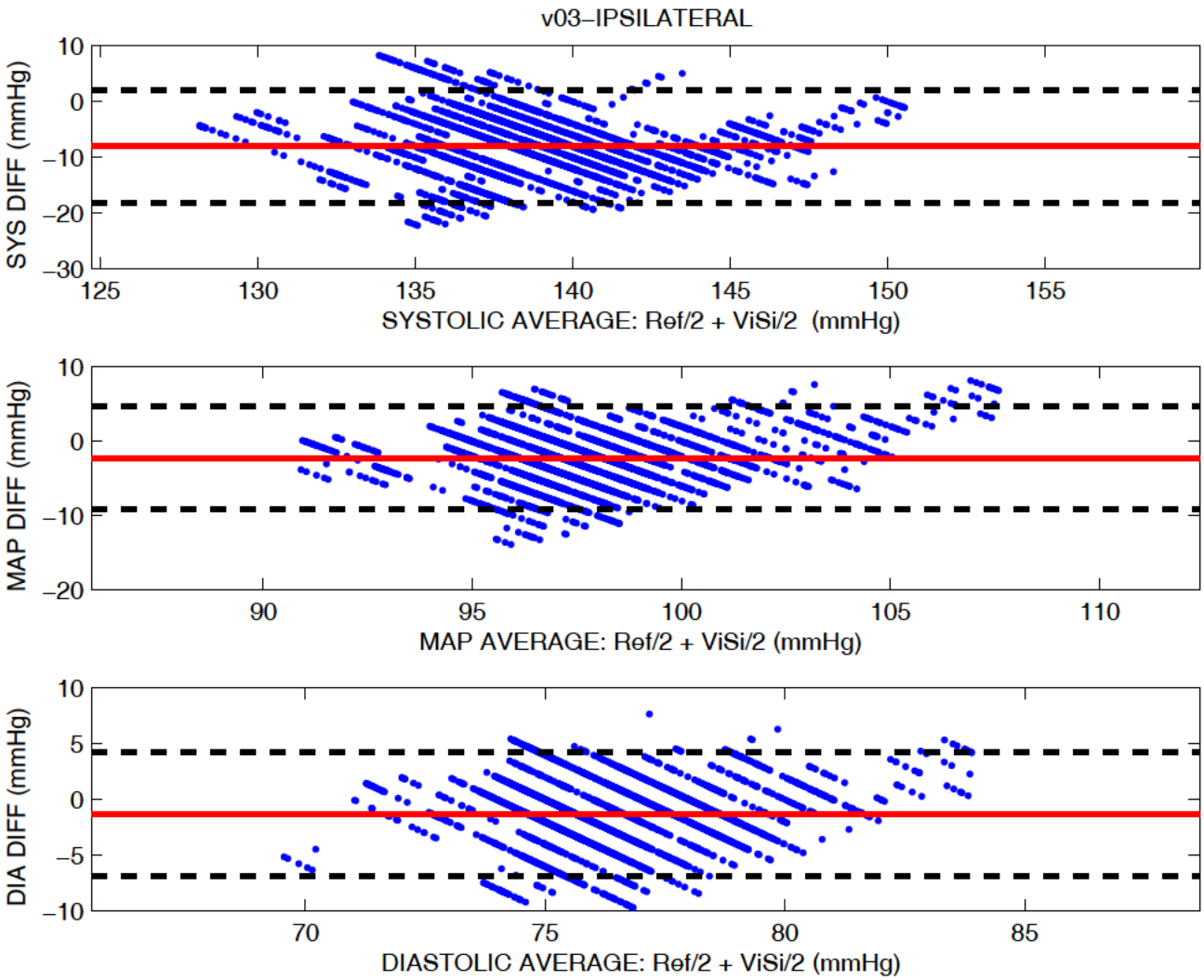


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

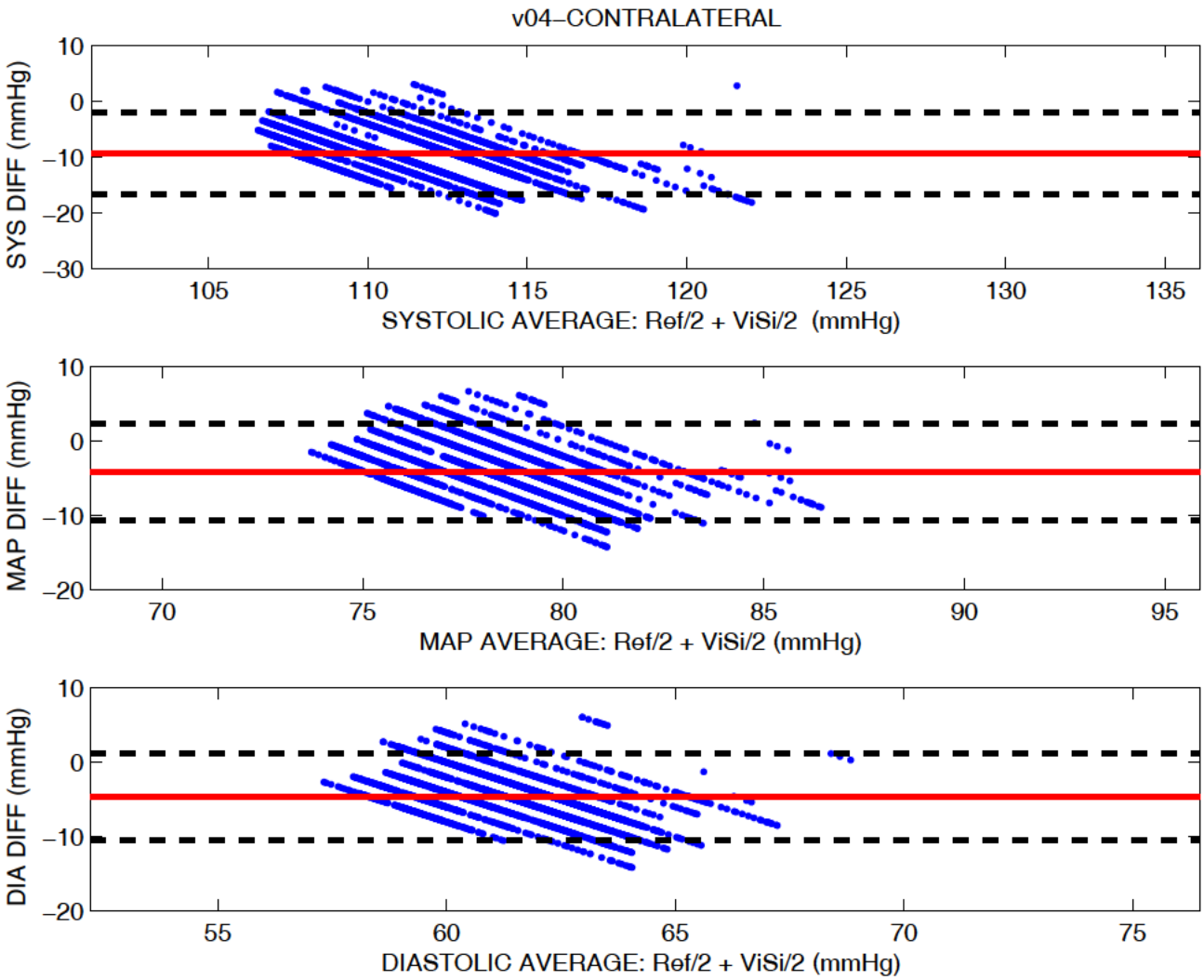


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

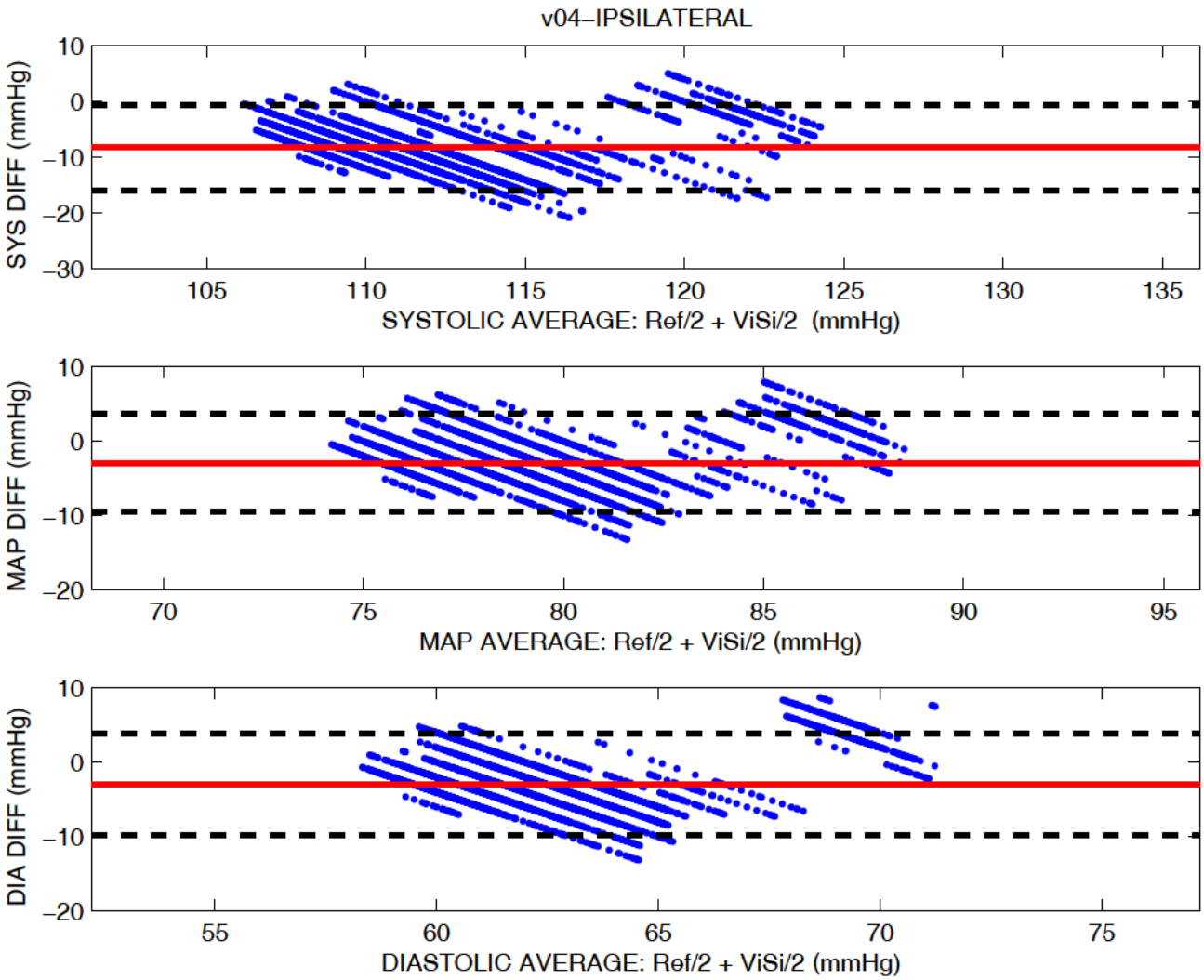


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

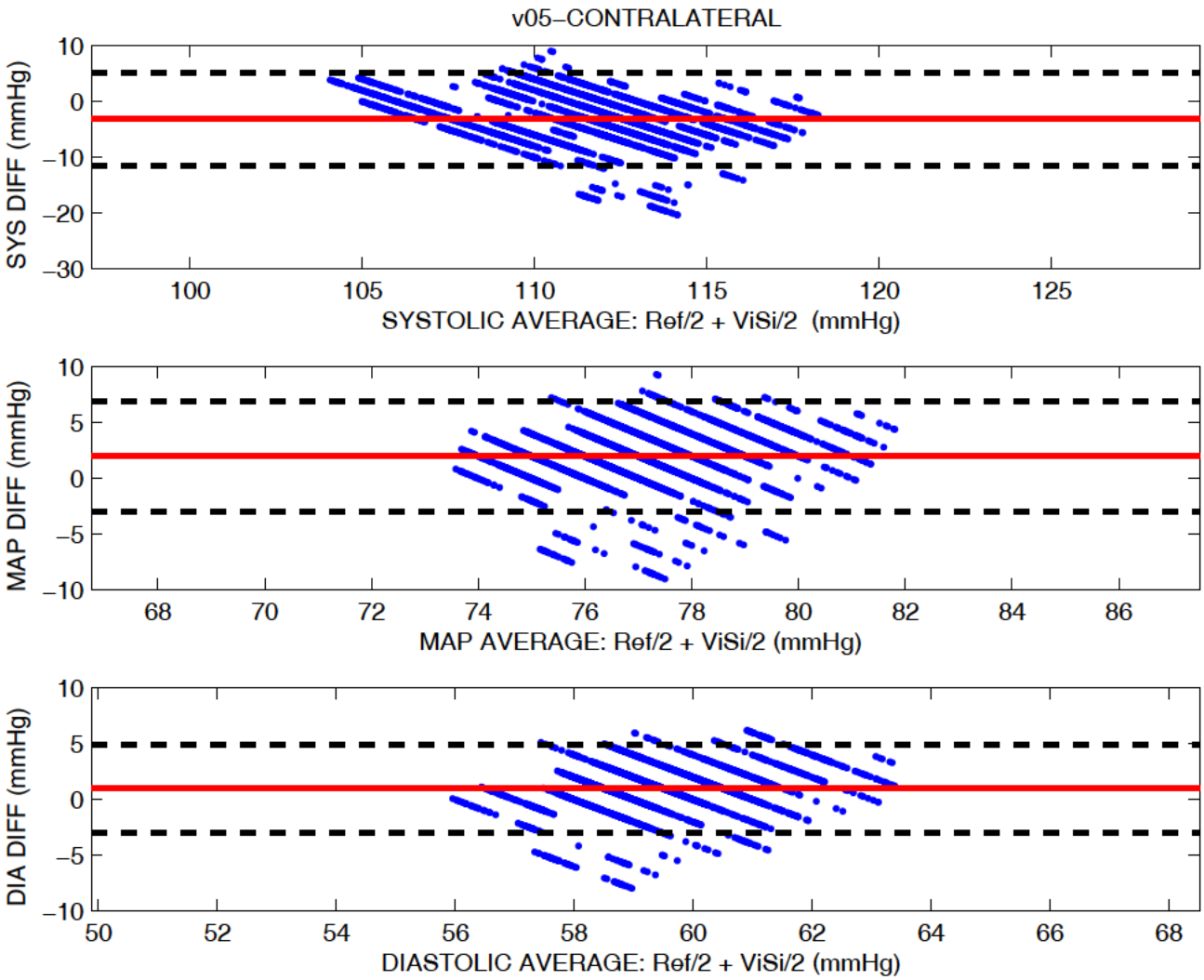


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

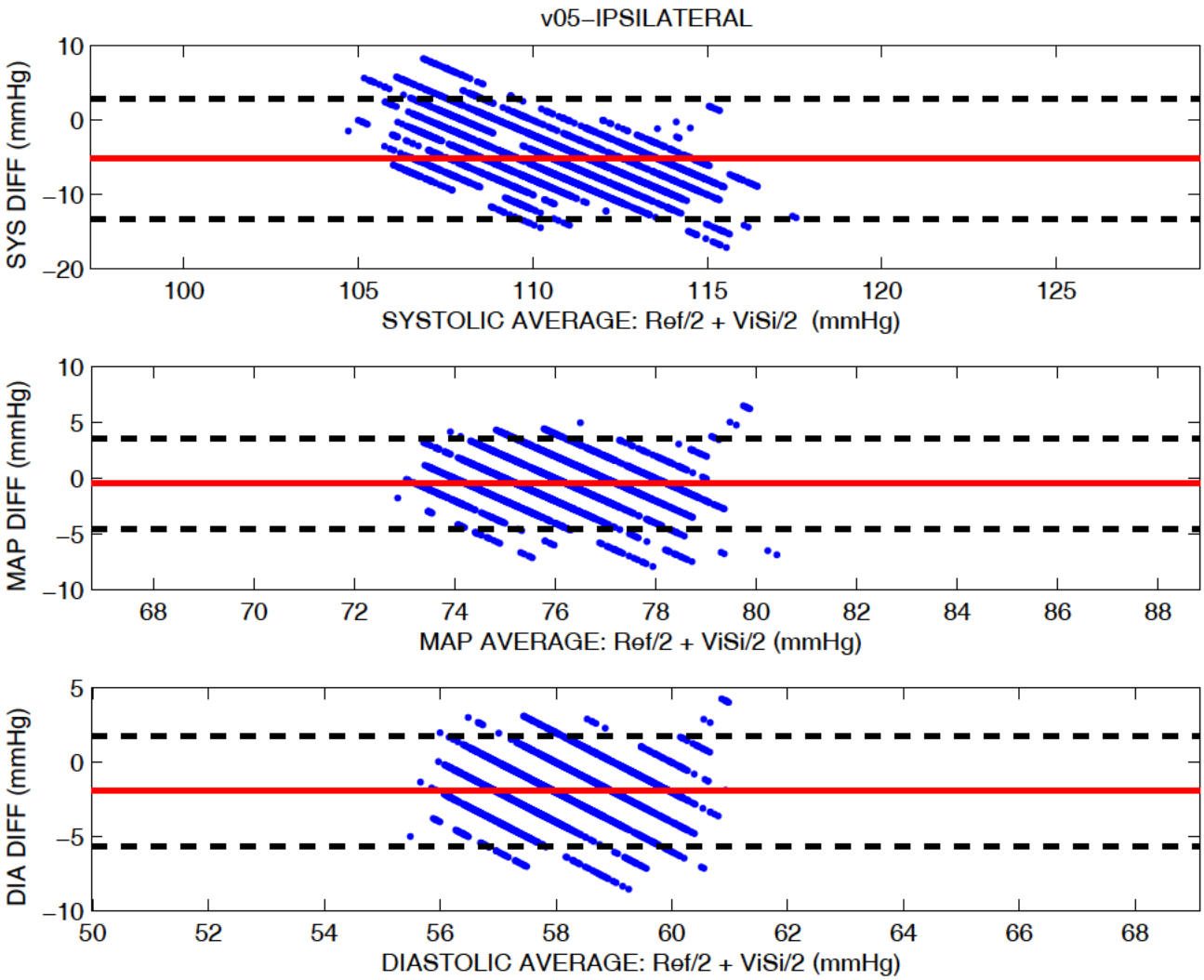


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

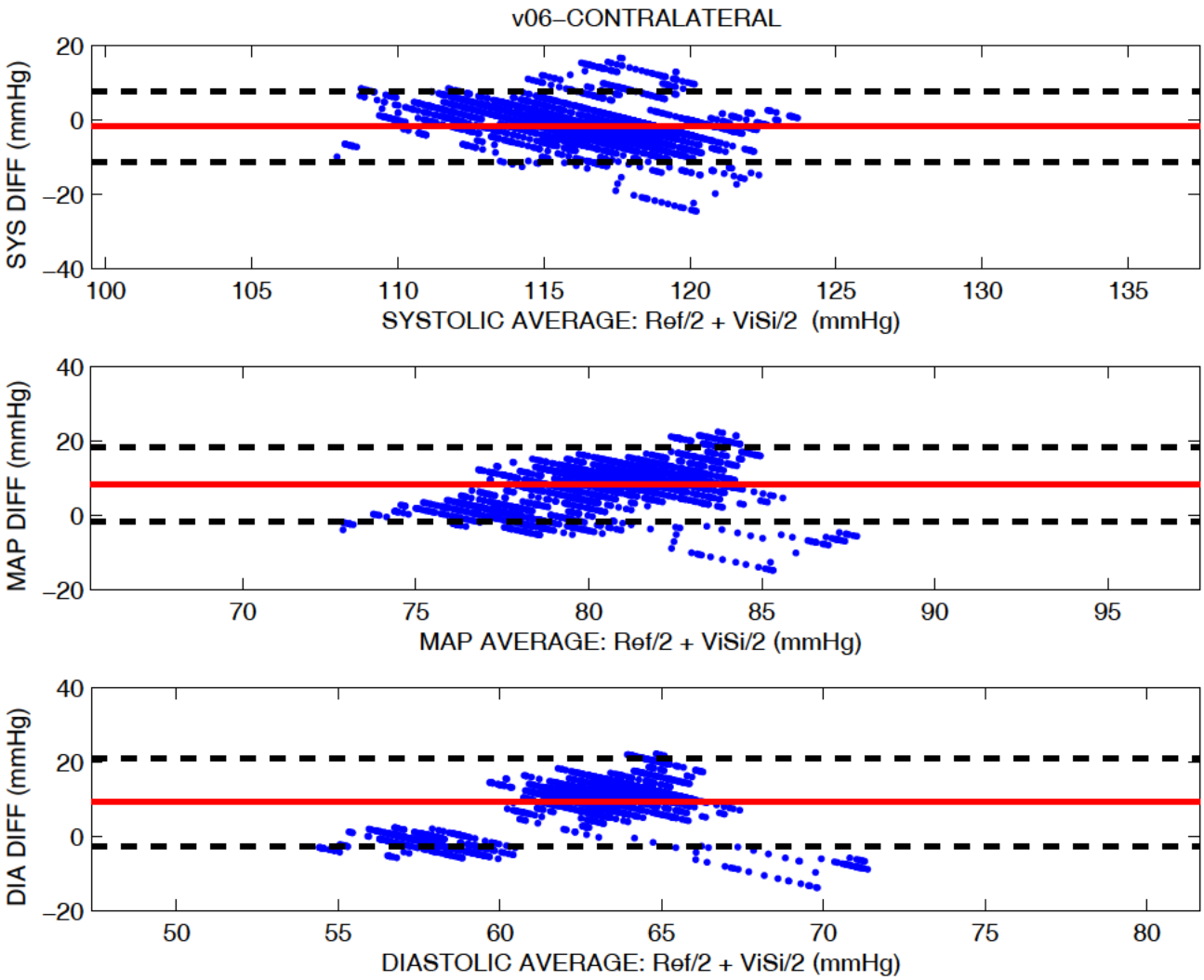


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

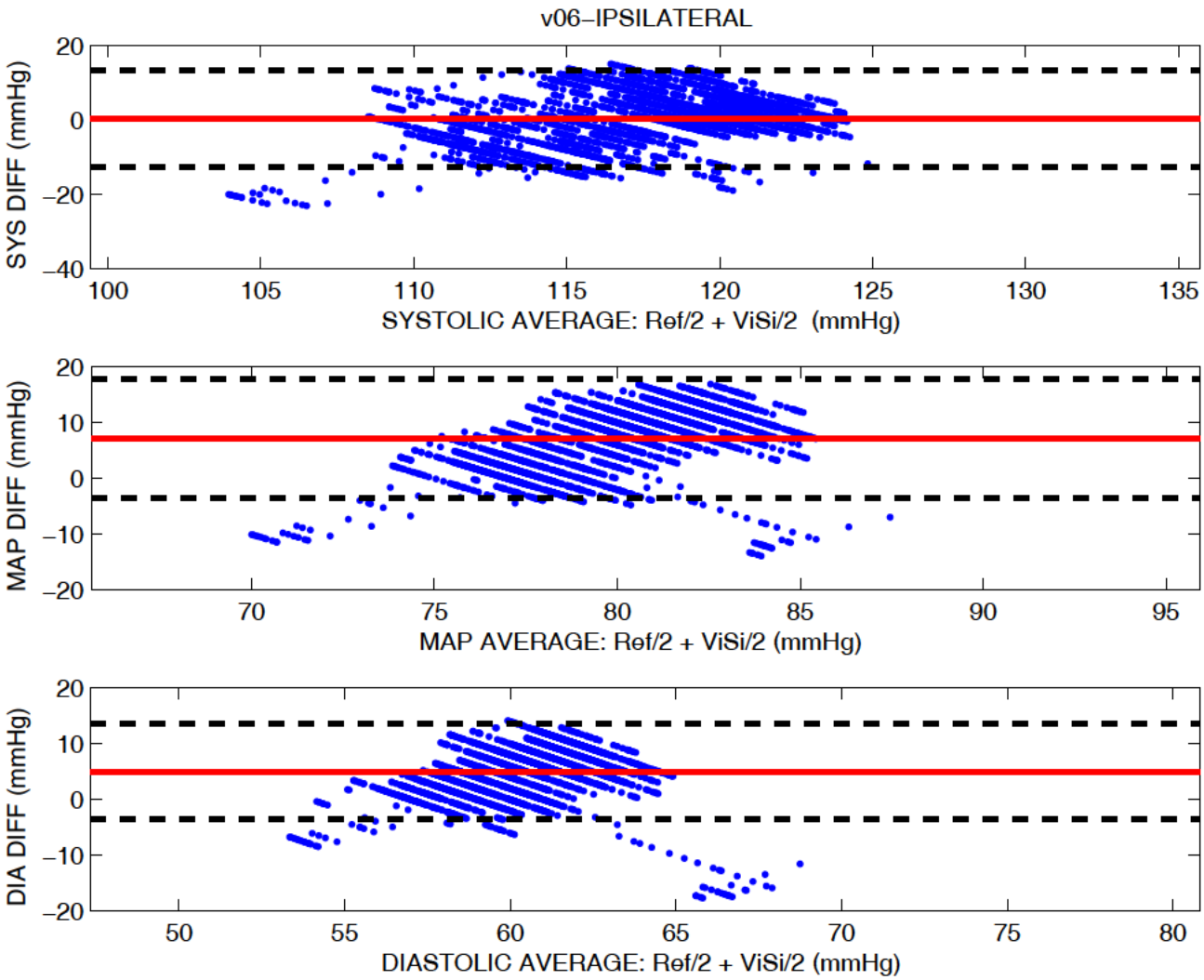


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

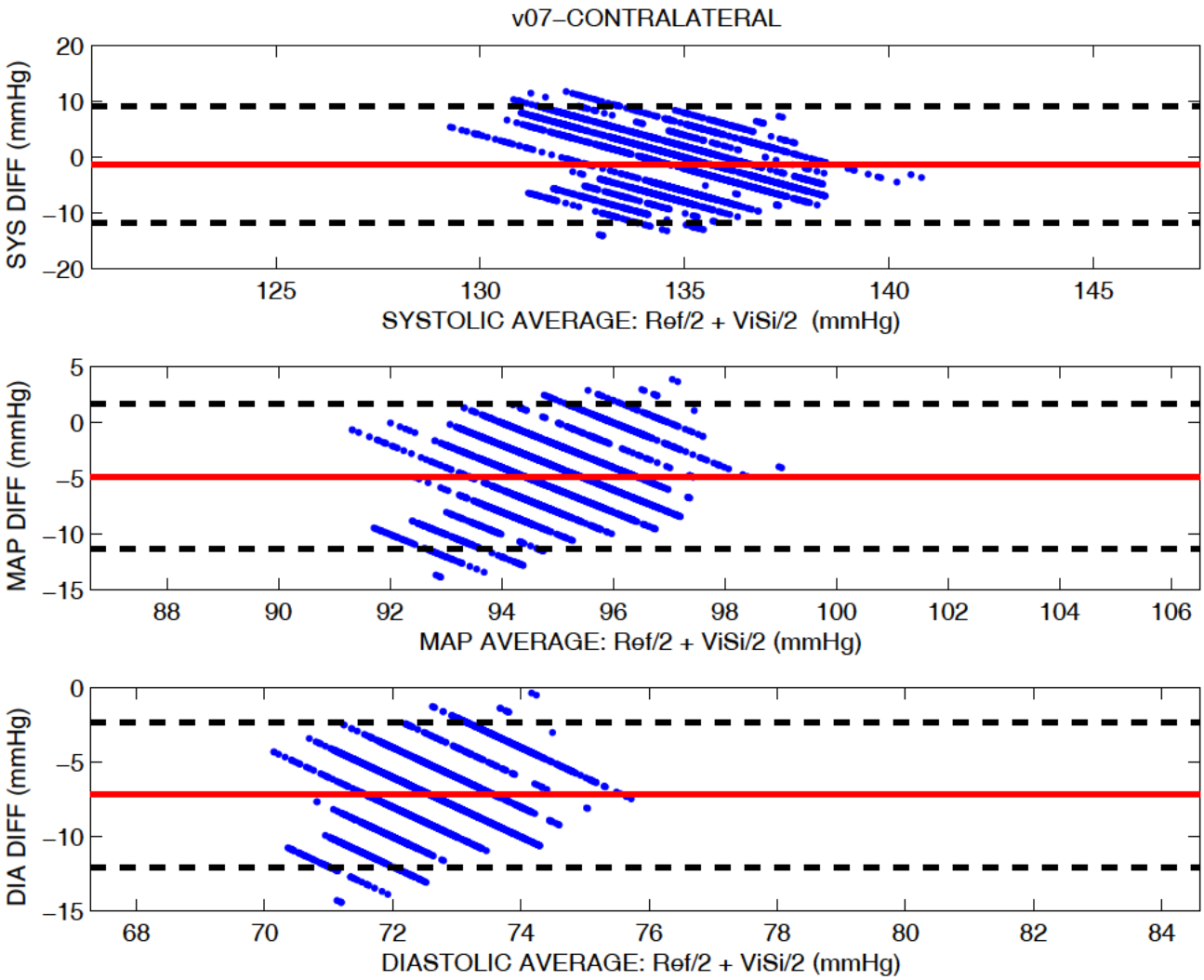


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

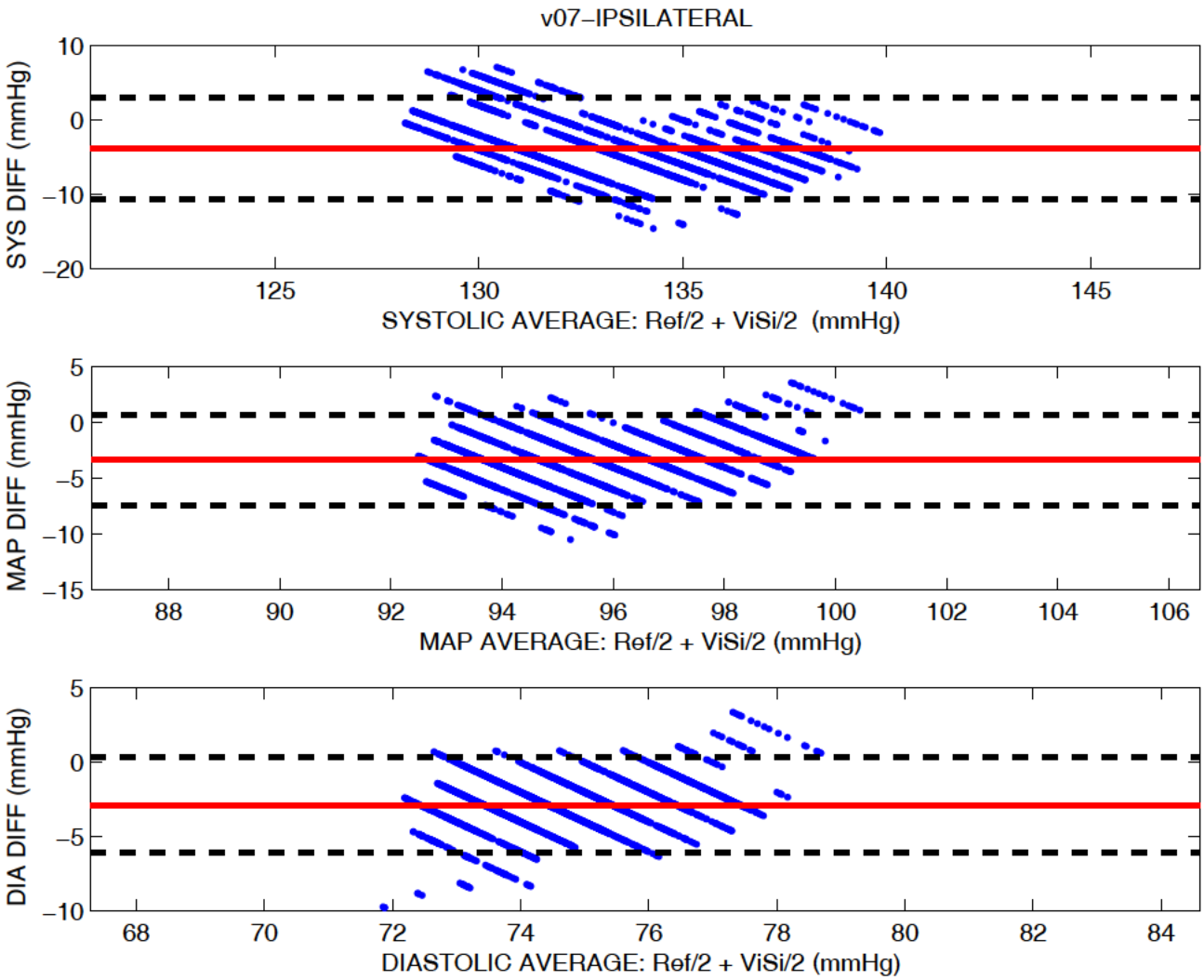


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

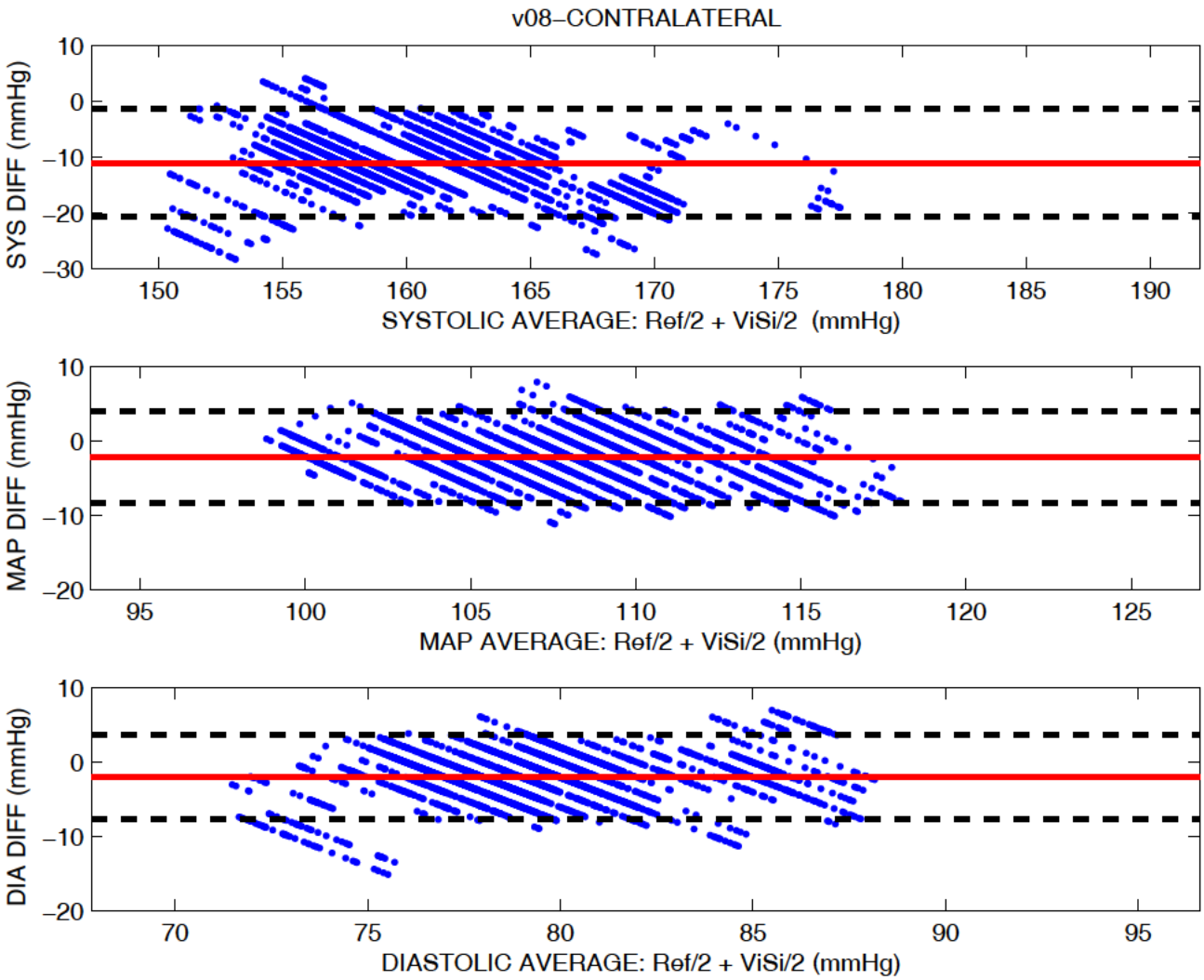


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

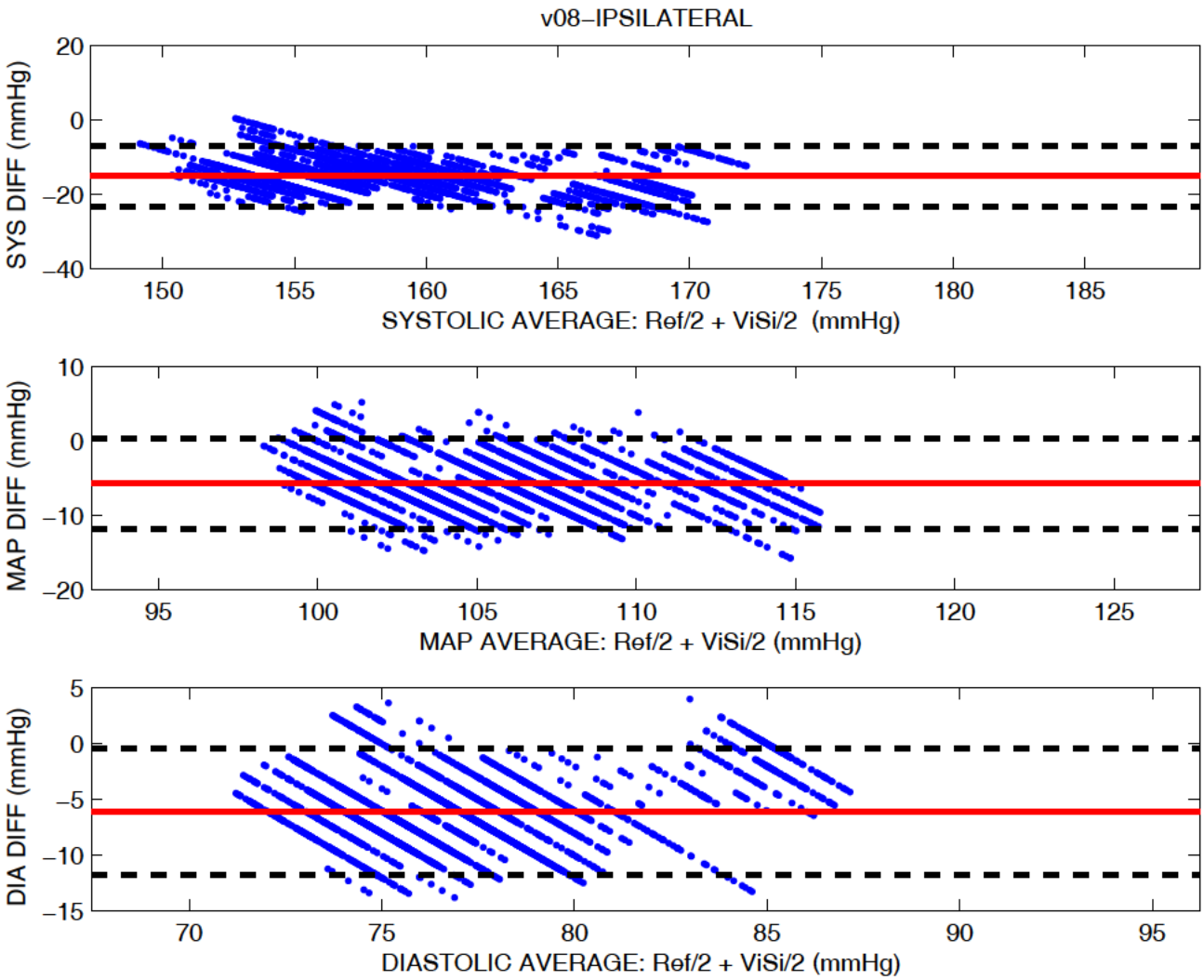


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

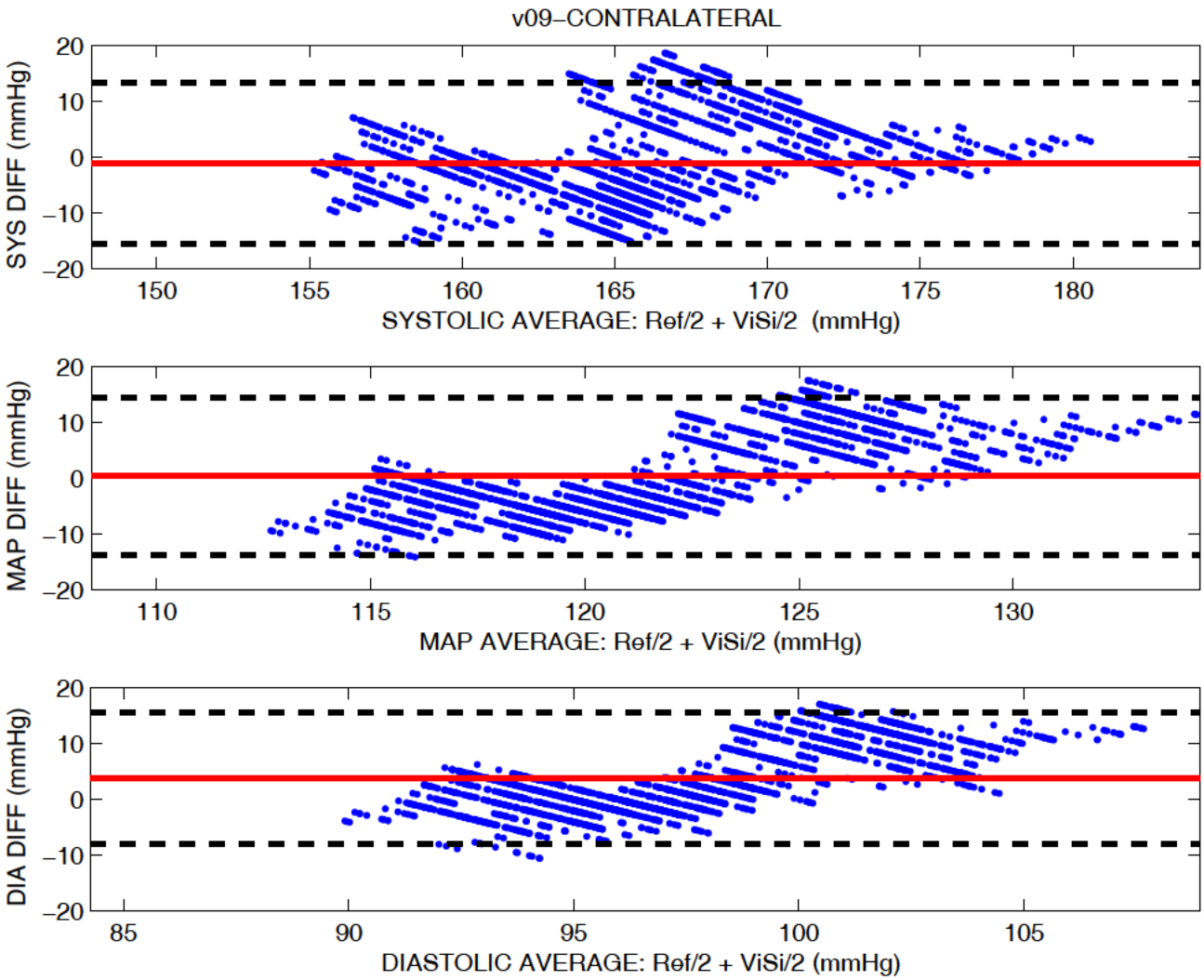


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

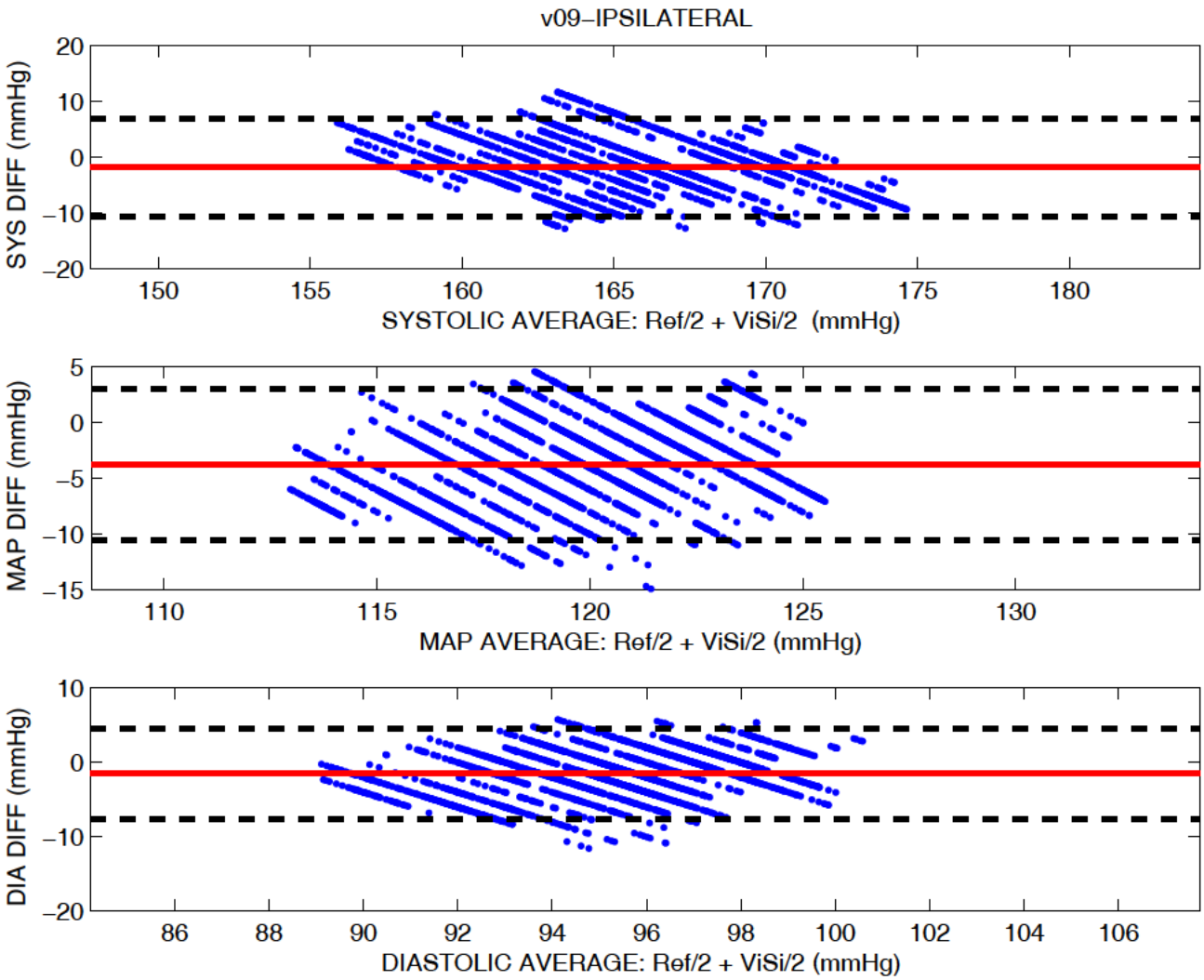


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

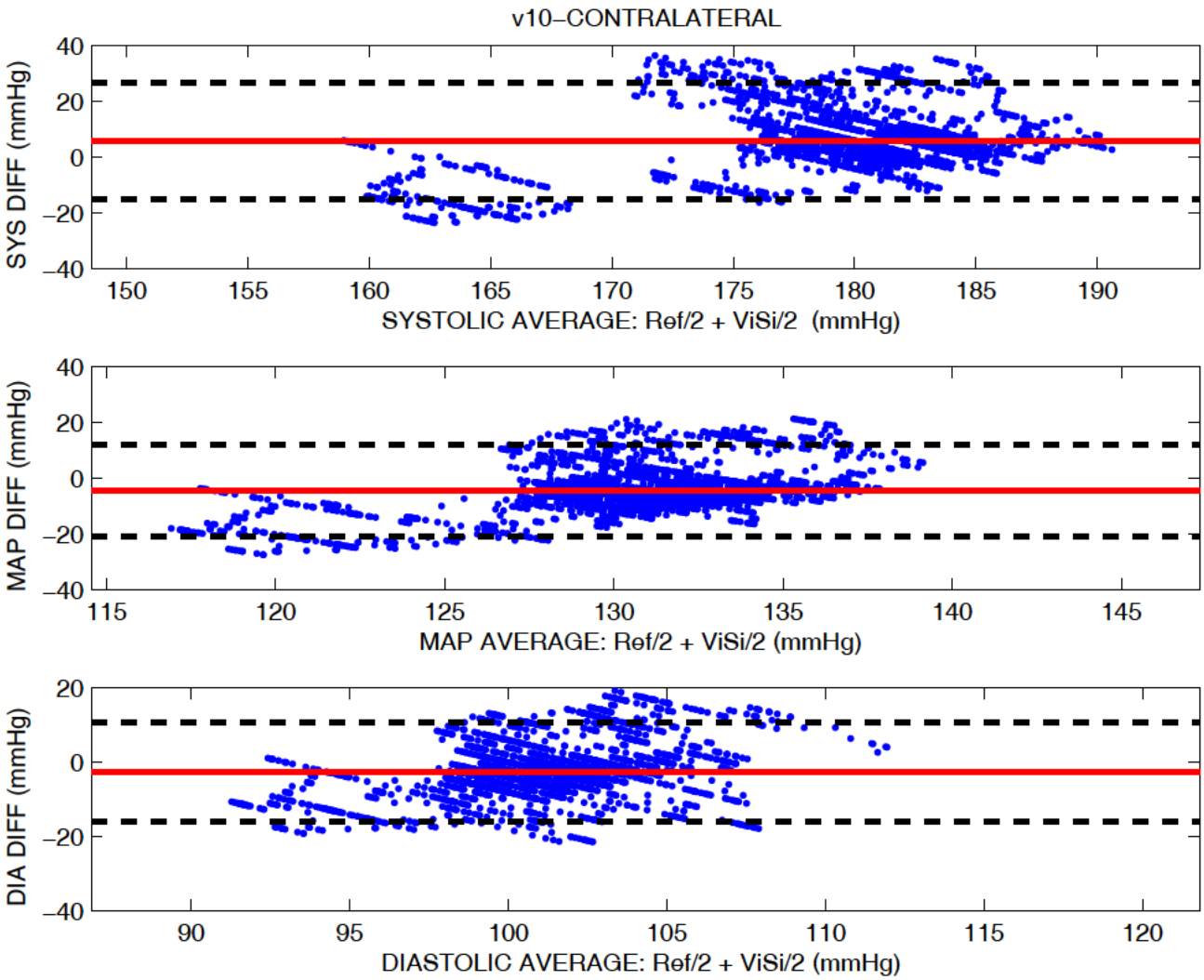


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

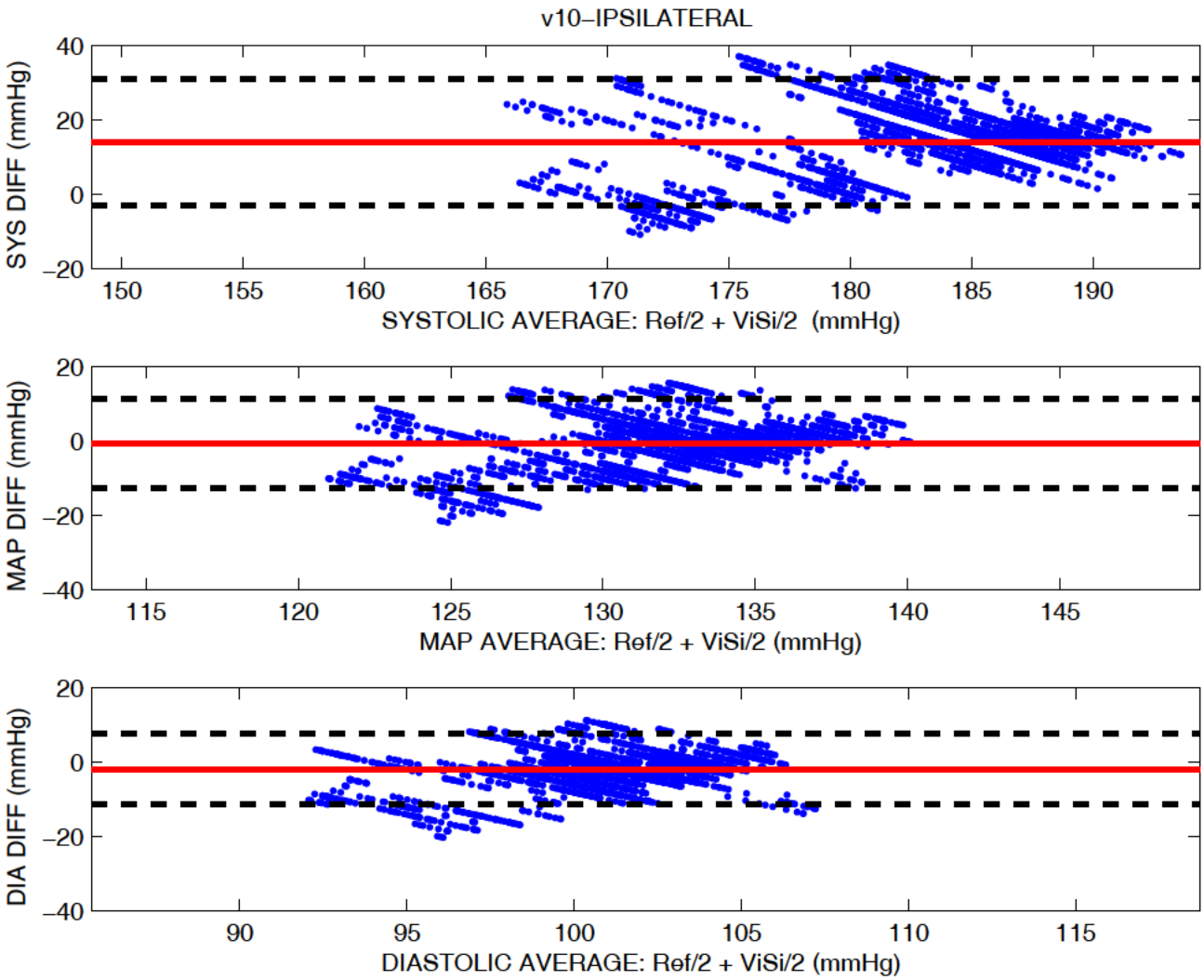


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

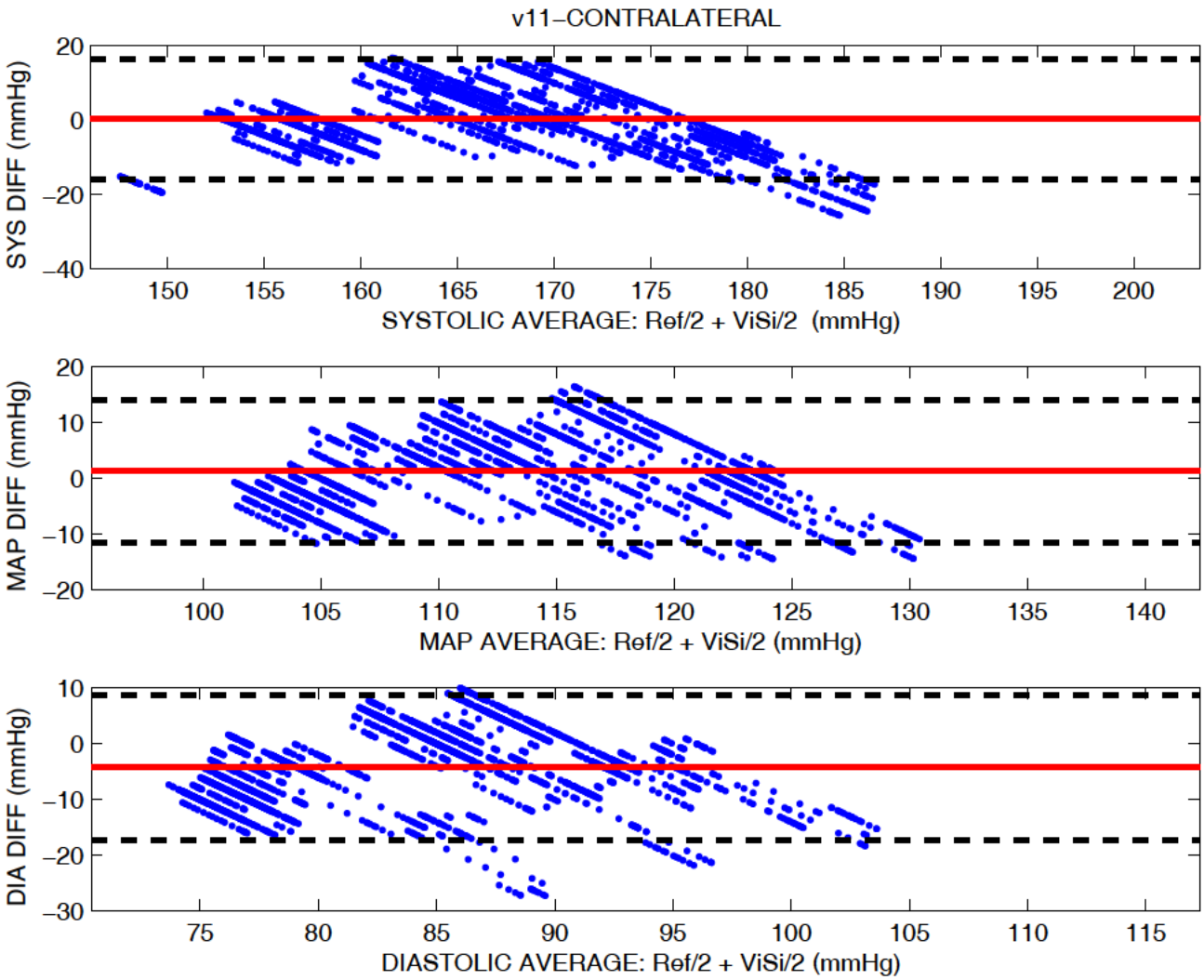


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

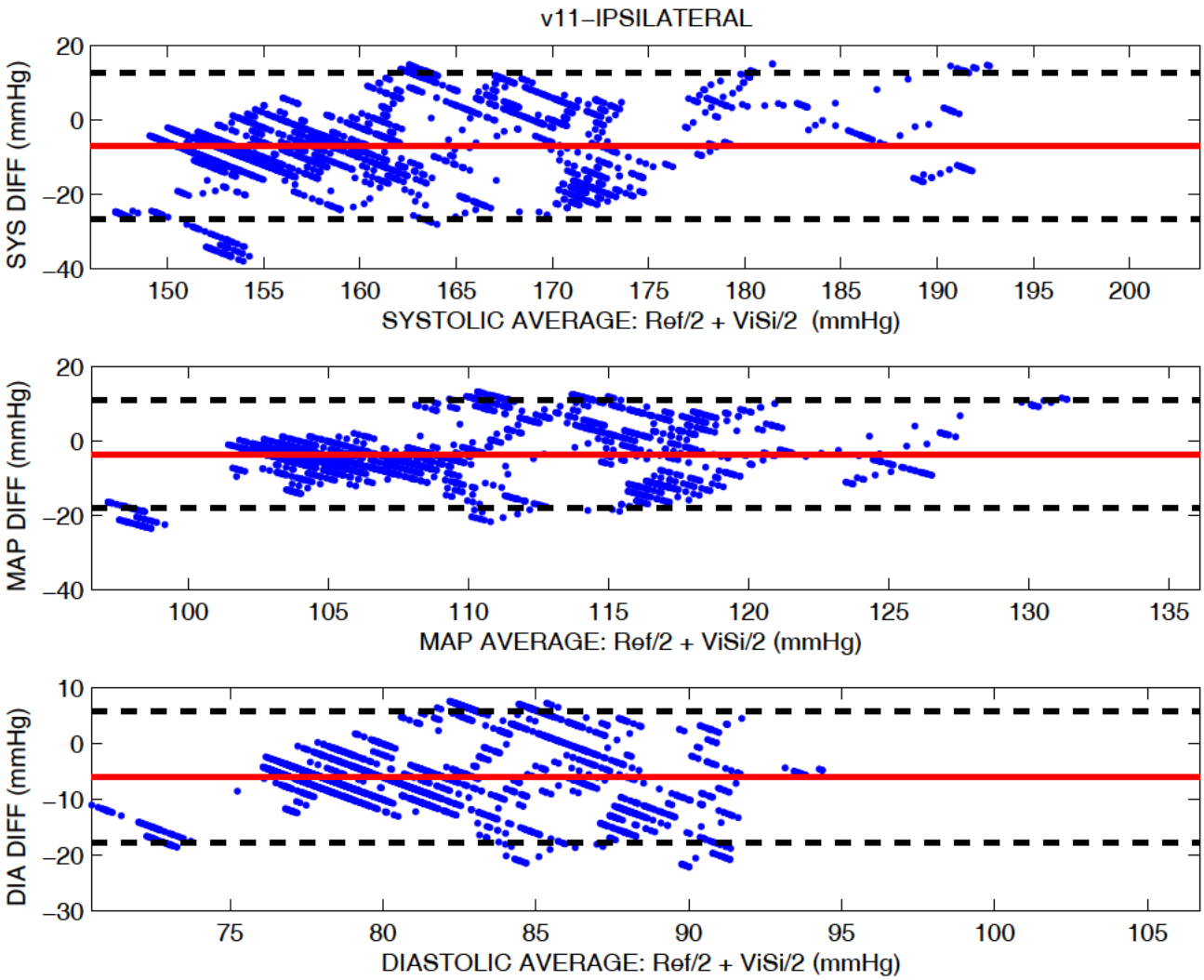


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

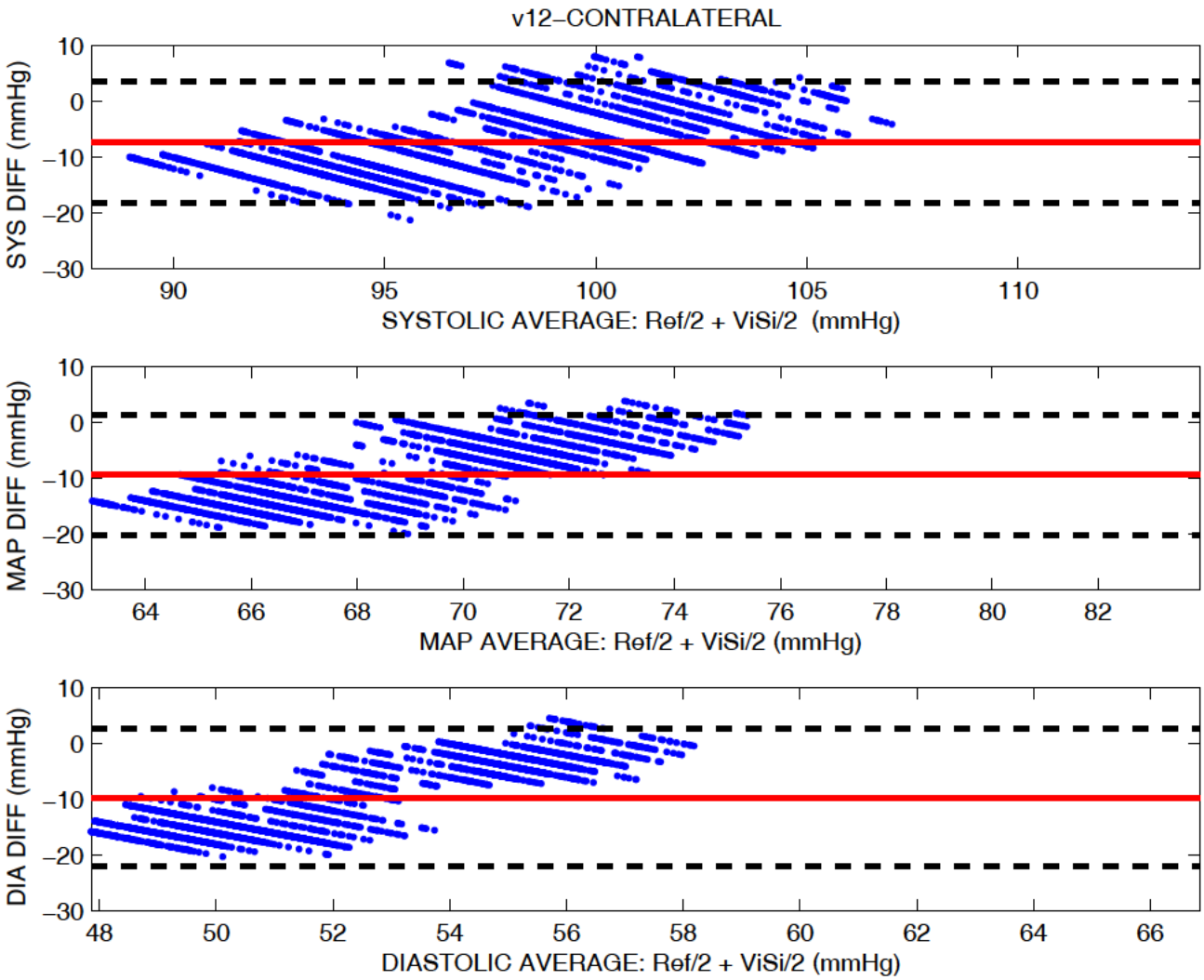


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

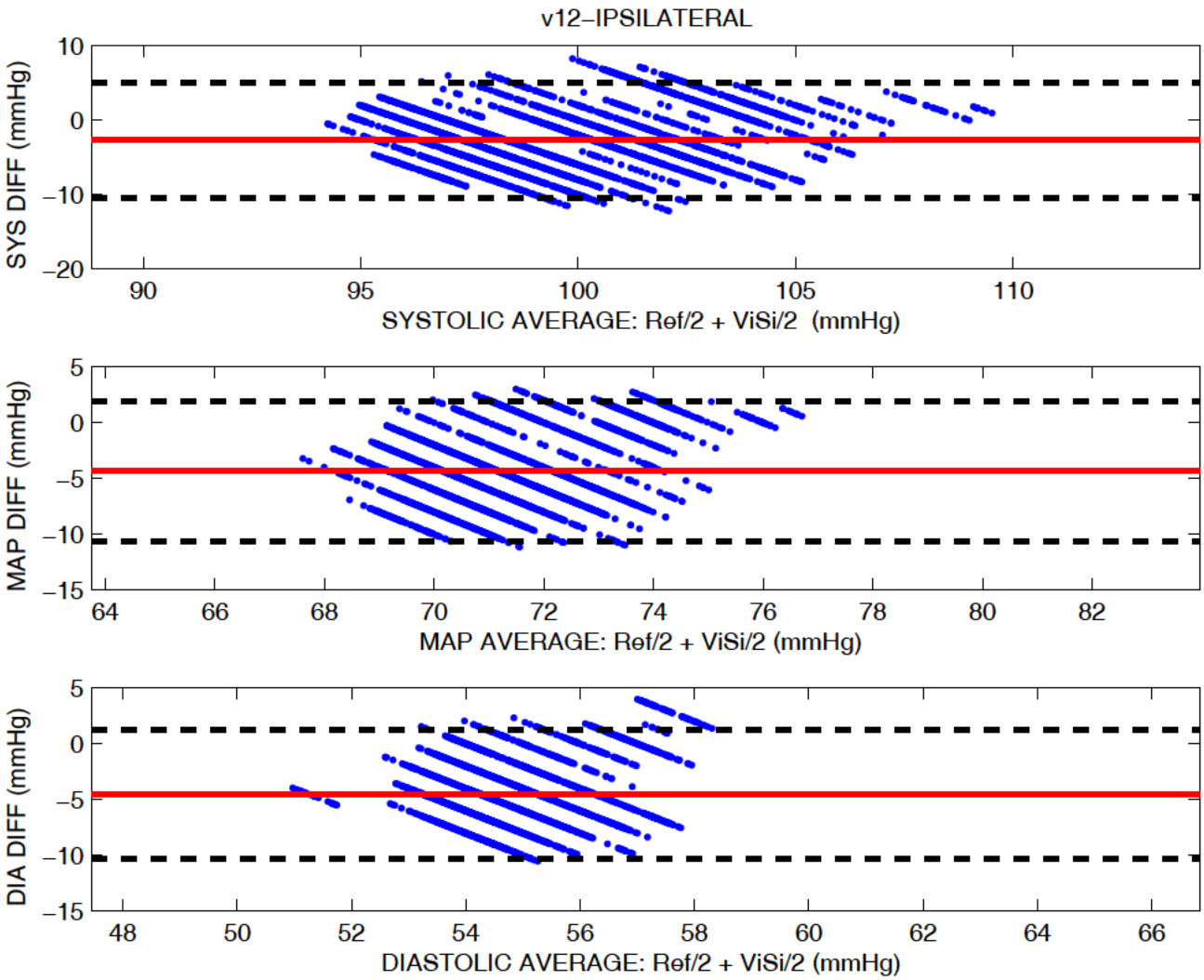


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

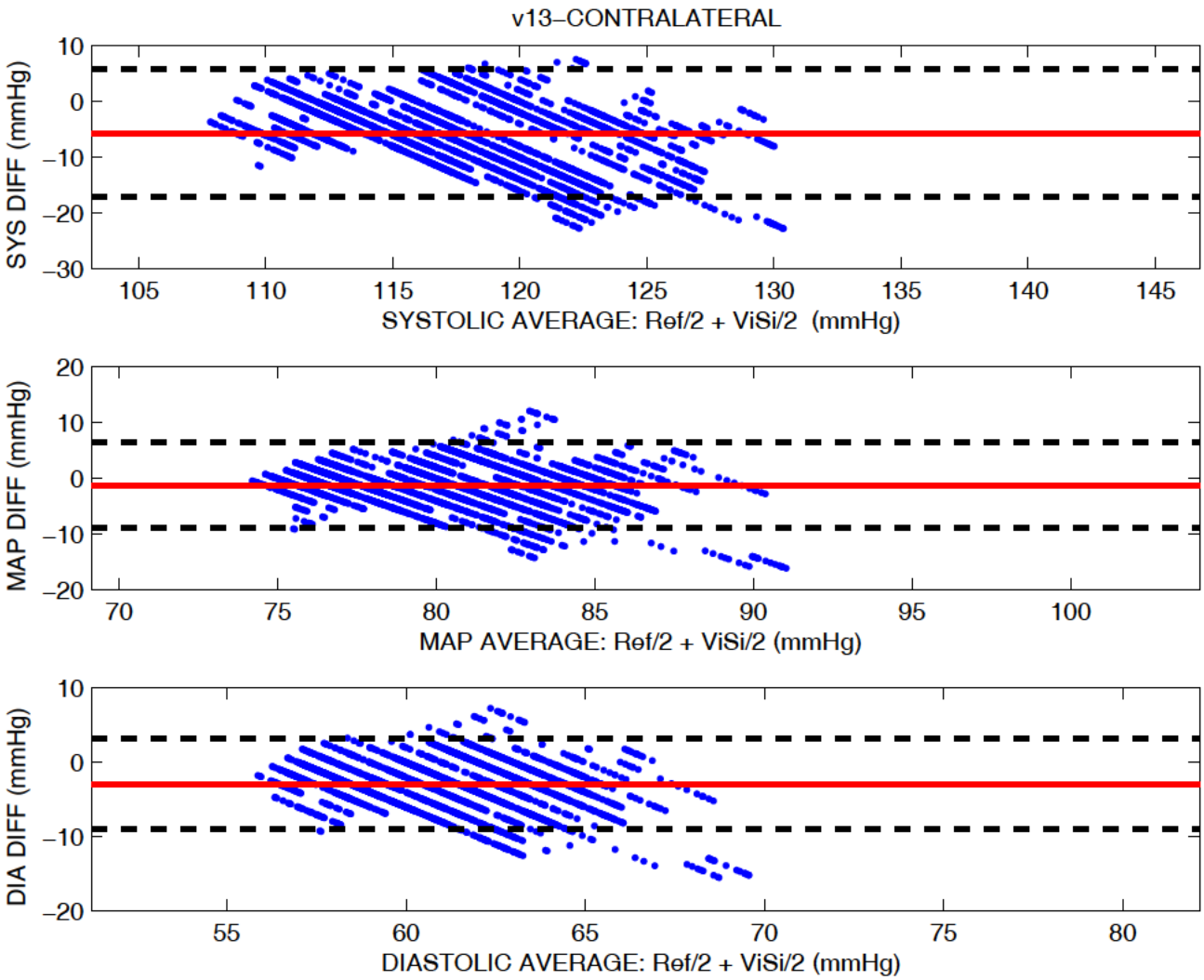


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

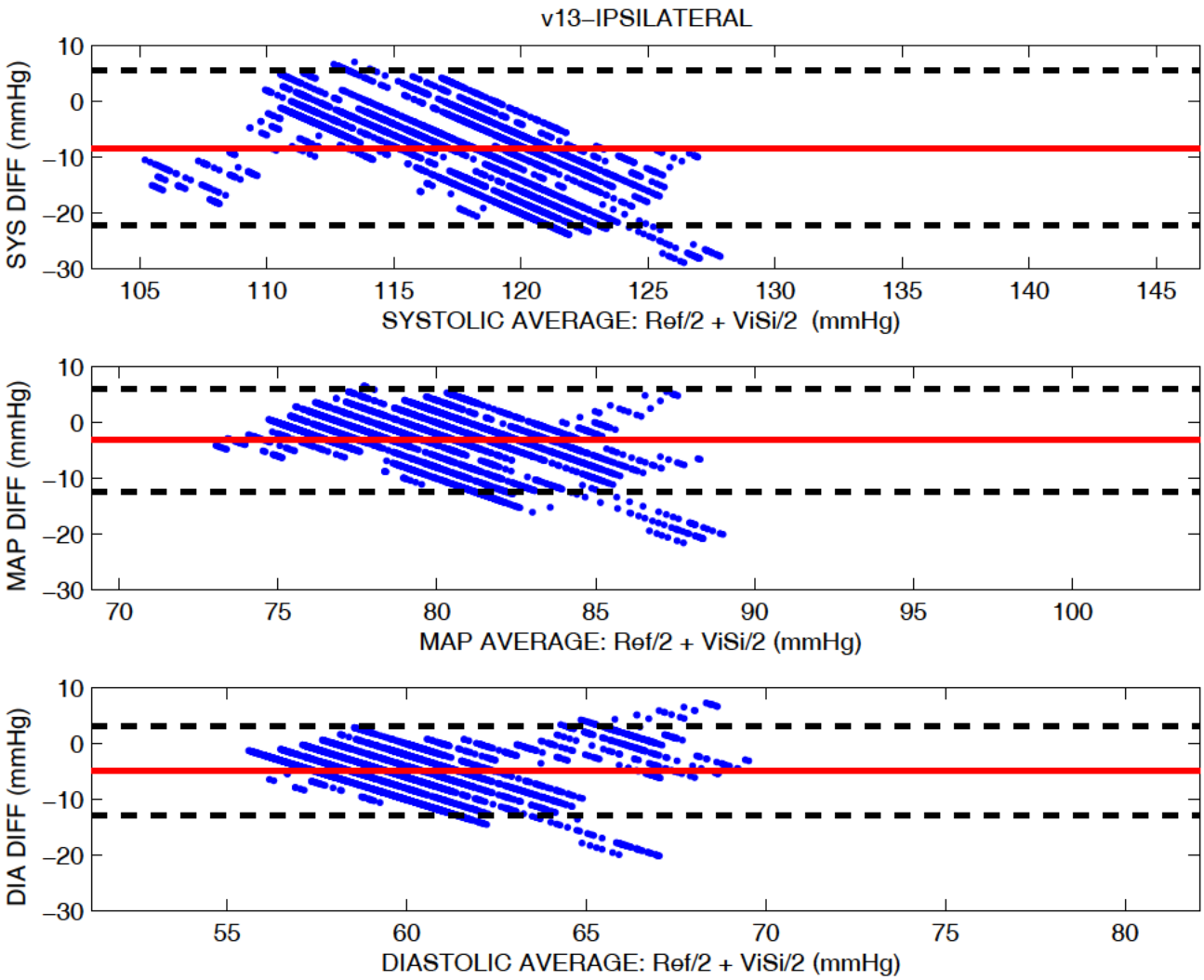


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

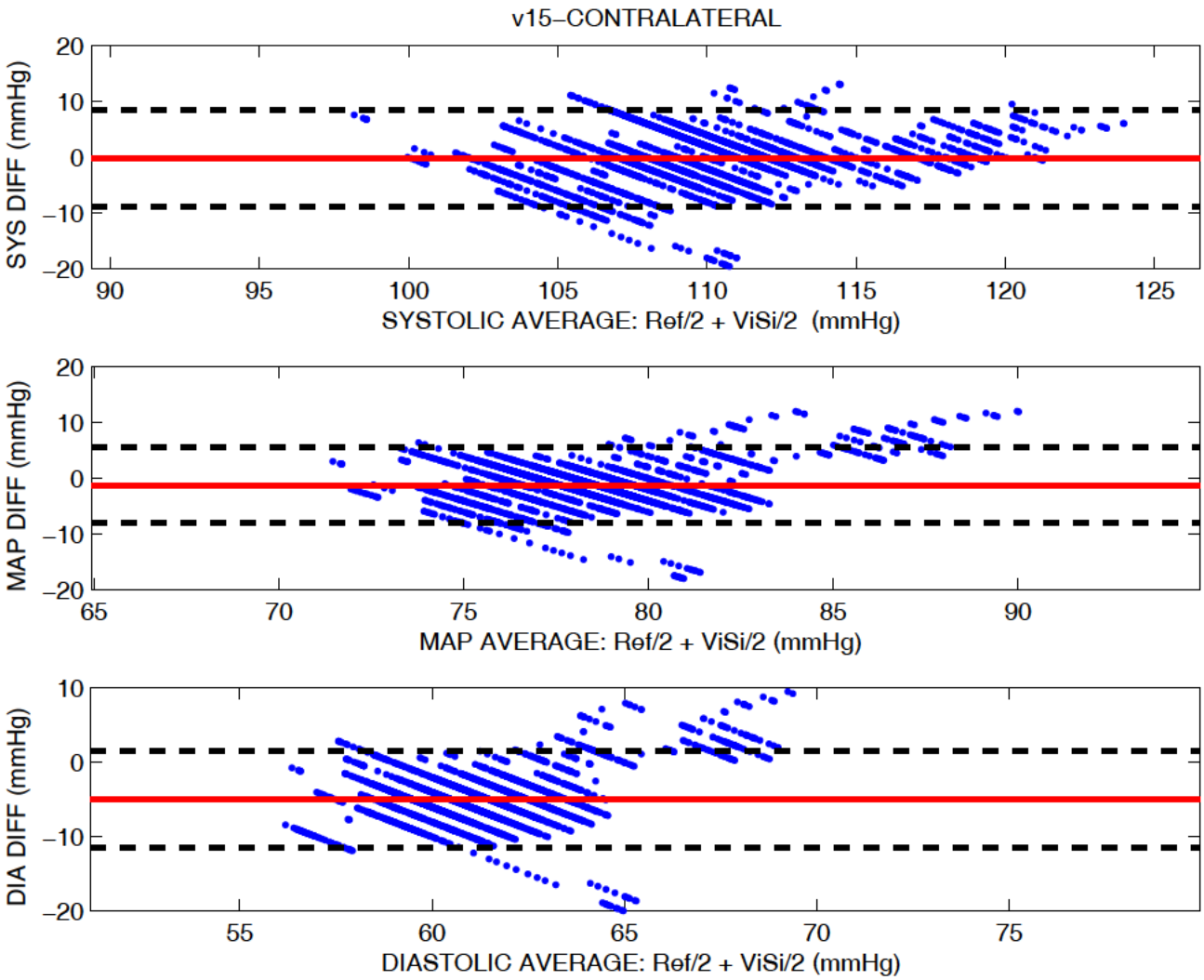


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

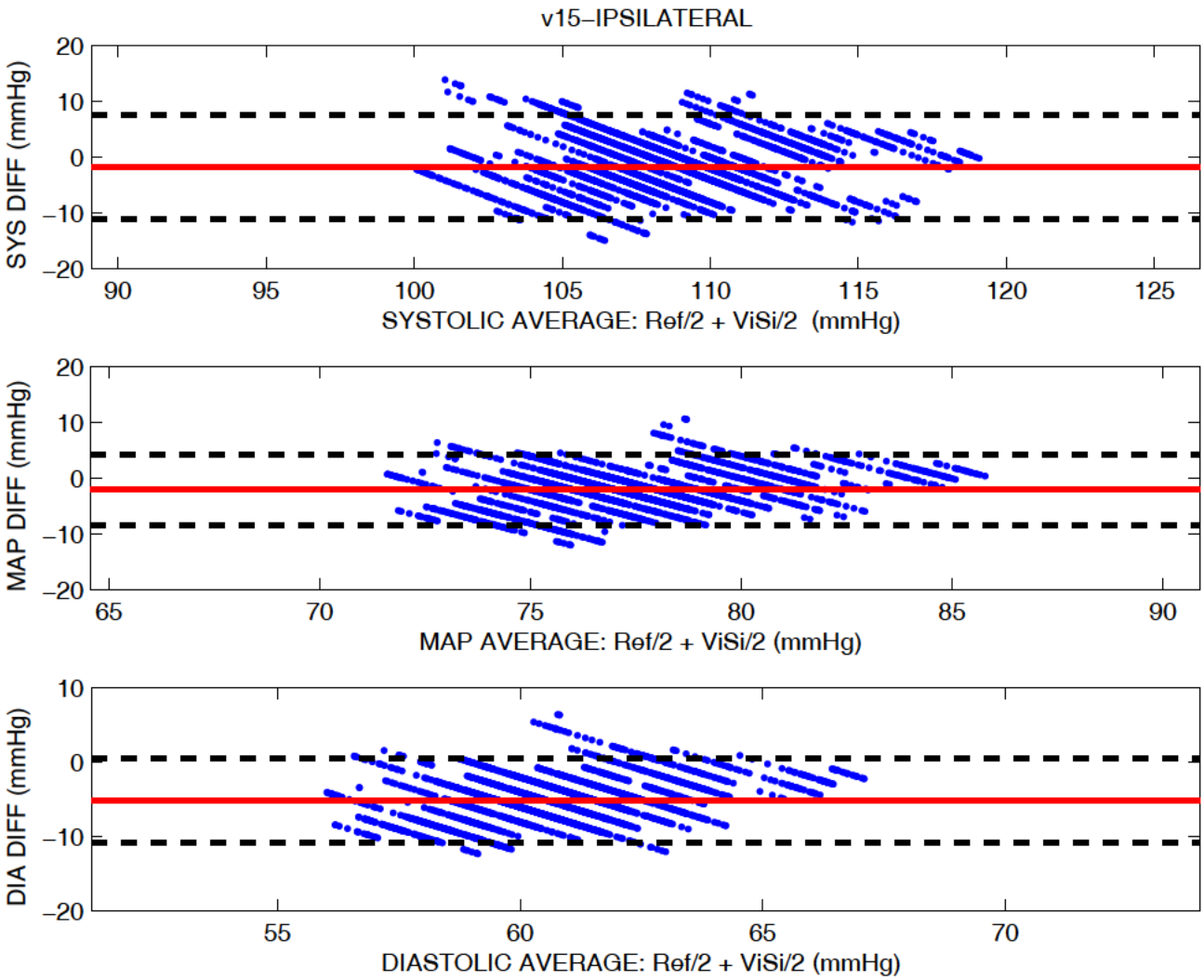


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

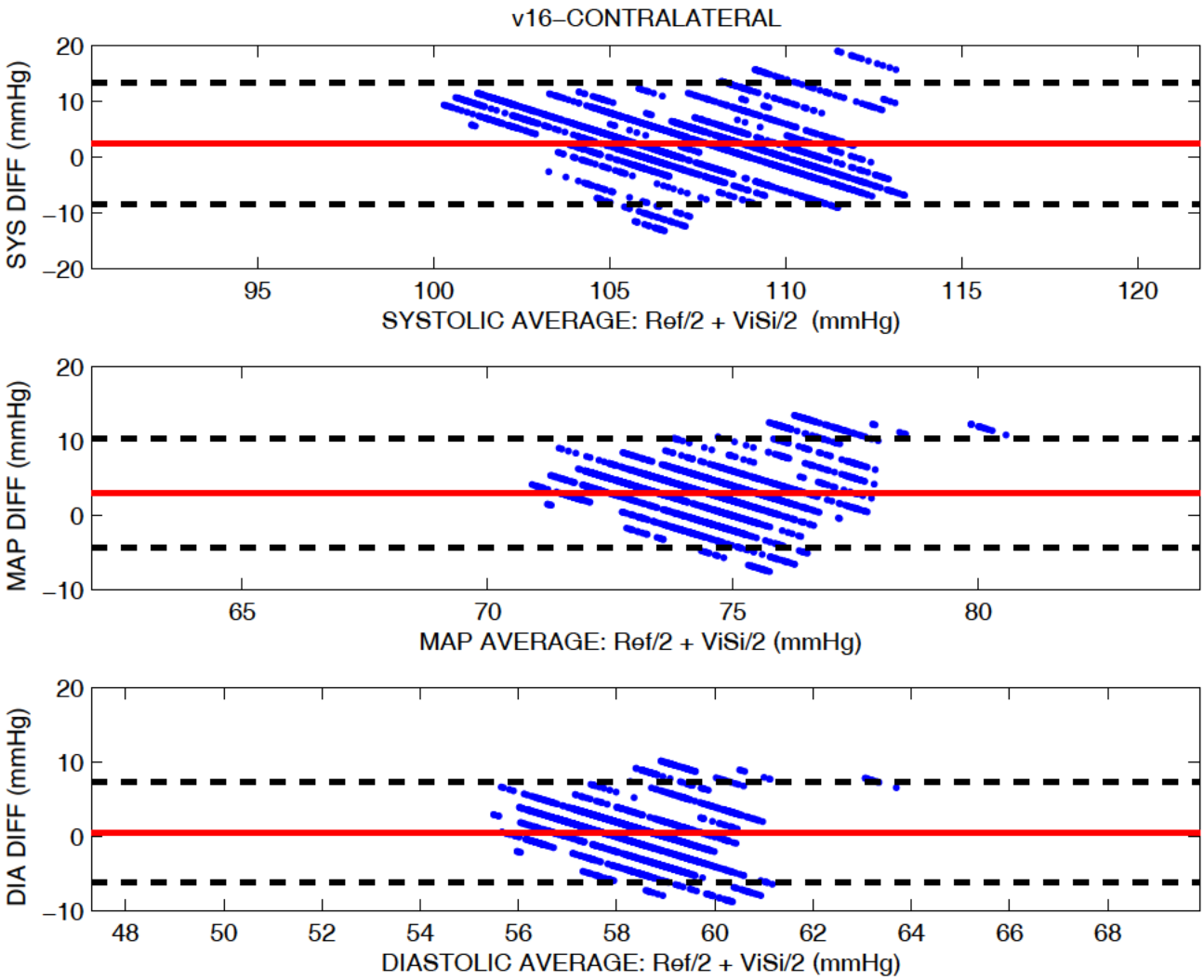


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

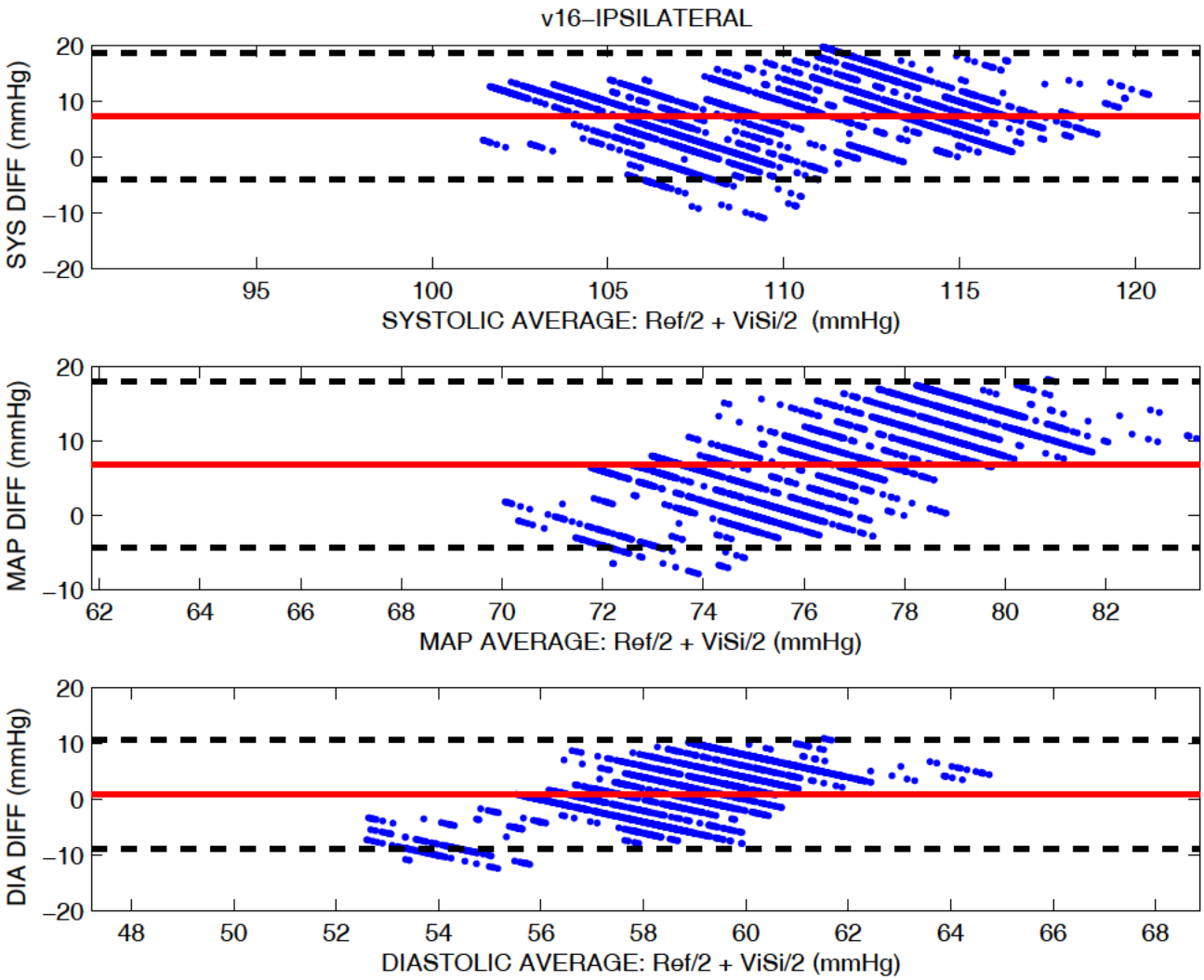


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis

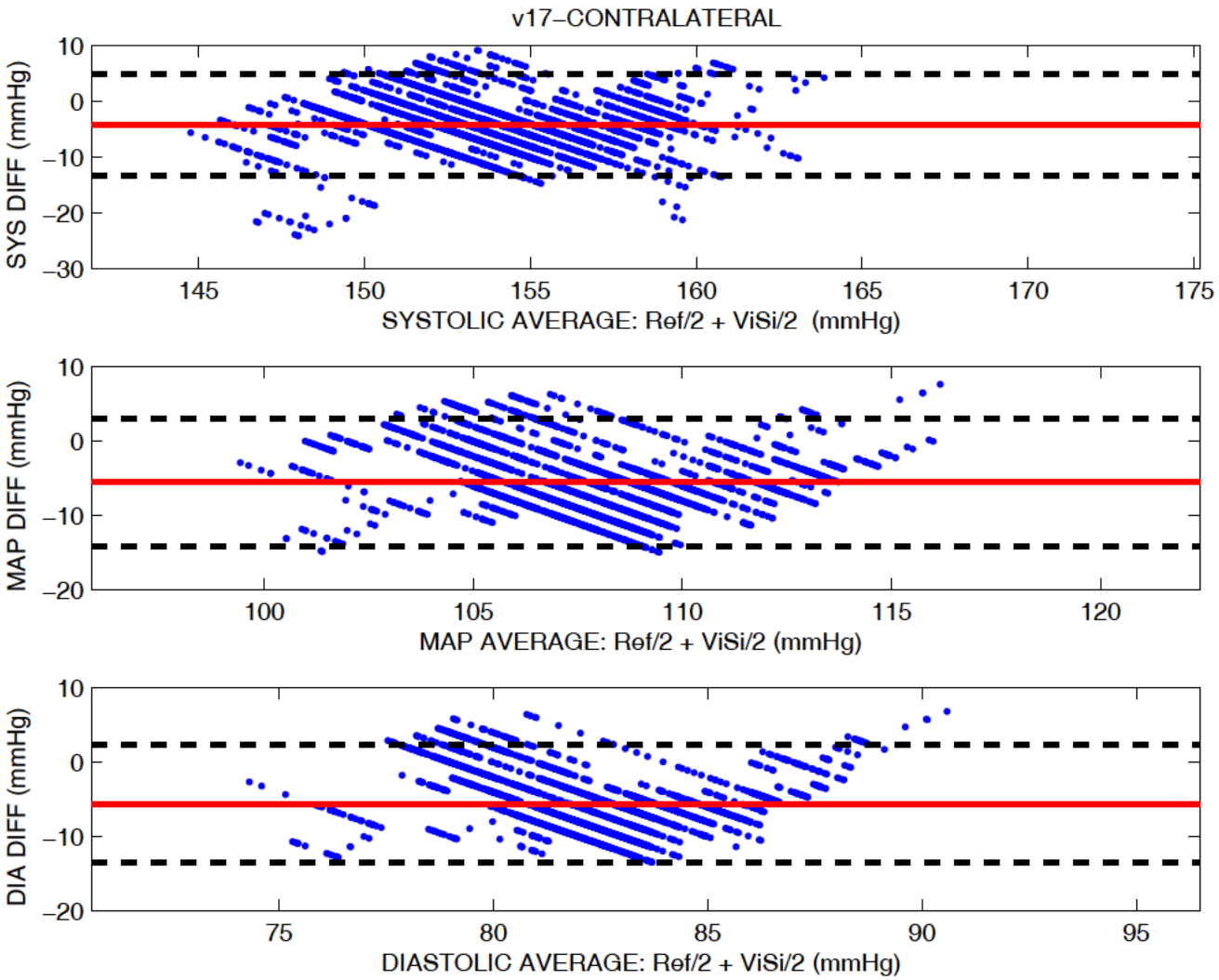
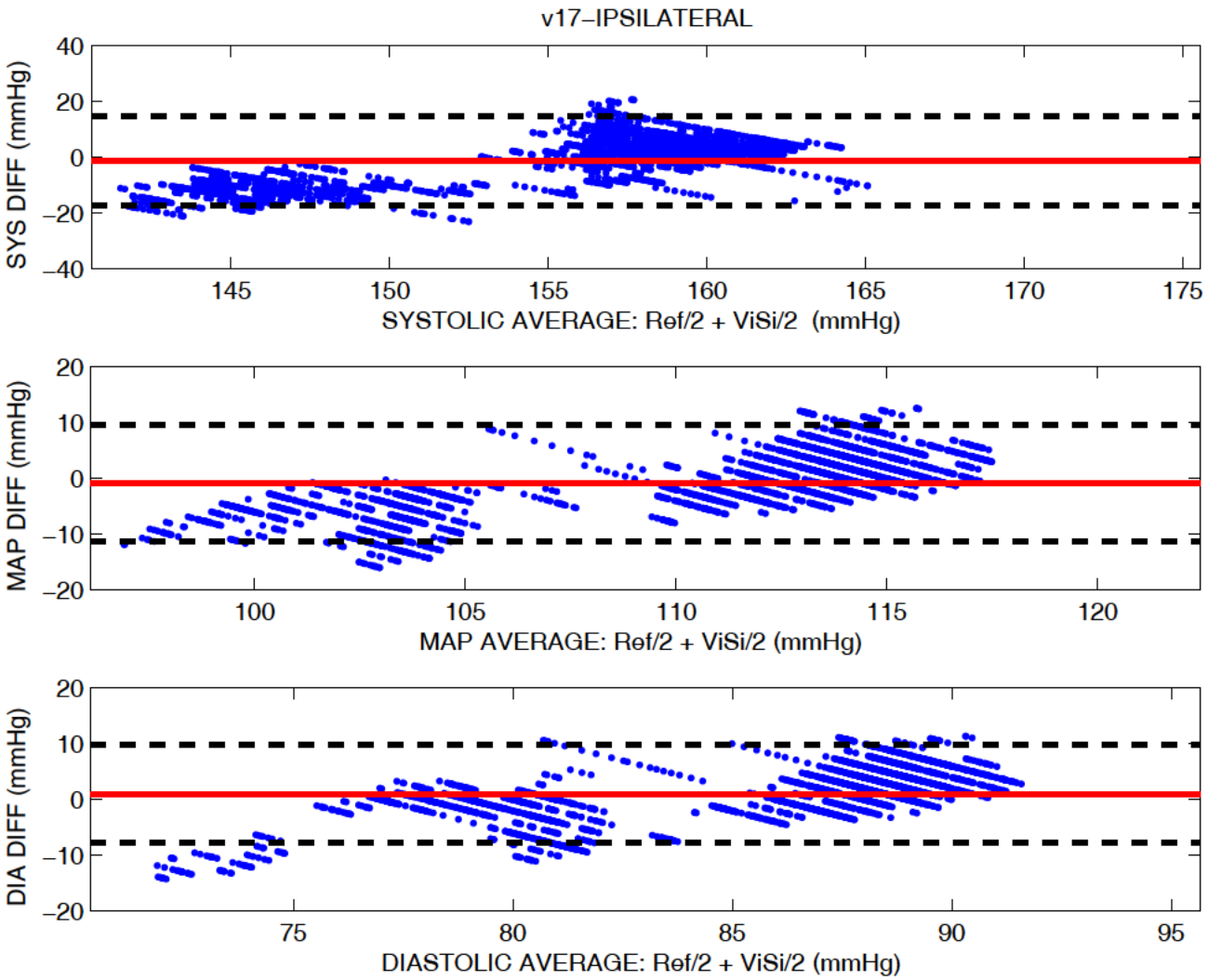


Exhibit 14 - Individual Bland-Altman plots using average of the ViSi device and the CRS on X-axis



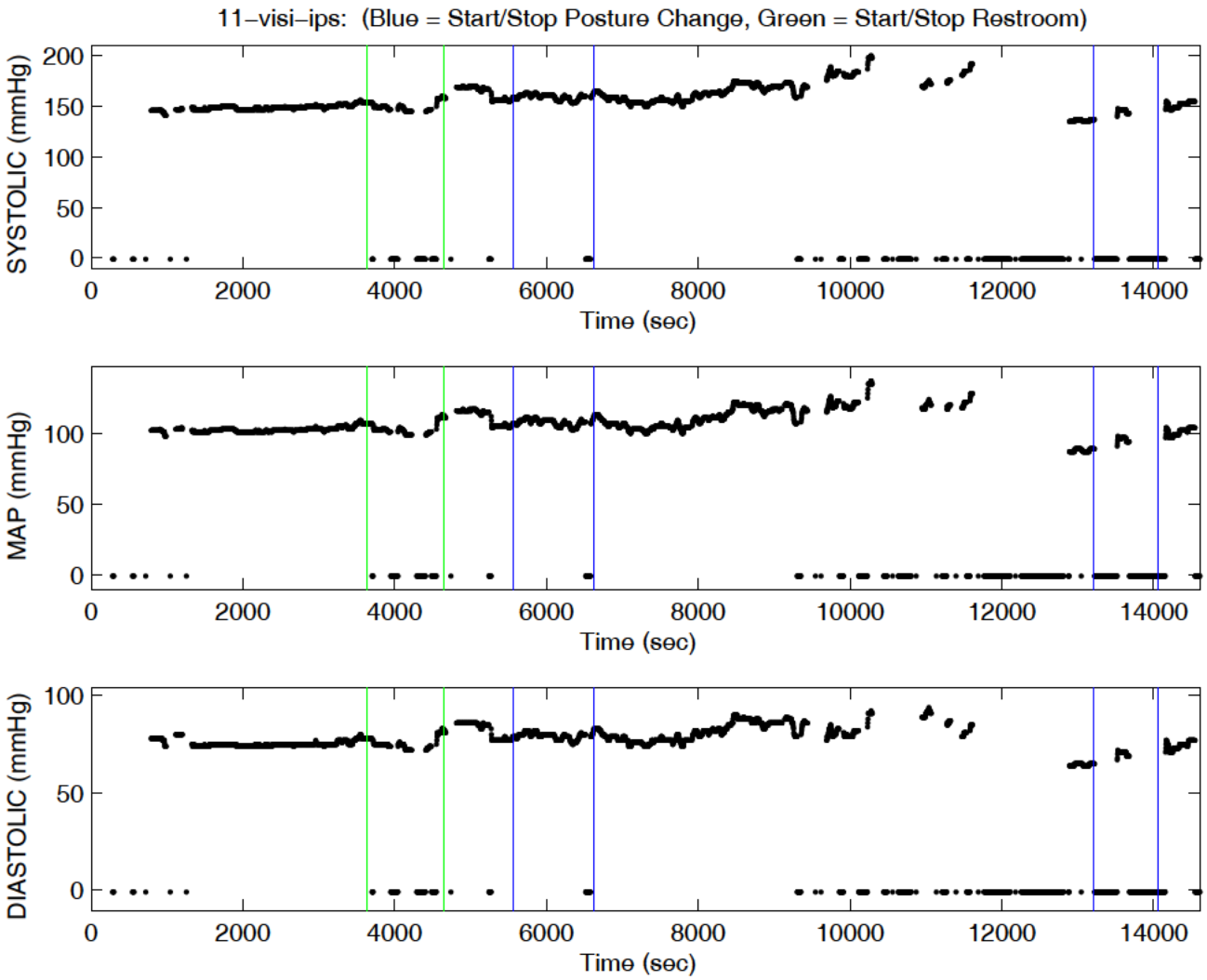

11–visi–ips: (Blue = Start/Stop Posture Change, Green = Start/Stop Restroom)
SYSTOLIC (mmHg)
200
150
100
50
0
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
MAP (mmHg)
100
50
0
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)
DIASTOLIC (mmHg)
100
50
0
0
2000
4000
6000
8000
10000
12000
14000
Time (sec)

Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

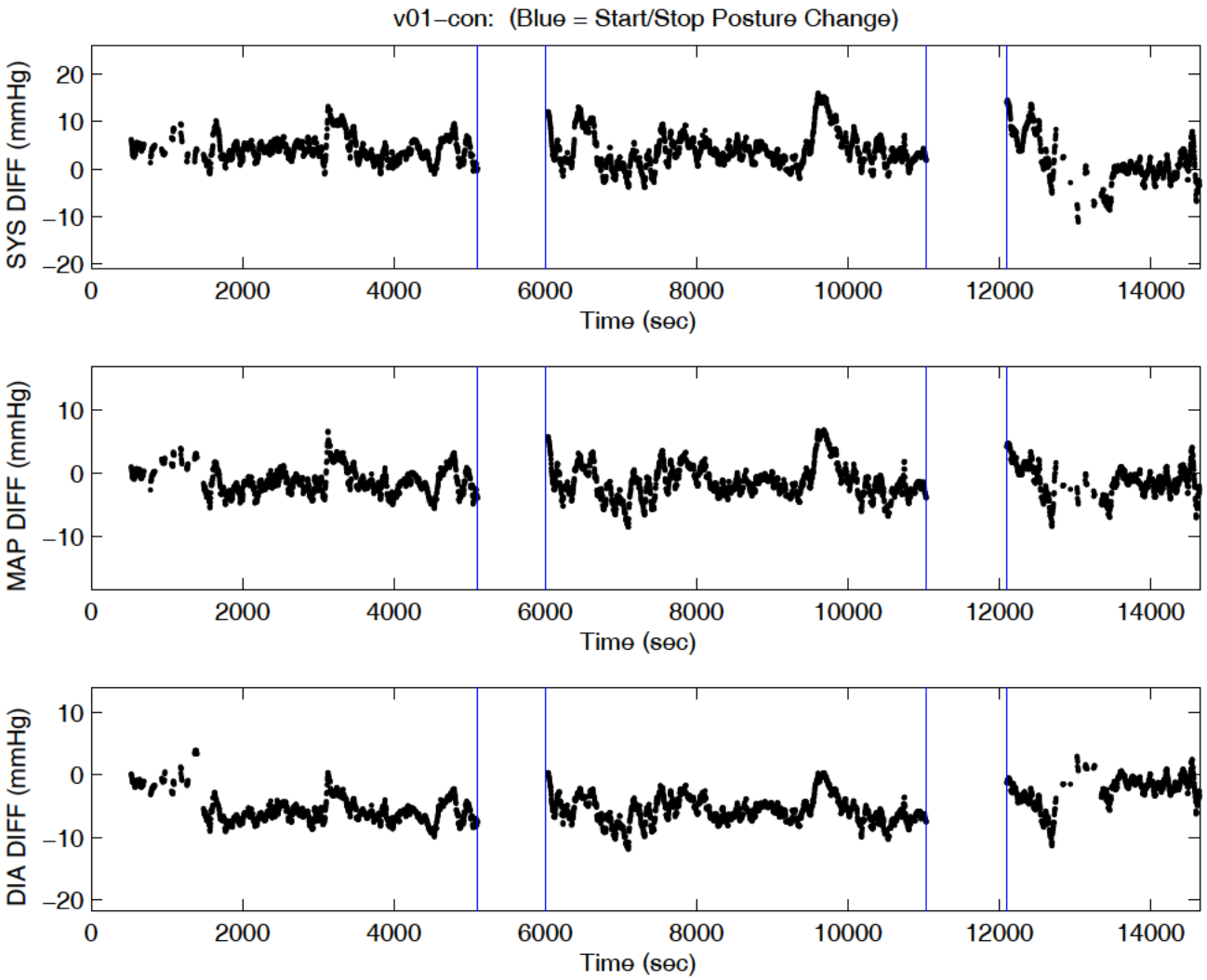


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

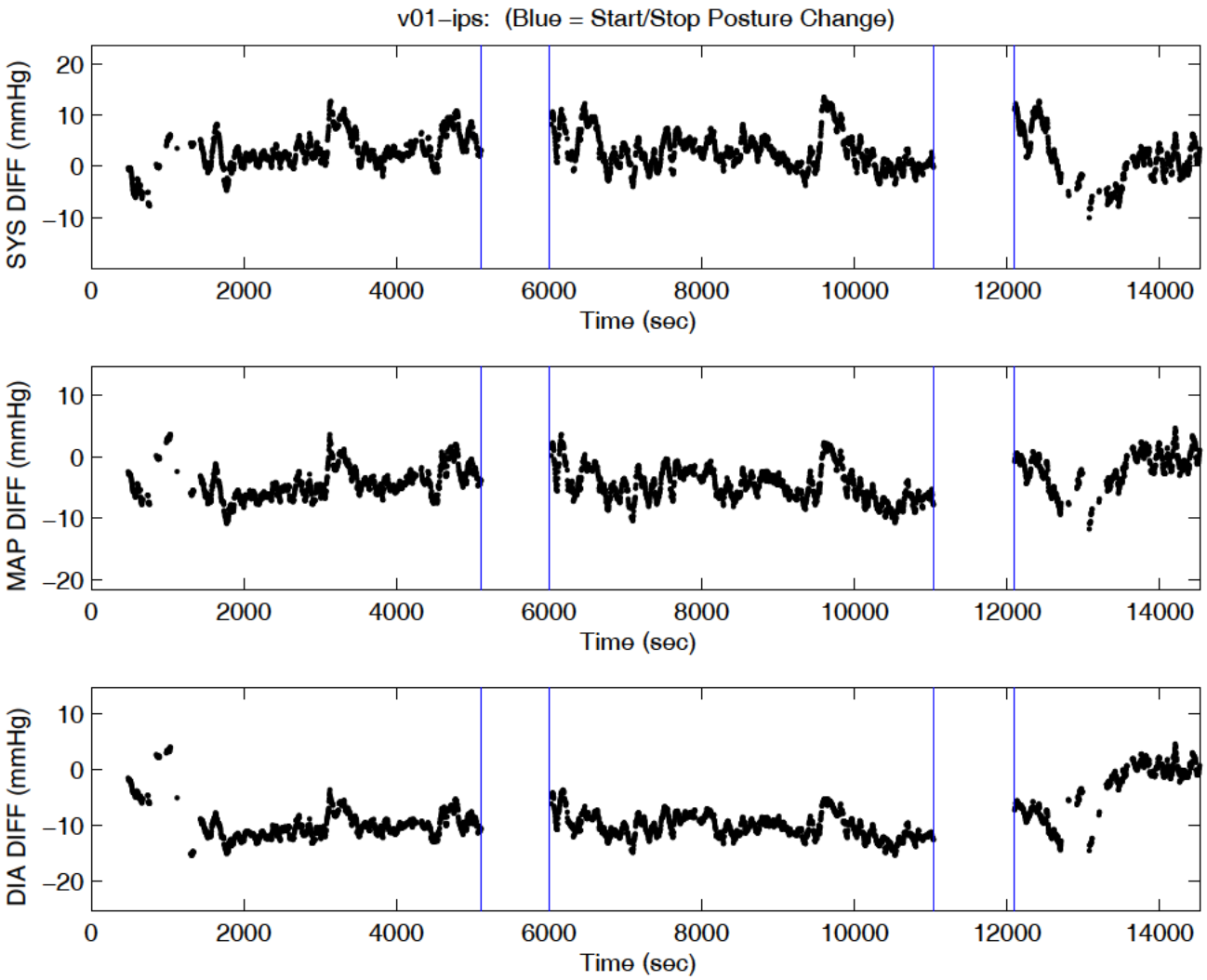


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

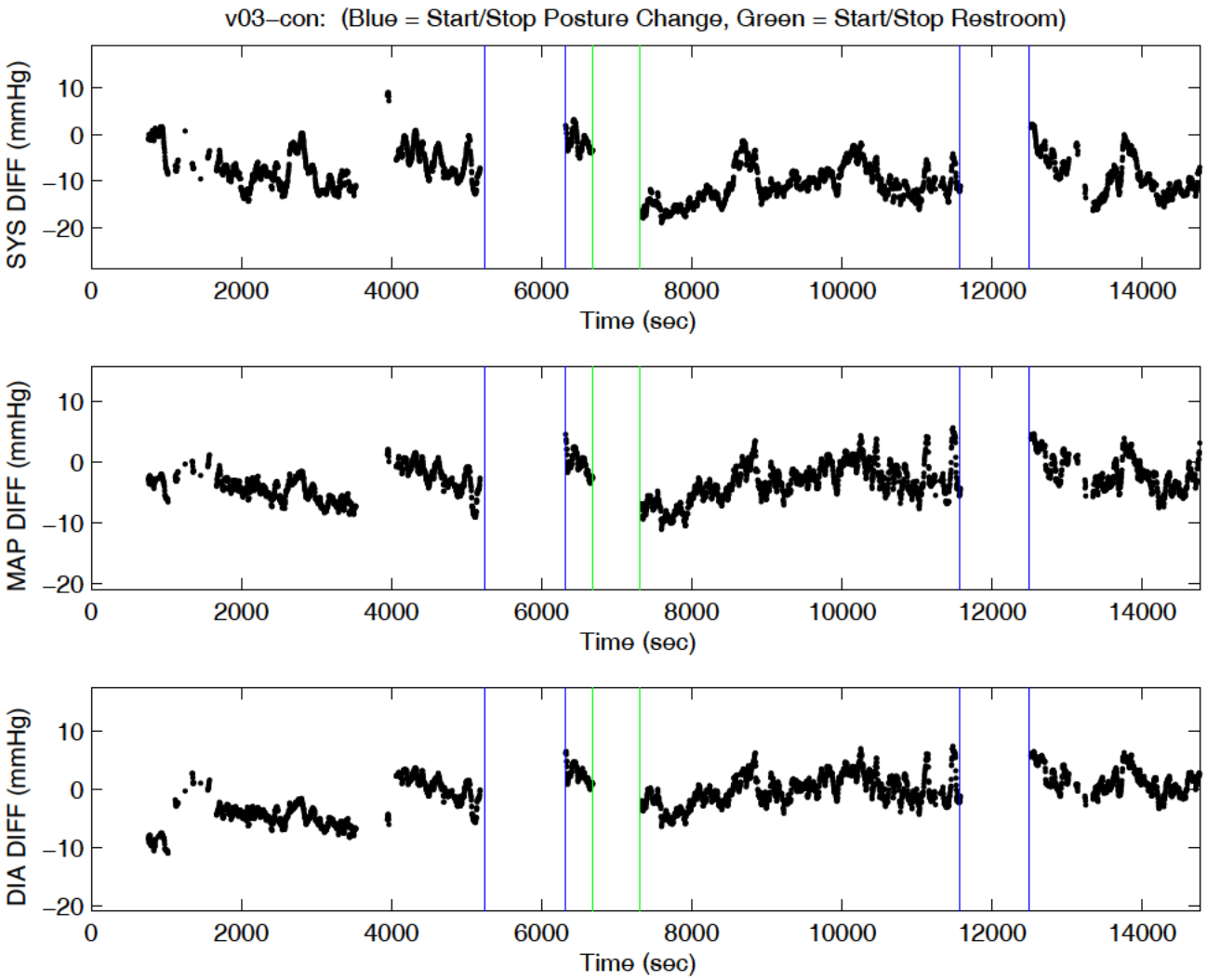


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

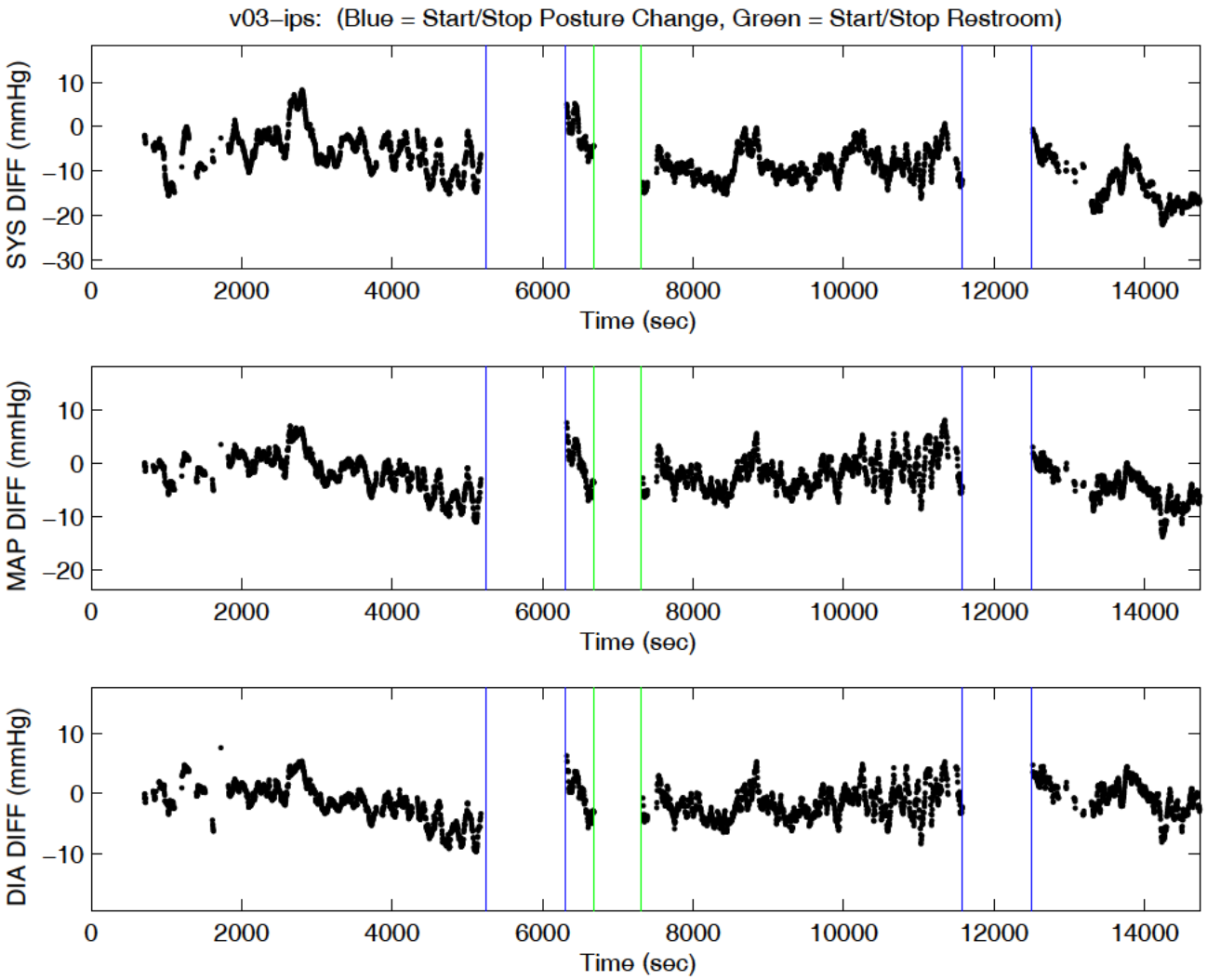


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

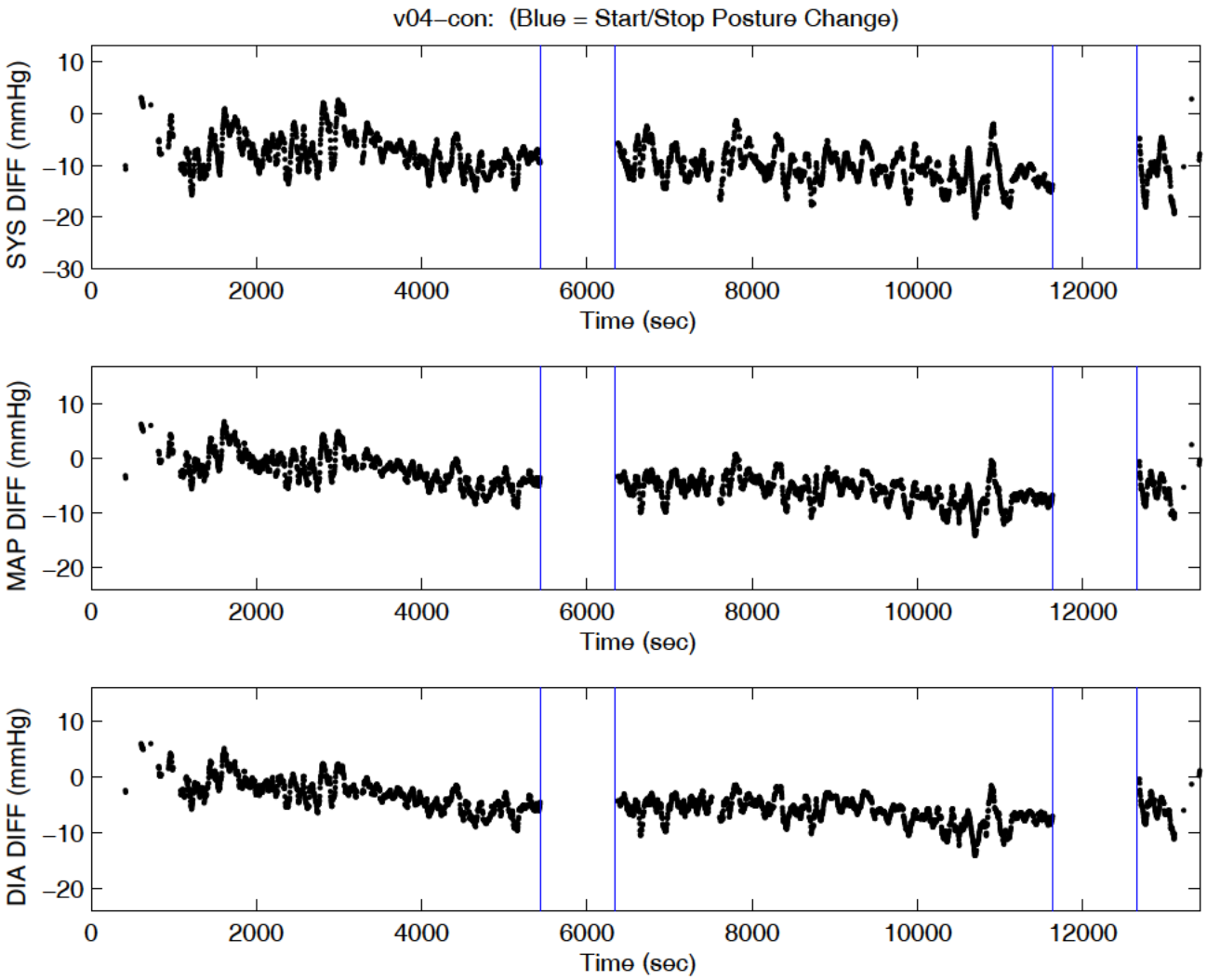


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

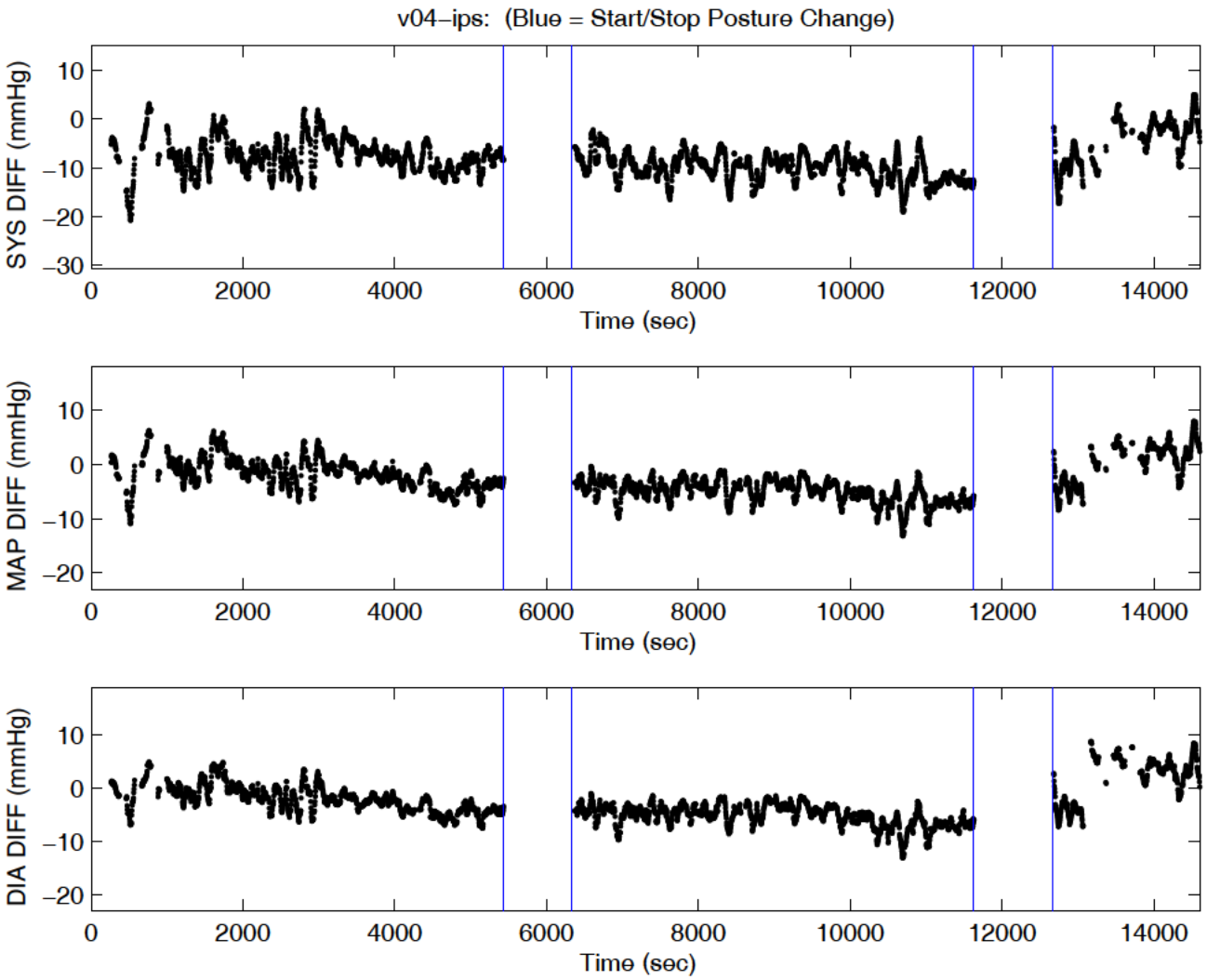


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

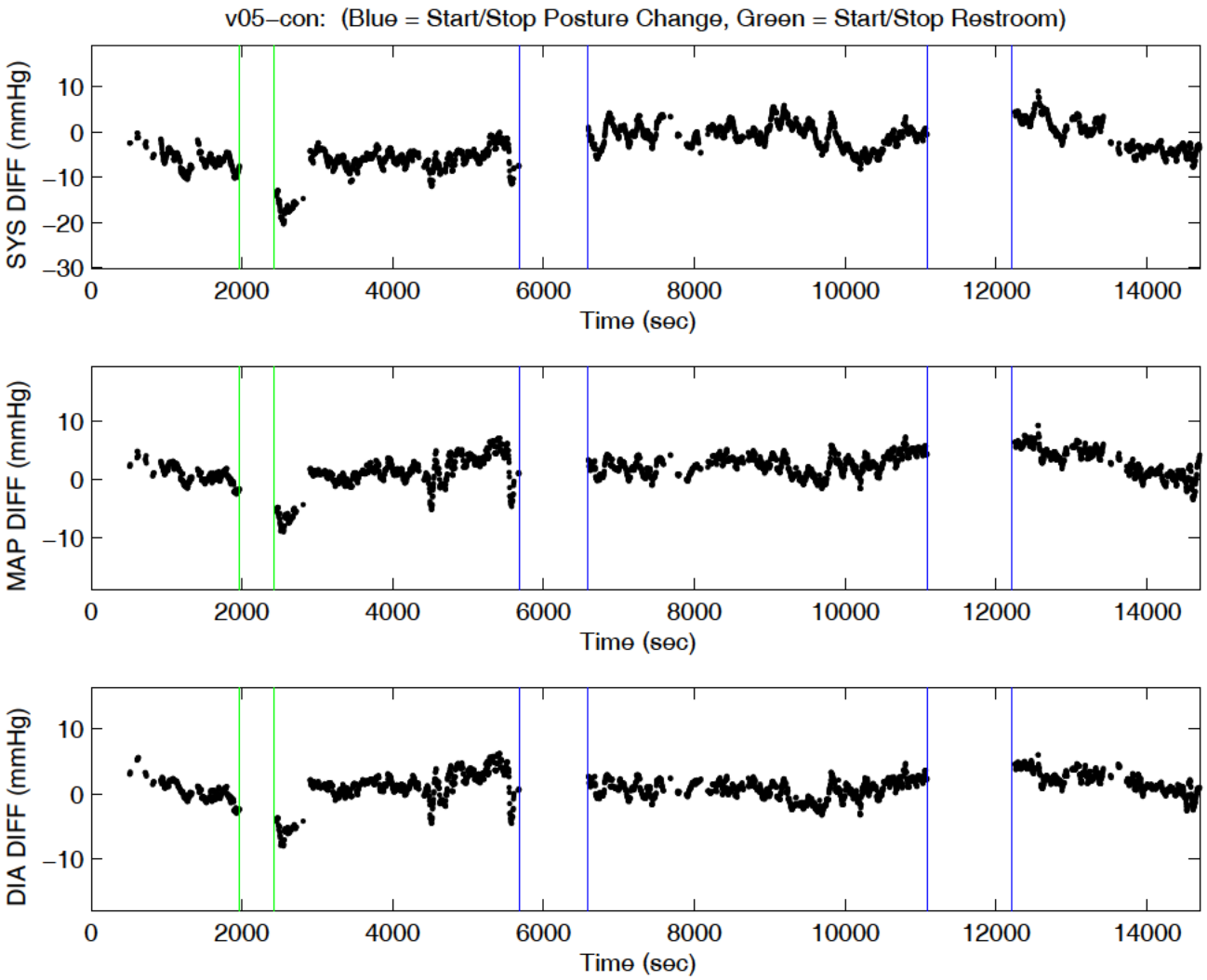


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

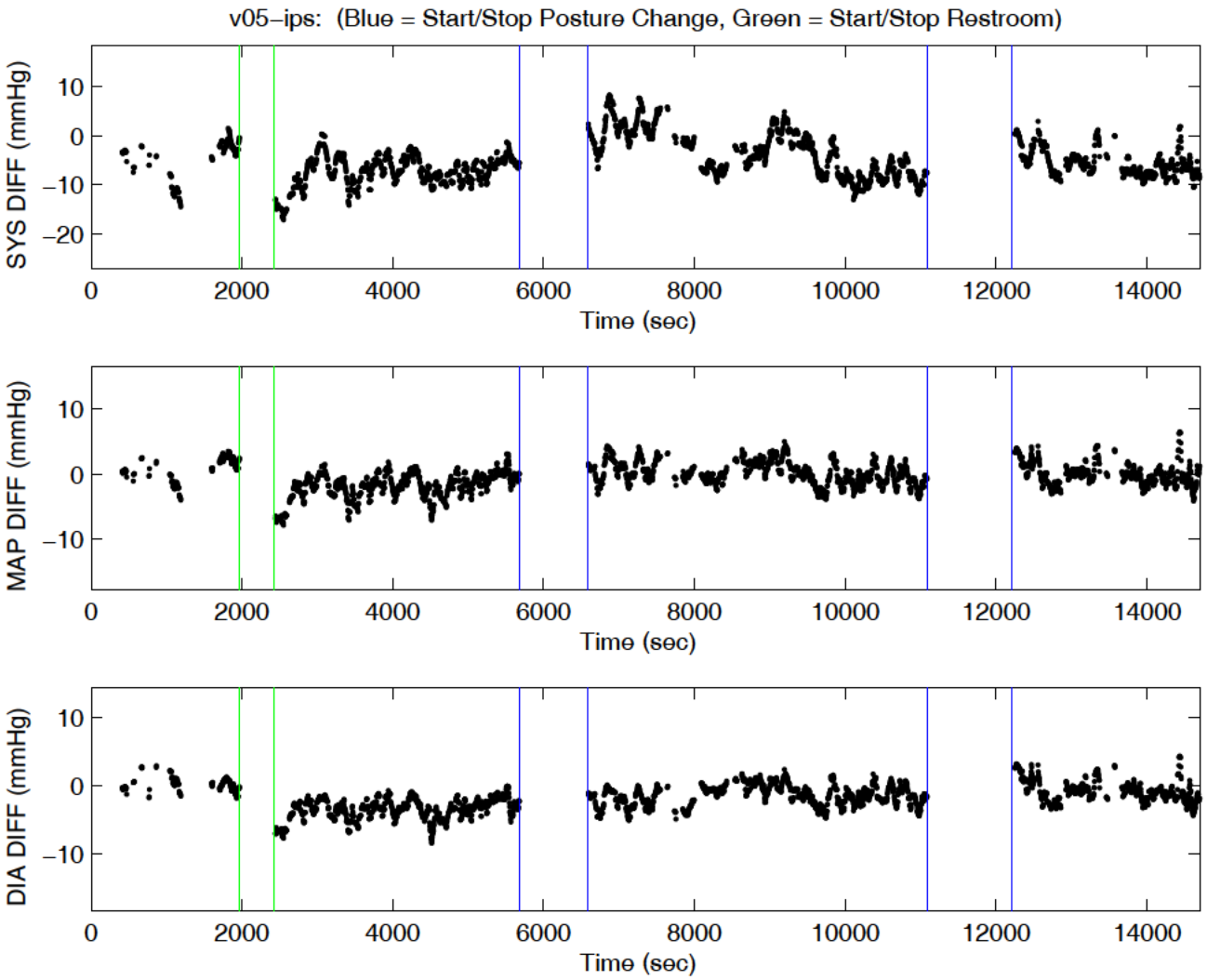


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

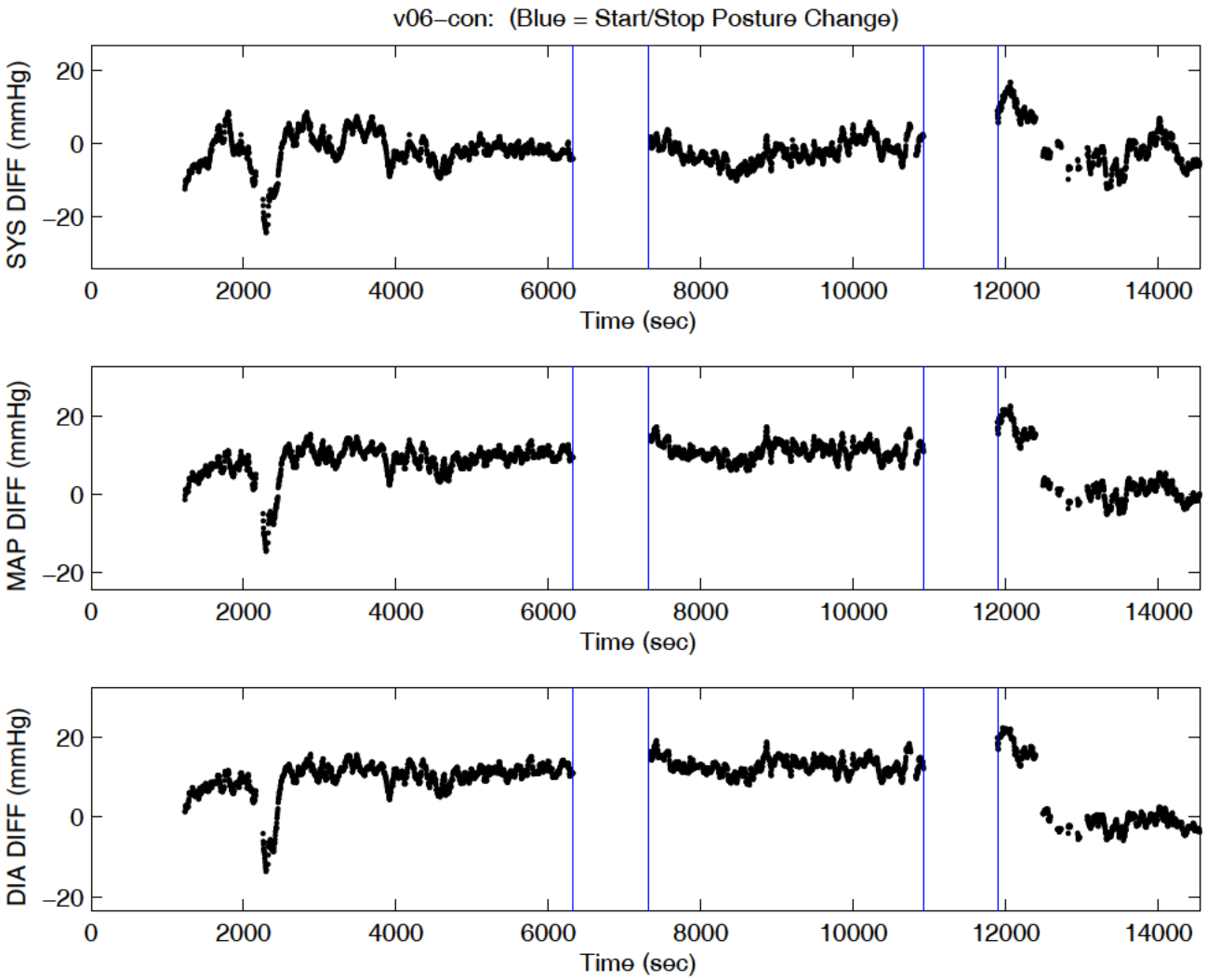


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

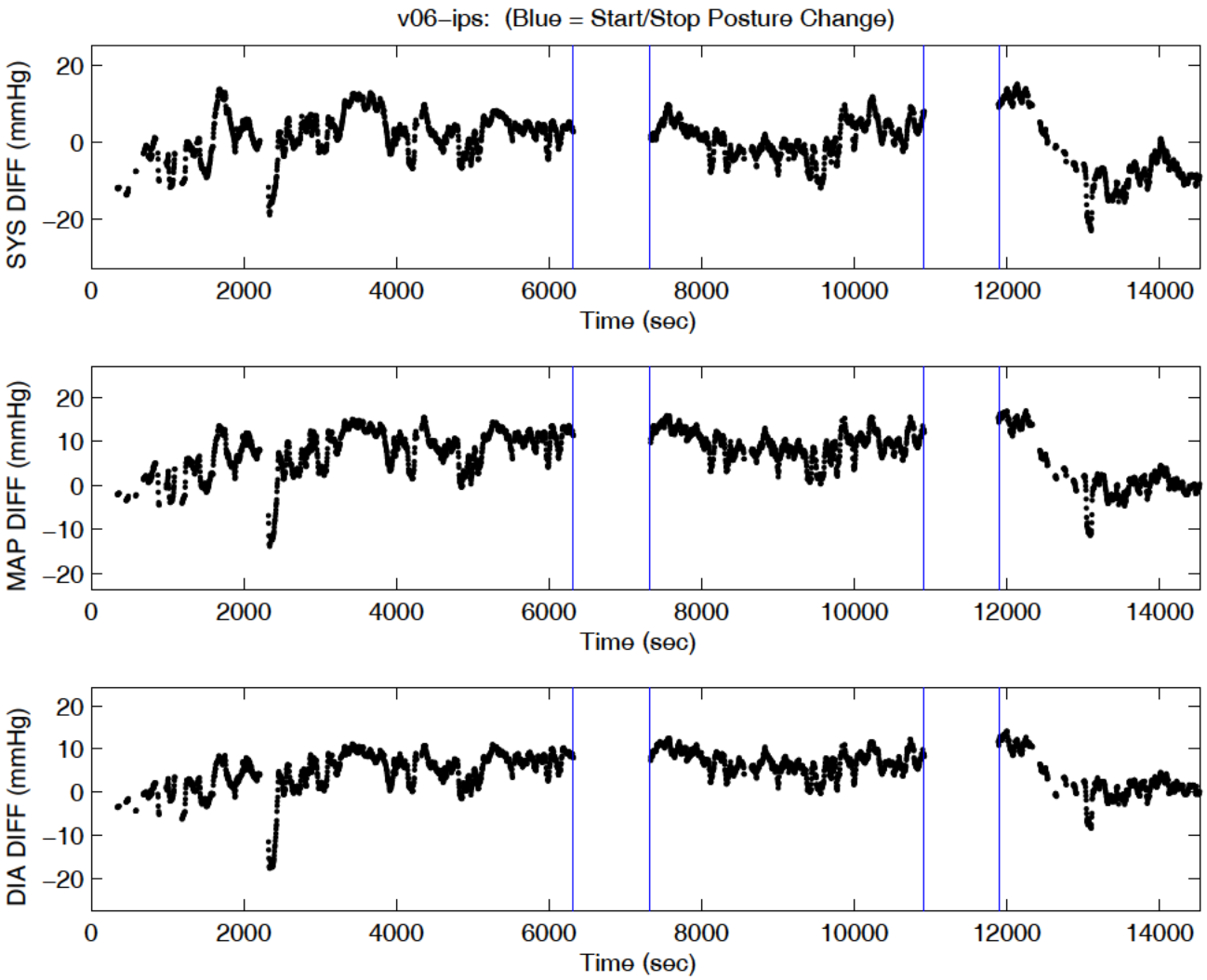


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

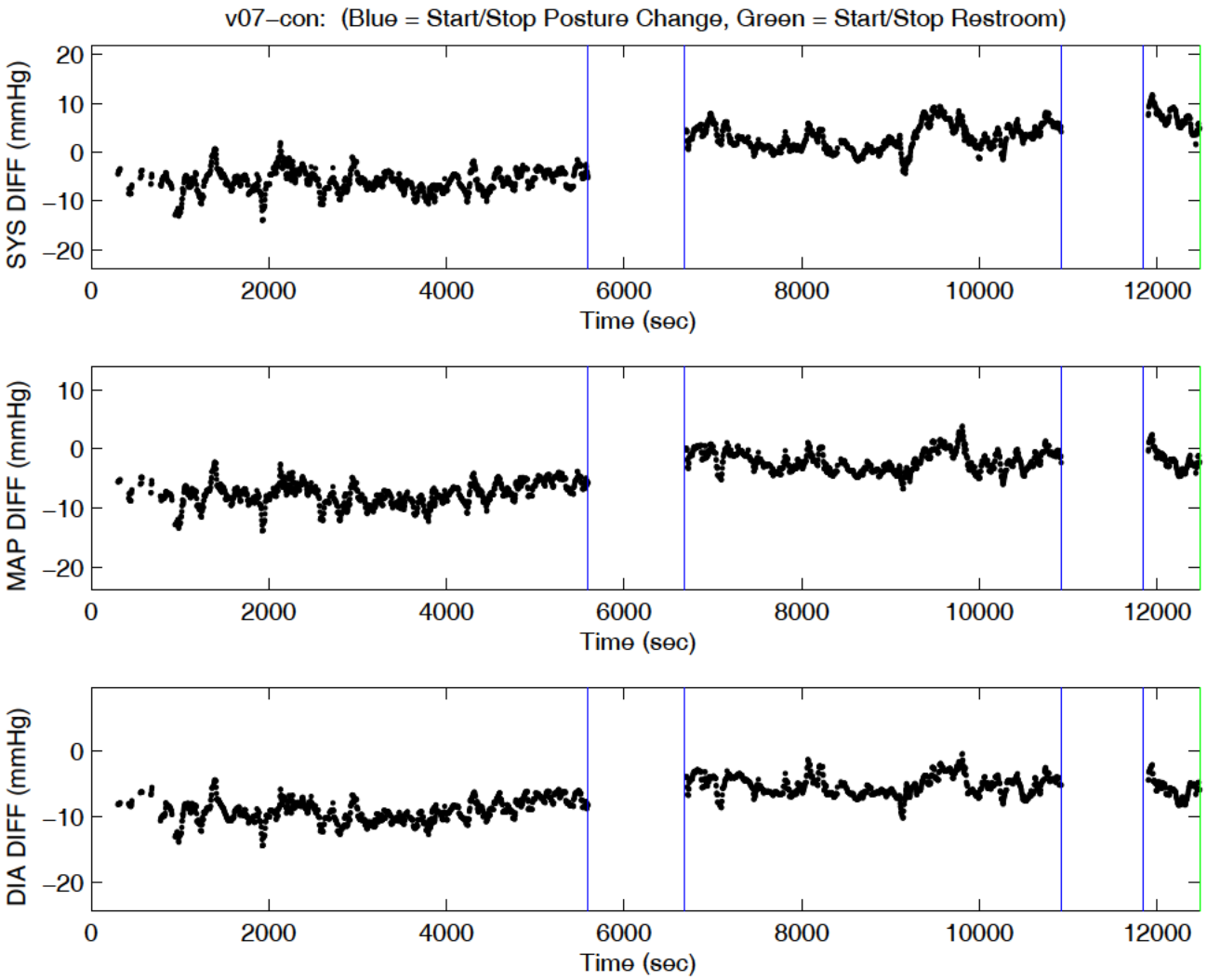


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

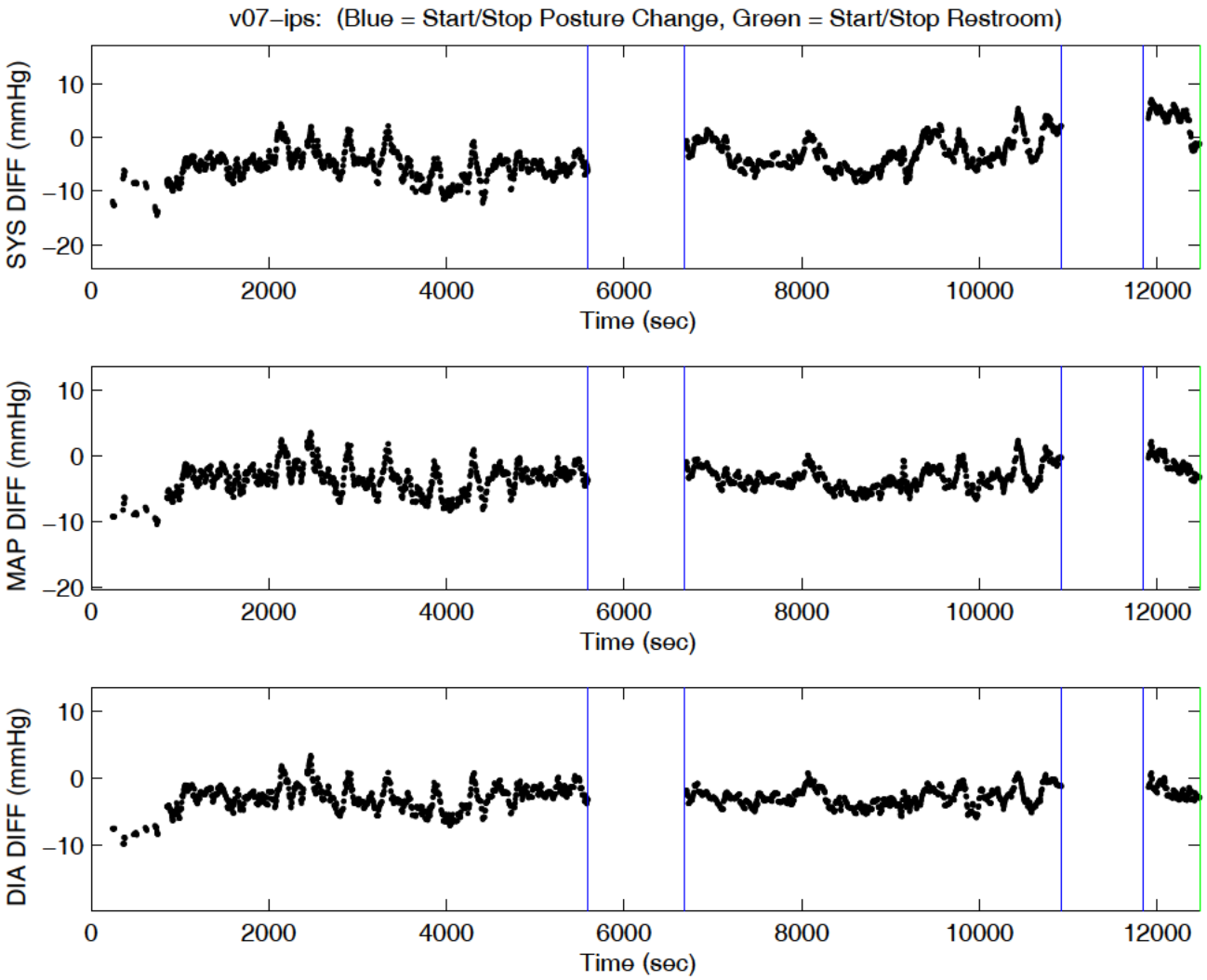


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

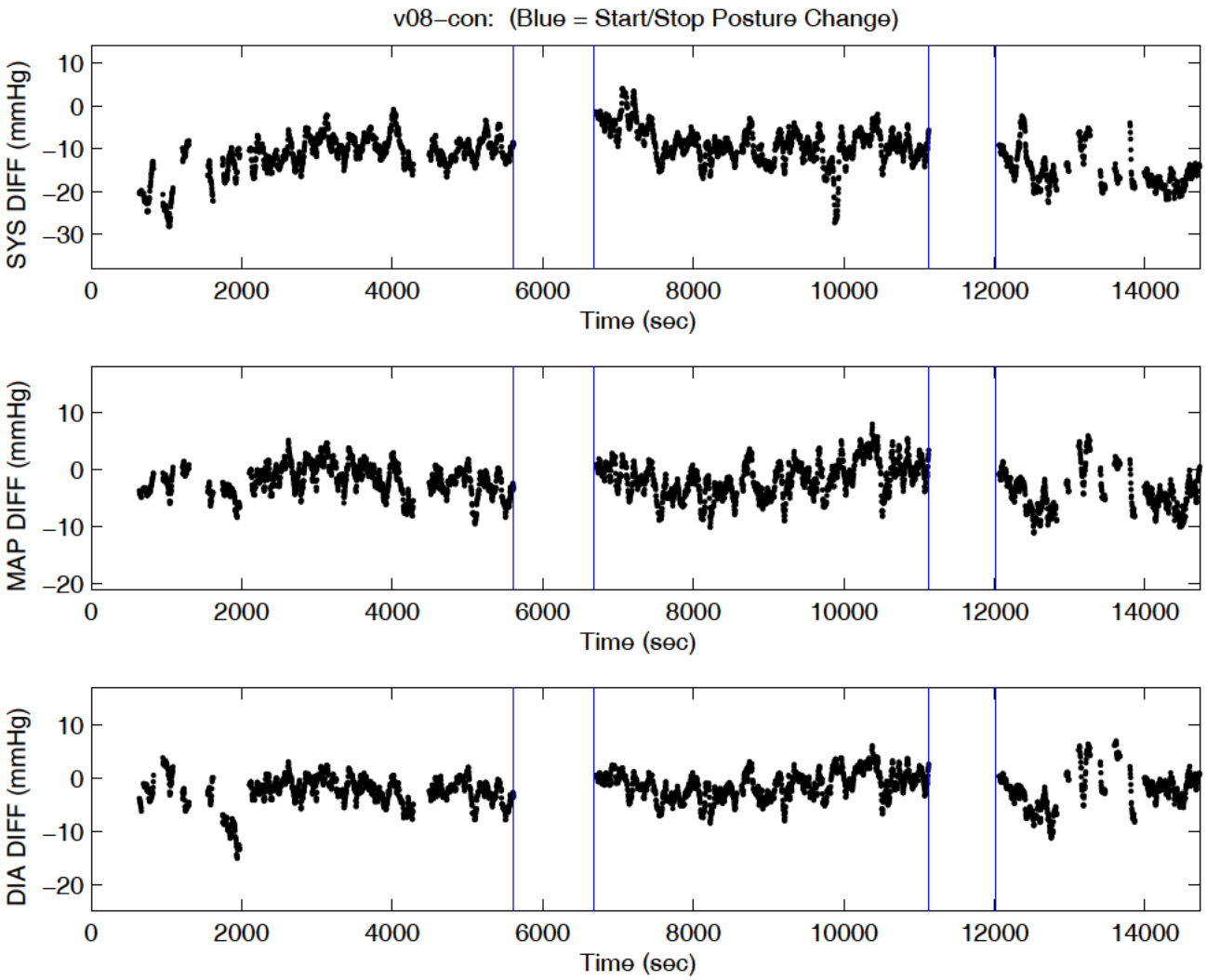


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

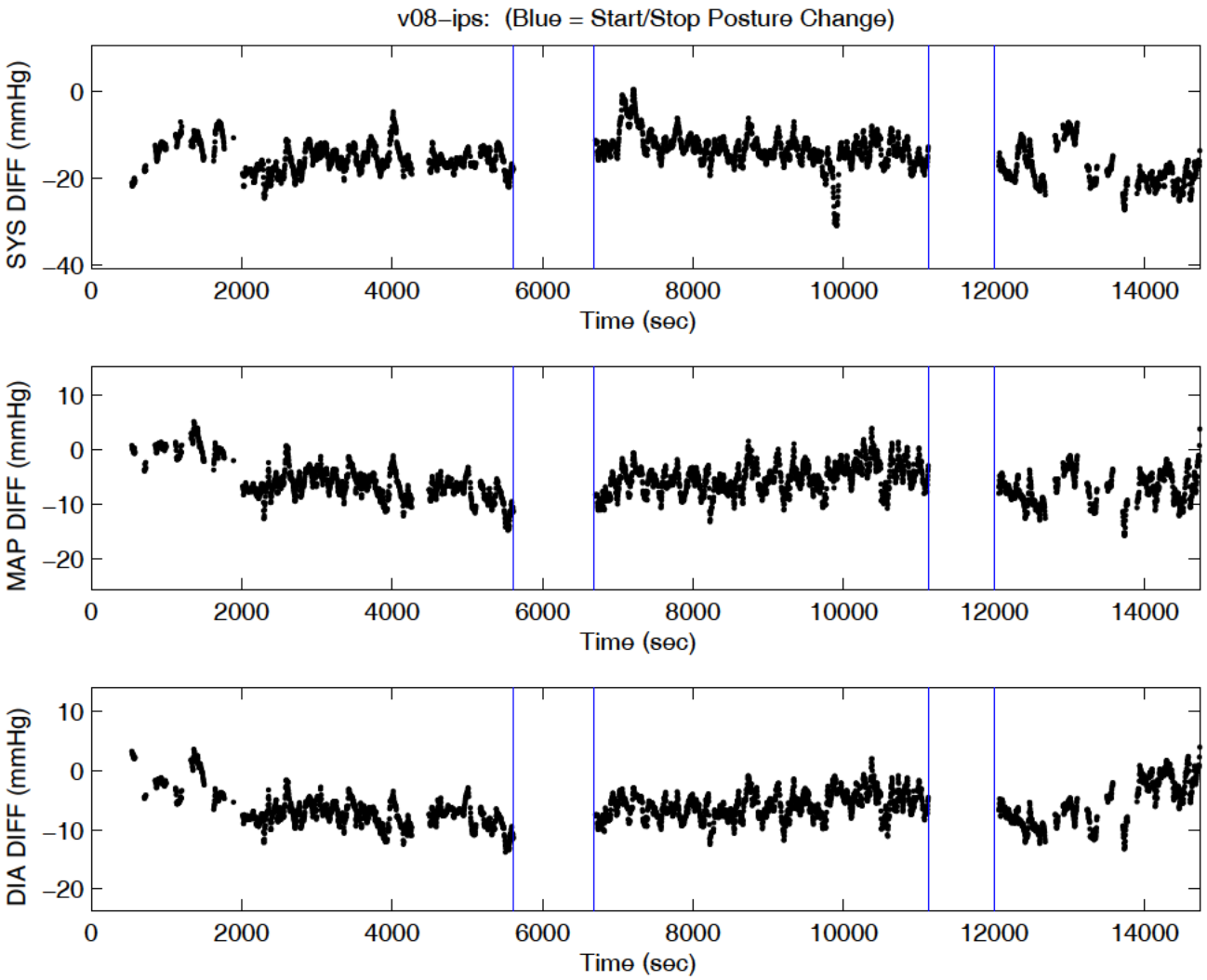


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

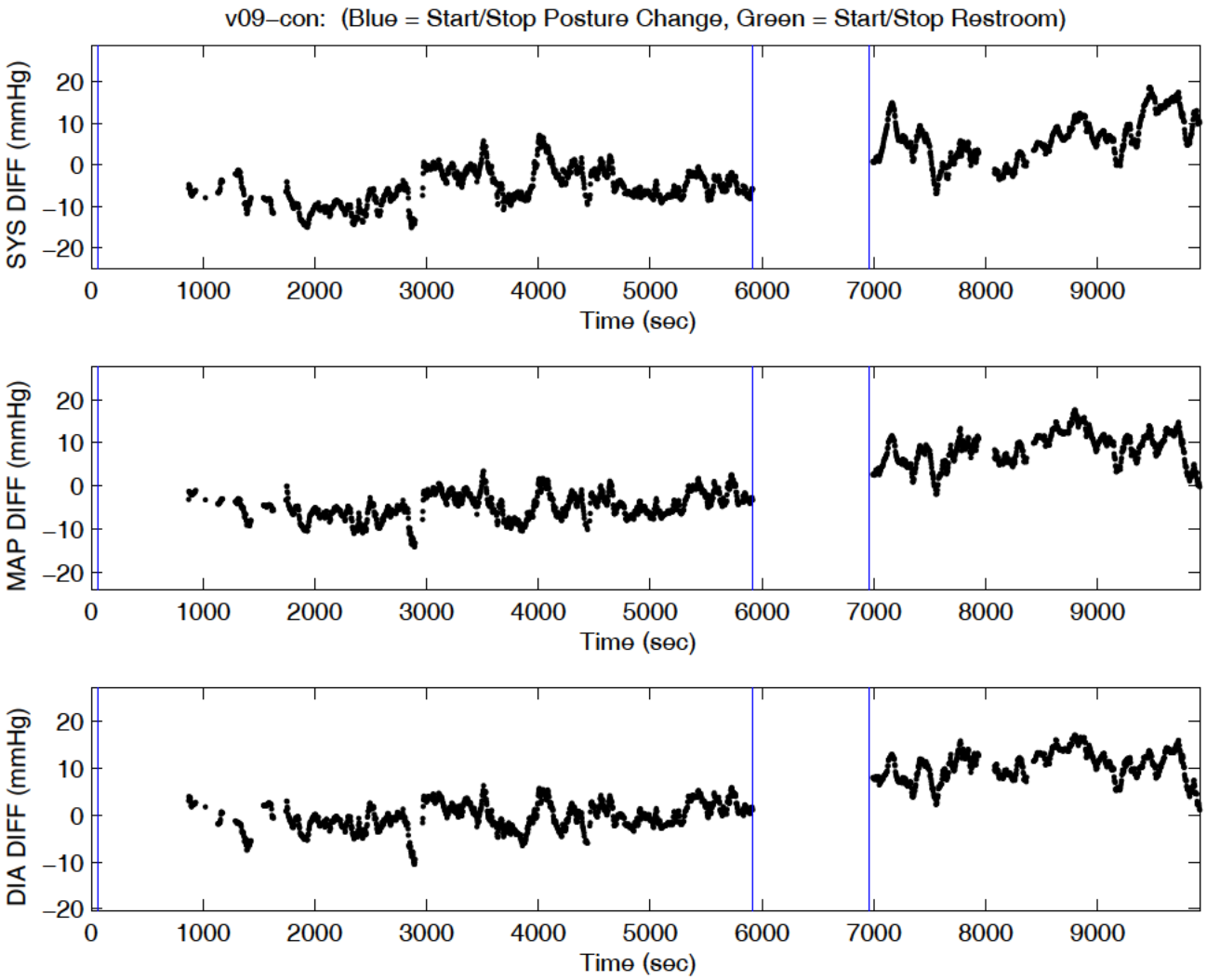


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

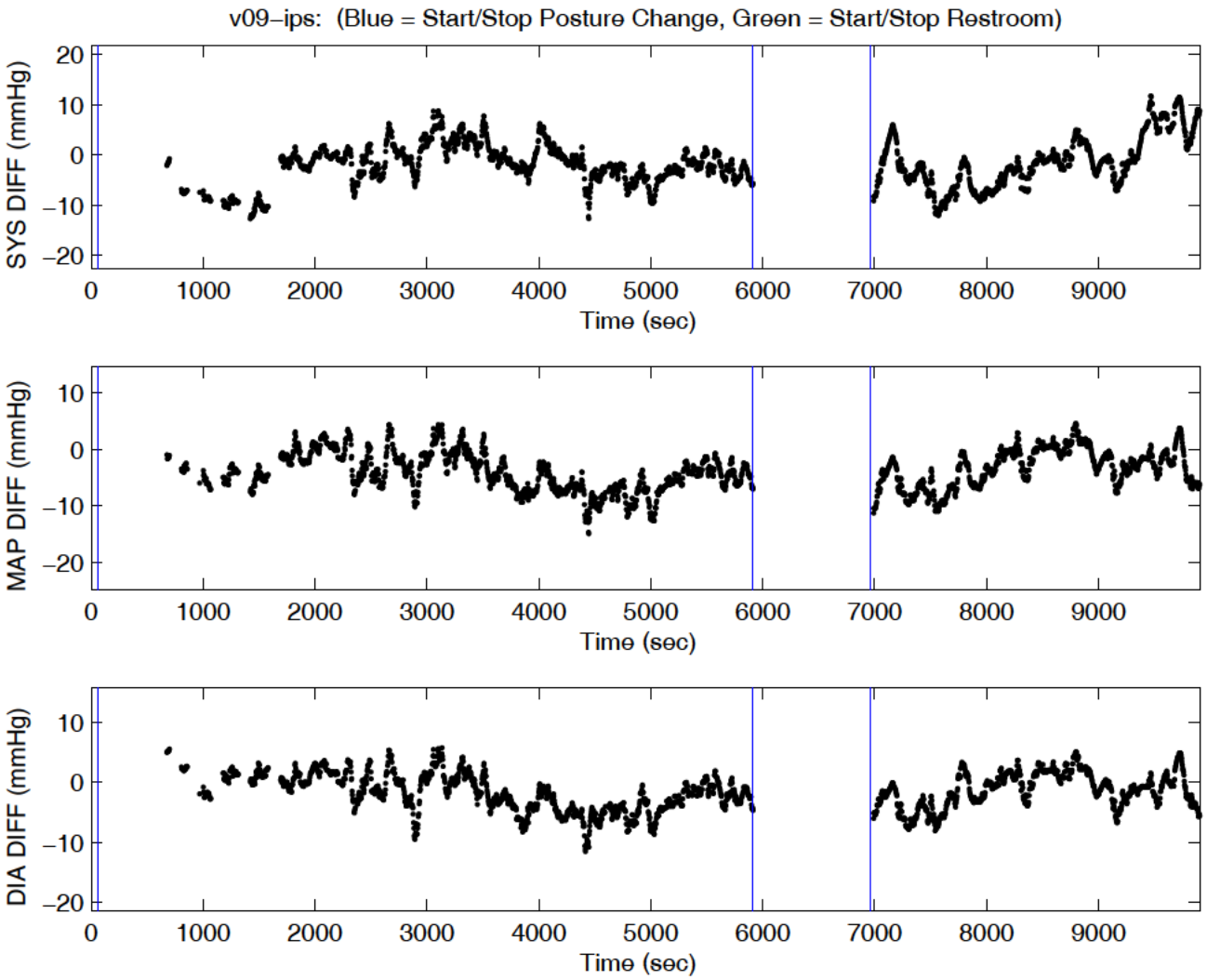


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

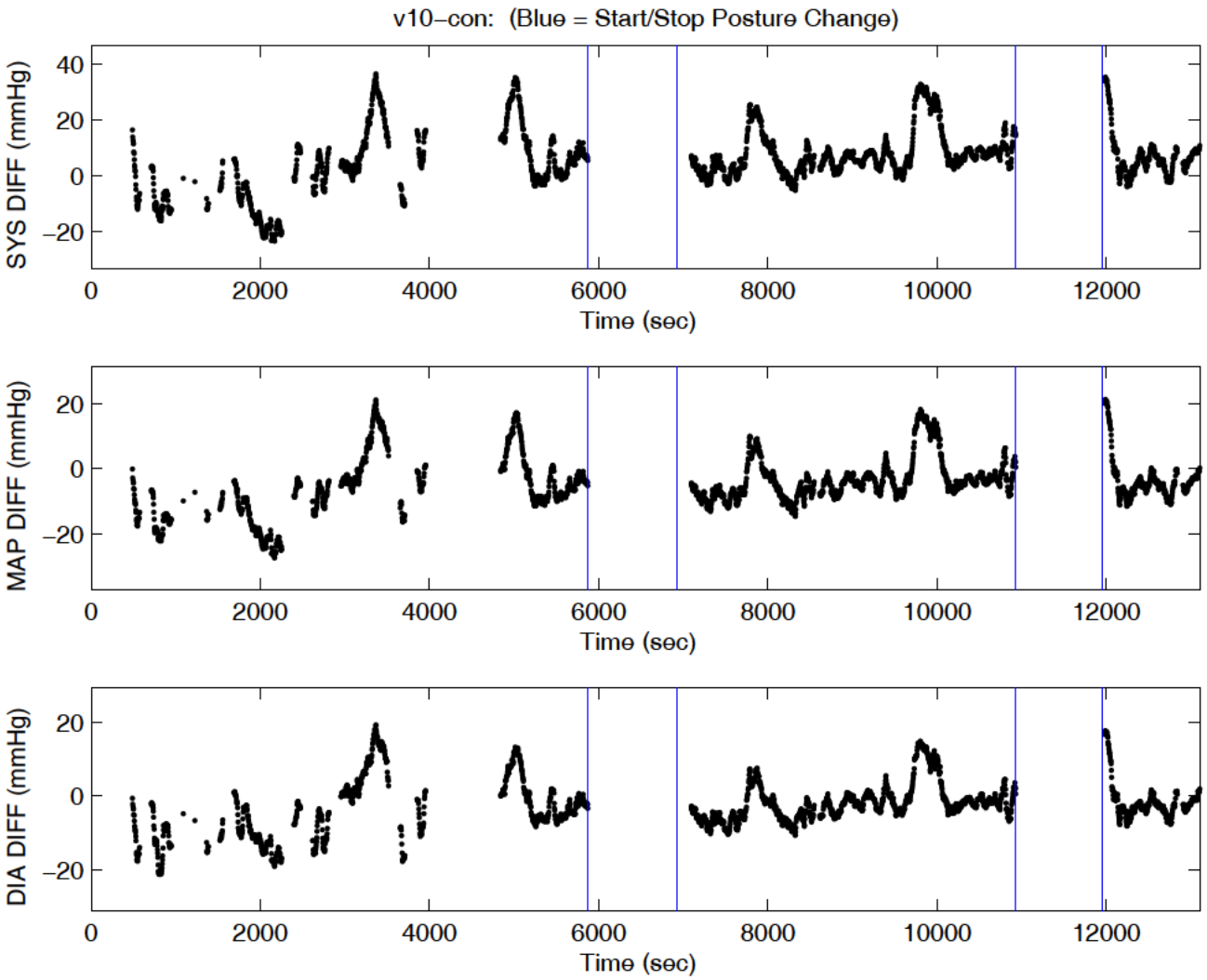


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

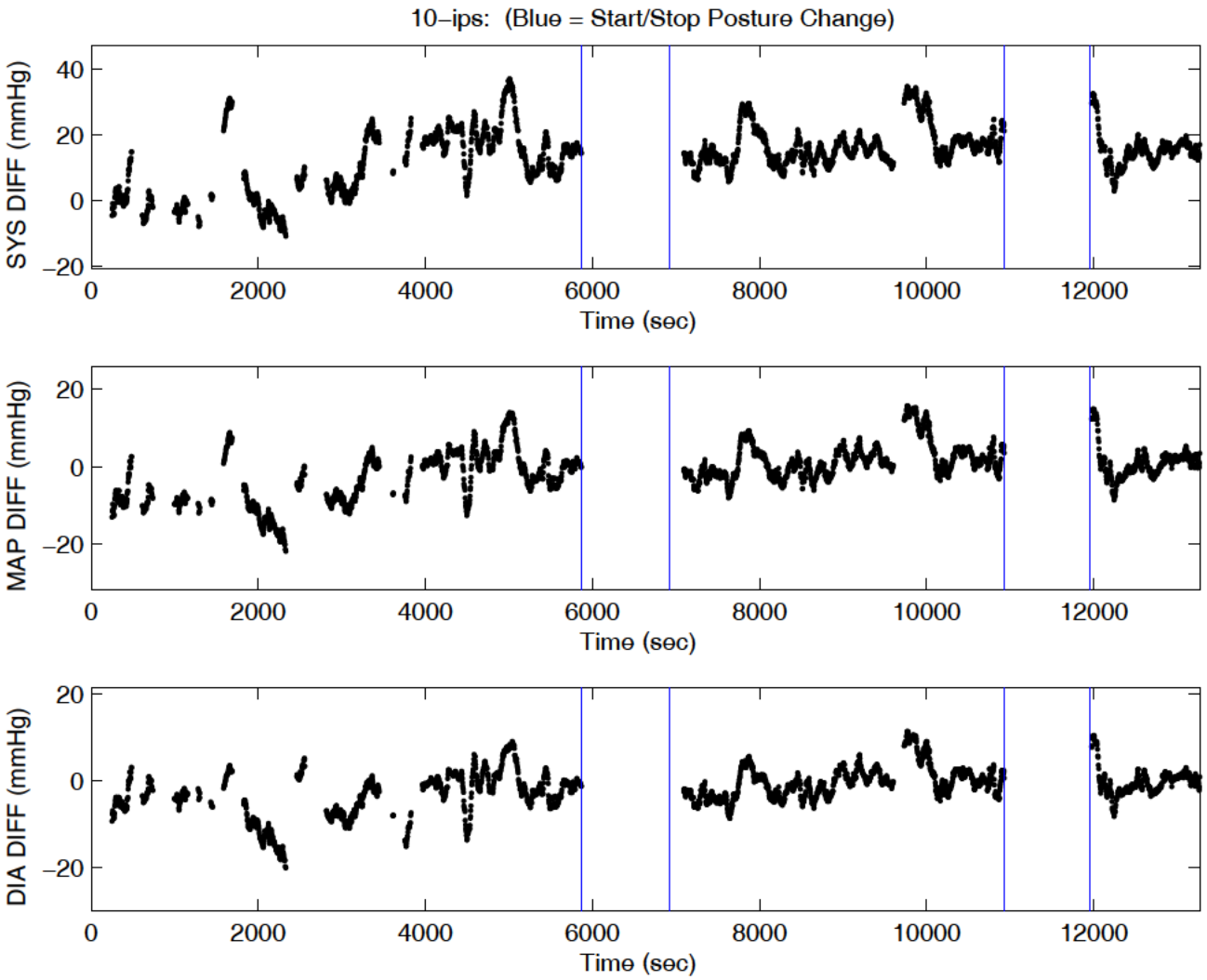


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

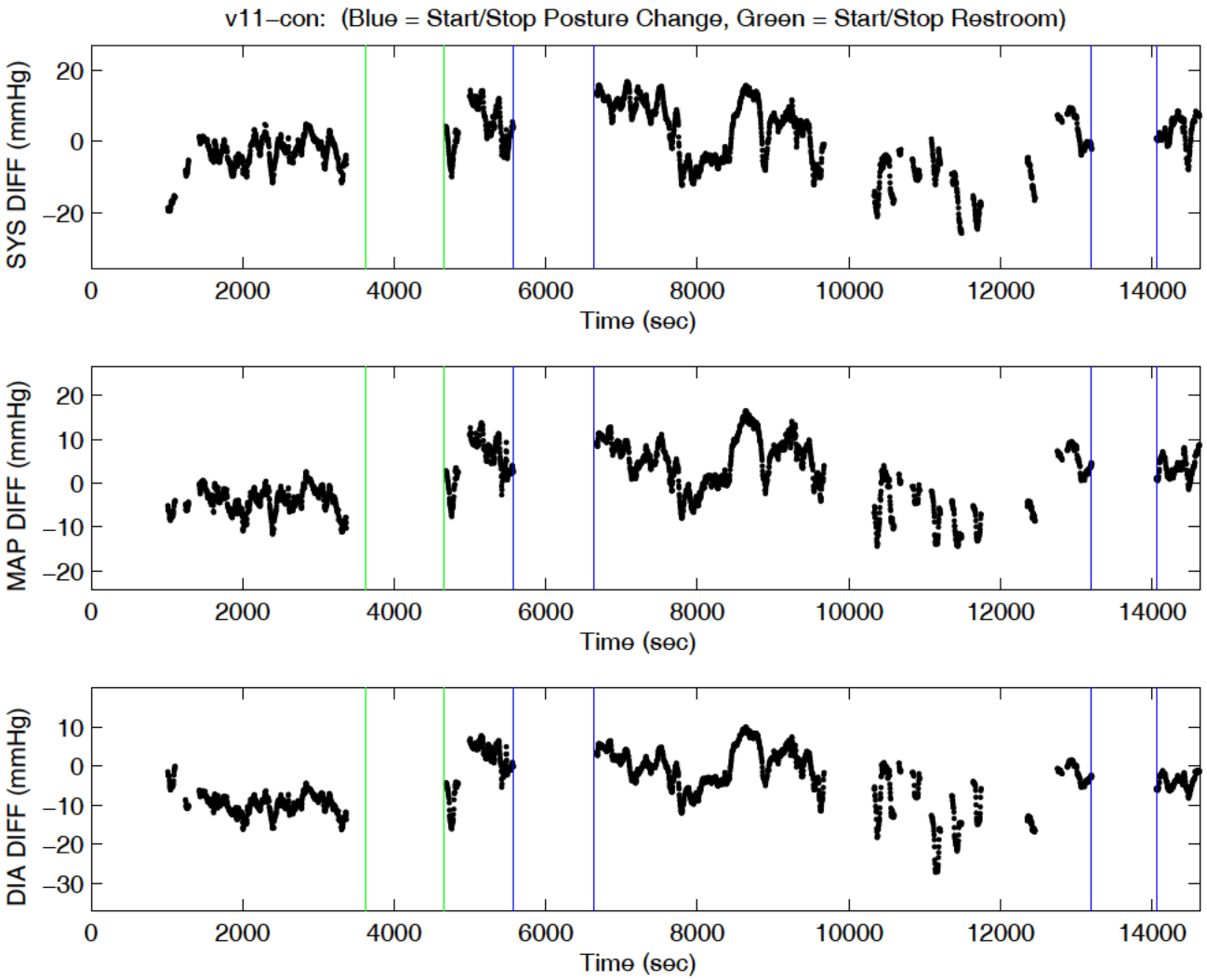


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

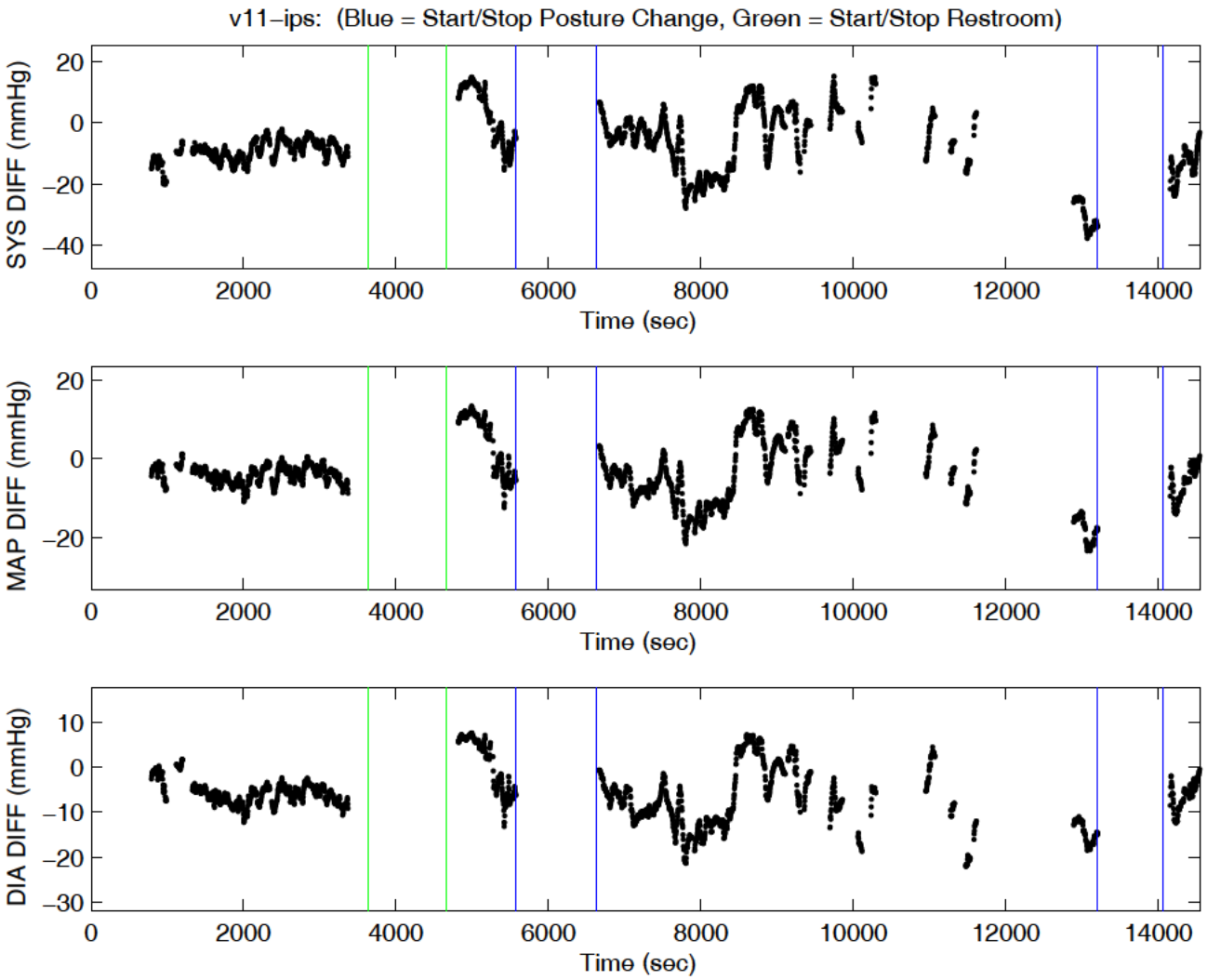


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

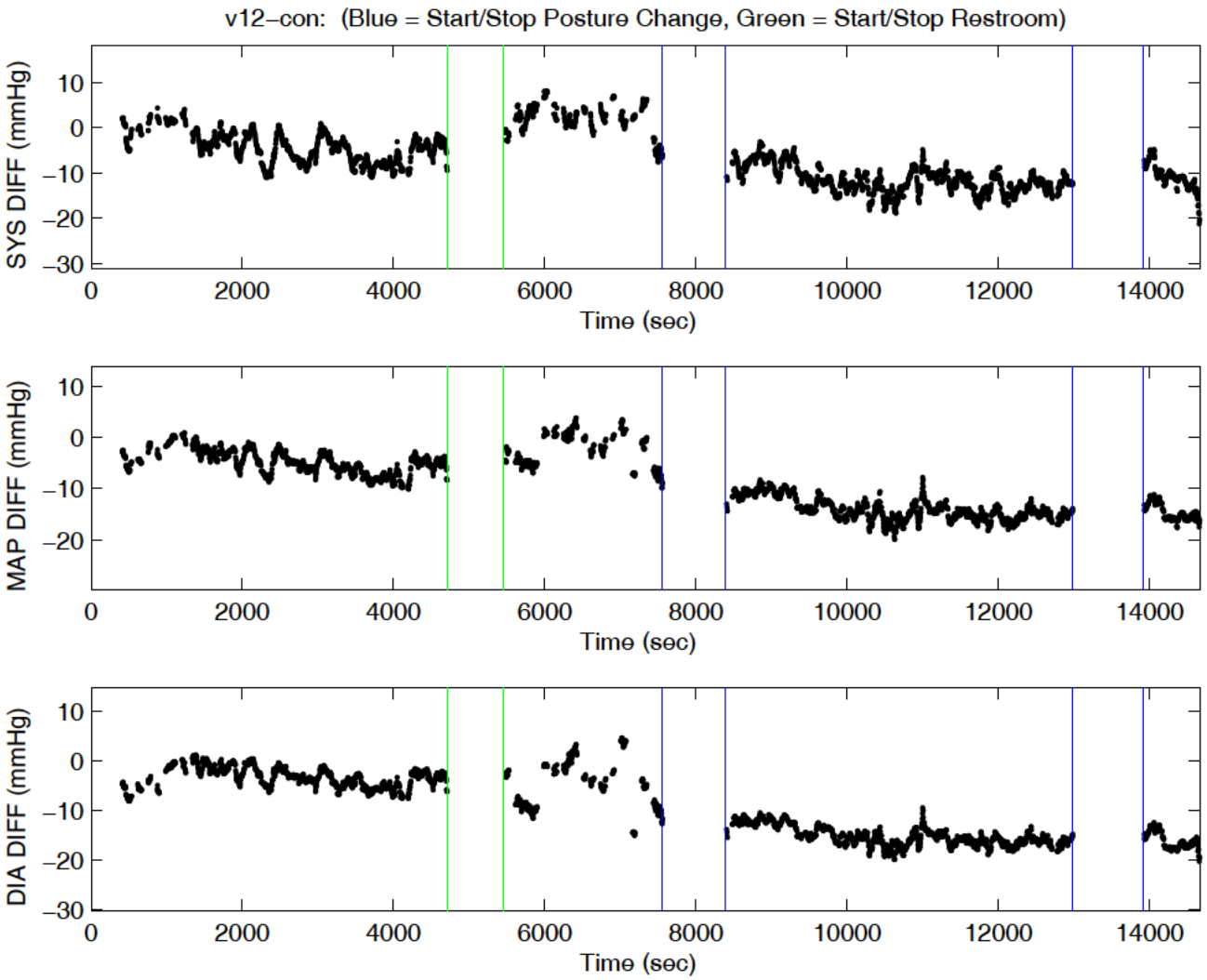


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

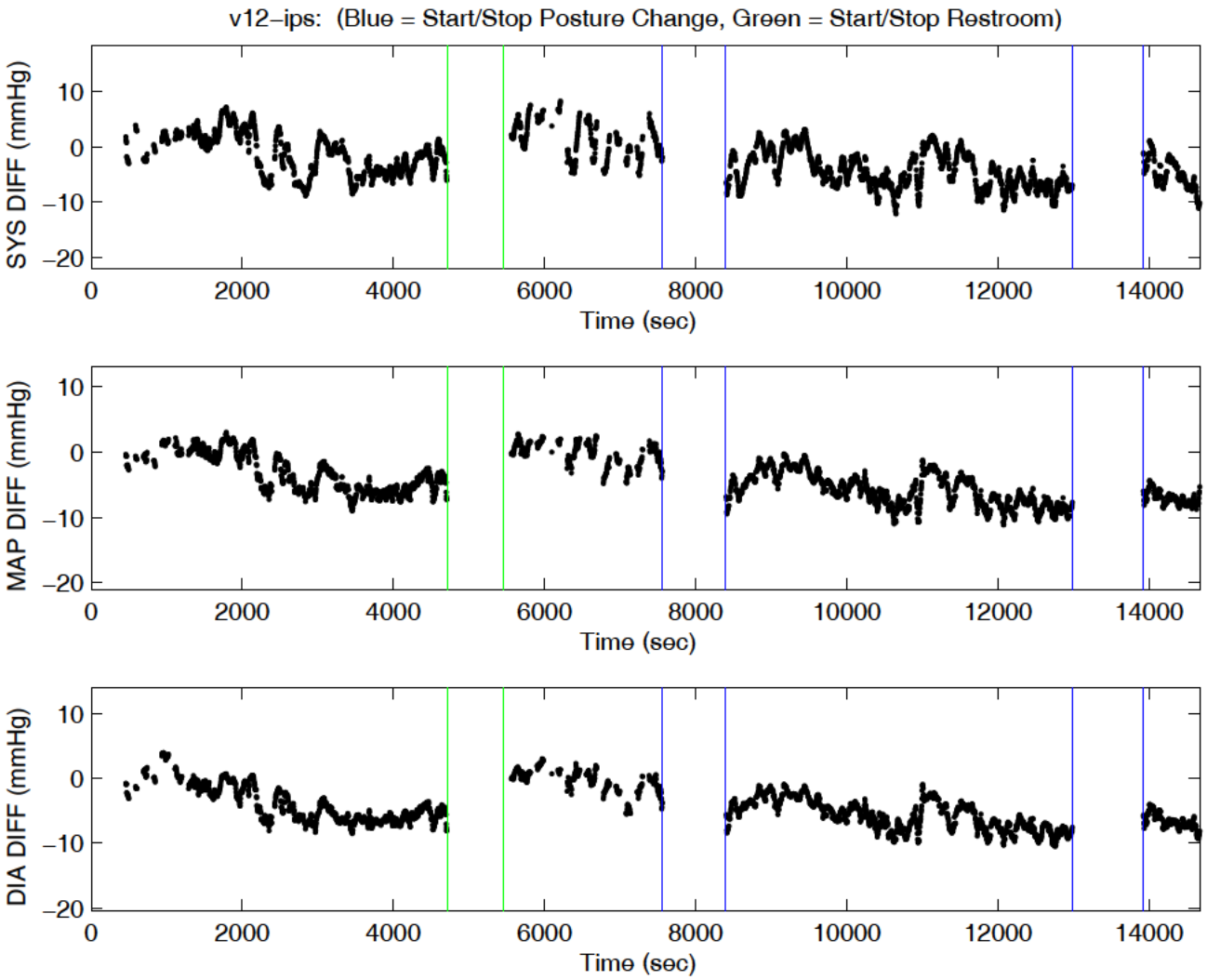


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

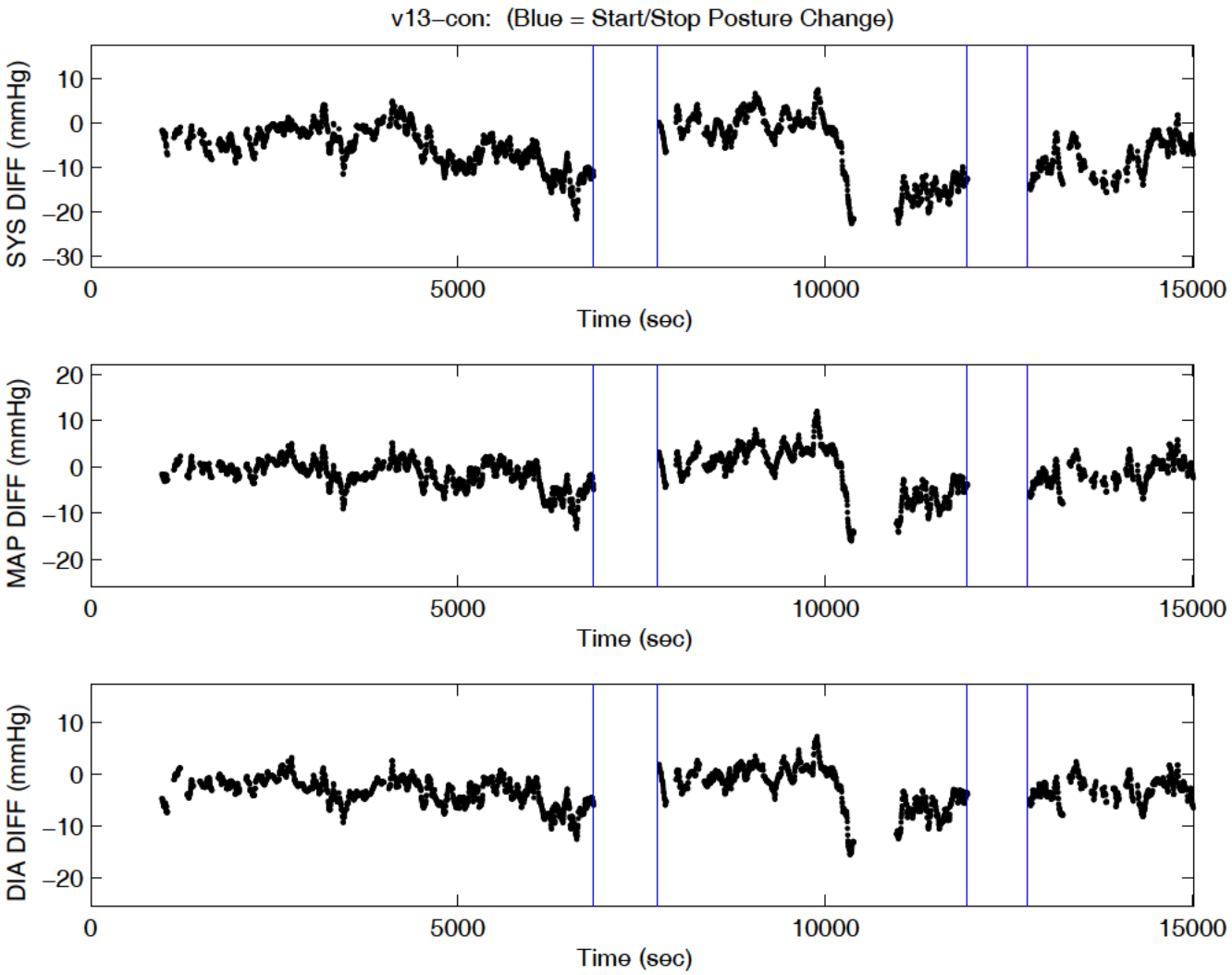


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

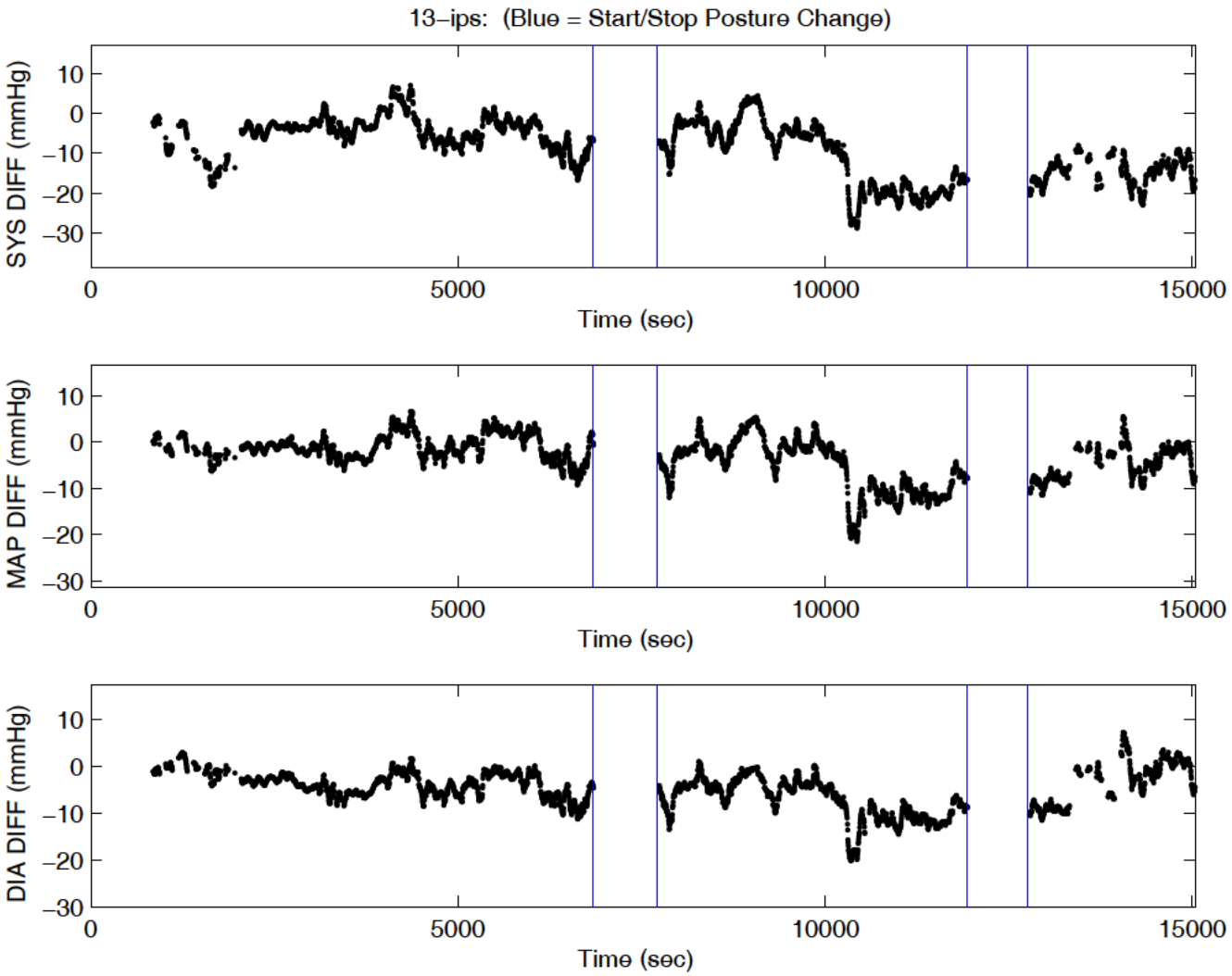


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

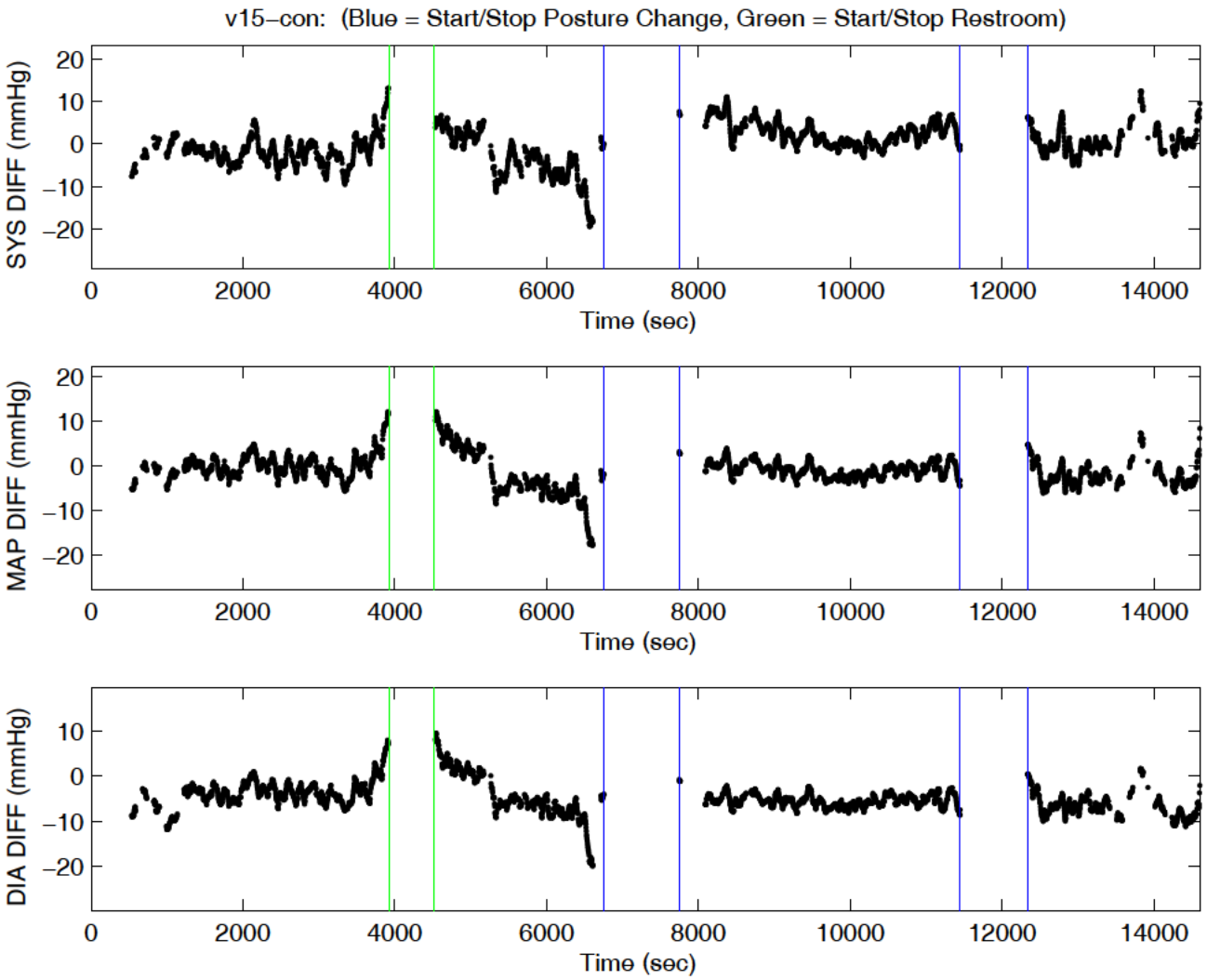


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

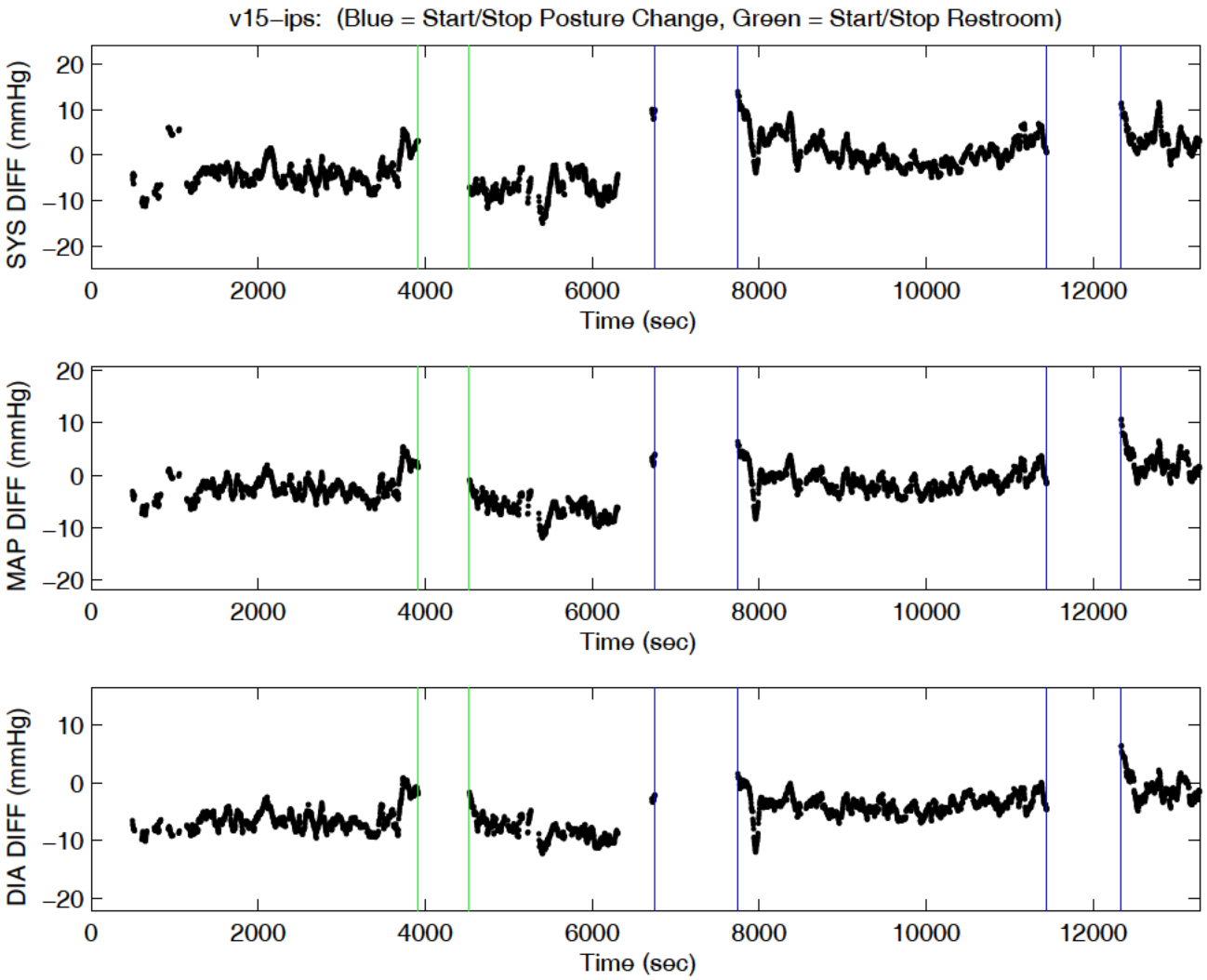


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

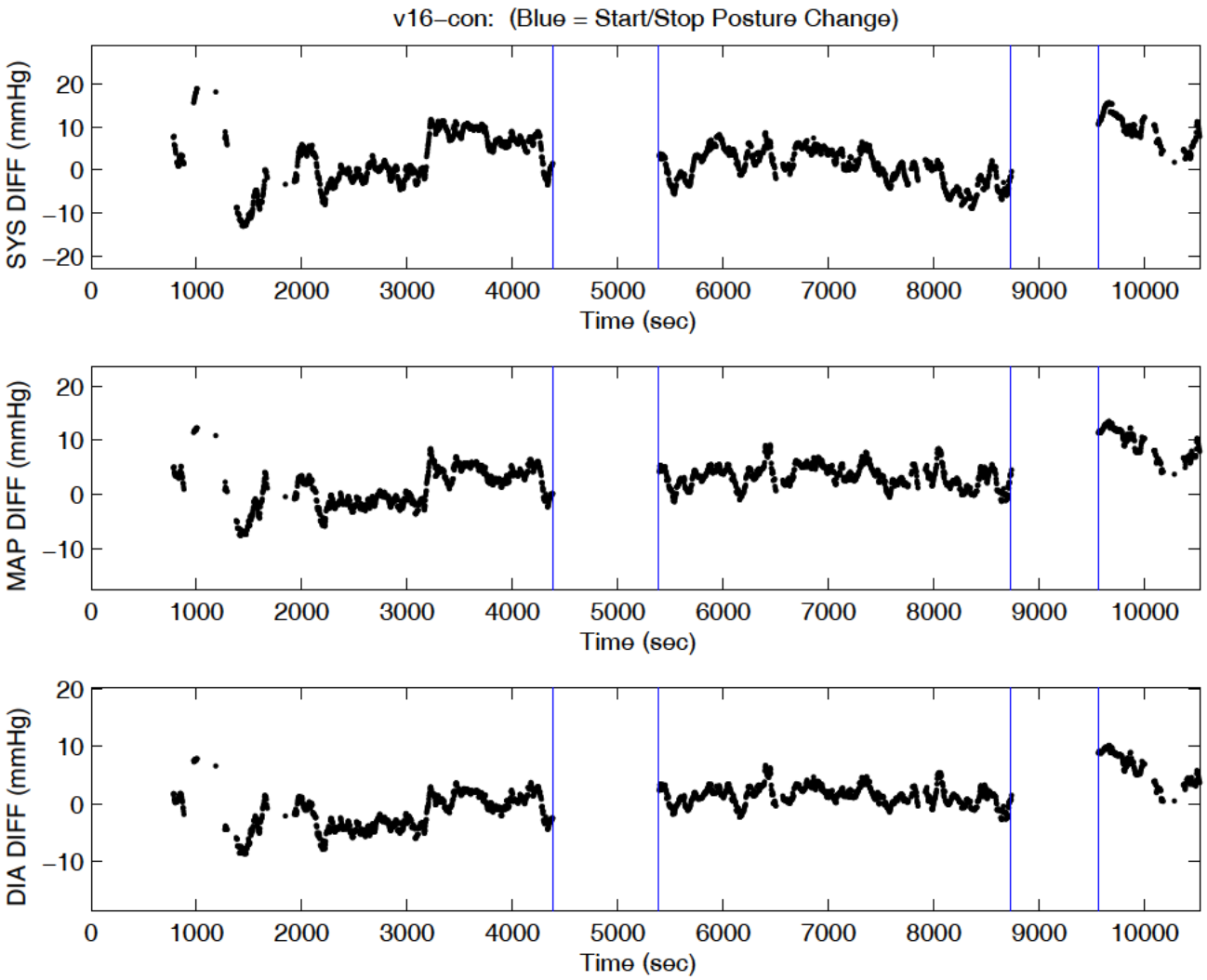


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

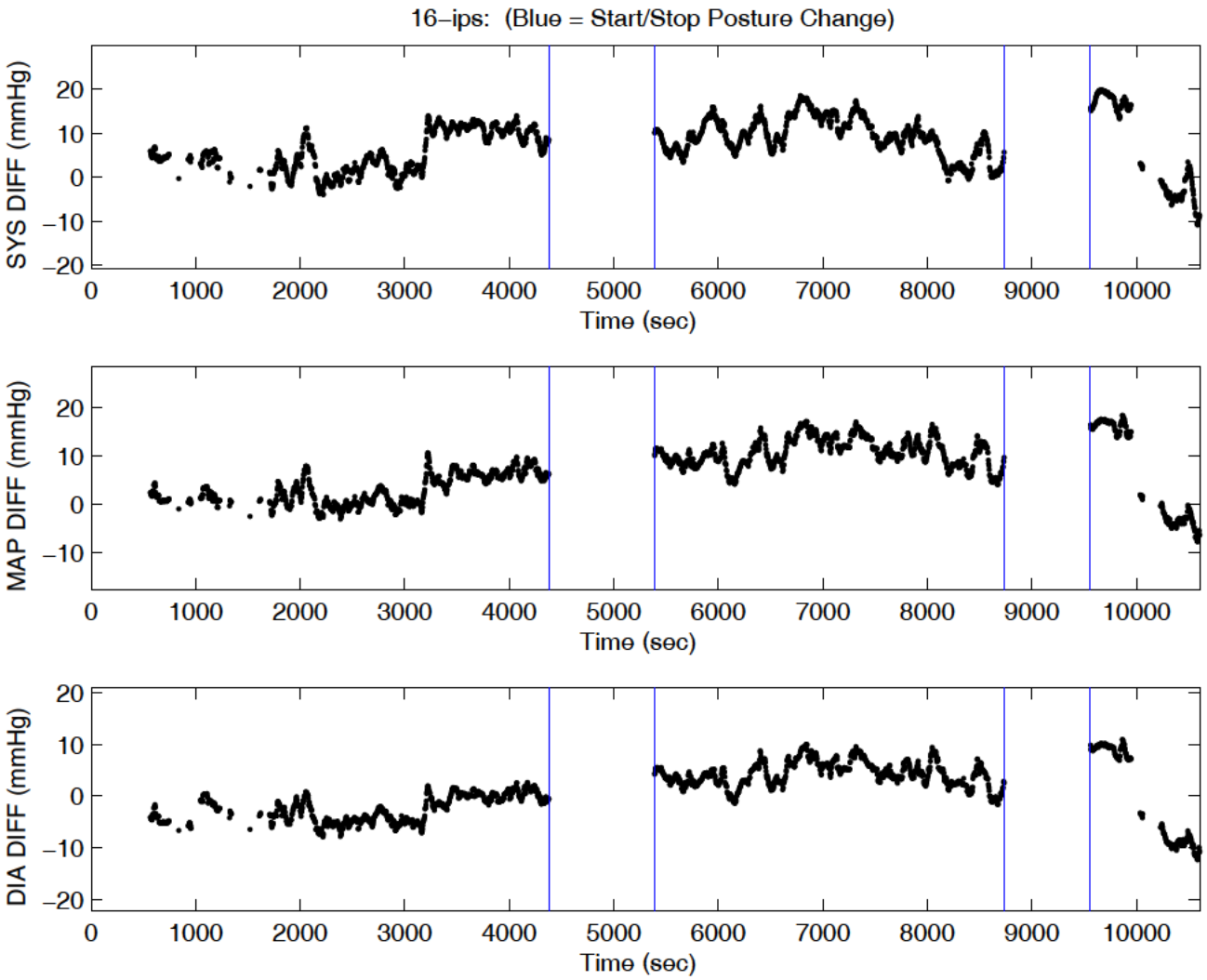


Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)

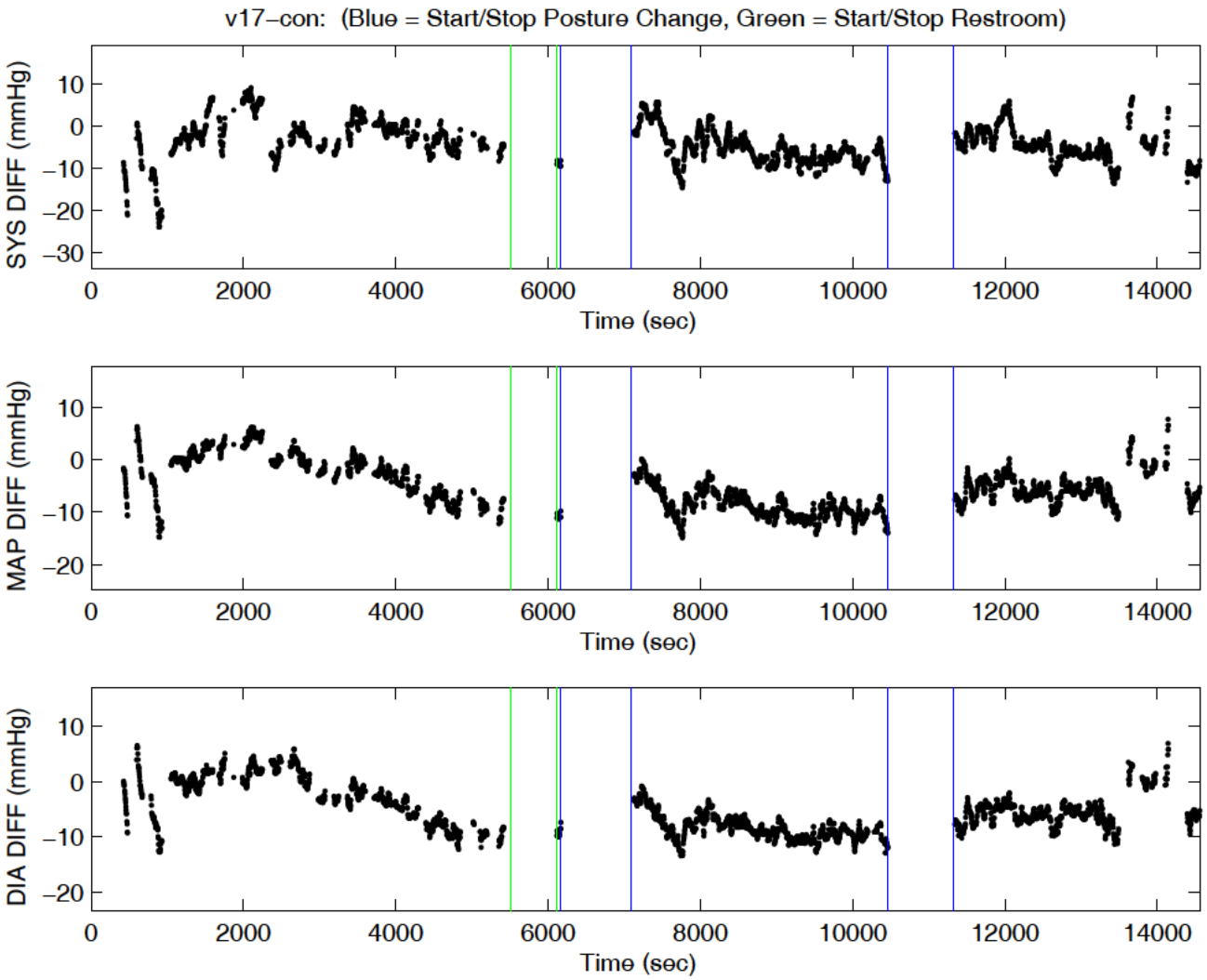
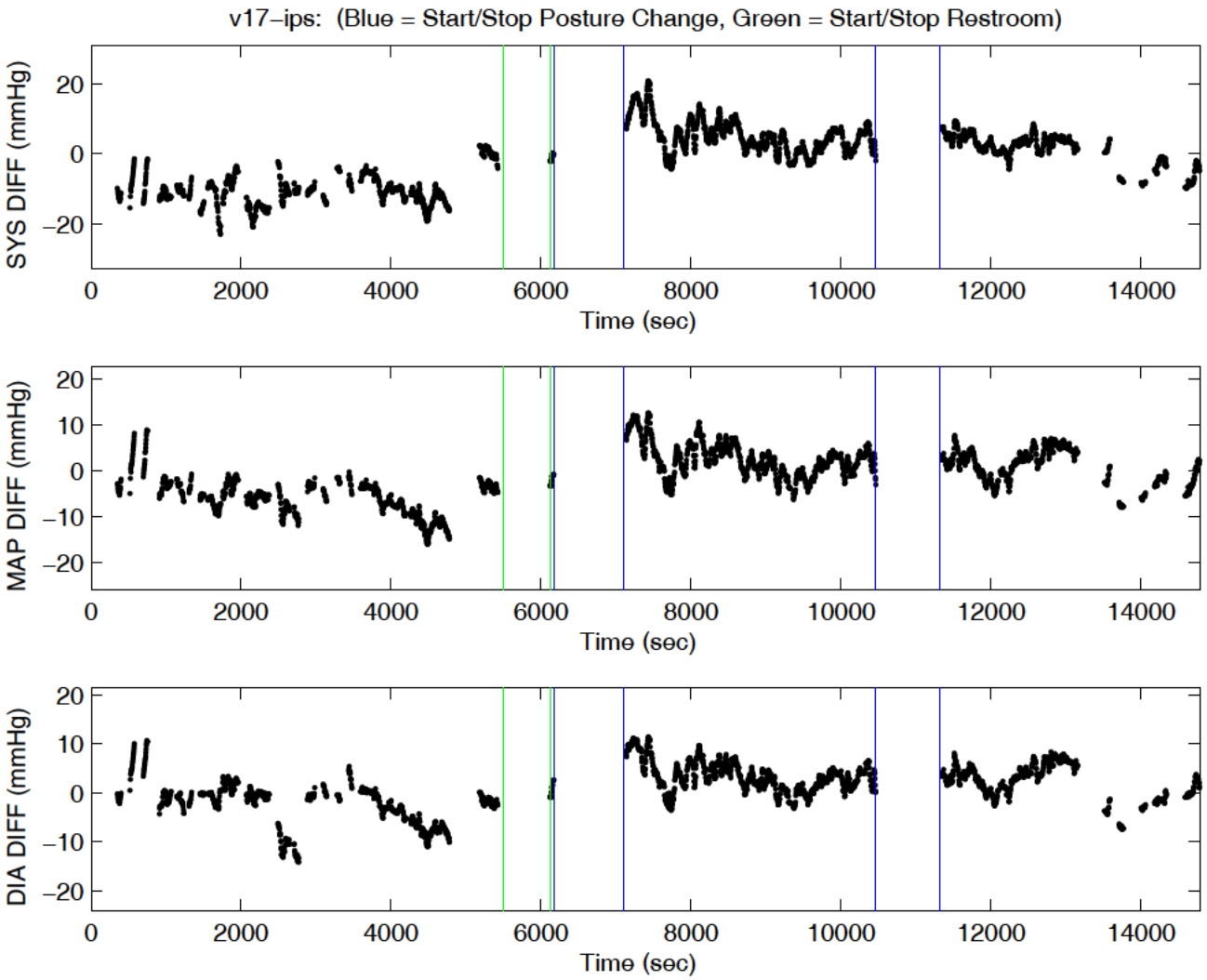



Exhibit 16 - Time series error plots using the difference between the ViSi and arterial line (Ipsilateral and contralateral)