

K133923

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

APR 11 2014

SECTION 5

510(k) SUMMARY

**SUMMARY OF SAFETY AND EFFECTIVENESS FOR
Multi-Parameter Mobile CareGuide™ 3100 Oximeter, with Tablet**

Submitter Information

Name: Reflectance Medical, Inc. (RMI)
Address: 116 Flanders Road, Suite 1000
Westborough, MA 01581 USA

Telephone Number: 508.366.4700

Registration Number: NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)

Contact Person: Dr. Babs Soller
Telephone Number: 508.366.4700, Ext 223
Fax Number: 508.366.4770
Email: Babs.Soller@reflectancemedical.com

Date Prepared: 12/19/2013

Device Name

Trade name of New Device: Multi-Parameter CareGuide™ Oximeter with Tablet
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc. (RMI)
510(k) Number: N/A
Product codes: 21 CFR § 870.2700, 21 CFR 868.1170
Classification Panel: Cardiovascular

Predicate Devices

Predicate Device #1: Mobile CareGuide
Trade Name of Device: Multi-Parameter Mobile CareGuide Oximeter
Model #: 3100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K130079, CareGuide 3100
Product codes: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

K133923

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Predicate Device #2: CareGuide
 Trade Name of Device: CareGuide Oximeter
 Model #: 1100
 510(k) Holder/Submitter: Reflectance Medical Inc.
 510(k) Numbers: K113656, CareGuide 1100
 Product code: MUD, 21 CFR 870.2700, Cardiovascular

Device Description

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses Near Infrared (NIR) Spectroscopy to calculate muscle oxygen saturation (SmO₂) and muscle pH (pHm) and displays those parameters as real-time values and historical trends on a tablet device.

Characteristics	Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor, disposable pad and display tablet
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO ₂) and muscle pH (pHm)

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is a multiple parameter oximeter. The sensor contains algorithms that calculate SmO₂ and pHm from collected spectra and communicates the current SmO₂ and pHm results to an Android tablet with display software through a proprietary protocol. The Android tablet (qualified models Acer A500 and Asus Google Nexus 7) contains 3rd party software that locks down the tablet so that only the CareGuide software may run and no other application or operating software can be modified. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with a USB connection to the Android tablet. The sensor is identical to the predicate (K130079) Multi-parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the same disposable element as the Multi-Parameter Mobile CareGuide 3100 Oximeter, a disposable sleeve that isolates the sensor optical elements from the patient's skin.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Rationale for Substantial Equivalence

The CareGuide 3100 device's oximetry feature has been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter. The device's pH_m feature has been already cleared under classification regulation 21 C.F.R § 868.1170, Anesthesiology. This 510(k) is seeking clearance for use of the CareGuide 3100 with a dedicated Android Display device.

There is no change in how the User would use the information generated by the Multi-Parameter Care Guide 3100 with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter CareGuide 3100 with Tablet nor any of the predicate devices identified by RMI provides diagnostic output.

The Multi-Parameter CareGuide 3100 with Tablet has the same technological characteristics as the previously cleared RMI devices, the CareGuide 1100 (K113656) and the Multi-Parameter Mobile CareGuide 2100 (K130079).

- The principle of operation of the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is identical to that of the predicate CareGuide devices. They use the exact same NIR spectroscopic platform to measure tissue oxygen saturation and muscle. The same software quantitative algorithm for SmO₂ and pH_m is used in both devices.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is equivalent to the Multi-Parameter Mobile CareGuide 3100 Oximeter predicate in reusable components. Both devices use the exact same sensor hardware: main sensor CPU board, battery, optical board (light sources, spectrometer and microprocessor), USB interfaces, plastic housing and cables.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Table is equivalent to the Multi-Parameter Mobile CareGuide 3100 Oximeter predicate in disposable components. Both devices use the exact same disposable sheath ("Ray") and disposable sensor check device ("Cradle").

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has the identical underlying LED light source as the CareGuide predicates, with the exact same range of wavelength (700-900 nm).
- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet and the predicated CareGuide 1100 Oximeter are equivalent. The CareGuide 1100 System includes a Monitor display while the CareGuide 3100 {subject of this 510(k)} includes a dedicated Android display. Both displays are functionally equivalent. Both CareGuide 1100 and 3110 displays are tools that interface with the CareGuide oximeter and display real-time parameters and historical trends per their cleared indications for use.
- The predicate Multi-Parameter Mobile CareGuide 3100 Oximeter is compatible with any USB-connected display device that supports the specified communications protocol. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet {subject of this 510(k)} now includes such a USB-connected display device (i.e. dedicated Android tablet), supporting that specified communications protocol.

Summary of Safety and Effectiveness Data

Bench testing demonstrates that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is safe and effective, meeting all relevant consensus and FDA recognized standards. The bench and software test results in this submission demonstrate that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet meets the expected performance requirements for an Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is therefore equivalent to the predicates by indications for use and device features and functionality.

Conclusion

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is equivalent to predicate device in terms of technology (NIR Spectroscopy) and intended use. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet does not raise new questions of safety or effectiveness, as compared to the predicate. Therefore, the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 11, 2014

Reflectance Medical, Inc.
Babs Soller
Chief Executive Officer
116 Flanders Road,
Suite 1000
Westborough, MA 01581 US

Re: K133923
Trade/Device Name: Multi-parameter Mobile CareGuide 3100 Oximeter with Tablet
Regulation Number: 21 CFR 870.8700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: March 7, 2014
Received: March 13, 2014

Dear Dr. Soller,

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

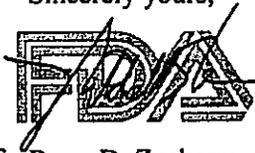
Page 2 - Dr. Babs Soller

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

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

Sincerely yours,

A stylized, handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over a faint, stylized outline of the FDA logo.

for Bram D. Zuckerman, M.D.

Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use Form

Indications for Use

510(k) Number (if known): K133923

Device Name: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 ___

Date: 2014:04:11 07:57:56 -04'00

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

K133923

SECTION 3

510(k) COVER LETTER

Dec 27, 2013

FDA CDRH DMC

DEC 30 2013

Received

Office of Device Evaluation [510(k)]
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Attention: CEDB Branch, ODE

RE: K133923 - Traditional 510(k) Premarket Notification for Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet (21 CFR 870.2700, Product code MUD, CBZ)

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with Title 21 of the Code of Federal Regulations, Part 807, Subpart E, Reflectance Medical Inc. submits this Traditional Premarket Notification of intention to introduce into interstate commerce for commercial distribution the following product: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet.

Per eCopy Hold Letter, dated 12/26/13, corrections were made to the volume labeling of the document. No content changes were made. Please find enclosed two (2) CDs of the eCopy version. The eCopy is an exact duplicate of the paper copy. Paper copy has already been submitted (received on 12/23/13) and is unchanged.

The purpose of this 510(k) Premarket Notification is to obtain a determination of Substantial Equivalence for the CareGuide 3100 Oximeter with tablet. The CareGuide 3100 was previously cleared by K130079. RMI now intends to commercialize the CareGuide 3100 with a dedicated Android tablet display. The Mobile CareGuide™ 3100 Oximeter with Tablet is indicated for the following use:

20

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

The Multi-Parameter CareGuide™ 3100 Oximeter with Tablet is shown to be Substantially Equivalent to the predicate devices:

Predicate Device #1: Mobile CareGuide
Trade Name of Device: Multi-Parameter Mobile CareGuide Oximeter
Model #: 3100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K130079, CareGuide 3100
Product code: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2: CareGuide
Trade Name of Device: CareGuide Oximeter
Model #: 1100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K113656, CareGuide 1100
Product code: MUD, 21 CFR 870.2700, Cardiovascular

In accordance with the United States Food and Drug Administration's (FDA's) August 12, 2005 *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (hereinafter FDA 2005 Guidance), this submission includes the following information:

- Type of 510(k) submission: Traditional 510k
- Common name of Device: Multi-Parameter Oximeter with Tablet
- 510(k) submitter: Reflectance Medical, Inc. (RMI)

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
 Phone: 508.366.4700
 Fax: 508.366.4770

- Contact person, by name, title, and phone number:
 - Dr. Babs Soller, President and Chief Executive Officer, Reflectance Medical, Inc.; Phone number: (508) 366-4700 x 223; (b)(6) (b)(6)
 - Nandini Murthy, Regulatory Consultant, Reflectance Medical, Inc.; (b)(6) (b)(6) number: (b)(6) (b)(6)
- Preference for continued confidentiality (21 CFR § 807.95): The descriptions and information contained in this 510(k) Premarket Notification constitute confidential commercial information. We request that the FDA regard the contents of this submission as subject to protection from public disclosure to the extent permitted by the provisions of 21 C.F.R. § 807.95(b). Please note that all trademarks, registered trademarks, and product names used within this 510(k) Premarket Notification are the property of their respective owners.
- Classification regulation: 21 C.F.R. § 870.2700, Oximeter
- Class: Class II 510(k)
- Review Panel: Cardiovascular
- Product code: CBZ, MUD
- FDA document numbers associated with prior correspondence with FDA: K130079
- Basis for the Submission: Additional display device for a FDA-cleared device

Per the FDA 2005 Guidance, the principal factors concerning the design and use of the CareGuide 3100 Oximeter with Tablet are:

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
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Question	YES	NO
Is the device intended for single use?		X*
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

*There is a disposable sleeve over the Sensor

Reflectance Medical, Inc. considers its intent to market the device as confidential commercial information and requests that FDA treat it in the same manner. It is Reflectance Medical, Inc.'s position that this submission includes trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61. Therefore, we request that the Food and Drug Administration not disclose any information included in this submission (except for the Indications for Use and 510(k) Summary) prior to providing Reflectance Medical, Inc. a predisclosure notification and a reasonable opportunity to redact information that should not be made public under 21 CFR § 20.61.

(b) (4)

(b)(4)

We believe that the information provided in this 510(k) Premarket Notification supports a determination of substantial equivalence of the Mobile CareGuide 3100 Oximeter with Tablet.

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

If you should have any questions or require further information, please contact Dr. Babs Soller by phone (b)(6) (email: babs.soller@reflectancemedical.com) or Nandini Murthy by phone at (b)(6) mail: nmurthy@enemconsulting.com).

Sincerely,

A handwritten signature in blue ink that reads "Babs Soller". The signature is fluid and cursive.

Babs Soller, Ph.D.
President and Chief Executive Officer
Reflectance Medical, Inc.
Phone: (508) 366-4700 x 223
(b)(6)
Fax: 508.366.4770
E-mail: babs.soller@reflectancemedical.com

K133923

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



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Phone: 508.366.4700
Fax: 508.366.4770

SECTION 3

510(k) COVER LETTER

FDA CDRH DMC

DEC 23 2013

Received

Dec 19, 2013

Office of Device Evaluation [510(k)]
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Attention: CEDB Branch, ODE

RE: Traditional 510(k) Premarket Notification for Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet (21 CFR 870.2700, Product code MUD, CBZ)

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with Title 21 of the Code of Federal Regulations, Part 807, Subpart E, Reflectance Medical Inc. submits this Traditional Premarket Notification of intention to introduce into interstate commerce for commercial distribution the following product: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet.

Please find enclosed one (1) paper hard copy and two (2) CDs of the eCopy version. The eCopy is an exact duplicate of the paper copy.

The purpose of this 510(k) Premarket Notification is to obtain a determination of Substantial Equivalence for the CareGuide 3100 Oximeter with tablet. The CareGuide 3100 was previously cleared by K130079. RMI now intends to commercialize the CareGuide 3100 with a dedicated Android tablet display. The Mobile CareGuide™ 3100 Oximeter with Tablet is indicated for the following use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



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The Multi-Parameter CareGuide™ 3100 Oximeter with Tablet is shown to be Substantially Equivalent to the predicate devices:

Predicate Device #1: Mobile CareGuide
Trade Name of Device: Multi-Parameter Mobile CareGuide Oximeter
Model #: 3100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K130079, CareGuide 3100
Product code: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2: CareGuide
Trade Name of Device: CareGuide Oximeter
Model #: 1100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K113656, CareGuide 1100
Product code: MUD, 21 CFR 870.2700, Cardiovascular

In accordance with the United States Food and Drug Administration's (FDA's) August 12, 2005 *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (hereinafter FDA 2005 Guidance), this submission includes the following information:

- Type of 510(k) submission: Traditional 510k
- Common name of Device: Multi-Parameter Oximeter with Tablet
- 510(k) submitter: Reflectance Medical, Inc. (RMI)
- Contact person, by name, title, and phone number:

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



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 116 Flanders Road, Suite 1000
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- o Dr. Babs Soller, President and Chief Executive Officer, Reflectance Medical, Inc.; Phone number: (508) 366-4700 x 223; (b)(6) (b)(6)
- o Nandini Murthy, Regulatory Consultant, Reflectance Medical, Inc.; (b)(6) (b)(6)
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- Classification regulation:
 21 C.F.R. § 870.2700, Oximeter
- Class: Class II 510(k)
- Review Panel: Cardiovascular
- Product code: CBZ, MUD
- FDA document numbers associated with prior correspondence with FDA: K130079
- Basis for the Submission: Additional display device for a FDA-cleared device

Per the FDA 2005 Guidance, the principal factors concerning the design and use of the CareGuide 3100 Oximeter with Tablet are:

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



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Question	YES	NO
Is the device intended for single use?		X*
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

*There is a disposable sleeve over the Sensor

Reflectance Medical, Inc. considers its intent to market the device as confidential commercial information and requests that FDA treat it in the same manner. It is Reflectance Medical, Inc.'s position that this submission includes trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61. Therefore, we request that the Food and Drug Administration not disclose any information included in this submission (except for the Indications for Use and 510(k) Summary) prior to providing Reflectance Medical, Inc. a predisclosure notification and a reasonable opportunity to redact information that should not be made public under 21 CFR § 20.61.

(b) (4)

(b)(4)

We believe that the information provided in this 510(k) Premarket Notification supports a determination of substantial equivalence of the Mobile CareGuide 3100 Oximeter with Tablet.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



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Phone: 508.366.4700
Fax: 508.366.4770

If you should have any questions or require further information, please contact Dr. Babs Soller by phone (b) (6) (email: babs.soller@reflectancemedical.com) or Nandini Murthy by phone at (b)(6) (email: nmurthy@enemconsulting.com).

Sincerely,

A handwritten signature in black ink that reads "Babs Soller". The signature is written in a cursive, flowing style.

Babs Soller, Ph.D.
President and Chief Executive Officer
Reflectance Medical, Inc.
Phone: (508) 366-4700 x 223
(b) (6)
Fax: 508.366.4770
E-mail: babs.soller@reflectancemedical.com

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

K133923

SECTION 3

510(k) COVER LETTER

Dec 27, 2013

FDA CDRH DMC

DEC 30 2013

Received

Office of Device Evaluation [510(k)]
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Attention: CEDB Branch, ODE

RE: K133923 - Traditional 510(k) Premarket Notification for Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet (21 CFR 870.2700, Product code MUD, CBZ)

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with Title 21 of the Code of Federal Regulations, Part 807, Subpart E, Reflectance Medical Inc. submits this Traditional Premarket Notification of intention to introduce into interstate commerce for commercial distribution the following product: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet.

Per eCopy Hold Letter, dated 12/26/13, corrections were made to the volume labeling of the document. No content changes were made. Please find enclosed two (2) CDs of the eCopy version. The eCopy is an exact duplicate of the paper copy. Paper copy has already been submitted (received on 12/23/13) and is unchanged.

The purpose of this 510(k) Premarket Notification is to obtain a determination of Substantial Equivalence for the CareGuide 3100 Oximeter with tablet. The CareGuide 3100 was previously cleared by K130079. RMI now intends to commercialize the CareGuide 3100 with a dedicated Android tablet display. The Mobile CareGuide™ 3100 Oximeter with Tablet is indicated for the following use:

20

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

The Multi-Parameter CareGuide™ 3100 Oximeter with Tablet is shown to be Substantially Equivalent to the predicate devices:

Predicate Device #1: Mobile CareGuide
Trade Name of Device: Multi-Parameter Mobile CareGuide Oximeter
Model #: 3100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K130079, CareGuide 3100
Product code: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2: CareGuide
Trade Name of Device: CareGuide Oximeter
Model #: 1100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K113656, CareGuide 1100
Product code: MUD, 21 CFR 870.2700, Cardiovascular

In accordance with the United States Food and Drug Administration's (FDA's) August 12, 2005 *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (hereinafter FDA 2005 Guidance), this submission includes the following information:

- Type of 510(k) submission: Traditional 510k
- Common name of Device: Multi-Parameter Oximeter with Tablet
- 510(k) submitter: Reflectance Medical, Inc. (RMI)

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
 Phone: 508.366.4700
 Fax: 508.366.4770

- Contact person, by name, title, and phone number:
 - Dr. Babs Soller, President and Chief Executive Officer, Reflectance Medical, Inc.; Phone number: (508) 366-4700 x 223; (b)(5) (b)(5)
 - Nandini Murthy, Regulatory Consultant, Reflectance Medical, Inc.; (b)(6) (b)(6)
- Preference for continued confidentiality (21 CFR § 807.95): The descriptions and information contained in this 510(k) Premarket Notification constitute confidential commercial information. We request that the FDA regard the contents of this submission as subject to protection from public disclosure to the extent permitted by the provisions of 21 C.F.R. § 807.95(b). Please note that all trademarks, registered trademarks, and product names used within this 510(k) Premarket Notification are the property of their respective owners.
- Classification regulation: 21 C.F.R. § 870.2700, Oximeter
- Class: Class II 510(k)
- Review Panel: Cardiovascular
- Product code: CBZ, MUD
- FDA document numbers associated with prior correspondence with FDA: K130079
- Basis for the Submission: Additional display device for a FDA-cleared device

Per the FDA 2005 Guidance, the principal factors concerning the design and use of the CareGuide 3100 Oximeter with Tablet are:

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
 Phone: 508.366.4700
 Fax: 508.366.4770

Question	YES	NO
Is the device intended for single use?		X*
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

*There is a disposable sleeve over the Sensor

Reflectance Medical, Inc. considers its intent to market the device as confidential commercial information and requests that FDA treat it in the same manner. It is Reflectance Medical, Inc.'s position that this submission includes trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61. Therefore, we request that the Food and Drug Administration not disclose any information included in this submission (except for the Indications for Use and 510(k) Summary) prior to providing Reflectance Medical, Inc. a predisclosure notification and a reasonable opportunity to redact information that should not be made public under 21 CFR § 20.61.

(b) (4)

(b)(4)

We believe that the information provided in this 510(k) Premarket Notification supports a determination of substantial equivalence of the Mobile CareGuide 3100 Oximeter with Tablet.

Reflectance Medical, Inc.

K133923 Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

If you should have any questions or require further information, please contact Dr. Babs Soller by phone (b)(6) (email: babs.soller@reflectancemedical.com) or Nandini Murthy by phone at (b)(6) mail: nmurthy@enemconsulting.com).

Sincerely,

A handwritten signature in blue ink that reads "Babs Soller". The signature is fluid and cursive.

Babs Soller, Ph.D.
President and Chief Executive Officer
Reflectance Medical, Inc.
Phone: (508) 366-4700 x 223
(b)(6)
Fax: 508.366.4770
E-mail: babs.soller@reflectancemedical.com

K133923

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

SECTION 3

510(k) COVER LETTER

FDA CDRH DMC

DEC 23 2013

Received

Dec 19, 2013

Office of Device Evaluation [510(k)]
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Attention: CEDB Branch, ODE

RE: Traditional 510(k) Premarket Notification for Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet (21 CFR 870.2700, Product code MUD, CBZ)

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with Title 21 of the Code of Federal Regulations, Part 807, Subpart E, Reflectance Medical Inc. submits this Traditional Premarket Notification of intention to introduce into interstate commerce for commercial distribution the following product: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet.

Please find enclosed one (1) paper hard copy and two (2) CDs of the eCopy version. The eCopy is an exact duplicate of the paper copy.

The purpose of this 510(k) Premarket Notification is to obtain a determination of Substantial Equivalence for the CareGuide 3100 Oximeter with tablet. The CareGuide 3100 was previously cleared by K130079. RMI now intends to commercialize the CareGuide 3100 with a dedicated Android tablet display. The Mobile CareGuide™ 3100 Oximeter with Tablet is indicated for the following use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of

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Page 1 of 5

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
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microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

The Multi-Parameter CareGuide™ 3100 Oximeter with Tablet is shown to be Substantially Equivalent to the predicate devices:

Predicate Device #1: Mobile CareGuide
Trade Name of Device: Multi-Parameter Mobile CareGuide Oximeter
Model #: 3100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K130079, CareGuide 3100
Product code: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2: CareGuide
Trade Name of Device: CareGuide Oximeter
Model #: 1100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K113656, CareGuide 1100
Product code: MUD, 21 CFR 870.2700, Cardiovascular

In accordance with the United States Food and Drug Administration's (FDA's) August 12, 2005 *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (hereinafter FDA 2005 Guidance), this submission includes the following information:

- Type of 510(k) submission: Traditional 510k
- Common name of Device: Multi-Parameter Oximeter with Tablet
- 510(k) submitter: Reflectance Medical, Inc. (RMI)
- Contact person, by name, title, and phone number:

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
 Phone: 508.366.4700
 Fax: 508.366.4770

- o Dr. Babs Soller, President and Chief Executive Officer, Reflectance Medical, Inc.; Phone number: (508) 366-4700 x 223; (b)(6) (b)(6)
- o Nandini Murthy, Regulatory Consultant, Reflectance Medical, Inc.; (b)(6) (b)(6)
- Preference for continued confidentiality (21 CFR § 807.95): The descriptions and information contained in this 510(k) Premarket Notification constitute confidential commercial information. We request that the FDA regard the contents of this submission as subject to protection from public disclosure to the extent permitted by the provisions of 21 C.F.R. § 807.95(b). Please note that all trademarks, registered trademarks, and product names used within this 510(k) Premarket Notification are the property of their respective owners.
- Classification regulation:
 21 C.F.R. § 870.2700, Oximeter
- Class: Class II 510(k)
- Review Panel: Cardiovascular
- Product code: CBZ, MUD
- FDA document numbers associated with prior correspondence with FDA: K130079
- Basis for the Submission: Additional display device for a FDA-cleared device

Per the FDA 2005 Guidance, the principal factors concerning the design and use of the CareGuide 3100 Oximeter with Tablet are:

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
 Phone: 508.366.4700
 Fax: 508.366.4770

Question	YES	NO
Is the device intended for single use?		X*
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

*There is a disposable sleeve over the Sensor

Reflectance Medical, Inc. considers its intent to market the device as confidential commercial information and requests that FDA treat it in the same manner. It is Reflectance Medical, Inc.'s position that this submission includes trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61. Therefore, we request that the Food and Drug Administration not disclose any information included in this submission (except for the Indications for Use and 510(k) Summary) prior to providing Reflectance Medical, Inc. a predisclosure notification and a reasonable opportunity to redact information that should not be made public under 21 CFR § 20.61.

(b) (4)

(b)(4)

We believe that the information provided in this 510(k) Premarket Notification supports a determination of substantial equivalence of the Mobile CareGuide 3100 Oximeter with Tablet.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
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If you should have any questions or require further information, please contact Dr. Babs Soller by phone: (b)(6) (b)(6) (email: babs.soller@reflectancemedical.com) or Nandini Murthy by phone at (b)(6) (b)(6) (email: nmurthy@enemconsulting.com).

Sincerely,

A handwritten signature in black ink that reads "Babs Soller". The signature is written in a cursive, flowing style.

Babs Soller, Ph.D.
President and Chief Executive Officer
Reflectance Medical, Inc.
Phone: (508) 366-4700 x 223
(b)(6) (b)(6)
Fax: 508.366.4770
E-mail: babs.soller@reflectancemedical.com

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

TRADITIONAL 510(k) PREMARKET NOTIFICATION SUBMISSION**Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet****TABLE OF CONTENTS: Volume 1 of 1**

Section	Contents	Page
1	Medical Device User Fee Cover Sheet	1
2	CDRH Premarket Notification Cover Sheet	5
3	510(k) Submission Cover Letter	14
4	Indications for Use	20
5	510(k) Summary of Safety and Effectiveness	22
6	Truthful and Accuracy Statement	27
7	Class III Certification and Summary (This section does not apply.)	29
8	Financial Disclosure Statement	31
9	Conformity to Standards	34
10	510(k) Executive Summary	37
11	Device Description	49
	Mobile CareGuide Marketing Requirements	62
12	Substantial Equivalence Rationale	70
	Predicate Device #1: K130079 Summary	80
	Predicate Device #2: K113656 Summary	83
13	Proposed Labeling	86
	Multi-Parameter Mobile CareGuide 3100 Oximeter Instructions For Use	96
	Mobile CareGuide 2100 Ray Instructions For Use	129
14	Sterilization and Shelf Life	134
15	Biocompatibility	139

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

TRADITIONAL 510(k) PREMARKET NOTIFICATION SUBMISSION**Multi-Parameter Mobile CareGuide™ 3100 Oximeter****TABLE OF CONTENTS: Volume 1 of 1**

Section	Contents	Page
16	Software	143
	Multi-Parameter Mobile CareGuide 3100 Design Input Requirements	159
	Multi-Parameter Mobile CareGuide Android Software Requirements	174
	Multi-Parameter Mobile CareGuide 3100 with Tablet Software Design Document	185
	Multi-Parameter Mobile CareGuide 3100 with Tablet Risk Analysis	203
	Multi-Parameter Mobile CareGuide 3100 FMEA	217
	Multi-Parameter Mobile CareGuide 3100 Clinical Tablet V&V 7" Tablet Test Results	240
	Multi-Parameter Mobile CareGuide 3100 Clinical Tablet V&V 10" Tablet Test Results	250
	Multi-Parameter Mobile CareGuide 3100 Android Software Unit Test 7" Tablet Results	260
	Multi-Parameter Mobile CareGuide 3100 Android Software Unit Test 10" Tablet Results	271
	Multi-Parameter Mobile CareGuide 3100 Communications Protocol	282
	Multi-Parameter Mobile CareGuide 3100 with Tablet Traceability Matrix	309
17	EMC and Electrical Safety	352
18	Bench Test Results	356

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

TRADITIONAL 510(k) PREMARKET NOTIFICATION SUBMISSION**Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet****TABLE OF CONTENTS: Volume 1 of 1**

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

TRADITIONAL 510(k) PREMARKET NOTIFICATION SUBMISSION**Multi-Parameter Mobile CareGuide™ 3100 Oximeter****TABLE OF CONTENTS: Volume 1 of 1**

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	Multi-Parameter Mobile CareGuide 3100 with Tablet Traceability Matrix	309
17	EMC and Electrical Safety	352
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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 1: Medical Device User Fee Cover Sheet

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Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 1

Use Fee Cover Sheet

1.1 User Fee Documentation

Reference Documents	Description
Section 1: FDA Device User Fee Cover Sheet	(b) (4)
Section 1: FDA fees payment –online receipt	(b)(4)

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on (b)(4)
---	---

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) REFLECTANCE MEDICAL INC 116 Flanders Rd Suite 1000 Westborough MA 015811072 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3862	2. CONTACT NAME Steve Weisner 2.1 E-MAIL ADDRESS steve.weisner@reflectancemedical.com 2.2 TELEPHONE NUMBER (include Area code) 508-3664700 233 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 508-3664770
---	--

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

Select an application type:

<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
--	---

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

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: SBD149008

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?

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

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

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

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> 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 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) 16-Dec-2013

["Close Window"](#) [Print Cover sheet](#)

From: paygovadmin@mail.doc.twai.gov
To: [Steve Weisner](#)
Subject: Pay.gov Payment Confirmation: FDA User Fees
Date: Monday, December 16, 2013 12:36:29 PM

(b) (4)

(b)(4)

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 1: Medical Device User Fee Cover Sheet

CONFIDENTIAL

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 1

Use Fee Cover Sheet

1.1 User Fee Documentation

Reference Documents	Description
Section 1: FDA Device User Fee Cover Sheet	(b)(4)
Section 1: FDA fees payment –online receipt	(b)(4)

Form Approved: OMB No. 0910-0511 Expiration Date: April 30

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: Write the Payment Identification number on	(b) (4) (b)(4)
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) REFLECTANCE MEDICAL INC 116 Flanders Rd Suite 1000 Westborough MA 015811072 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3862		2. CONTACT NAME Steve Weisner 2.1 E-MAIL ADDRESS steve.weisner@reflectancemedical.com 2.2 TELEPHONE NUMBER (include Area code) 508-3664700 233 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 508-3664770	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm Select an application type:			
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD149008			
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? <input checked="" type="checkbox"/> 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.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> 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). <input type="checkbox"/> YES <input checked="" type="checkbox"/> 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) (b)(4)		16-Dec-2013	

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

From: paygovadmin@mail.doc.twai.gov
To: [Steve Weisner](#)
Subject: Pay.gov Payment Confirmation: FDA User Fees
Date: Monday, December 16, 2013 12:36:29 PM

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact FDA User Fees at (301) 796-7200.

(b) (4)

(b)(4)

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 2: CDRH Premarket Notification Cover Sheet

CONFIDENTIAL

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 12/19/2013	(b) (4) er (b)(4)	FDA Submission Document Number (if known)
----------------------------------	-------------------------	---

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (120 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA &HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Reflectance Medical, Inc.		Establishment Registration Number (if known) NA	
Division Name (if applicable)		Phone Number (including area code) 508-366-4700	
Street Address 116 Flanders Road, Suite 1000		FAX Number (including area code) 508-366-4770	
City Westborough	State / Province MA	ZIP/Postal Code 01581	Country USA
Contact Name Dr. Babs Soller			
Contact Title Chief Executive Officer		Contact E-mail Address babs.soller@reflectancemedical.com	

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

Company / Institution Name Reflectance Medical, Inc.		Establishment Registration Number (if known) NA	
Division Name (if applicable)		Phone Number (including area code) (781) 710-5378	
Street Address 116 Flanders Road, Suite 1000		FAX Number (including area code) 508-366-4770	
City Westborough	State / Province MA	ZIP/Postal Code 01581	Country USA
Contact Name Nandini Murthy			
Contact Title Regulatory Consultant, RMI		Contact E-mail Address nmurthy@enemconsulting.com	

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

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D2**REASON FOR APPLICATION – IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D3**REASON FOR SUBMISSION - 510(k)**

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Added another display tool (Android tablet) for FDA cleared CareGuide Oximeter 3100		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	MUD	2		3		4		
5		6		7		8		

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K130079	1	Multi-Parameter Mobile CareGuide™ 3100 Oximeter	1	Reflectance Medical, Inc.
2	K113656	2	CareGuide™ 1100 Oximeter	2	Reflectance Medical, Inc.
3					
4					
5					
6					
7					

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Existing Classification: Oximeter, 21 CFR 870.2700

	Trade or Proprietary or Model Name for This Device		Model Number
1	Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet	1	3100
2		2	
3		3	

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

1	2	3	4	5	6
K130079					
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing (Software) Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code MUD	C.F.R. Section (if applicable) 21 CFR 870.2700	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Cardiovascular		

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Note: Submission of this information does not affect the need for FDORA Request # 2014-3652; Released by CDRH on 02/18/2016 or 2891a Device Establishment Registration form.

FDA Document Number (if known)
14-3652; Released by CDRH on 02/18/2016

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number NA		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Reflectance Medical, Inc.			Establishment Registration Number NA		
Division Name (if applicable)			Phone Number (including area code) 508-366-4700		
Street Address 116 Flanders Road, Suite 1000			FAX Number (including area code) 508-366-4770		
City Westborough		State / Province MA	ZIP/Postal Code 01581	Country USA	
Contact Name Dr. Babs Soller		Contact Title Chief Executive Officer		Contact E-mail Address babs.soller@reflectancemedical.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number NA		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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 MA	ZIP/Postal Code	Country US	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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/Postal Code	Country US	
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			See attached table		
2					
3					
4					
5					
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

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

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 9**Declarations of Conformity**

Table 1 lists the standards that are claimed for conformity by the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet. All of the standards are identical to the standards referenced in the predicate K130079. No new data forms are being submitted.

Table 1 Declarations of Conformity

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
12-168	IEC60825-1 Ed 2.0 (2007)	Safety of laser products - Part 1: Equipment classification, and requirements	Pass (Class 1 Laser Device)	None	Included in predicate K130079 pages 43-44 and on file at RMI
5-27	IEC 60601-1-1: 2005	Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standards: Safety requirements for medical electrical systems	Pass	None	Included in predicate K130079 pages 45-46 and on file at RMI
5-35	IEC 60601-1-2: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Pass	None	Included in predicate K130079 pages 47-48 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
2-153	ISO 10993-5 2009	Biological evaluation of medical devices-Part 5: Test for <i>in vitro</i> cytotoxicity	Pass	None	Included in predicate K130079 pages 49-50 and on file at RMI
2-87	ISO 10993-10 2010	Biological evaluation of medical devices-Part 10: Tests for irritation and delay-type hypersensitivity	Pass	None	Included in predicate K130079 pages 51-52 and on file at RMI
NA	AAMI TIR 12:2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	Pass	None	Included in predicate K130079 pages 53-54 and on file at RMI
NA	AAMI TIR 30:2003	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	Pass	None	Included in predicate K130079 pages 55-56 and on file at RMI
NA	ISTA 1A	Series Non-Simulation Integrity Performance Test Procedure: Packaged-Products 150 lb (68 kg) or Less	Pass	None	Included in predicate K130079 pages 57-58 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 2: CDRH Premarket Notification Cover Sheet

CONFIDENTIAL

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 12/19/2013	(b) (4) (b)(4)	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<input type="checkbox"/> Regular (120 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA &HDE Supplement <input type="checkbox"/> Other	<input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
<input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Reflectance Medical, Inc.	Establishment Registration Number (if known) NA		
Division Name (if applicable)	Phone Number (including area code) 508-366-4700		
Street Address 116 Flanders Road, Suite 1000	FAX Number (including area code) 508-366-4770		
City Westborough	State / Province MA	ZIP/Postal Code 01581	Country USA
Contact Name Dr. Babs Soller			
Contact Title Chief Executive Officer		Contact E-mail Address babs.soller@reflectancemedical.com	

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

Company / Institution Name Reflectance Medical, Inc.	Establishment Registration Number (if known) NA		
Division Name (if applicable)	Phone Number (including area code) (781) 710-5378		
Street Address 116 Flanders Road, Suite 1000	FAX Number (including area code) 508-366-4770		
City Westborough	State / Province MA	ZIP/Postal Code 01581	Country USA
Contact Name Nandini Murthy			
Contact Title Regulatory Consultant, RMI		Contact E-mail Address nmurthy@enemconsulting.com	

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

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D2**REASON FOR APPLICATION – IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D3**REASON FOR SUBMISSION - 510(k)**

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Added another display tool (Android tablet) for FDA cleared CareGuide Oximeter 3100		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	MUD	2		3		4		
5		6		7		8		

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K130079	1	Multi-Parameter Mobile CareGuide™ 3100 Oximeter	1	Reflectance Medical, Inc.
2	K113656	2	CareGuide™ 1100 Oximeter	2	Reflectance Medical, Inc.
3					
4					
5					
6					
7					

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Existing Classification: Oximeter, 21 CFR 870.2700

	Trade or Proprietary or Model Name for This Device		Model Number
1	Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet	1	3100
2		2	
3		3	

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

1	2	3	4	5	6
K130079					
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing (Software)
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code MUD	C.F.R. Section (if applicable) 21 CFR 870.2700	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Cardiovascular		

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Note: Submission of this information does not affect the need for FDORA Request # 2014-3652; Released by CDRH on 02/18/2016 or 2891a Device Establishment Registration form.

FDA Document Number (if known)
14-3652; Released by CDRH on 02/18/2016

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number NA		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Reflectance Medical, Inc.			Establishment Registration Number NA		
Division Name (if applicable)			Phone Number (including area code) 508-366-4700		
Street Address 116 Flanders Road, Suite 1000			FAX Number (including area code) 508-366-4770		
City Westborough		State / Province MA	ZIP/Postal Code 01581	Country USA	
Contact Name Dr. Babs Soller		Contact Title Chief Executive Officer		Contact E-mail Address babs.soller@reflectancemedical.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number NA		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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 MA	ZIP/Postal Code	Country US	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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/Postal Code	Country US	
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			See attached table		
2					
3					
4					
5					
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

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

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 9**Declarations of Conformity**

Table 1 lists the standards that are claimed for conformity by the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet. All of the standards are identical to the standards referenced in the predicate K130079. No new data forms are being submitted.

Table 1 Declarations of Conformity

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
12-168	IEC60825-1 Ed 2.0 (2007)	Safety of laser products - Part 1: Equipment classification, and requirements	Pass (Class 1 Laser Device)	None	Included in predicate K130079 pages 43-44 and on file at RMI
5-27	IEC 60601-1-1: 2005	Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standards: Safety requirements for medical electrical systems	Pass	None	Included in predicate K130079 pages 45-46 and on file at RMI
5-35	IEC 60601-1-2: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Pass	None	Included in predicate K130079 pages 47-48 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
2-153	ISO 10993-5 2009	Biological evaluation of medical devices-Part 5: Test for <i>in vitro</i> cytotoxicity	Pass	None	Included in predicate K130079 pages 49-50 and on file at RMI
2-87	ISO 10993-10 2010	Biological evaluation of medical devices-Part 10: Tests for irritation and delay-type hypersensitivity	Pass	None	Included in predicate K130079 pages 51-52 and on file at RMI
NA	AAMI TIR 12:2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	Pass	None	Included in predicate K130079 pages 53-54 and on file at RMI
NA	AAMI TIR 30:2003	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	Pass	None	Included in predicate K130079 pages 55-56 and on file at RMI
NA	ISTA 1A	Series Non-Simulation Integrity Performance Test Procedure: Packaged-Products 150 lb (68 kg) or Less	Pass	None	Included in predicate K130079 pages 57-58 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 3: 510(k) Submission Cover Letter

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

SECTION 3

510(k) COVER LETTER

Dec 19, 2013

Office of Device Evaluation [510(k)]
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Attention: CEDB Branch, ODE

RE: Traditional 510(k) Premarket Notification for Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet (21 CFR 870.2700, Product code MUD, CBZ)

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with Title 21 of the Code of Federal Regulations, Part 807, Subpart E, Reflectance Medical Inc. submits this Traditional Premarket Notification of intention to introduce into interstate commerce for commercial distribution the following product: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet.

Please find enclosed one (1) paper hard copy and two (2) CDs of the eCopy version. The eCopy is an exact duplicate of the paper copy.

The purpose of this 510(k) Premarket Notification is to obtain a determination of Substantial Equivalence for the CareGuide 3100 Oximeter with tablet. The CareGuide 3100 was previously cleared by K130079. RMI now intends to commercialize the CareGuide 3100 with a dedicated Android tablet display. The Mobile CareGuide™ 3100 Oximeter with Tablet is indicated for the following use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

The Multi-Parameter CareGuide™ 3100 Oximeter with Tablet is shown to be Substantially Equivalent to the predicate devices:

Predicate Device #1: Mobile CareGuide
Trade Name of Device: Multi-Parameter Mobile CareGuide Oximeter
Model #: 3100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K130079, CareGuide 3100
Product code: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2: CareGuide
Trade Name of Device: CareGuide Oximeter
Model #: 1100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K113656, CareGuide 1100
Product code: MUD, 21 CFR 870.2700, Cardiovascular

In accordance with the United States Food and Drug Administration's (FDA's) August 12, 2005 *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (hereinafter FDA 2005 Guidance), this submission includes the following information:

- Type of 510(k) submission: Traditional 510k
- Common name of Device: Multi-Parameter Oximeter with Tablet
- 510(k) submitter: Reflectance Medical, Inc. (RMI)
- Contact person, by name, title, and phone number:

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
 Phone: 508.366.4700
 Fax: 508.366.4770

- Dr. Babs Soller, President and Chief Executive Officer, Reflectance Medical, Inc.; Phone number: (508) 366-4700 x 223; (b)(6)
- Nandini Murthy, Regulatory Consultant, Reflectance Medical, Inc.; (b)(6)
- Preference for continued confidentiality (21 CFR § 807.95): The descriptions and information contained in this 510(k) Premarket Notification constitute confidential commercial information. We request that the FDA regard the contents of this submission as subject to protection from public disclosure to the extent permitted by the provisions of 21 C.F.R. § 807.95(b). Please note that all trademarks, registered trademarks, and product names used within this 510(k) Premarket Notification are the property of their respective owners.
- Classification regulation:
21 C.F.R. § 870.2700, Oximeter
- Class: Class II 510(k)
- Review Panel: Cardiovascular
- Product code: CBZ, MUD
- FDA document numbers associated with prior correspondence with FDA: K130079
- Basis for the Submission: Additional display device for a FDA-cleared device

Per the FDA 2005 Guidance, the principal factors concerning the design and use of the CareGuide 3100 Oximeter with Tablet are:

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
 Phone: 508.366.4700
 Fax: 508.366.4770

Question	YES	NO
Is the device intended for single use?		X*
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

*There is a disposable sleeve over the Sensor

Reflectance Medical, Inc. considers its intent to market the device as confidential commercial information and requests that FDA treat it in the same manner. It is Reflectance Medical, Inc.'s position that this submission includes trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61. Therefore, we request that the Food and Drug Administration not disclose any information included in this submission (except for the Indications for Use and 510(k) Summary) prior to providing Reflectance Medical, Inc. a predisclosure notification and a reasonable opportunity to redact information that should not be made public under 21 CFR § 20.61.

(b) (4)

(b)(4)

We believe that the information provided in this 510(k) Premarket Notification supports a determination of substantial equivalence of the Mobile CareGuide 3100 Oximeter with Tablet.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

If you should have any questions or require further information, please contact Dr. Babs Soller by phone at (b)(6) email: babs.soller@reflectancemedical.com) or Nandini Murthy by phone at (b)(6) email: nmurthy@enemconsulting.com).

Sincerely,

A handwritten signature in blue ink that reads "Babs Soller".

Babs Soller, Ph.D.
President and Chief Executive Officer
Reflectance Medical, Inc.

Phone: (508) 366 4700 x 223

(b)(6)

(b)(6)

Fax: 508.366.4770

E-mail: babs.soller@reflectancemedical.com

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 3: 510(k) Submission Cover Letter

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

SECTION 3

510(k) COVER LETTER

Dec 19, 2013

Office of Device Evaluation [510(k)]
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Attention: CEDB Branch, ODE

RE: Traditional 510(k) Premarket Notification for Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet (21 CFR 870.2700, Product code MUD, CBZ)

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with Title 21 of the Code of Federal Regulations, Part 807, Subpart E, Reflectance Medical Inc. submits this Traditional Premarket Notification of intention to introduce into interstate commerce for commercial distribution the following product: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet.

Please find enclosed one (1) paper hard copy and two (2) CDs of the eCopy version. The eCopy is an exact duplicate of the paper copy.

The purpose of this 510(k) Premarket Notification is to obtain a determination of Substantial Equivalence for the CareGuide 3100 Oximeter with tablet. The CareGuide 3100 was previously cleared by K130079. RMI now intends to commercialize the CareGuide 3100 with a dedicated Android tablet display. The Mobile CareGuide™ 3100 Oximeter with Tablet is indicated for the following use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

The Multi-Parameter CareGuide™ 3100 Oximeter with Tablet is shown to be Substantially Equivalent to the predicate devices:

Predicate Device #1: Mobile CareGuide
Trade Name of Device: Multi-Parameter Mobile CareGuide Oximeter
Model #: 3100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K130079, CareGuide 3100
Product code: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2: CareGuide
Trade Name of Device: CareGuide Oximeter
Model #: 1100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K113656, CareGuide 1100
Product code: MUD, 21 CFR 870.2700, Cardiovascular

In accordance with the United States Food and Drug Administration's (FDA's) August 12, 2005 *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s* (hereinafter FDA 2005 Guidance), this submission includes the following information:

- Type of 510(k) submission: Traditional 510k
- Common name of Device: Multi-Parameter Oximeter with Tablet
- 510(k) submitter: Reflectance Medical, Inc. (RMI)
- Contact person, by name, title, and phone number:

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
 Phone: 508.366.4700
 Fax: 508.366.4770

- Dr. Babs Soller, President and Chief Executive Officer, Reflectance Medical, Inc.; Phone number: (508) 366-4700 x 223; (b)(6) (b)(6)
- (b)(6) (b)(6)
 Nandini Murthy, Regulatory Consultant, Reflectance Medical, Inc.; (b)(6) (b)(6)
 number: (781) 710-5378
- Preference for continued confidentiality (21 CFR § 807.95): The descriptions and information contained in this 510(k) Premarket Notification constitute confidential commercial information. We request that the FDA regard the contents of this submission as subject to protection from public disclosure to the extent permitted by the provisions of 21 C.F.R. § 807.95(b). Please note that all trademarks, registered trademarks, and product names used within this 510(k) Premarket Notification are the property of their respective owners.
- Classification regulation:
 21 C.F.R. § 870.2700, Oximeter
- Class: Class II 510(k)
- Review Panel: Cardiovascular
- Product code: CBZ, MUD
- FDA document numbers associated with prior correspondence with FDA: K130079
- Basis for the Submission: Additional display device for a FDA-cleared device

Per the FDA 2005 Guidance, the principal factors concerning the design and use of the CareGuide 3100 Oximeter with Tablet are:

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
 116 Flanders Road, Suite 1000
 Westborough, MA 01581 USA
 Phone: 508.366.4700
 Fax: 508.366.4770

Question	YES	NO
Is the device intended for single use?		X*
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

*There is a disposable sleeve over the Sensor

Reflectance Medical, Inc. considers its intent to market the device as confidential commercial information and requests that FDA treat it in the same manner. It is Reflectance Medical, Inc.'s position that this submission includes trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61. Therefore, we request that the Food and Drug Administration not disclose any information included in this submission (except for the Indications for Use and 510(k) Summary) prior to providing Reflectance Medical, Inc. a predisclosure notification and a reasonable opportunity to redact information that should not be made public under 21 CFR § 20.61.

(b) (6)

(b)(6)

We believe that the information provided in this 510(k) Premarket Notification supports a determination of substantial equivalence of the Mobile CareGuide 3100 Oximeter with Tablet.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

If you should have any questions or require further information, please contact Dr. Babs Soller by phone (b) (6) email: babs.soller@reflectancemedical.com) or Nandini Murthy by phone at (b)(6) ail: nmurthy@enemconsulting.com).

Sincerely,

A handwritten signature in blue ink that reads 'Babs Soller'.

Babs Soller, Ph.D.
President and Chief Executive Officer
Reflectance Medical, Inc.

Phone: (508) 366 4700 x 222

(b) (6)
(b)(6)

Fax: 508.366.4770

E-mail: babs.soller@reflectancemedical.com

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 4: Indications for Use

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use Form

Indications for Use

510(k) Number (if known): _____

Device Name: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 __

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 4: Indications for Use

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use Form

Indications for Use

510(k) Number (if known): _____

Device Name: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 __

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 5: 510(k) Summary of Safety and Effectiveness

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 5

510(k) SUMMARY

**SUMMARY OF SAFETY AND EFFECTIVENESS FOR
Multi-Parameter Mobile CareGuide™ 3100 Oximeter, with Tablet**

Submitter Information

Name: Reflectance Medical, Inc. (RMI)
Address: 116 Flanders Road, Suite 1000
Westborough, MA 01581 USA

Telephone Number: 508.366.4700

Registration Number: NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)

Contact Person: Dr. Babs Soller
Telephone Number: 508.366.4700, Ext 223
Fax Number: 508.366.4770
Email: Babs.Soller@reflectancemedical.com

Date Prepared: 12/19/2013

Device Name

Trade name of New Device: Multi-Parameter CareGuide™ Oximeter with Tablet
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc. (RMI)
510(k) Number: N/A
Product codes: 21 CFR § 870.2700, 21 CFR 868.1170
Classification Panel: Cardiovascular

Predicate Devices

Predicate Device #1: Mobile CareGuide
Trade Name of Device: Multi-Parameter Mobile CareGuide Oximeter
Model #: 3100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K130079, CareGuide 3100
Product codes: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Predicate Device #2: CareGuide
 Trade Name of Device: CareGuide Oximeter
 Model #: 1100
 510(k) Holder/Submitter: Reflectance Medical Inc.
 510(k) Numbers: K113656, CareGuide 1100
 Product code: MUD, 21 CFR 870.2700, Cardiovascular

Device Description

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses Near Infrared (NIR) Spectroscopy to calculate muscle oxygen saturation (SmO₂) and muscle pH (pHm) and displays those parameters as real-time values and historical trends on a tablet device.

Characteristics	Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor, disposable pad and display tablet
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO ₂) and muscle pH (pHm)

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is a multiple parameter oximeter. The sensor contains algorithms that calculate SmO₂ and pHm from collected spectra and communicates the current SmO₂ and pHm results to an Android tablet with display software through a proprietary protocol. The Android tablet (qualified models Acer A500 and Asus Google Nexus 7) contains 3rd party software that locks down the tablet so that only the CareGuide software may run and no other application or operating software can be modified. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with a USB connection to the Android tablet. The sensor is identical to the predicate (K130079) Multi-parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the same disposable element as the Multi-Parameter Mobile CareGuide 3100 Oximeter, a disposable sleeve that isolates the sensor optical elements from the patient's skin.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Rationale for Substantial Equivalence

The CareGuide 3100 device's oximetry feature has been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter. The device's pH_m feature has been already cleared under classification regulation 21 C.F.R § 868.1170, Anesthesiology. This 510(k) is seeking clearance for use of the CareGuide 3100 with a dedicated Android Display device.

There is no change in how the User would use the information generated by the Multi-Parameter Care Guide 3100 with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter CareGuide 3100 with Tablet nor any of the predicate devices identified by RMI provides diagnostic output.

The Multi-Parameter CareGuide 3100 with Tablet has the same technological characteristics as the previously cleared RMI devices, the CareGuide 1100 (K113656) and the Multi-Parameter Mobile CareGuide 2100 (K130079).

- The principle of operation of the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is identical to that of the predicate CareGuide devices. They use the exact same NIR spectroscopic platform to measure tissue oxygen saturation and muscle. The same software quantitative algorithm for SmO₂ and pH_m is used in both devices.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is equivalent to the Multi-Parameter Mobile CareGuide 3100 Oximeter predicate in reusable components. Both devices use the exact same sensor hardware: main sensor CPU board, battery, optical board (light sources, spectrometer and microprocessor), USB interfaces, plastic housing and cables.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Table is equivalent to the Multi-Parameter Mobile CareGuide 3100 Oximeter predicate in disposable components. Both devices use the exact same disposable sheath ("Ray") and disposable sensor check device ("Cradle").

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has the identical underlying LED light source as the CareGuide predicates, with the exact same range of wavelength (700-900 nm).
- The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet and the predicated CareGuide 1100 Oximeter are equivalent. The CareGuide 1100 System includes a Monitor display while the CareGuide 3100 {subject of this 510(k)} includes a dedicated Android display. Both displays are functionally equivalent. Both CareGuide 1100 and 3110 displays are tools that interface with the CareGuide oximeter and display real-time parameters and historical trends per their cleared indications for use.
- The predicate Multi-Parameter Mobile CareGuide 3100 Oximeter is compatible with any USB-connected display device that supports the specified communications protocol. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet {subject of this 510(k)} now includes such a USB-connected display device (i.e. dedicated Android tablet), supporting that specified communications protocol.

Summary of Safety and Effectiveness Data

Bench testing demonstrates that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is safe and effective, meeting all relevant consensuses and FDA recognized standards. The bench and software test results in this submission demonstrate that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet meets the expected performance requirements for an Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is therefore equivalent to the predicates by indications for use and device features and functionality.

Conclusion

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is equivalent to predicate device in terms of technology (NIR Spectroscopy) and intended use. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet does not raise new questions of safety or effectiveness, as compared to the predicate. Therefore, the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is substantially equivalent to the predicate device.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 5: 510(k) Summary of Safety and Effectiveness

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 5

510(k) SUMMARY

**SUMMARY OF SAFETY AND EFFECTIVENESS FOR
Multi-Parameter Mobile CareGuide™ 3100 Oximeter, with Tablet**

Submitter Information

Name: Reflectance Medical, Inc. (RMI)
Address: 116 Flanders Road, Suite 1000
Westborough, MA 01581 USA

Telephone Number: 508.366.4700

Registration Number: NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)

Contact Person: Dr. Babs Soller
Telephone Number: 508.366.4700, Ext 223
Fax Number: 508.366.4770
Email: Babs.Soller@reflectancemedical.com

Date Prepared: 12/19/2013

Device Name

Trade name of New Device: Multi-Parameter CareGuide™ Oximeter with Tablet
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc. (RMI)
510(k) Number: N/A
Product codes: 21 CFR § 870.2700, 21 CFR 868.1170
Classification Panel: Cardiovascular

Predicate Devices

Predicate Device #1: Mobile CareGuide
Trade Name of Device: Multi-Parameter Mobile CareGuide Oximeter
Model #: 3100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Numbers: K130079, CareGuide 3100
Product codes: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Predicate Device #2: CareGuide
 Trade Name of Device: CareGuide Oximeter
 Model #: 1100
 510(k) Holder/Submitter: Reflectance Medical Inc.
 510(k) Numbers: K113656, CareGuide 1100
 Product code: MUD, 21 CFR 870.2700, Cardiovascular

Device Description

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses Near Infrared (NIR) Spectroscopy to calculate muscle oxygen saturation (SmO₂) and muscle pH (pHm) and displays those parameters as real-time values and historical trends on a tablet device.

Characteristics	Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor, disposable pad and display tablet
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO ₂) and muscle pH (pHm)

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is a multiple parameter oximeter. The sensor contains algorithms that calculate SmO₂ and pHm from collected spectra and communicates the current SmO₂ and pHm results to an Android tablet with display software through a proprietary protocol. The Android tablet (qualified models Acer A500 and Asus Google Nexus 7) contains 3rd party software that locks down the tablet so that only the CareGuide software may run and no other application or operating software can be modified. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with a USB connection to the Android tablet. The sensor is identical to the predicate (K130079) Multi-parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the same disposable element as the Multi-Parameter Mobile CareGuide 3100 Oximeter, a disposable sleeve that isolates the sensor optical elements from the patient's skin.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Indications for Use

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

Rationale for Substantial Equivalence

The CareGuide 3100 device's oximetry feature has been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter. The device's pH_m feature has been already cleared under classification regulation 21 C.F.R § 868.1170, Anesthesiology. This 510(k) is seeking clearance for use of the CareGuide 3100 with a dedicated Android Display device.

There is no change in how the User would use the information generated by the Multi-Parameter Care Guide 3100 with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter CareGuide 3100 with Tablet nor any of the predicate devices identified by RMI provides diagnostic output.

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- The principle of operation of the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is identical to that of the predicate CareGuide devices. They use the exact same NIR spectroscopic platform to measure tissue oxygen saturation and muscle. The same software quantitative algorithm for SmO₂ and pH_m is used in both devices.
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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

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- The predicate Multi-Parameter Mobile CareGuide 3100 Oximeter is compatible with any USB-connected display device that supports the specified communications protocol. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet {subject of this 510(k)} now includes such a USB-connected display device (i.e. dedicated Android tablet), supporting that specified communications protocol.

Summary of Safety and Effectiveness Data

Bench testing demonstrates that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is safe and effective, meeting all relevant consensus and FDA recognized standards. The bench and software test results in this submission demonstrate that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet meets the expected performance requirements for an Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is therefore equivalent to the predicates by indications for use and device features and functionality.

Conclusion

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is equivalent to predicate device in terms of technology (NIR Spectroscopy) and intended use. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet does not raise new questions of safety or effectiveness, as compared to the predicate. Therefore, the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is substantially equivalent to the predicate device.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 6: Truthful and Accuracy Statement

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

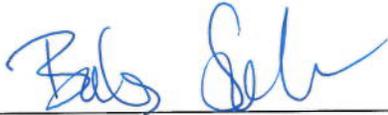
SECTION 6

TRUTHFUL AND ACCURACY STATEMENT

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

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



(Signature)

Babs R. Soller
(Typed Name)

12/19/2013
(Date)

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

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

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 6: Truthful and Accuracy Statement

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

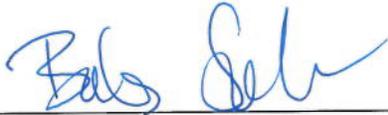
SECTION 6

TRUTHFUL AND ACCURACY STATEMENT

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

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



(Signature)

Babs R. Soller
(Typed Name)

12/19/2013
(Date)

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

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

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 7: Class III Summary

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 7

Class III Certification and Summary

This section does not apply. The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet, subject of this premarket notification, is classified as Class II.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 7: Class III Summary

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 7

Class III Certification and Summary

This section does not apply. The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet, subject of this premarket notification, is classified as Class II.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 8: Financial Disclosures

CONFIDENTIAL



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 Reflectance Medical, Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Dec 19, 2013
3. ADDRESS (Number, Street, State, and ZIP Code) 116 Flanders Road Suite 1000 Westborough, MA 01581	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 508-366-4700 (Fax) 508-366-4770

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)

Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet

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):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Babs Soller (Title) President and CEO
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 116 Flanders Road Suite 1000 Westborough, MA 01581	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 508-366-4700 (Fax) 508-366-4770
15. DATE OF CERTIFICATION Dec 19, 2013	

Instructions for Completion of Form FDA 3674

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))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information** - For **Drugs/Biologics**: Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. For **Devices**: Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. 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, Room 400
Rockville, MD 20850

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

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 8: Financial Disclosures

CONFIDENTIAL



DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with
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Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet

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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):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Babs Soller (Title) President and CEO
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 116 Flanders Road Suite 1000 Westborough, MA 01581	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 508-366-4700 (Fax) 508-366-4770
15. DATE OF CERTIFICATION Dec 19, 2013	

Instructions for Completion of Form FDA 3674

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))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information** - For **Drugs/Biologics**: Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. For **Devices**: Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.
Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.
Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. 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, Room 400
Rockville, MD 20850

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

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 9: Conformity to Standards

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 9**Declarations of Conformity**

Table 1 lists the standards that are claimed for conformity by the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet. All of the standards are identical to the standards referenced in the predicate K130079. No new data forms are being submitted.

Table 1 Declarations of Conformity

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
12-168	IEC60825-1 Ed 2.0 (2007)	Safety of laser products - Part 1: Equipment classification, and requirements	Pass (Class 1 Laser Device)	None	Included in predicate K130079 pages 43-44 and on file at RMI
5-27	IEC 60601-1-1: 2005	Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standards: Safety requirements for medical electrical systems	Pass	None	Included in predicate K130079 pages 45-46 and on file at RMI
5-35	IEC 60601-1-2: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Pass	None	Included in predicate K130079 pages 47-48 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
2-153	ISO 10993-5 2009	Biological evaluation of medical devices-Part 5: Test for <i>in vitro</i> cytotoxicity	Pass	None	Included in predicate K130079 pages 49-50 and on file at RMI
2-87	ISO 10993-10 2010	Biological evaluation of medical devices-Part 10: Tests for irritation and delay-type hypersensitivity	Pass	None	Included in predicate K130079 pages 51-52 and on file at RMI
NA	AAMI TIR 12:2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	Pass	None	Included in predicate K130079 pages 53-54 and on file at RMI
NA	AAMI TIR 30:2003	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	Pass	None	Included in predicate K130079 pages 55-56 and on file at RMI
NA	ISTA 1A	Series Non-Simulation Integrity Performance Test Procedure: Packaged-Products 150 lb (68 kg) or Less	Pass	None	Included in predicate K130079 pages 57-58 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

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5-35	IEC 60601-1-2: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Pass	None	Included in predicate K130079 pages 47-48 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
2-153	ISO 10993-5 2009	Biological evaluation of medical devices-Part 5: Test for <i>in vitro</i> cytotoxicity	Pass	None	Included in predicate K130079 pages 49-50 and on file at RMI
2-87	ISO 10993-10 2010	Biological evaluation of medical devices-Part 10: Tests for irritation and delay-type hypersensitivity	Pass	None	Included in predicate K130079 pages 51-52 and on file at RMI
NA	AAMI TIR 12:2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	Pass	None	Included in predicate K130079 pages 53-54 and on file at RMI
NA	AAMI TIR 30:2003	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	Pass	None	Included in predicate K130079 pages 55-56 and on file at RMI
NA	ISTA 1A	Series Non-Simulation Integrity Performance Test Procedure: Packaged-Products 150 lb (68 kg) or Less	Pass	None	Included in predicate K130079 pages 57-58 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 10: 510(k) Executive Summary

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 10

510(k) EXECUTIVE SUMMARY

Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

10.1 OVERVIEW OF SUBMISSION LAYOUT

The Traditional 510(k) follows the format of the FDA August 12, 2005 guidance “Format for Traditional and Abbreviated 510(k)s”.

Accordingly, the following is a layout of key sections of this traditional 510(k) submission:

Section 4: Proposed Indications for Use

Section 5: 510(k) Summary

Section 9: Conformance documents for applicable standards

Section 10: Executive Summary

Section 11: Device Description

Section 12: Brief description of predicate comparison and rationale for Substantial Equivalence.

Section 13: Proposed Labeling

Section 14: Packaging/Shipping/Shelf life information.

Section 15: Biocompatibility testing summary

Section 16: Software description and test results summary

Section 17: Electrical Safety and EMC test results summary

Section 18: Bench testing summary

10.2 EXECUTIVE SUMMARY

The Executive Summary has been prepared in accordance with the guidelines provided in the above-referenced 2005 FDA guidance document. The sections of this Executive Summary are:

- Submitter information
- Device name

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

- Proposed intended use/indication for use
- Device description summary
- Standards summary
- Substantial equivalence rationale
- Substantial equivalence determination summary
- Summary of test results in this submission – Bench Studies
- Proposed Labeling

10.3 SUBMITTER INFORMATION

Name: Reflectance Medical, Inc. (RMI)
Address: 116 Flanders Road, Suite 1000
Westborough, MA 01581 USA

Registration Number: NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)

Contact Person: ~~Dr. Babs Soller~~
Telephone Number: (b)(6)
Fax Number: 508.366.4770
Email: babs.soller@reflectancemedical.com

Date Prepared: Dec 19, 2013

10.4 DEVICE NAME

Trade name of New Device: Multi-Parameter CareGuide™ Oximeter with Tablet
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc. (RMI)
510(k) Number: N/A

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Proposed product codes MUD, Oximeter, 21 CFR 870.2700 Cardiovascular

Classification Panel: Cardiovascular

10.5 PROPOSED INTENDED USE/INDICATION FOR USE

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

Except for reference to the Android Tablet display, the indications for use statement is identical to the indications for use statement for:

- Multi-Parameter Mobile CareGuide 3100 (K130079)

This device’s tissue oxygenation feature has been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter. The devices’ muscle pH feature has already cleared under classification regulation 21 CFR 868.1170, Indwelling blood hydrogen ion concentration (pH) analyzer.

- The Multi-Parameter CareGuide 3100 Oximeter with Tablet has the same intended use as one of the identified predicates, the Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079)
- The tablet portion (hardware and software) of the Multi-Parameter CareGuide 3100 with Tablet has the same display function, i.e. to interface with the sensor and display parameter values and trends, as one of the identified predicates, the CareGuide Oximeter (K113656)

Conclusion:

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

The Intended Use is identical to the predicate devices. There is no change in how the User would use the information generated by the Multi-Parameter CareGuide 3100 Oximeter with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter CareGuide 3100 Oximeter with Tablet nor any of the predicate devices identified by RMI provide any diagnostic output.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

10.6 DEVICE DESCRIPTION SUMMARY

A detailed Device Description is provided in Section 11, a Software Overview is provided in Section 16 of the 510(k) submission.

The CareGuide sensor uses Near Infrared (NIR) Spectroscopy to calculate muscle oxygen saturation (SmO2) and muscle pH (pHm).

Table 10-1. Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet technology summary

Characteristics	Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet
Principle of Operation	NIR spectroscopy
Components	Reusable sensor, disposable sleeve and commercial Android tablet
Light Source	LEDs
Parameters Measured	Muscle oxygen saturation (SmO2); Muscle pH (pHm);

The predicate CareGuide 1100 Oximeter cleared via K113656 is a complete system, including the display. The Multi-Parameter Mobile CareGuide 3100 Oximeter cleared via K130079 is an OEM sensor that outputs SmO2 and pHm trend data to a third party monitoring device or a display device such as a tablet computer. The Multi-Parameter CareGuide 3100 Oximeter with Tablet validates a specific set of tablets and associated software to display the SmO2 and pHm trend data.

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the sensor hardware or the disposable sleeve from the Multi-Parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the sensor software from the Multi-Parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the fundamental way in which SmO2 and pHm are calculated, maintaining the same optical hardware and algorithms for calculating SmO2 as was previously cleared in K113656 and K122645 and calculating pHm as was previously cleared in K130079. The main difference between CareGuide models 3100 and 3100 with Tablet is the addition of an Android Tablet with software that is compliant with the Mobile CareGuide 3100 Communications Protocol (Section 16) and displays the SmO2 and pHm current and trended parameters, battery level, error information and device state.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet contains 3rd party software that ‘locks down’ the Tablet. The device has a version of the Android operating system, a limited set of Android applications, the CareGuide 3100 display software and a software locking application. The locking application only allows a single application, the CareGuide 3100 display application, to run. The user cannot load any new software applications, or any operating system updates to the tablet. All external communications (Wi-Fi, Bluetooth) are disabled. The only communication channel enabled is the USB connection to the Multi-parameter Mobile CareGuide 3100 oximeter sensor. There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.

Please note that this 510(k) requests FDA clearance for the Multi-Parameter CareGuide 3100 Oximeter with Tablet, specifying specific Android tablets and Android operating systems that have been qualified by Reflectance Medical. It is Reflectance Medical’s intent to qualify other devices and/or operating systems to support the same functionality in the future.

10.6.1 System Hardware and Software

Reusable Sensor: The sensor acquires the spectral data from the patient, derives the physiological measurements and communicates with the Android tablet. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet reusable sensor is identical to the sensor component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

Mobile CareGuide Ray: The Mobile CareGuide Ray is a disposable sleeve which isolates the sensor optical elements from the patient’s skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet disposable is identical to the disposable component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

Mobile CareGuide Cradle: Before being used on a new patient, a new cradle, packaged with each Ray, is used to check the sensor against the standard cradle used during manufacturing. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet cradle is identical to the cradle component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

Mobile CareGuide Software: The Multi-Parameter Mobile CareGuide 3100 with Tablet sensor software interfaces with the Multi-Parameter CareGuide 3100 with Tablet Sensor to control the LEDs and detector, check the sensor, acquire spectral data, calculate SmO2 and pHm, communicate the parameter values and sensor state conditions to the Android tablet, check thermistors for safe temperature levels, store SmO2 and pHm values and spectral data, and communicate with external service software to control settings,

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

download stored data and upgrade the device. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet sensor software is identical to the software component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

Mobile CareGuide Android Tablet: The tablet is a commercial Android tablet. For this filing, two devices have been validated: Acer A500 and Asus Google Nexus 7. The product is used as is with additional software

Mobile CareGuide Android Tablet Software: The Android software consists of 4 components (further described in Section 16):

1. Android operating system: Android OS 4.0 and OS 4.3 have been validated. The OS is used 'as is' from the tablet manufacturer.
2. CareGuide display software: consists of three components: 1. Communication software to interface with the sensor via the USB port; 2. Display software to start/pause/stop the sensor, enter patient identification, perform a sensor check, display real-time SmO₂ and pHm values, display a trend of historical SmO₂ and pHm values and display any fault conditions reported by the sensor; 3. Store historical trend data and fault conditions in a text file.
3. Lock down software: a 3rd party software package: SureLock from 42Gears Mobility Systems Pvt Ltd is installed on the Android tablet. It restricts the user to only be able to run the CareGuide 3100 display software application. It disables the ability to load any new software applications, or any operating system updates to the tablet. It disables all external communications (Wi-Fi, Bluetooth). There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.
4. Utility tools: there are a set of 3rd party tools that are installed as part of the installation process for the Mobile CareGuide Android Tablet. These tools include APK installer, task manager, file explorer, screen shortcut creator, anti-virus software and USB test program. None of these applications are accessible to the end-user and are used only for installation or service purposes.

The *level of concern* for the CareGuide System is **Moderate** prior to mitigation of hazards (Section 16.2): a failure of the Software Device could result in minor injury, either to a patient or to a user of the device.

10.6.2 Multi-Parameter CareGuide 3100 Algorithms

The fundamental principle behind the algorithms used to calculate SmO₂ and pHm is that each of the parameters has a quantifiable perturbation on the NIR absorbance spectrum of hemoglobin. Each spectrum of hemoglobin the CareGuide sensor collects, is confounded by absorbance and scattering from skin, fat and muscle. The Multi-Parameter Mobile CareGuide 3100 Oximeter with

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Tablet algorithms are identical to the algorithm component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

10.7 STANDARDS SUMMARY

The CareGuide Oximeter complies with the standards listed in Table 10-2. Declarations of conformity and summary reports for these standards are provided in Section 9. These standards are identical to the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details. No new standards are claimed for the Tablet portion of the device.

Table 10-2 List of Relevant Consensus and FDA Recognized Standards

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
12-168	IEC60825-1 Ed 2.0 (2007)	Safety of laser products - Part 1: Equipment classification, and requirements	Pass (Class 1 Laser Device)	None	Included in predicate K130079 pages 43-44 and on file at RMI
5-27	IEC 60601-1-1: 2005	Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standards: Safety requirements for medical electrical systems	Pass	None	Included in predicate K130079 pages 45-46 and on file at RMI
5-35	IEC 60601-1-2: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Pass	None	Included in predicate K130079 pages 47-48 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
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NA	AAMI TIR 12:2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	Pass	None	Included in predicate K130079 pages 53-54 and on file at RMI
NA	AAMI TIR 30:2003	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	Pass	None	Included in predicate K130079 pages 55-56 and on file at RMI
NA	ISTA 1A	Series Non-Simulation Integrity Performance Test Procedure: Packaged-Products 150 lb (68 kg) or Less	Pass	None	Included in predicate K130079 pages 57-58 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

10.8 SUBSTANTIAL EQUIVALENCE RATIONALE: INTENDED USE

The Intended Use is identical to the predicates. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has the same intended use as the:

- Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079) for sensor hardware, software, interfaces and algorithms.
- Reflectance Medical CareGuide 1100 Oximeter (K113656) for displaying real-time parameters, historical trend data and sensor fault conditions;

There is no change in how the User would use the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. None of them provide any diagnostic output.

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has the same principle of operation (optical) as the Multi-Parameter Mobile CareGuide 3100 Oximeter.

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has the same technological characteristics as the previously cleared CareGuide 1100 and CareGuide 3100.

10.9 SUBSTANTIAL EQUIVALENCE RATIONALE – Technological characteristics:

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the sensor hardware or the disposable sleeve from the Multi-Parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the sensor software from the Multi-Parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the fundamental way in which SmO₂ and pHm are calculated, maintaining the same optical hardware and algorithms for calculating SmO₂ as was previously cleared in K113656 and K122645 and calculating pHm as was previously cleared in K130079.

10.10 SUBSTANTIAL EQUIVALENCE DETERMINATION SUMMARY

The Multi-Parameter CareGuide 3100 is substantially equivalent to the predicate devices:

- The Indications for use for SmO₂ and pHm are identical with that of the predicates.
- The reference to multiple classification codes in this 510(k) is the same as the predicates.
- Technologically, the Multi-Parameter CareGuide 3100 with Tablet is identical to the predicate.
- The accuracy of the Multi-Parameter CareGuide 3100 with Tablet is identical to the accuracy of the predicate.

Therefore, the Multi-Parameter CareGuide 3100 Oximeter with Tablet is Substantially Equivalent to the predicate devices.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

10.11 SUMMARY OF TEST RESULTS IN THIS SUBMISSION

The test results in this 510(k) submission include Bench Studies, as part of Device V&V to support the Android Tablet display (per design controls). No animal or clinical studies were required.

The test results collectively all support a determination of substantial equivalence.

10.11.1 BENCH TEST RESULTS SUMMARY

The following is a roadmap to the various Bench Test Results in the 510(k):

- Section 9 includes declarations of conformity and summary reports for the standards listed in Table 10-1 above. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet complies with these standards.
- Section 14 includes references to the predicate device (K130079) shipping, shelf life and reuse cleaning validation test results and protocols (TIR 12 and TIR 30).
- Section 15 includes references to the predicate device (K130079) biocompatibility test results showing compliance to ISO 10993. There are no changes to the case or disposable in the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet as it is equivalent in those aspects to the predicate device (K130079) and can therefore be declared conformant.
- Section 16 includes Android Tablet software V&V test results.
- Section 17 includes references to the predicate device (K130079) EMC and electrical safety tests (IEC 60601-1-1 and IEC 60601-1-2). There are no hardware changes in the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet as it is equivalent in those aspects to the predicate device (K130079) and can therefore be declared conformant.
- Section 18 includes references to the predicate device (K130079) hardware bench test results including laser standards testing, System level hardware V&V testing, component level hardware V&V and unit testing. There are no hardware changes in the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet as it is equivalent in those aspects to the predicate device (K130079) and can therefore be declared conformant.

10.12 PROPOSED LABELING

Proposed labeling for the Multi-Parameter Mobile CareGuide 3100 with Tablet is provided in Section 13 of the 510(k). Draft labeling includes package labeling, device labeling and the Instructions for Use (Operator's Manual) for the Sensor, Ray and Tablet.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 10: 510(k) Executive Summary

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 10

510(k) EXECUTIVE SUMMARY

Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

10.1 OVERVIEW OF SUBMISSION LAYOUT

The Traditional 510(k) follows the format of the FDA August 12, 2005 guidance “Format for Traditional and Abbreviated 510(k)s”.

Accordingly, the following is a layout of key sections of this traditional 510(k) submission:

Section 4: Proposed Indications for Use

Section 5: 510(k) Summary

Section 9: Conformance documents for applicable standards

Section 10: Executive Summary

Section 11: Device Description

Section 12: Brief description of predicate comparison and rationale for Substantial Equivalence.

Section 13: Proposed Labeling

Section 14: Packaging/Shipping/Shelf life information.

Section 15: Biocompatibility testing summary

Section 16: Software description and test results summary

Section 17: Electrical Safety and EMC test results summary

Section 18: Bench testing summary

10.2 EXECUTIVE SUMMARY

The Executive Summary has been prepared in accordance with the guidelines provided in the above-referenced 2005 FDA guidance document. The sections of this Executive Summary are:

- Submitter information
- Device name

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

- Proposed intended use/indication for use
- Device description summary
- Standards summary
- Substantial equivalence rationale
- Substantial equivalence determination summary
- Summary of test results in this submission – Bench Studies
- Proposed Labeling

10.3 SUBMITTER INFORMATION

Name: Reflectance Medical, Inc. (RMI)
Address: 116 Flanders Road, Suite 1000
Westborough, MA 01581 USA

Registration Number: NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)

Contact Person: (b) (6)
Telephone Number: (b)(6)
Fax Number: 508.366.4770
Email: babs.soller@reflectancemedical.com

Date Prepared: Dec 19, 2013

10.4 DEVICE NAME

Trade name of New Device: Multi-Parameter CareGuide™ Oximeter with Tablet
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc. (RMI)
510(k) Number: N/A

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Proposed product codes MUD, Oximeter, 21 CFR 870.2700 Cardiovascular

Classification Panel: Cardiovascular

10.5 PROPOSED INTENDED USE/INDICATION FOR USE

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

Except for reference to the Android Tablet display, the indications for use statement is identical to the indications for use statement for:

- Multi-Parameter Mobile CareGuide 3100 (K130079)

This device’s tissue oxygenation feature has been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter. The devices’ muscle pH feature has already cleared under classification regulation 21 CFR 868.1170, Indwelling blood hydrogen ion concentration (pH) analyzer.

- The Multi-Parameter CareGuide 3100 Oximeter with Tablet has the same intended use as one of the identified predicates, the Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079)
- The tablet portion (hardware and software) of the Multi-Parameter CareGuide 3100 with Tablet has the same display function, i.e. to interface with the sensor and display parameter values and trends, as one of the identified predicates, the CareGuide Oximeter (K113656)

Conclusion:

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

The Intended Use is identical to the predicate devices. There is no change in how the User would use the information generated by the Multi-Parameter CareGuide 3100 Oximeter with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter CareGuide 3100 Oximeter with Tablet nor any of the predicate devices identified by RMI provide any diagnostic output.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

10.6 DEVICE DESCRIPTION SUMMARY

A detailed Device Description is provided in Section 11, a Software Overview is provided in Section 16 of the 510(k) submission.

The CareGuide sensor uses Near Infrared (NIR) Spectroscopy to calculate muscle oxygen saturation (SmO2) and muscle pH (pHm).

Table 10-1. Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet technology summary

Characteristics	Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet
Principle of Operation	NIR spectroscopy
Components	Reusable sensor, disposable sleeve and commercial Android tablet
Light Source	LEDs
Parameters Measured	Muscle oxygen saturation (SmO2); Muscle pH (pHm);

The predicate CareGuide 1100 Oximeter cleared via K113656 is a complete system, including the display. The Multi-Parameter Mobile CareGuide 3100 Oximeter cleared via K130079 is an OEM sensor that outputs SmO2 and pHm trend data to a third party monitoring device or a display device such as a tablet computer. The Multi-Parameter CareGuide 3100 Oximeter with Tablet validates a specific set of tablets and associated software to display the SmO2 and pHm trend data.

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the sensor hardware or the disposable sleeve from the Multi-Parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the sensor software from the Multi-Parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the fundamental way in which SmO2 and pHm are calculated, maintaining the same optical hardware and algorithms for calculating SmO2 as was previously cleared in K113656 and K122645 and calculating pHm as was previously cleared in K130079. The main difference between CareGuide models 3100 and 3100 with Tablet is the addition of an Android Tablet with software that is compliant with the Mobile CareGuide 3100 Communications Protocol (Section 16) and displays the SmO2 and pHm current and trended parameters, battery level, error information and device state.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet contains 3rd party software that ‘locks down’ the Tablet. The device has a version of the Android operating system, a limited set of Android applications, the CareGuide 3100 display software and a software locking application. The locking application only allows a single application, the CareGuide 3100 display application, to run. The user cannot load any new software applications, or any operating system updates to the tablet. All external communications (Wi-Fi, Bluetooth) are disabled. The only communication channel enabled is the USB connection to the Multi-parameter Mobile CareGuide 3100 oximeter sensor. There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.

Please note that this 510(k) requests FDA clearance for the Multi-Parameter CareGuide 3100 Oximeter with Tablet, specifying specific Android tablets and Android operating systems that have been qualified by Reflectance Medical. It is Reflectance Medical’s intent to qualify other devices and/or operating systems to support the same functionality in the future.

10.6.1 System Hardware and Software

Reusable Sensor: The sensor acquires the spectral data from the patient, derives the physiological measurements and communicates with the Android tablet. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet reusable sensor is identical to the sensor component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

Mobile CareGuide Ray: The Mobile CareGuide Ray is a disposable sleeve which isolates the sensor optical elements from the patient’s skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet disposable is identical to the disposable component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

Mobile CareGuide Cradle: Before being used on a new patient, a new cradle, packaged with each Ray, is used to check the sensor against the standard cradle used during manufacturing. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet cradle is identical to the cradle component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

Mobile CareGuide Software: The Multi-Parameter Mobile CareGuide 3100 with Tablet sensor software interfaces with the Multi-Parameter CareGuide 3100 with Tablet Sensor to control the LEDs and detector, check the sensor, acquire spectral data, calculate SmO2 and pHm, communicate the parameter values and sensor state conditions to the Android tablet, check thermistors for safe temperature levels, store SmO2 and pHm values and spectral data, and communicate with external service software to control settings,

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

download stored data and upgrade the device. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet sensor software is identical to the software component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

Mobile CareGuide Android Tablet: The tablet is a commercial Android tablet. For this filing, two devices have been validated: Acer A500 and Asus Google Nexus 7. The product is used as is with additional software

Mobile CareGuide Android Tablet Software: The Android software consists of 4 components (further described in Section 16):

1. Android operating system: Android OS 4.0 and OS 4.3 have been validated. The OS is used 'as is' from the tablet manufacturer.
2. CareGuide display software: consists of three components: 1. Communication software to interface with the sensor via the USB port; 2. Display software to start/pause/stop the sensor, enter patient identification, perform a sensor check, display real-time SmO2 and pHm values, display a trend of historical SmO2 and pHm values and display any fault conditions reported by the sensor; 3. Store historical trend data and fault conditions in a text file.
3. Lock down software: a 3rd party software package: SureLock from 42Gears Mobility Systems Pvt Ltd is installed on the Android tablet. It restricts the user to only be able to run the CareGuide 3100 display software application. It disables the ability to load any new software applications, or any operating system updates to the tablet. It disables all external communications (Wi-Fi, Bluetooth). There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.
4. Utility tools: there are a set of 3rd party tools that are installed as part of the installation process for the Mobile CareGuide Android Tablet. These tools include APK installer, task manager, file explorer, screen shortcut creator, anti-virus software and USB test program. None of these applications are accessible to the end-user and are used only for installation or service purposes.

The *level of concern* for the CareGuide System is **Moderate** prior to mitigation of hazards (Section 16.2): a failure of the Software Device could result in minor injury, either to a patient or to a user of the device.

10.6.2 Multi-Parameter CareGuide 3100 Algorithms

The fundamental principle behind the algorithms used to calculate SmO2 and pHm is that each of the parameters has a quantifiable perturbation on the NIR absorbance spectrum of hemoglobin. Each spectrum of hemoglobin the CareGuide sensor collects, is confounded by absorbance and scattering from skin, fat and muscle. The Multi-Parameter Mobile CareGuide 3100 Oximeter with

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Tablet algorithms are identical to the algorithm component of the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details.

10.7 STANDARDS SUMMARY

The CareGuide Oximeter complies with the standards listed in Table 10-2. Declarations of conformity and summary reports for these standards are provided in Section 9. These standards are identical to the predicate Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). Please refer to the K130079 filing for further details. No new standards are claimed for the Tablet portion of the device.

Table 10-2 List of Relevant Consensus and FDA Recognized Standards

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
12-168	IEC60825-1 Ed 2.0 (2007)	Safety of laser products - Part 1: Equipment classification, and requirements	Pass (Class 1 Laser Device)	None	Included in predicate K130079 pages 43-44 and on file at RMI
5-27	IEC 60601-1-1: 2005	Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standards: Safety requirements for medical electrical systems	Pass	None	Included in predicate K130079 pages 45-46 and on file at RMI
5-35	IEC 60601-1-2: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Pass	None	Included in predicate K130079 pages 47-48 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Section
2-153	ISO 10993-5 2009	Biological evaluation of medical devices-Part 5: Test for <i>in vitro</i> cytotoxicity	Pass	None	Included in predicate K130079 pages 49-50 and on file at RMI
2-87	ISO 10993-10 2010	Biological evaluation of medical devices-Part 10: Tests for irritation and delay-type hypersensitivity	Pass	None	Included in predicate K130079 pages 51-52 and on file at RMI
NA	AAMI TIR 12:2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	Pass	None	Included in predicate K130079 pages 53-54 and on file at RMI
NA	AAMI TIR 30:2003	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	Pass	None	Included in predicate K130079 pages 55-56 and on file at RMI
NA	ISTA 1A	Series Non-Simulation Integrity Performance Test Procedure: Packaged-Products 150 lb (68 kg) or Less	Pass	None	Included in predicate K130079 pages 57-58 and on file at RMI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

10.8 SUBSTANTIAL EQUIVALENCE RATIONALE: INTENDED USE

The Intended Use is identical to the predicates. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has the same intended use as the:

- Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079) for sensor hardware, software, interfaces and algorithms.
- Reflectance Medical CareGuide 1100 Oximeter (K113656) for displaying real-time parameters, historical trend data and sensor fault conditions;

There is no change in how the User would use the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. None of them provide any diagnostic output.

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has the same principle of operation (optical) as the Multi-Parameter Mobile CareGuide 3100 Oximeter.

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has the same technological characteristics as the previously cleared CareGuide 1100 and CareGuide 3100.

10.9 SUBSTANTIAL EQUIVALENCE RATIONALE – Technological characteristics:

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the sensor hardware or the disposable sleeve from the Multi-Parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the sensor software from the Multi-Parameter Mobile CareGuide 3100 Oximeter. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has no change in the fundamental way in which SmO₂ and pHm are calculated, maintaining the same optical hardware and algorithms for calculating SmO₂ as was previously cleared in K113656 and K122645 and calculating pHm as was previously cleared in K130079.

10.10 SUBSTANTIAL EQUIVALENCE DETERMINATION SUMMARY

The Multi-Parameter CareGuide 3100 is substantially equivalent to the predicate devices:

- The Indications for use for SmO₂ and pHm are identical with that of the predicates.
- The reference to multiple classification codes in this 510(k) is the same as the predicates.
- Technologically, the Multi-Parameter CareGuide 3100 with Tablet is identical to the predicate.
- The accuracy of the Multi-Parameter CareGuide 3100 with Tablet is identical to the accuracy of the predicate.

Therefore, the Multi-Parameter CareGuide 3100 Oximeter with Tablet is Substantially Equivalent to the predicate devices.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

10.11 SUMMARY OF TEST RESULTS IN THIS SUBMISSION

The test results in this 510(k) submission include Bench Studies, as part of Device V&V to support the Android Tablet display (per design controls). No animal or clinical studies were required.

The test results collectively all support a determination of substantial equivalence.

10.11.1 BENCH TEST RESULTS SUMMARY

The following is a roadmap to the various Bench Test Results in the 510(k):

- Section 9 includes declarations of conformity and summary reports for the standards listed in Table 10-1 above. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet complies with these standards.
- Section 14 includes references to the predicate device (K130079) shipping, shelf life and reuse cleaning validation test results and protocols (TIR 12 and TIR 30).
- Section 15 includes references to the predicate device (K130079) biocompatibility test results showing compliance to ISO 10993. There are no changes to the case or disposable in the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet as it is equivalent in those aspects to the predicate device (K130079) and can therefore be declared conformant.
- Section 16 includes Android Tablet software V&V test results.
- Section 17 includes references to the predicate device (K130079) EMC and electrical safety tests (IEC 60601-1-1 and IEC 60601-1-2). There are no hardware changes in the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet as it is equivalent in those aspects to the predicate device (K130079) and can therefore be declared conformant.
- Section 18 includes references to the predicate device (K130079) hardware bench test results including laser standards testing, System level hardware V&V testing, component level hardware V&V and unit testing. There are no hardware changes in the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet as it is equivalent in those aspects to the predicate device (K130079) and can therefore be declared conformant.

10.12 PROPOSED LABELING

Proposed labeling for the Multi-Parameter Mobile CareGuide 3100 with Tablet is provided in Section 13 of the 510(k). Draft labeling includes package labeling, device labeling and the Instructions for Use (Operator's Manual) for the Sensor, Ray and Tablet.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 11: Device Description

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 11

Device Description

**Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet–
Device Description Product Description**

Background from 510(k)-cleared K130079:

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is a noninvasive optical sensor that monitors two physiological parameters, SmO_2 and pHm , and reports them to the User via a display device. Light sources in the sensor illuminate the skin with near infrared (NIR) light. NIR light passes through the skin and fat, with only some loss to be primarily absorbed by blood vessels in the muscle tissue. Light which is not absorbed is scattered back and analyzed by the spectroscopic detector, also contained in the sensor. The microprocessor in the sensor converts the reflected light to an absorbance spectrum which is then analyzed by two separate algorithms, also stored in the sensor's microprocessor. The two algorithms calculate muscle oxygen saturation (SmO_2), and muscle pH (pHm).

The sensor is attached to the patient using the CareGuide Ray. The Ray is an adhesive-backed sleeve that isolates the sensor optics from direct contact with the patient's skin, keeping the sensor firmly attached to the skin. The Ray also provides a light shield to prevent ambient light from reaching the sensor spectrometer. One Ray is used per patient, but the CareGuide Sensor is reusable. Prior to use on each patient the Multi-Parameter Mobile CareGuide sensor is placed in a new ray and the assembly is placed on the cradle, which is packaged with the Ray. Software in the sensor performs an optical sensor check to determine that the sensor optics remain within specification. The result of the sensor check is communicated to the user. Once the sensor check is passed, the adhesive liner is removed from the Ray and the sensor, within the Ray, is adhered to the patient's skin over either the deltoid, calf or thigh muscle.

When the sensor is first placed on the patient software in the sensor automatically performs an initialization routine which sets up the spectral data collection parameters for the individual patient. Once conditions are established the sensor begins collecting spectra and reporting parameter values.

The Multi-Parameter Mobile CareGuide 3100 with Tablet's sensor measures and provides for output of SmO_2 and pHm data. There is no change in hardware or software from the previous version of the device, RMI's Multi-Parameter Mobile CareGuide 3100. The Multi-Parameter Mobile CareGuide 3100 with Tablet uses the same disposable and battery charger as the Multi-Parameter Mobile CareGuide 3100. The Multi-Parameter Mobile CareGuide 3100 with Tablet also had no changes in the algorithm by which SmO_2 and pHm are calculated.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Addition of Android Tablet display {subject of this 510(k)}:

The main differences between the 3100 with Tablet and 3100 is the addition of qualified display devices (Android Tablet) and software on the Tablet to display real-time and historical trend data. This section describes these changes in detail.

The Multi-Parameter Mobile CareGuide 3100 sensor communicates with the Multi-Parameter Mobile CareGuide 3100, which is compliant with the Mobile CareGuide communications protocol. SmO₂ and pH_m values suitable for display and trending are sent via the Mobile CareGuide communications protocol to the Tablet as well as battery level, error information and device states. The Mobile CareGuide communications protocol can be found as part of the predicate K130079 submission.

Table 1. Key difference between RMI's Multi-Parameter Mobile CareGuide 3100 with Tablet and the Multi-Parameter CareGuide 3100

Tablet	Qualified two tablets hardware platforms:
Tablet software	Software on tablet: a. Android operating system; b. CareGuide display software; c. Utility tools; d. Lockdown software

Table 2. Key similarities between RMI's Multi-parameter Mobile CareGuide 3100 with Tablet and the Multi-Parameter CareGuide 3100

Optics	The optical circuit board is unchanged.
Power	The power (rechargeable battery and battery charger) is unchanged
Computing Element	The embedded main processor is unchanged.
Interface	The USB interface is unchanged.
Communications Protocol	The communications protocol between the sensor and the Tablet is unchanged.
Mechanical	The size, shape and material of the sensor case is unchanged
Disposable	The ray (disposable) is unchanged
Algorithm	The calculation algorithms for SmO ₂ and pH _m are unchanged.
Flow of Operation	The overall flow of operation from the perspective of the user is unchanged
Safety	Both products contain the same safety check of thermistors to prevent excessive heat exposure on the skin.

Pages 131 through 140 redacted for the following reasons:

(b)(4)-TS/CCI

(b)(4)-Trade Secret (TS)/Commercial Confidential Information (CCI)

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 11: Device Description

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 11

Device Description

**Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet–
Device Description Product Description**

Background from 510(k)-cleared K130079:

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is a noninvasive optical sensor that monitors two physiological parameters, SmO_2 and pHm , and reports them to the User via a display device. Light sources in the sensor illuminate the skin with near infrared (NIR) light. NIR light passes through the skin and fat, with only some loss to be primarily absorbed by blood vessels in the muscle tissue. Light which is not absorbed is scattered back and analyzed by the spectroscopic detector, also contained in the sensor. The microprocessor in the sensor converts the reflected light to an absorbance spectrum which is then analyzed by two separate algorithms, also stored in the sensor's microprocessor. The two algorithms calculate muscle oxygen saturation (SmO_2), and muscle pH (pHm).

The sensor is attached to the patient using the CareGuide Ray. The Ray is an adhesive-backed sleeve that isolates the sensor optics from direct contact with the patient's skin, keeping the sensor firmly attached to the skin. The Ray also provides a light shield to prevent ambient light from reaching the sensor spectrometer. One Ray is used per patient, but the CareGuide Sensor is reusable. Prior to use on each patient the Multi-Parameter Mobile CareGuide sensor is placed in a new ray and the assembly is placed on the cradle, which is packaged with the Ray. Software in the sensor performs an optical sensor check to determine that the sensor optics remain within specification. The result of the sensor check is communicated to the user. Once the sensor check is passed, the adhesive liner is removed from the Ray and the sensor, within the Ray, is adhered to the patient's skin over either the deltoid, calf or thigh muscle.

When the sensor is first placed on the patient software in the sensor automatically performs an initialization routine which sets up the spectral data collection parameters for the individual patient. Once conditions are established the sensor begins collecting spectra and reporting parameter values.

The Multi-Parameter Mobile CareGuide 3100 with Tablet's sensor measures and provides for output of SmO_2 and pHm data. There is no change in hardware or software from the previous version of the device, RMI's Multi-Parameter Mobile CareGuide 3100. The Multi-Parameter Mobile CareGuide 3100 with Tablet uses the same disposable and battery charger as the Multi-Parameter Mobile CareGuide 3100. The Multi-Parameter Mobile CareGuide 3100 with Tablet also had no changes in the algorithm by which SmO_2 and pHm are calculated.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Addition of Android Tablet display {subject of this 510(k)}:

The main differences between the 3100 with Tablet and 3100 is the addition of qualified display devices (Android Tablet) and software on the Tablet to display real-time and historical trend data. This section describes these changes in detail.

The Multi-Parameter Mobile CareGuide 3100 sensor communicates with the Multi-Parameter Mobile CareGuide 3100, which is compliant with the Mobile CareGuide communications protocol. SmO₂ and pH_m values suitable for display and trending are sent via the Mobile CareGuide communications protocol to the Tablet as well as battery level, error information and device states. The Mobile CareGuide communications protocol can be found as part of the predicate K130079 submission.

Table 1. Key difference between RMI's Multi-Parameter Mobile CareGuide 3100 with Tablet and the Multi-Parameter CareGuide 3100

Tablet	Qualified two tablets hardware platforms:
Tablet software	Software on tablet: a. Android operating system; b. CareGuide display software; c. Utility tools; d. Lockdown software

Table 2. Key similarities between RMI's Multi-parameter Mobile CareGuide 3100 with Tablet and the Multi-Parameter CareGuide 3100

Optics	The optical circuit board is unchanged.
Power	The power (rechargeable battery and battery charger) is unchanged
Computing Element	The embedded main processor is unchanged.
Interface	The USB interface is unchanged.
Communications Protocol	The communications protocol between the sensor and the Tablet is unchanged.
Mechanical	The size, shape and material of the sensor case is unchanged
Disposable	The ray (disposable) is unchanged
Algorithm	The calculation algorithms for SmO ₂ and pH _m are unchanged.
Flow of Operation	The overall flow of operation from the perspective of the user is unchanged
Safety	Both products contain the same safety check of thermistors to prevent excessive heat exposure on the skin.

Pages 144 through 169 redacted for the following reasons:

- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 12: Substantial Equivalence Rationale

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 12

SUBSTANTIAL EQUIVALENCE DETERMINATION

12.1 Substantial Equivalence – Predicates

Trade name of New Device: Multi-Parameter CareGuide™ Oximeter with Tablet
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc. (RMI)
510(k) Number: N/A
Proposed additional product codes: None

Predicate Device #1: Mobile CareGuide 3100
Trade name of Device: Multi-Parameter CareGuide™ Oximeter 3100
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc.
510(k) Number: K130079
Product codes: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2: CareGuide
Trade Name of Device: Multi-Parameter CareGuide™ Oximeter
Model Number: 1100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Number: K113656
Product code: MUD, 21 C.F.R. § 870.2700, Cardiovascular

12.2 Multi-Parameter Mobile CareGuide 3100 with Tablet Proposed Indications for use:

The proposed indications for use for RMI’s Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet are:

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

12.3 SUBSTANTIAL EQUIVALENCE – REVIEW OF PREDICATES:

The Mobile CareGuide 3100 with Tablet is a multi-parameter oximeter, calculating and displaying SmO₂ and pH_m trends on an Android Tablet. Earlier versions of the device were cleared to monitor and display SmO₂ trends through K113656 (CareGuide 1100) and K130079 (Mobile CareGuide 3100, which cleared monitoring and display of both SmO₂ and pH_m trends through an interface to third party displays). K113656 was cleared under product code MUD, 21 C.F.R. § 870.2700. K130079 was cleared under the product codes MUD, 21 C.F.R. § 870.2700 and CBZ, 21 CFR 868.1170, Anesthesiology.

12.3.1 SmO₂ and pH_m Predicates: Mobile CareGuide 3100 (K130079)

The algorithms for calculating SmO₂ and pH_m are unchanged from the predicate Mobile CareGuide 3100. The hardware platform, including the optical components, described for the Mobile CareGuide 3100 is identical to the hardware platform for the Mobile CareGuide 3100 with Tablet. The software deployed for the Mobile CareGuide 3100 sensor is identical to the software for the Mobile CareGuide 3100 with Tablet. The communications protocol that allows the Mobile CareGuide 3100 sensor to communicate with 3rd party display devices is identical to the protocol used to communicate with the Tablet component of the Mobile CareGuide 3100 with Tablet. The Mobile CareGuide 3100 Oximeter with Tablet is technologically equivalent to the predicate Mobile CareGuide 3100. The Mobile CareGuide 3100 Oximeter with Tablet has the same Indications for Use statement as the predicate Mobile CareGuide 3100.

Mobile CareGuide 3100 Indications for Use Statement (K130079):

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on a third party device, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.”

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

12.3.2 Predicate (for display component in indications): CareGuide 1100 (K113656)

CareGuide 1100 Indications for Use Statement:

“The CareGuide™ Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The CareGuide displays the most recent value of SmO₂, as well as a graphical trend of previous SmO₂ measurements. The CareGuide System should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the CareGuide™ Oximeter has not been demonstrated in disease states.”

12.3.3 Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet {subject of this 510(k)}:

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

Table 12-1 Substantial Equivalence: Comparison of RMI’s Multi-Parameter CareGuide 3100 with Tablet to Mobile CareGuide 3100 and CareGuide 1100

Characteristics	RMI Multi-Parameter CareGuide Oximeter 3100 with Tablet	RMI Multi-Parameter CareGuide Oximeter 3100 K130079	RMI CareGuide Oximeter 1100 K113656
Muscle tissue SmO ₂ algorithm	Same as CareGuide 1100	Same as CareGuide 1100	SmO ₂ calculated from preprocessed spectra
Local tissue pH algorithm	Same as CareGuide 3100	pHm calculated from preprocessed spectra	N.A.

Pages 174 through 175 redacted for the following reasons:

(b)(4)-TS/CCI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

12.4 SUBSTANTIAL EQUIVALENCE DETERMINATION

RMI has addressed the following questions from the FDA Substantial Equivalence flowchart (appended as the last page of this section), available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134783.htm>.

New device is compared to marketed device?

Yes. The Multi-Parameter CareGuide 3100 with Tablet is compared to RMI's CareGuide 1100 Oximeter and Multi-Parameter Mobile CareGuide 3100 Oximeter (K113656, K130079).

Does new Device have same indication statement?

Yes, the RMI Multi-Parameter CareGuide 3100 with Tablet has the same intended use as the predicate devices. The indications for use statement proposed by RMI is:

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

This indications for use statement draws from the indications for use statements for:

- Multi-Parameter Mobile CareGuide 3100 Oximeter: SmO2 and pHm measurements and USB communications to a display device (K130079)
- CareGuide 1100 Oximeter: display of SmO2 and pHm data (K113656)

There is no change in how the User would use the information generated by the Multi-Parameter Mobile CareGuide 3100 with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter Mobile CareGuide 3100 with Tablet nor any of the predicate devices identified by RMI provides any diagnostic output. Please see Section 13 of this submission for Proposed Multi-Parameter Mobile CareGuide 3100 with Tablet Labeling.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

New Device has same intended use and may be “substantially equivalent”

Yes.

This device’s oximetry and pHm features have been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter and pH (21 CFR 868.1170).

The Multi-Parameter Mobile CareGuide 3100 with Tablet has the same intended use as one of the identified predicates, the Multi-Parameter Mobile CareGuide 3100 (K130079).

Does new Device have same Technological Characteristics, e.g. Design, Materials, Etc.?

Yes. The Multi-Parameter Mobile CareGuide 3100 with Tablet has the same principle of operation (an optical technological platform that relies on light absorption) and identical algorithms as both predicate devices. The Multi-Parameter Mobile CareGuide 3100 with Tablet uses the identical hardware, software, mechanical components and disposable sleeve as the Mobile CareGuide 3100 (K130079). The Multi-Parameter Mobile CareGuide 3100 includes a sensor and monitor and, outputs a numeric trend like the CareGuide 1100 predicate device (K113656).

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. The descriptive characteristics of the proposed device are not precise enough to ensure equivalence. However, as explained below, and in additional sections of this submission, performance data demonstrate Substantial Equivalence to the predicate devices. Therefore, the fact that the descriptive characteristics of the Multi-Parameter Mobile CareGuide 3100 with Tablet are not precise enough to ensure equivalence do not preclude a determination of Substantial Equivalence under FDA’s laws, regulations and guidance.

Are Performance Data Available to Assess Equivalence?

Yes. Please see the following sections of this submission:

- Section 14: Packaging/Shipping/Shelf life (there are no sterile components)
- Section 15: Biocompatibility
- Section 16: Software
- Section 17: Electrical Safety and EMC
- Section 18: Bench tests

Performance Data Demonstrate Equivalence?

Yes.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

The Multi-Parameter Mobile CareGuide 3100 with Tablet meets relevant consensus and FDA recognized standards for Oximeters, which support substantial equivalence. Biocompatibility, Electrical safety and EMC testing from the predicate device (K130079) were successfully completed. Validation of performance in the form of an Animal study, and a Clinical study for the predicate device (K130079) was successful. Bench Testing is summarized in Sections 18 of this submission.

Substantial Equivalence Determination:

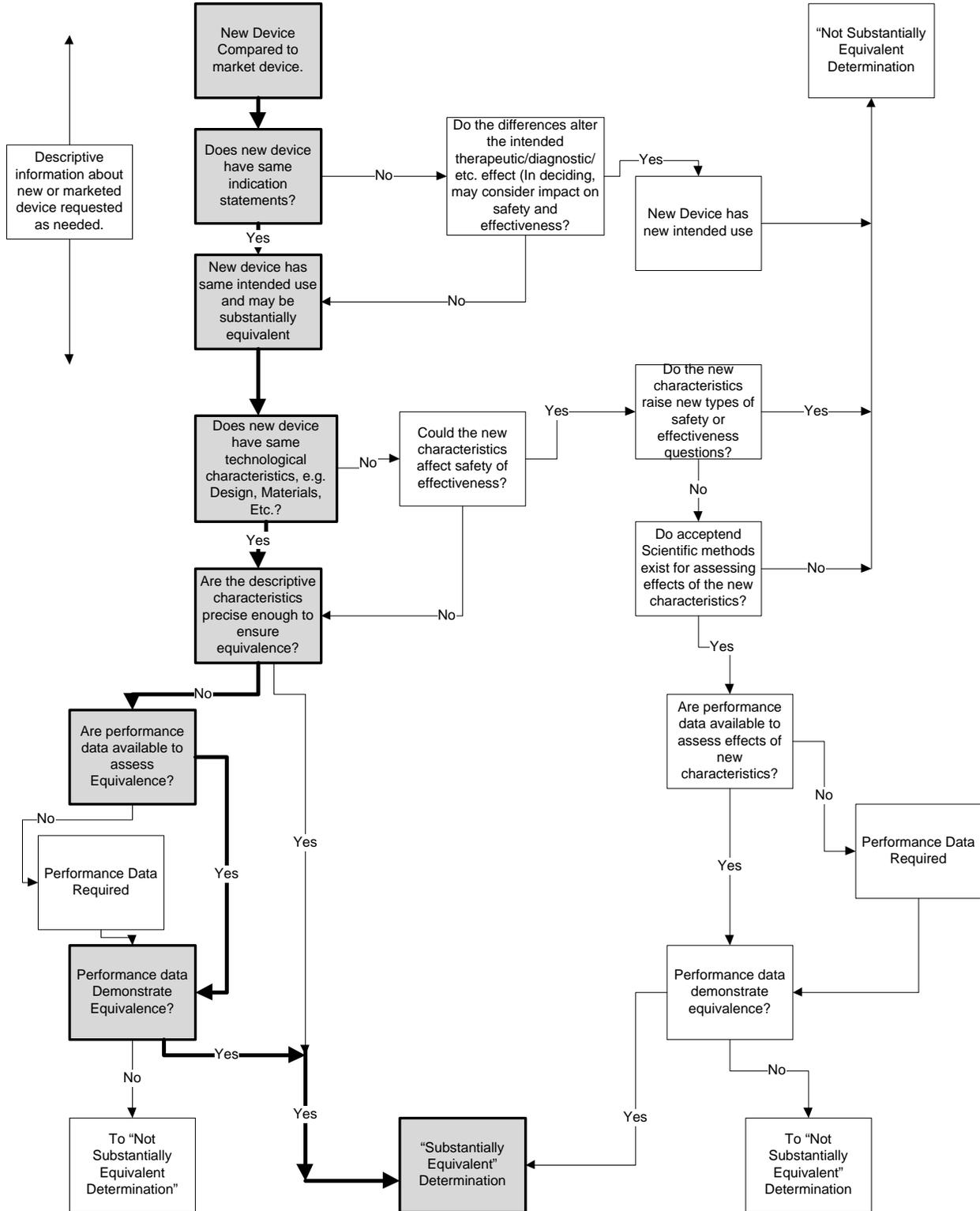
The Multi-Parameter Mobile CareGuide 3100 with Tablet is substantially equivalent to the predicate devices:

- The Indications for use for SmO₂ and pHm are identical with that of the predicates. They are all monitors.
- The reference to multiple classification codes in this 510(k) is identical with that of the predicates.
- Technologically, the Multi-Parameter Mobile CareGuide 3100 with Tablet is similar to the predicates.
- There is no change in the algorithm for monitoring of SmO₂ and pHm. Therefore, the accuracy of the Multi-Parameter Mobile CareGuide 3100 with Tablet is identical to the accuracy of the predicates.

Therefore, the Multi-Parameter Mobile CareGuide Oximeter 3100 with Tablet is Substantially Equivalent to the predicate devices.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 12: Substantial Equivalence Rationale

CONFIDENTIAL

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 12

SUBSTANTIAL EQUIVALENCE DETERMINATION

12.1 Substantial Equivalence – Predicates

Trade name of New Device: Multi-Parameter CareGuide™ Oximeter with Tablet
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc. (RMI)
510(k) Number: N/A
Proposed additional product codes: None

Predicate Device #1: Mobile CareGuide 3100
Trade name of Device: Multi-Parameter CareGuide™ Oximeter 3100
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc.
510(k) Number: K130079
Product codes: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2: CareGuide
Trade Name of Device: Multi-Parameter CareGuide™ Oximeter
Model Number: 1100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Number: K113656
Product code: MUD, 21 C.F.R. § 870.2700, Cardiovascular

12.2 Multi-Parameter Mobile CareGuide 3100 with Tablet Proposed Indications for use:

The proposed indications for use for RMI’s Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet are:

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

12.3 SUBSTANTIAL EQUIVALENCE – REVIEW OF PREDICATES:

The Mobile CareGuide 3100 with Tablet is a multi-parameter oximeter, calculating and displaying SmO₂ and pH_m trends on an Android Tablet. Earlier versions of the device were cleared to monitor and display SmO₂ trends through K113656 (CareGuide 1100) and K130079 (Mobile CareGuide 3100, which cleared monitoring and display of both SmO₂ and pH_m trends through an interface to third party displays). K113656 was cleared under product code MUD, 21 C.F.R. § 870.2700. K130079 was cleared under the product codes MUD, 21 C.F.R. § 870.2700 and CBZ, 21 CFR 868.1170, Anesthesiology.

12.3.1 SmO₂ and pH_m Predicates: Mobile CareGuide 3100 (K130079)

The algorithms for calculating SmO₂ and pH_m are unchanged from the predicate Mobile CareGuide 3100. The hardware platform, including the optical components, described for the Mobile CareGuide 3100 is identical to the hardware platform for the Mobile CareGuide 3100 with Tablet. The software deployed for the Mobile CareGuide 3100 sensor is identical to the software for the Mobile CareGuide 3100 with Tablet. The communications protocol that allows the Mobile CareGuide 3100 sensor to communicate with 3rd party display devices is identical to the protocol used to communicate with the Tablet component of the Mobile CareGuide 3100 with Tablet. The Mobile CareGuide 3100 Oximeter with Tablet is technologically equivalent to the predicate Mobile CareGuide 3100. The Mobile CareGuide 3100 Oximeter with Tablet has the same Indications for Use statement as the predicate Mobile CareGuide 3100.

Mobile CareGuide 3100 Indications for Use Statement (K130079):

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on a third party device, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.”

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

12.3.2 Predicate (for display component in indications): CareGuide 1100 (K113656)

CareGuide 1100 Indications for Use Statement:

“The CareGuide™ Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The CareGuide displays the most recent value of SmO2, as well as a graphical trend of previous SmO2 measurements. The CareGuide System should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the CareGuide™ Oximeter has not been demonstrated in disease states.”

12.3.3 Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet {subject of this 510(k)}:

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

Table 12-1 Substantial Equivalence: Comparison of RMI’s Multi-Parameter CareGuide 3100 with Tablet to Mobile CareGuide 3100 and CareGuide 1100

Characteristics	RMI Multi-Parameter CareGuide Oximeter 3100 with Tablet	RMI Multi-Parameter CareGuide Oximeter 3100 K130079	RMI CareGuide Oximeter 1100 K113656
Muscle tissue SmO2 algorithm	Same as CareGuide 1100	Same as CareGuide 1100	SmO2 calculated from preprocessed spectra
Local tissue pH algorithm	Same as CareGuide 3100	pHm calculated from preprocessed spectra	N.A.

Pages 184 through 185 redacted for the following reasons:

(b)(4)-TS/CCI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

12.4 SUBSTANTIAL EQUIVALENCE DETERMINATION

RMI has addressed the following questions from the FDA Substantial Equivalence flowchart (appended as the last page of this section), available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134783.htm>.

New device is compared to marketed device?

Yes. The Multi-Parameter CareGuide 3100 with Tablet is compared to RMI's CareGuide 1100 Oximeter and Multi-Parameter Mobile CareGuide 3100 Oximeter (K113656, K130079).

Does new Device have same indication statement?

Yes, the RMI Multi-Parameter CareGuide 3100 with Tablet has the same intended use as the predicate devices. The indications for use statement proposed by RMI is:

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

This indications for use statement draws from the indications for use statements for:

- Multi-Parameter Mobile CareGuide 3100 Oximeter: SmO2 and pHm measurements and USB communications to a display device (K130079)
- CareGuide 1100 Oximeter: display of SmO2 and pHm data (K113656)

There is no change in how the User would use the information generated by the Multi-Parameter Mobile CareGuide 3100 with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter Mobile CareGuide 3100 with Tablet nor any of the predicate devices identified by RMI provides any diagnostic output. Please see Section 13 of this submission for Proposed Multi-Parameter Mobile CareGuide 3100 with Tablet Labeling.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

New Device has same intended use and may be “substantially equivalent”

Yes.

This device’s oximetry and pHm features have been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter and pH (21 CFR 868.1170).

The Multi-Parameter Mobile CareGuide 3100 with Tablet has the same intended use as one of the identified predicates, the Multi-Parameter Mobile CareGuide 3100 (K130079).

Does new Device have same Technological Characteristics, e.g. Design, Materials, Etc.?

Yes. The Multi-Parameter Mobile CareGuide 3100 with Tablet has the same principle of operation (an optical technological platform that relies on light absorption) and identical algorithms as both predicate devices. The Multi-Parameter Mobile CareGuide 3100 with Tablet uses the identical hardware, software, mechanical components and disposable sleeve as the Mobile CareGuide 3100 (K130079). The Multi-Parameter Mobile CareGuide 3100 includes a sensor and monitor and, outputs a numeric trend like the CareGuide 1100 predicate device (K113656).

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. The descriptive characteristics of the proposed device are not precise enough to ensure equivalence. However, as explained below, and in additional sections of this submission, performance data demonstrate Substantial Equivalence to the predicate devices. Therefore, the fact that the descriptive characteristics of the Multi-Parameter Mobile CareGuide 3100 with Tablet are not precise enough to ensure equivalence do not preclude a determination of Substantial Equivalence under FDA’s laws, regulations and guidance.

Are Performance Data Available to Assess Equivalence?

Yes. Please see the following sections of this submission:

- Section 14: Packaging/Shipping/Shelf life (there are no sterile components)
- Section 15: Biocompatibility
- Section 16: Software
- Section 17: Electrical Safety and EMC
- Section 18: Bench tests

Performance Data Demonstrate Equivalence?

Yes.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

The Multi-Parameter Mobile CareGuide 3100 with Tablet meets relevant consensus and FDA recognized standards for Oximeters, which support substantial equivalence. Biocompatibility, Electrical safety and EMC testing from the predicate device (K130079) were successfully completed. Validation of performance in the form of an Animal study, and a Clinical study for the predicate device (K130079) was successful. Bench Testing is summarized in Sections 18 of this submission.

Substantial Equivalence Determination:

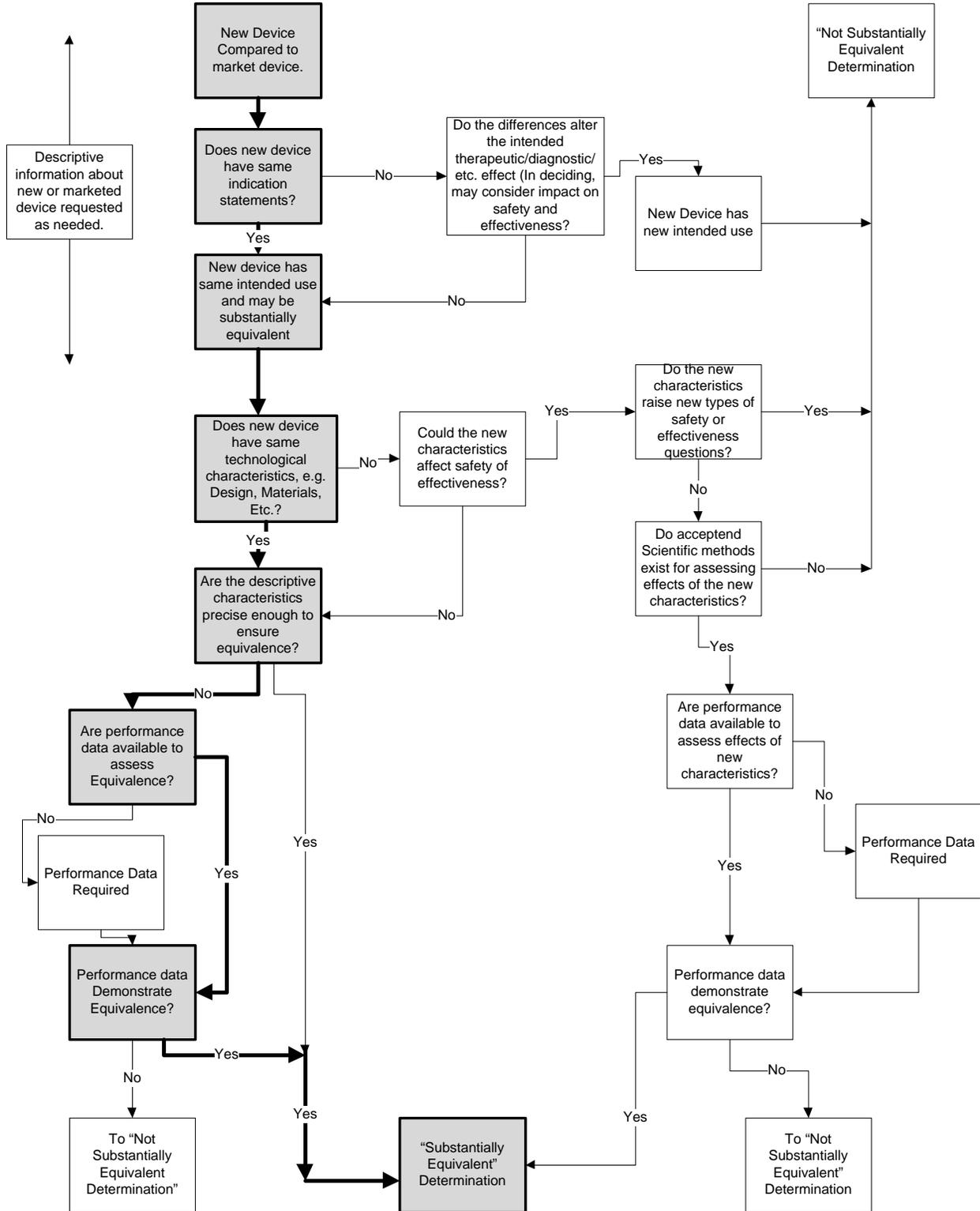
The Multi-Parameter Mobile CareGuide 3100 with Tablet is substantially equivalent to the predicate devices:

- The Indications for use for SmO₂ and pHm are identical with that of the predicates. They are all monitors.
- The reference to multiple classification codes in this 510(k) is identical with that of the predicates.
- Technologically, the Multi-Parameter Mobile CareGuide 3100 with Tablet is similar to the predicates.
- There is no change in the algorithm for monitoring of SmO₂ and pHm. Therefore, the accuracy of the Multi-Parameter Mobile CareGuide 3100 with Tablet is identical to the accuracy of the predicates.

Therefore, the Multi-Parameter Mobile CareGuide Oximeter 3100 with Tablet is Substantially Equivalent to the predicate devices.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet





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

July 19, 2013

Reflectance Medical, Inc.
c/o Ms. Nandini Murthy
116 Flaunders Road, Suite 1000
Westborough, MA 01581

Re: K130079

Trade/Device Name: Multi-Parameter Mobile CareGuide 3100 Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD CBZ
Dated: June 13, 2013
Received: June 18, 2013

Dear Ms. Nandini Murthy:

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

Page 2 – Ms. Nandini Murthy

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

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

Sincerely yours,

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

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter

Indications for Use Form

Indications for Use

510(k) Number (if known): K130079

Device Name: Multi-Parameter Mobile CareGuide™ 3100 Oximeter

Indications for Use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on a third party device, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.

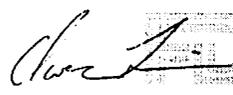
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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: 2013.07.19
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Page 1 of 1



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

July 19, 2013

Reflectance Medical, Inc.
c/o Ms. Nandini Murthy
116 Flaunders Road, Suite 1000
Westborough, MA 01581

Re: K130079

Trade/Device Name: Multi-Parameter Mobile CareGuide 3100 Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD CBZ
Dated: June 13, 2013
Received: June 18, 2013

Dear Ms. Nandini Murthy:

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

Page 2 – Ms. Nandini Murthy

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

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

Sincerely yours,

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

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter

Indications for Use Form

Indications for Use

510(k) Number (if known): K130079

Device Name: Multi-Parameter Mobile CareGuide™ 3100 Oximeter

Indications for Use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on a third party device, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.

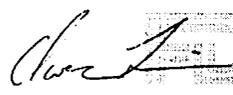
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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: 2013.07.19
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Page 1 of 1

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

JUL 26 2012

Reflectance Medical, Inc.
c/o Nandini Murthy
Regulatory Consultant, RMI
116 Flanders Road, Suite 100
Westborough, MA 01581

Re: K113656
Trade/Device Name: CareGuide Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter, tissue saturation
Regulatory Class: Class II (two)
Product Code: MUD
Dated: July 20, 2012
Received: July 23, 2012

Dear Ms. Murthy:

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.

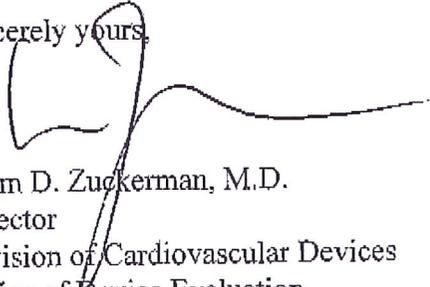
Page 2 – Ms. Nandini Murthy

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,



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

Enclosure

Reflectance Medical, Inc.
510(k) Premarket Notification Submission: CareGuide Oximeter

Indications for Use Form

Indications for Use

510(k) Number (if known): K113656

Device Name: CareGuide™ Oximeter

Indications for Use:

The CareGuide™ Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The CareGuide displays the most recent value of SmO2, as well as a graphical trend of previous SmO2 measurements. The CareGuide System should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the CareGuide™ Oximeter has not been demonstrated in disease states.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page of



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113656

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Page 1 of 1

Page 4 of 325

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

JUL 26 2012

Reflectance Medical, Inc.
c/o Nandini Murthy
Regulatory Consultant, RMI
116 Flanders Road, Suite 100
Westborough, MA 01581

Re: K113656
Trade/Device Name: CareGuide Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter, tissue saturation
Regulatory Class: Class II (two)
Product Code: MUD
Dated: July 20, 2012
Received: July 23, 2012

Dear Ms. Murthy:

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.

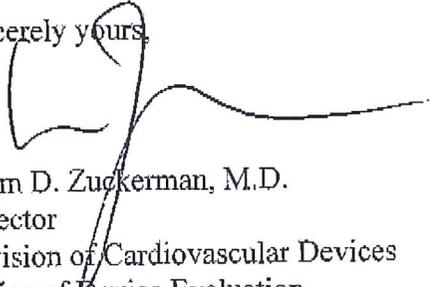
Page 2 – Ms. Nandini Murthy

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.

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Sincerely yours,



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

Enclosure

Reflectance Medical, Inc.
510(k) Premarket Notification Submission: CareGuide Oximeter

Indications for Use Form

Indications for Use

510(k) Number (if known): K113656

Device Name: CareGuide™ Oximeter

Indications for Use:

The CareGuide™ Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The CareGuide displays the most recent value of SmO2, as well as a graphical trend of previous SmO2 measurements. The CareGuide System should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the CareGuide™ Oximeter has not been demonstrated in disease states.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page of



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113656

CONFIDENTIAL

Page 1 of 1

Page 4 of 325

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 13: Proposed Labeling

CONFIDENTIAL

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 13

PROPOSED LABELING

13.1 DRAFT PRODUCT LABELING

Labeling for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet consists of:

- Primary packaging label
- Secondary packaging label
- Device labeling
- Instructions for Use (Operator's Manual)

Draft labeling is included in this section. The product labels support compliance to requirements Section 16: DIR 11.1 through 11.16.

13.2 PRIMARY PACKAGING (immediate packaging) LABEL

Draft primary packaging labeling for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet components are provided in Figures 13.1, 13.2, 13.3, 13.4 and 13.5.

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

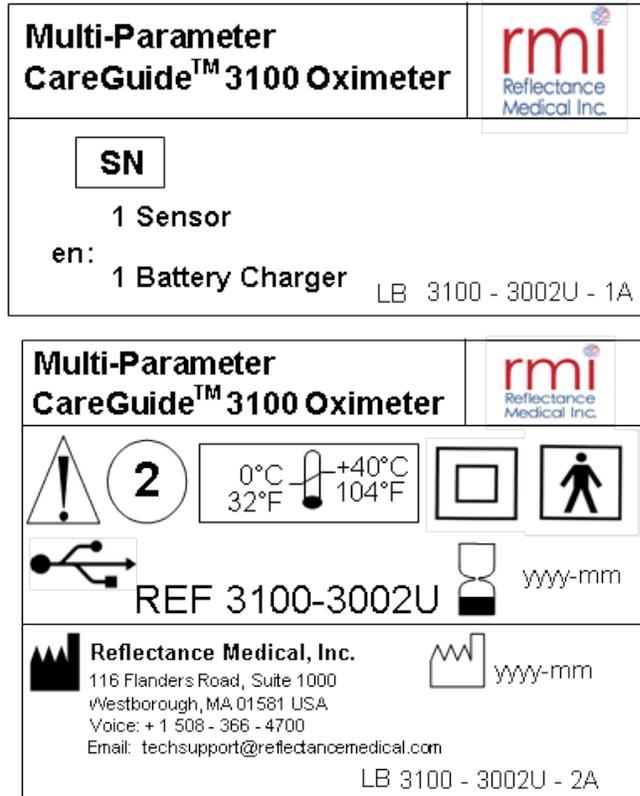


Figure 13.1: Sensor for USB interface Primary Packaging label:
Part 3002U-1A and Part 3002U-2A
(unchanged from predicate K130079)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Figure 13.2: Disposable (Ray/Cradle) Primary packaging label:
 Part 3003-1A and Part 3003-2A
 (unchanged from predicate K130079)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Figure 13.3: Battery Charger Primary packaging label:
Part 3004-1A and Part 3004-2A
(unchanged from predicate K130079)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Figure 13.4: 7" Android Tablet Primary Packaging label:
Part 3006-1A and Part 3006-2A

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

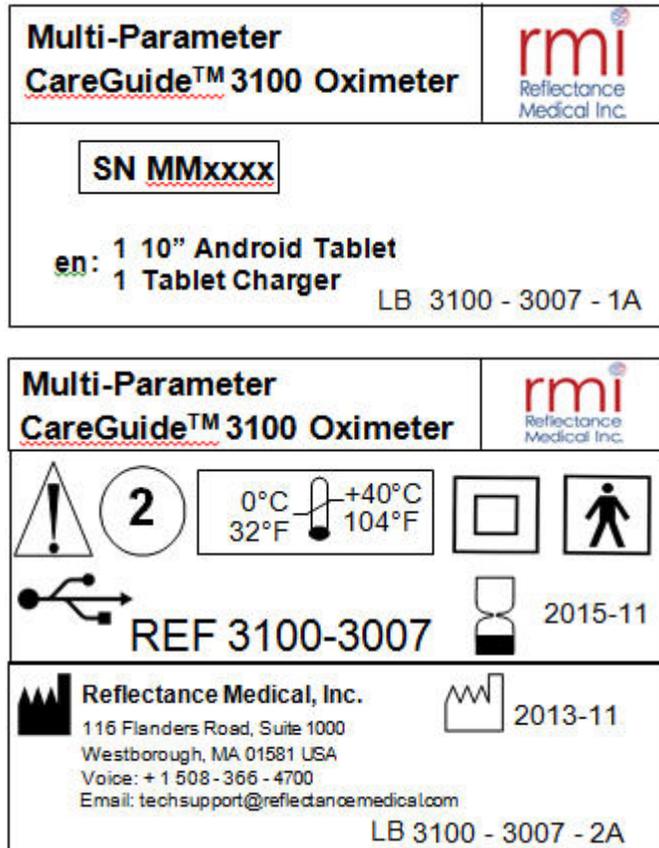


Figure 13.5: 10" Android Tablet Primary Packaging label:
Part 3007-1A and Part 3007-2A

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

13.3 SECONDARY PACKAGING (outside shipping container) LABEL

Draft secondary packaging labeling for the Mobile CareGuide™ 3100 Oximeter with Tablet components are provided in Figure 13.6.

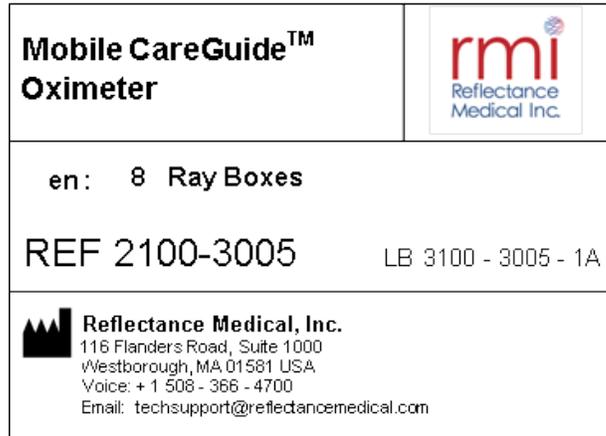


Figure 13.6: Disposable (“Ray”) Secondary Packaging label
(unchanged from predicate K130079)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

13.4 DEVICE LABELING

The following labeling is included directly on the Mobile CareGuide device. Device labelling is unchanged from predicate K130079.

- “CareGuide” is printed on the exterior of the Ray (Figure 13.7).



Figure 13.7: “CareGuide” logo printed on the exterior of the Ray

- Sensor with USB connector label (Figure 13.8) is printed on the cable of the Sensor (Figure 13.9).



Figure 13.8: Sensor with USB connector device label (Part 3002U-3A)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Figure 13.9: Sensor device label on the cable of the sensor

13.5 INSTRUCTIONS FOR USE (OPERATOR'S MANUAL)

The following draft Instructions for Use (IFU) for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet are included in Section 13:

1. Multi-Parameter Mobile CareGuide™ 3100 Oximeter instructions for use – 13DEC2013 IFU REV A.

Multi-Parameter Mobile CareGuide™ 3100 Oximeter IFU will accompany the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet system when shipped as a unit.

2. Mobile CareGuide™ Ray instructions for use - Instructions for Use - Ray Mars v5.0 20NOV2012 (unchanged from predicate K130079)

Mobile CareGuide™ Ray IFU will accompany the box of 8 Mobile CareGuide™ Ray when shipped as separate order.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 13: Proposed Labeling

CONFIDENTIAL

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 13

PROPOSED LABELING

13.1 DRAFT PRODUCT LABELING

Labeling for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet consists of:

- Primary packaging label
- Secondary packaging label
- Device labeling
- Instructions for Use (Operator's Manual)

Draft labeling is included in this section. The product labels support compliance to requirements Section 16: DIR 11.1 through 11.16.

13.2 PRIMARY PACKAGING (immediate packaging) LABEL

Draft primary packaging labeling for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet components are provided in Figures 13.1, 13.2, 13.3, 13.4 and 13.5.

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

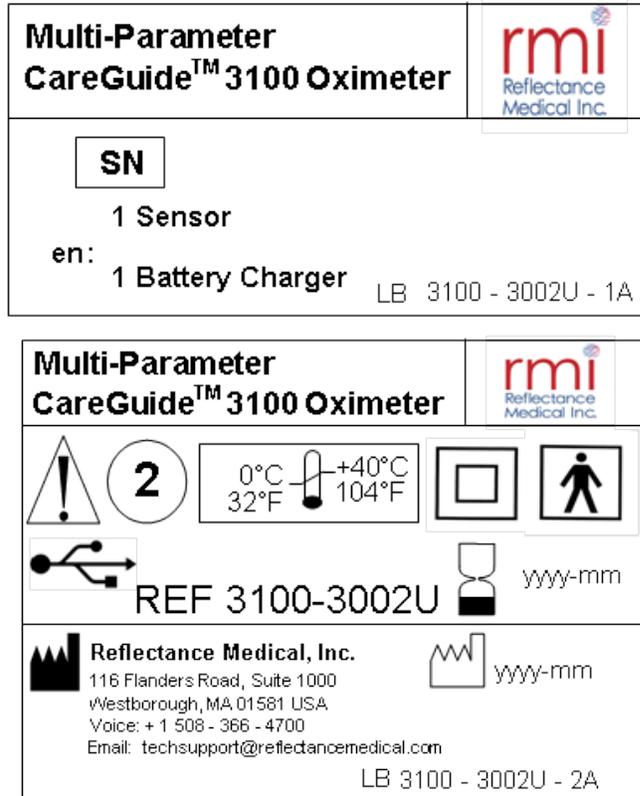


Figure 13.1: Sensor for USB interface Primary Packaging label:
Part 3002U-1A and Part 3002U-2A
(unchanged from predicate K130079)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Figure 13.2: Disposable (Ray/Cradle) Primary packaging label:
Part 3003-1A and Part 3003-2A
(unchanged from predicate K130079)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Figure 13.3: Battery Charger Primary packaging label:
Part 3004-1A and Part 3004-2A
(unchanged from predicate K130079)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

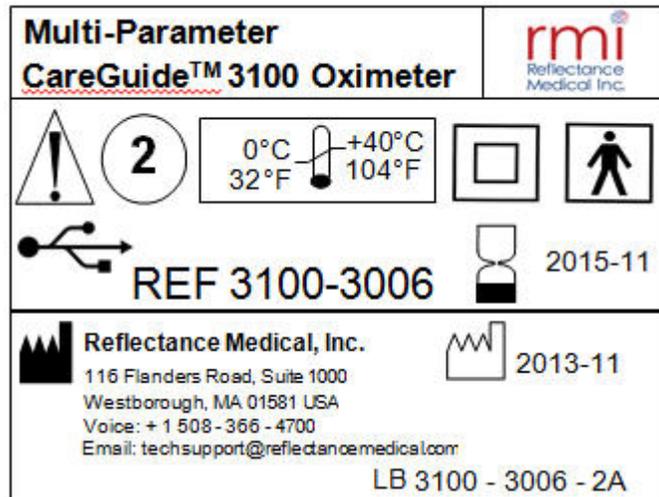
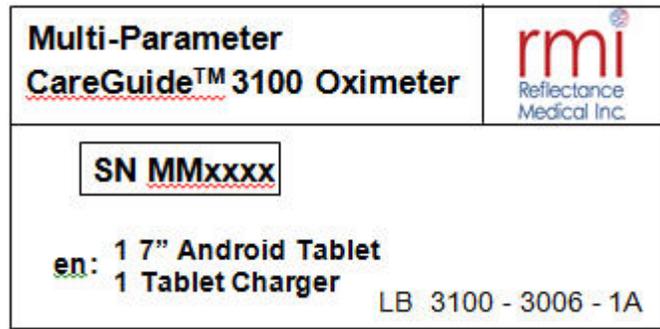


Figure 13.4: 7" Android Tablet Primary Packaging label:
Part 3006-1A and Part 3006-2A

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

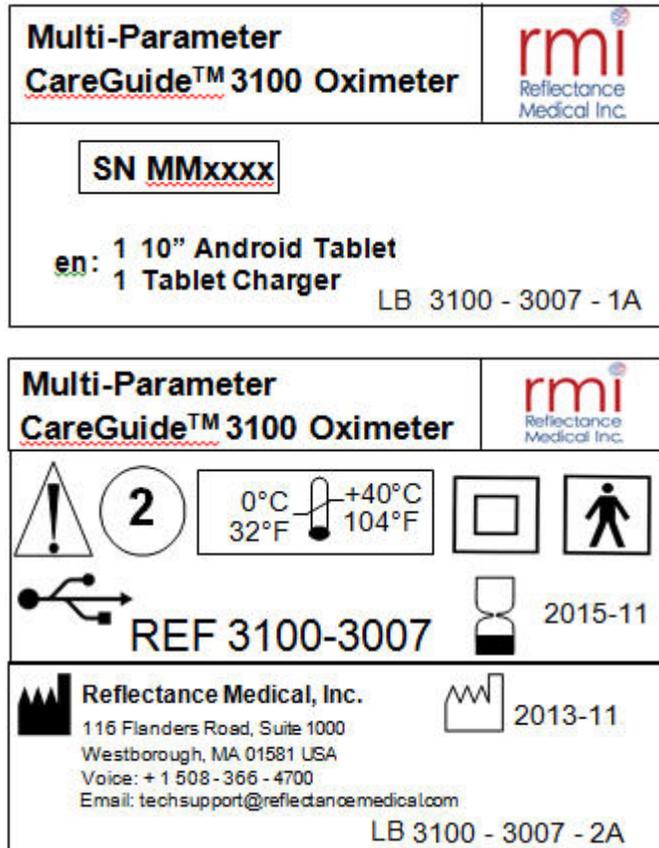


Figure 13.5: 10" Android Tablet Primary Packaging label:
Part 3007-1A and Part 3007-2A

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

13.3 SECONDARY PACKAGING (outside shipping container) LABEL

Draft secondary packaging labeling for the Mobile CareGuide™ 3100 Oximeter with Tablet components are provided in Figure 13.6.

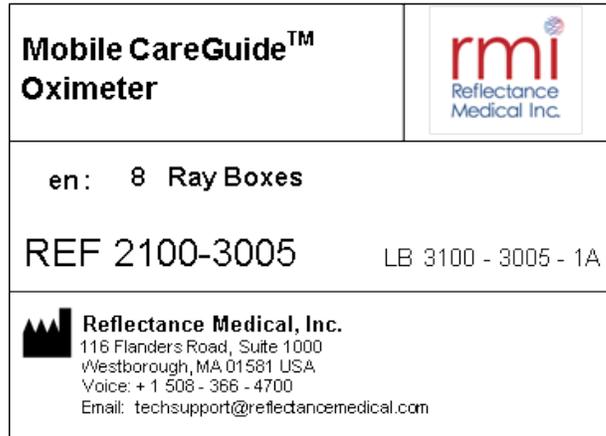


Figure 13.6: Disposable (“Ray”) Secondary Packaging label
(unchanged from predicate K130079)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

13.4 DEVICE LABELING

The following labeling is included directly on the Mobile CareGuide device. Device labelling is unchanged from predicate K130079.

- “CareGuide” is printed on the exterior of the Ray (Figure 13.7).



Figure 13.7: “CareGuide” logo printed on the exterior of the Ray

- Sensor with USB connector label (Figure 13.8) is printed on the cable of the Sensor (Figure 13.9).



Figure 13.8: Sensor with USB connector device label (Part 3002U-3A)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Figure 13.9: Sensor device label on the cable of the sensor

13.5 INSTRUCTIONS FOR USE (OPERATOR'S MANUAL)

The following draft Instructions for Use (IFU) for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet are included in Section 13:

1. Multi-Parameter Mobile CareGuide™ 3100 Oximeter instructions for use – 13DEC2013 IFU REV A.

Multi-Parameter Mobile CareGuide™ 3100 Oximeter IFU will accompany the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet system when shipped as a unit.

2. Mobile CareGuide™ Ray instructions for use - Instructions for Use - Ray Mars v5.0 20NOV2012 (unchanged from predicate K130079)

Mobile CareGuide™ Ray IFU will accompany the box of 8 Mobile CareGuide™ Ray when shipped as separate order.



Multi-Parameter Mobile 3100 OXIMETER

USER MANUAL

Instructions for Using the Multi-Parameter Mobile CareGuide™ 3100 Oximeter

CAUTION: Investigational device.
Limited by Federal law to investigational use



R_x Only

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IFU-0005/Rev. A

Multi-Parameter Mobile CareGuide™

Model Number: 3100

Serial Number: _____
(user records)

License Number: _____
(user records)

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IFU-0005/Rev. A

Multi-Parameter Mobile CareGuide™ 3100 Oximeter

IFU-0005/Rev. A Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (301)-796-8118 Page 97 of 361

Table of Contents

1	Introduction.....	4
1.1	Features	4
1.2	Indications for Use	5
1.3	Contraindications.....	5
1.4	Instructions Prior to Use	5
1.5	Components.....	6
2	Patient Monitoring.....	7
2.1	Setup	7
2.2	Starting Use.....	8
2.3	Checking Sensors & Rays.....	9
2.4	Placing Sensor & Ray on Patient.....	10
2.4.1	Shoulder Placement.....	11
2.4.2	Thigh Placement.....	12
2.4.3	Calf Placement.....	13
2.5	Beginning Monitoring.....	14
2.6	Other Operations	15
2.6.1	Display Options	15
2.6.2	Pausing & Resuming for the Same Patient.....	17
2.6.3	Changing to a New Patient.....	17
2.7	Ending Monitoring	18
3	Care & Maintenance	19
3.1	Cleaning the Sensor.....	19
3.2	Recharging the Sensor	21
3.3	Recharging the Display.....	22
3.4	Storing the System	22
4	Troubleshooting	23
4.1	Handling Error Messages	23
4.2	System Tools.....	24
4.2.1	Testing the Sensor Connection.....	24
4.2.2	Resetting the Sensor.....	24
4.2.3	Battery Charge Level	24
5	Safety Precautions	25
5.1	Warnings and Cautions	25
5.2	Disposal.....	27
6	Warranty.....	28
7	Technical Specifications.....	29

Table of Figures

Figure 1. System Components.....	6
Figure 2. Display Power Button and USB port, Connected to Sensor for Use	7
Figure 3. USB Access Prompt.....	7
Figure 4. Main Screen	8
Figure 5. Patient ID Screen.....	8
Figure 6. Patient ID Entered	8
Figure 7. Sensor Check Screen.....	9
Figure 8. Sensor Check In Progress.....	9
Figure 9. Placement Instructions Screen.....	10
Figure 10. Peeling Liner Off Ray	10
Figure 11. Optimal Shoulder Location	11
Figure 12. Ray Placed on Shoulder	11
Figure 13. Optimal Thigh Location.....	12
Figure 14. Ray Placed on Thigh	12
Figure 15. Optimal Calf Location	13
Figure 16. Ray Placed on Calf	13
Figure 17. Placement Instructions Screen	14
Figure 18. Sensor Optimizing	14
Figure 19. Monitoring Screen.....	14
Figure 20. Monitoring Screen- SmO ₂ Trend.....	15
Figure 21. Monitoring Screen- pHm Trend.....	15
Figure 22. Monitoring Screen- Graph Area for Accessing Options	16
Figure 23. Graphing Options Screen- Using On-Screen Keyboard.....	16
Figure 24. Graphing Options Screen	16
Figure 25. Example Monitoring Screen.....	17
Figure 26. Paused Monitoring Screen	17
Figure 27. Example Monitoring Screen.....	18
Figure 28. Display Power Button.....	18
Figure 29. Power Off	18
Figure 30. Overview photo including front face of Sensor and cord	19
Figure 31. Front face of Sensor	19
Figure 32. Layout of optical windows including LED banks and spectrometer.....	19
Figure 33. Sensor LED and Charger Connector	21
Figure 34. Sensor Battery Status LED States.....	21
Figure 35. Sensor Charger Connected to Sensor	21
Figure 36. Display Battery Status Icon.....	22
Figure 37. Charging the Display	22
Figure 38. System Tools Screen	24

1 Introduction

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter provides non-invasive assessment of hemoglobin-oxygen saturation (SmO₂) and pH (pHm) of microvascular blood in a region of skeletal muscle tissues beneath the oximeter sensor. It displays the most recent value of SmO₂ and pHm, as well as a graphical trend of previous measurements.

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is:

- Non-invasive, for acute use, and poses no significant safety questions.
- Uses infrared energy in a way that does not introduce excessive heat (i.e., no safety issue).
- Used in the clinical environment, in an *adjunctive* fashion, where clinicians also use other monitors, patient symptoms, and tests to guide decision-making.
- Not used for screening, nor does it provide diagnosis or determine patient treatment.

1.1 Features

Measurement Features

- SmO₂ and pHm measurements are automatically performed at the set measurement interval.
- Measurements require no individual patient learning or calibration
- SmO₂ and pHm measurements are absolute numbers representing the percentage of oxygen saturation of the muscle tissue and pH of the muscle tissue, respectively
- Sensor can accurately measure SmO₂ and pHm independent of skin pigmentation

Usability Features

- Operation is plug and play into the respective patient monitor or smart display device
- No configuration or calibration steps required
- Disposable Ray comes with cradle sensor check to perform a 1 minute integrity check on both ray and sensor
- Reusable sensor never touches the patient and can be easily cleaned
- Disposable Ray has simple, peel and stick operation to attach to the patient
- Disposable Ray is easily conformable to fit most size adult patients at six different body locations

1.2 Indications for Use

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy.

Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

1.3 Contraindications

The Multi-Parameter CareGuide™ 3100 should not be used for on patients with body temperatures below 34 degrees Celsius.

Do not place a Ray onto skin with nevi, bruises, burns, scars, tattoos, irregular freckling, discoloration, or large raised veins.

The Multi-Parameter CareGuide™ 3100 is not recommended for patients with a BMI <19 or >40.

1.4 Instructions Prior to Use

✱WARNING

Before using the Multi-Parameter Mobile CareGuide™ 3100 Oximeter, carefully read this entire manual. Users must fully understand and consistently follow all warnings, precautions, and instructions for safe and effective use of the system.

Failure to follow instructions for use may result in potentially serious outcomes for the patient or user (including adverse events, injury, or death), or may lead to system malfunction or failure.

For a full list of warnings and cautions when using this device, see Section 5.1 *Warnings and Cautions*.

1.5 Components

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter has three main components and a charger:

- 1 **Mobile CareGuide™ 2100 Ray** A single-use, latex-free disposable Ray (Figure 1 ❶) has a pocket to receive the Multi-Parameter CareGuide™ 3100 Sensor, providing a barrier between the reusable Sensor and the patient. The Ray is designed to adhere onto the skin of the patient's shoulder, thigh, or calf. A single Ray can remain in the same location for up to 72 hours. During this time, the inserted Sensor may be removed from the Ray (e.g., if the patient needs to be relocated for testing or procedures). Later, the Sensor can be re-inserted to resume monitoring (e.g., when the patient returns to his or her room).
- 2 **Multi-Parameter CareGuide™ 3100 Sensor** When inserted into a Ray placed on a patient and connected to the Display via the Sensor cable, the reusable Sensor (Figure 1 ❷) transmits pHm and SmO₂ measurements from the patient to the monitoring display.
- 3 **Display** Measurements from the Multi-Parameter CareGuide 3100 Sensor can be displayed as the Sensor communicates with an Android display containing CareGuide display software using a USB interface (Figure 1 ❸).
- 4 **Battery Charger** The Multi-Parameter CareGuide™ 3100 Sensor operates on enclosed rechargeable Lithium-polymer battery. The Sensor may be recharged (while in use or idle) using only the supplied Reflectance Medical medical-grade battery charger.



Figure 1. System Components

2 Patient Monitoring

2.1 Setup

Prior to use, ensure the Sensor and Display are charged (see 3.2 *Recharging the Sensor* & 3.3 *Recharging the Display*). Both components may be charged during monitoring, if needed.

- 1 Power on the Display by holding down the power button for ~6 seconds (Figure 2 ❶).
- 2 Connect the Sensor cable to the Display USB port (Figure 2 ❷) to ready the system for use (Figure 2 ❸).

Note: If using a Display with only a micro-USB port, plug the supplied micro-USB to Type A USB adapter cable into the Display first, then plug Sensor cable into the adapter cable.

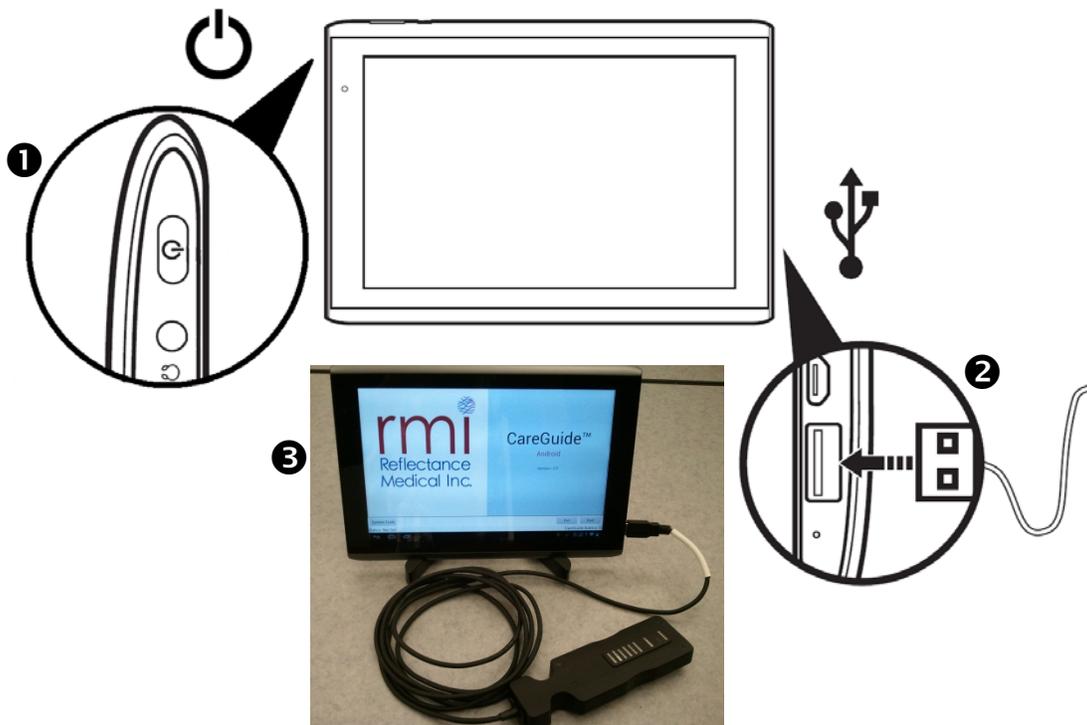


Figure 2. Display Power Button and USB port, Connected to Sensor for Use

- 3 If not already launched, click the CareGuide icon to launch the software.
- 4 Click 'OK' when prompted 'Allow the app CareGuide to access the USB device?' (Figure 3 ❹).

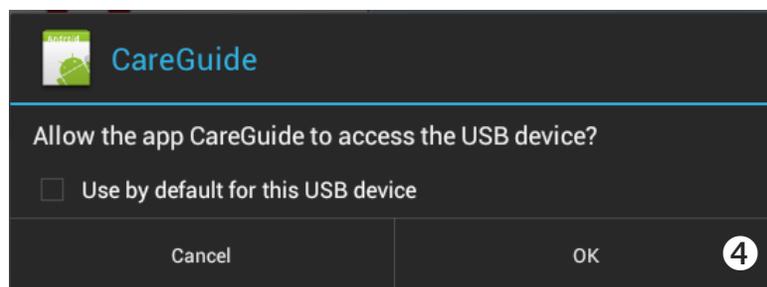


Figure 3. USB Access Prompt

2.2 Starting Use

- 1 Click 'Start' on the Main Screen to begin (Figure 4 ①).



Figure 4. Main Screen

- 2 If needed, click the Patient ID box to bring up the on-screen keyboard (Figure 5 ②).
- 3 Enter the patient ID (up to 50 characters), then hide the keyboard (Figure 5 ③).

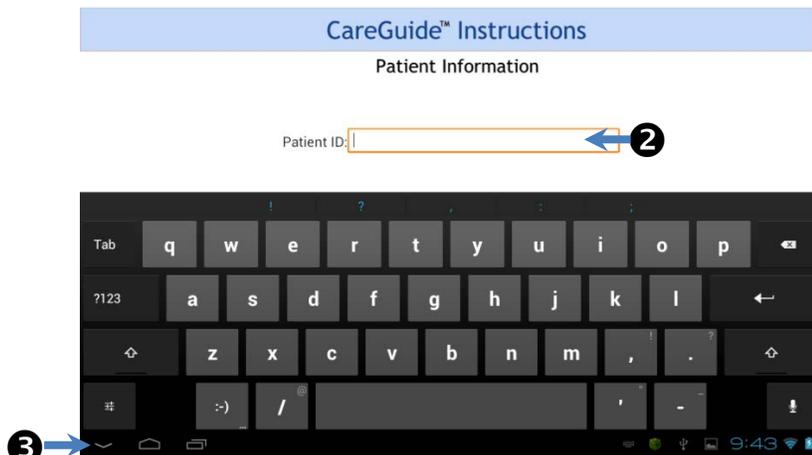


Figure 5. Patient ID Screen

- 4 Click 'Continue' (Figure 6 ④).

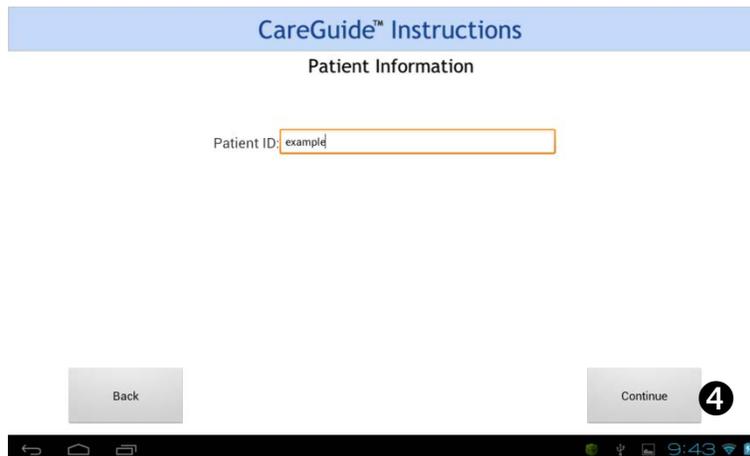


Figure 6. Patient ID Entered

2.3 Checking Sensors & Rays

If it has been 24 hours since the last Sensor Check, you will see the Sensor Check prompt (Figure 7). Otherwise, go straight to Sensor placement (see 2.4 *Placing Sensor & Ray on Patient*).

- 1 Remove the Ray from Cradle and insert Sensor fully (Figure 7 ❶).
- 2 Use the window of the Ray to check Sensor insertion (Figure 7 ❷).
- 3 Replace the Sensor in Ray onto the Cradle, ensuring a snug fit (Figure 7 ❸).
- 4 Verify the arrow on the Ray aligns with the arrow on the Cradle (Figure 7 ❹).
- 5 On the Display, click 'Begin Sensor Check' (Figure 7 ❺).

CareGuide™ Ray Instructions

❶ 1. Insert Sensor into Ray



❸ 2. Place Ray on Cradle

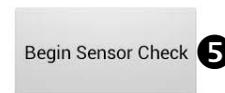
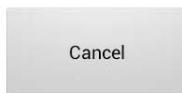


Figure 7. Sensor Check Screen

- 6 Checking takes about 45-50 seconds (Figure 8 ❻).

❻ CareGuide™ Sensor Check

Performing Sensor Check... Please stand by....



Figure 8. Sensor Check In Progress

- 7 If the Sensor Check passes, the Display will prompt you to place the Sensor & Ray on the patient (Figure 9 ⑦).

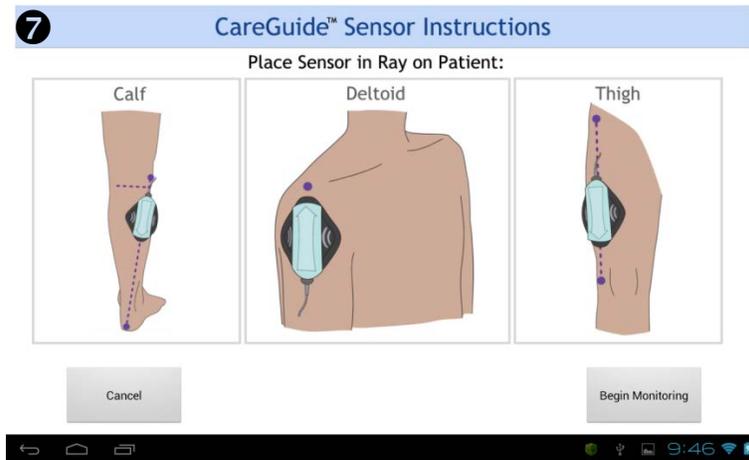


Figure 9. Placement Instructions Screen

- 8 If Sensor Check fails, see 4 *Troubleshooting*.

2.4 Placing Sensor & Ray on Patient

Recommended placement locations for the Ray are:

- Shoulder
- Thigh
- Calf

Preparing skin:

For the best results, skin at the Ray placement site should be clean and dry. If needed, use an alcohol prep pad to clean the skin. Do not place the Ray until skin has dried.

Note: For excessively hairy patients, consider shaving the placement location.

Preparing Ray:

- 1 Without withdrawing the Sensor from the Ray, remove the Ray from the Cradle.
- 2 Expose Ray adhesive by using the pull tab to peel off the clear liner (Figure 10).



Figure 10. Peeling Liner Off Ray

2.4.1 Shoulder Placement

Recommended for use when:

- Patient is supine or prone, if lying down
- No blood pressure cuff is present
- Shoulder is large enough so that the tips of the Ray do not go beyond half way around the circumference of the upper arm
- No large, raised veins are present
- No nevi, bruises, burns, scars, tattoos or uneven freckling are present

To place the Ray on the shoulder (deltoid):

- 1 Locate the deltoid as you would to for an IM injection (Figure 11 ❶).
- 2 Palpate the acromion process (Figure 11 ❷).
- 3 Align the Ray so the arrow is pointing towards the shoulder joint with the tip of the Ray one fingers' width inferior to the acromion process along the deltoid (Figure 12 ❸).
- 4 Ensure the Ray is centered dorsoventrally over the deltoid muscle before pressing it onto the patient's skin (Figure 12 ❹).

Note: To minimize gaps between the Ray and the patient, press the center (blue) section of the Ray onto the skin first, then smooth down the black foam onto the skin.

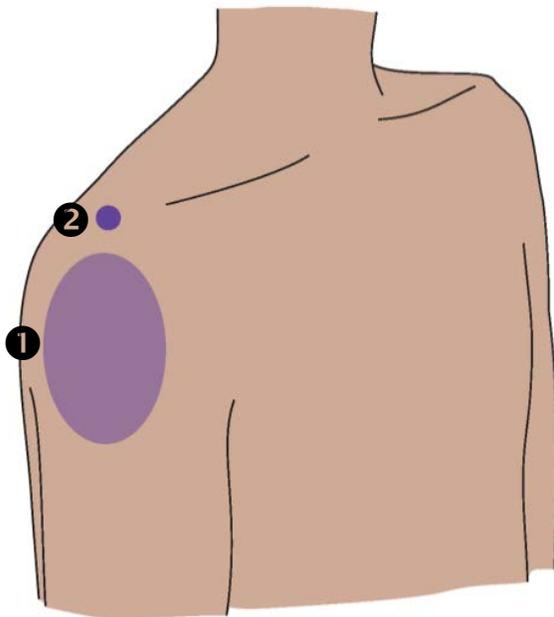


Figure 11. Optimal Shoulder Location

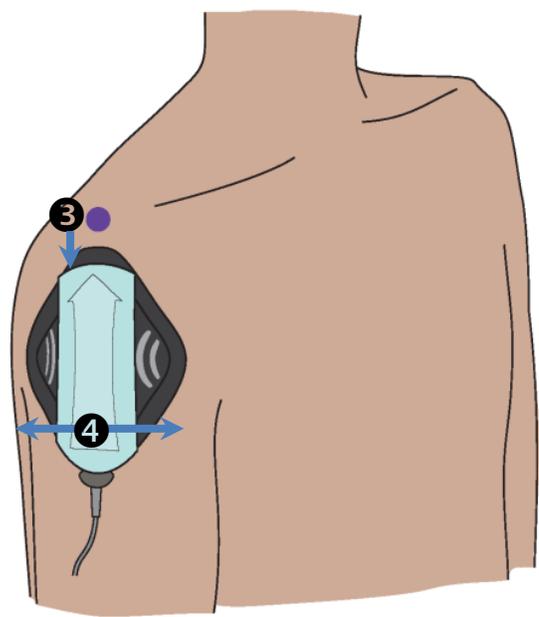


Figure 12. Ray Placed on Shoulder

2.4.2 Thigh Placement

Recommended for use when:

- Patient is supine, if lying down
- Blood pressure cuff or other instruments present on both shoulders
- Ray is too big for shoulder placement
- No large, raised veins are present
- No nevi, bruises, burns, scars, tattoos or uneven freckling are present

To place the Ray on the thigh (vastus lateralis):

- 1 Locate the vastus lateralis, as you would for an IM injection (Figure 13 ❶).
- 2 Use the lateral femoral condyle and point of hip as landmarks to draw an imaginary line along the thigh (Figure 13 ❷).
- 3 Align the Ray so the arrow is pointing towards the lateral femoral condyle, with the tip of the Ray a hand's breadth superior to the lateral femoral condyle (Figure 14 ❸).
- 4 Ensure the length of the blue part of the Ray aligns with the length of the imaginary line before pressing it onto the patient's skin (Figure 14 ❹).

Note: To minimize gaps between the Ray and the patient, press the center (blue) section of the Ray onto the skin first, then smooth down the black foam onto the skin.

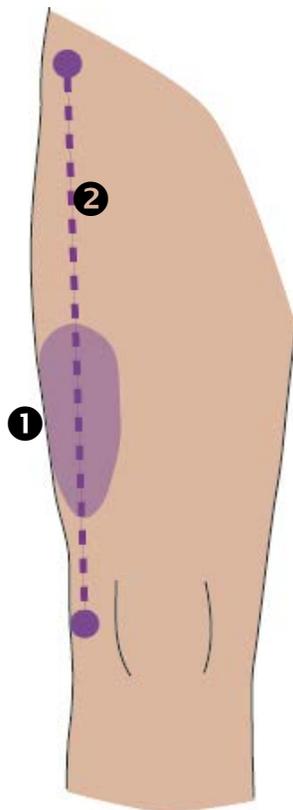


Figure 13. Optimal Thigh Location

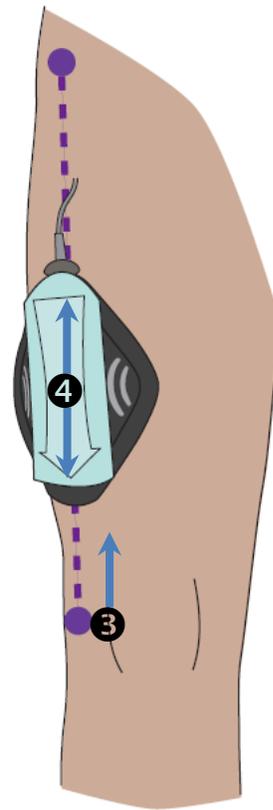


Figure 14. Ray Placed on Thigh

2.4.3 Calf Placement

Recommended for use when:

- Patient is prone, if lying down
- Blood pressure cuff or other instruments present on both shoulders
- Ray is too big for shoulder placement
- No large, raised veins are present
- No nevi, bruises, burns, scars, tattoos or uneven freckling are present

To place the Ray on the calf (lateral gastrocnemius):

- 1 The target muscle for calf placement is the lateral gastrocnemius (Figure 15 ❶).
- 2 Use the lateral femoral condyle and heel as landmarks to draw an imaginary line along the calf (Figure 15 ❷).
- 3 Align the Ray so the arrow is pointing towards the heel, with the cable end of the sensor two fingers' widths inferior to the line of the knee joint (Figure 16 ❸).
- 4 Ensure the length of the blue part of the Ray is aligned with the length of the imaginary line before pressing it onto the patient's skin (Figure 16 ❹).

Note: For ambulatory patients, consider angling the cable end of the sensor slightly toward the fibular head to allow for better range of motion.

Note: To minimize gaps between the Ray and the patient, press the center (blue) section of the Ray onto the skin first, then smooth down the black foam onto the skin.

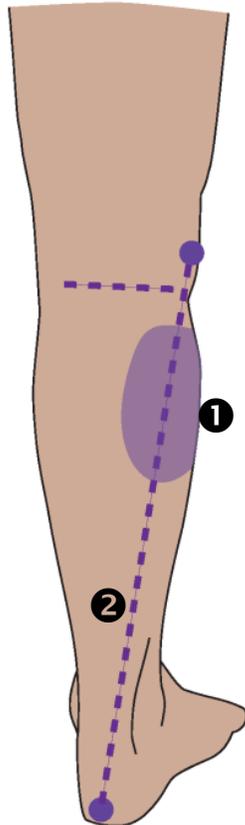


Figure 15. Optimal Calf Location

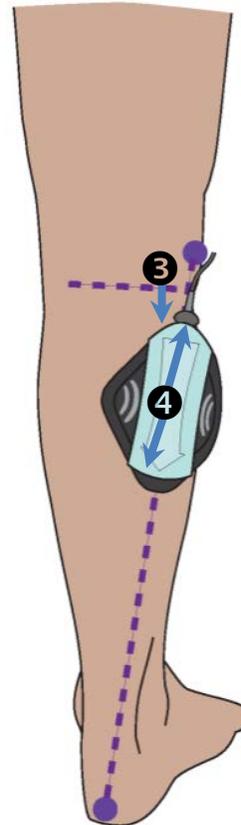


Figure 16. Ray Placed on Calf

2.5 Beginning Monitoring

- 1 Once the Ray is placed on the patient, click 'Begin Monitoring' (Figure 17 ①).

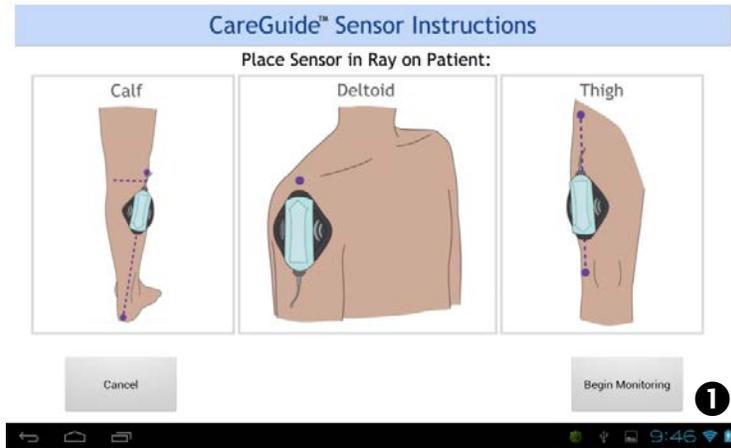


Figure 17. Placement Instructions Screen

- 2 The Sensor optimizes to the patient, which can take 60-90 seconds (Figure 18 ②).

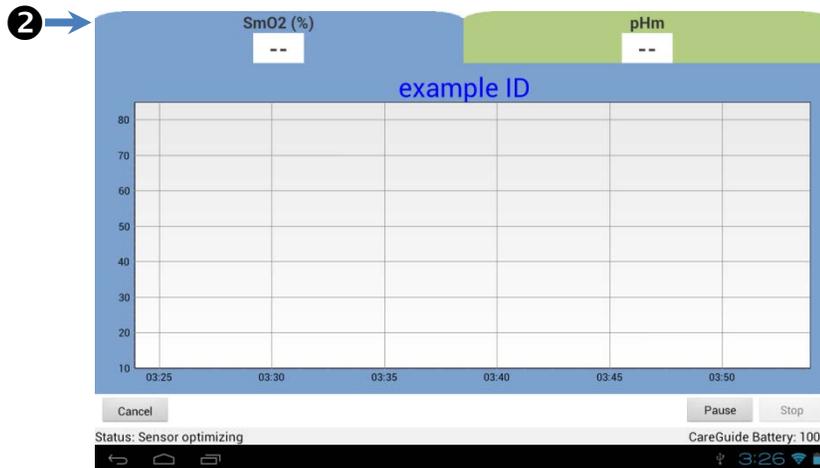


Figure 18. Sensor Optimizing

- 3 Monitoring begins, and SmO₂ and pHm data are displayed (Figure 19 ③).

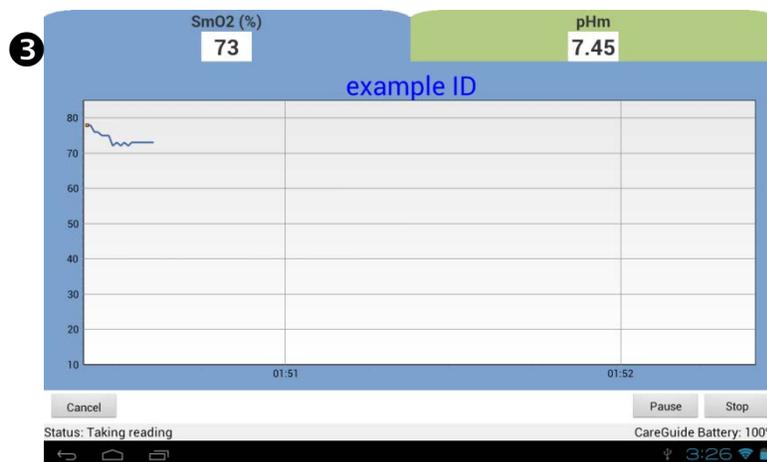


Figure 19. Monitoring Screen

2.6 Other Operations

2.6.1 Display Options

To select which parameter displays on the trend graph:

- 1 Click on the parameter button below the values for the desired trend. Example: to change from SmO₂ trend to pHm, click the green 'pHm' tab (Figure 20 ①).



Figure 20. Monitoring Screen- SmO₂ Trend

- 2 The color of the graph surround will match the parameter currently selected for trend display (Figure 21 ②).



Figure 21. Monitoring Screen- pHm Trend

To adjust the scale of the current parameter's trend graph:

- 1 Touch anywhere on the graph on the Monitoring Screen (Figure 22 ①).

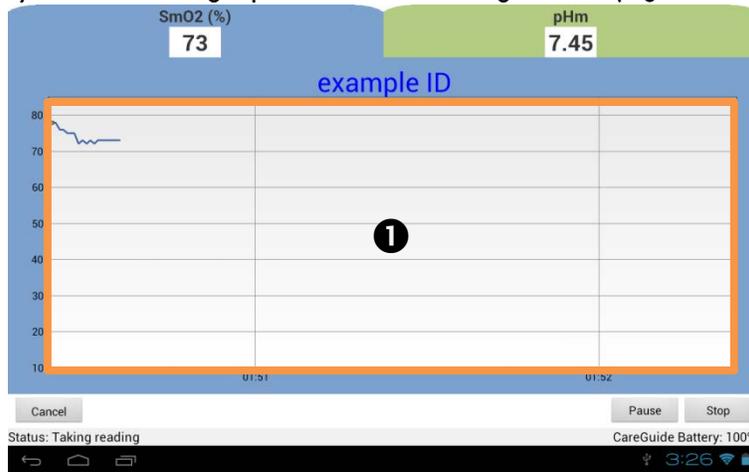


Figure 22. Monitoring Screen- Graph Area for Accessing Options

- 2 Adjust X and Y Axes values using + and – buttons (Figure 23 ②)
- 3 If desired, click the value box to bring up the on-screen keyboard for editing (Figure 23 ③) Hide the on-screen keyboard when adjustments are complete (Figure 23 ④).

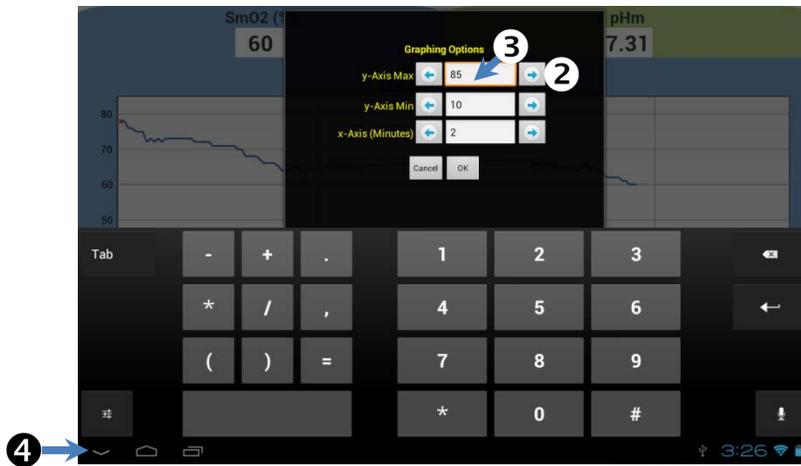


Figure 23. Graphing Options Screen- Using On-Screen Keyboard

- 4 Click 'OK' to save changes and return to Monitoring Screen (Figure 24 ⑤)

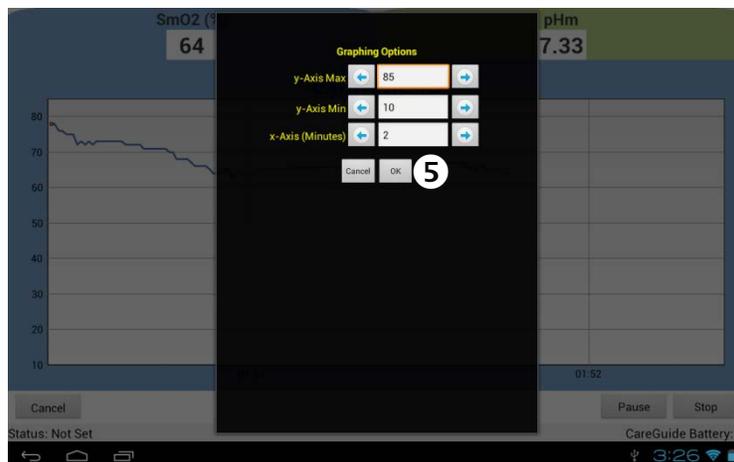


Figure 24. Graphing Options Screen

2.6.2 Pausing & Resuming for the Same Patient

To temporarily pause monitoring (e.g., for testing or procedures):

- 1 Click the 'Pause' button on the Monitoring screen (Figure 25 ❶).

Note: The Multi-Parameter CareGuide 3100 Sensor does contain metal and must be removed from the Ray prior to a patient entering the MRI or similar imaging environment. The Ray may remain attached to the patient during these procedures.

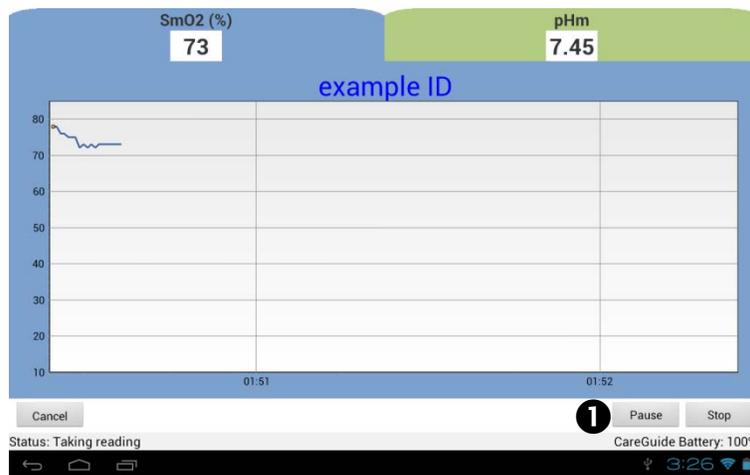


Figure 25. Example Monitoring Screen

- 2 If it had been removed, reinsert the Sensor into the Ray on the patient.
- 3 Click the 'Restart' button on the paused Monitoring screen (Figure 26 ❷) to resume monitoring for the current patient.

Note: If not resumed after 2 hrs of being paused, the system returns to the main screen.



Figure 26. Paused Monitoring Screen

2.6.3 Changing to a New Patient

To change from monitoring the current patient to monitoring a new patient:

- 1 Click the 'Stop' button on the Monitoring Screen (Figure 25) to end current monitoring.
- 2 Once at the Main Screen, see Sections 2.2 *Starting Use* through 2.5 *Beginning Monitoring*.

2.7 Ending Monitoring

- 1 To end monitoring for the current patient, click the 'Stop' button on the Monitoring Screen (Figure 27 ❶).

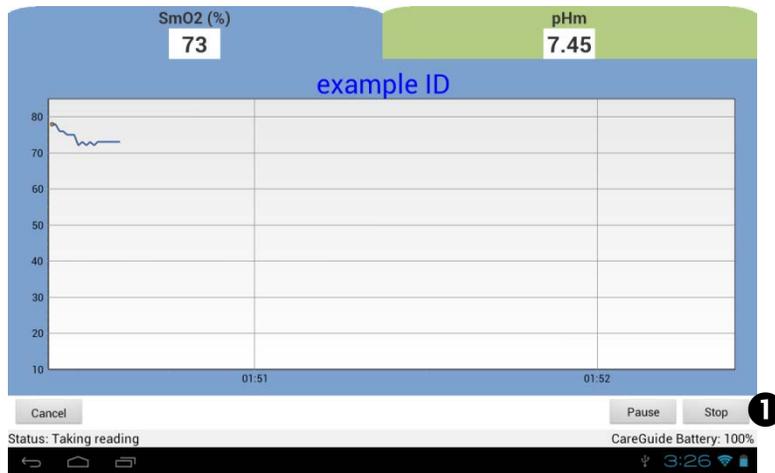


Figure 27. Example Monitoring Screen

- 2 The system returns to the Main screen.
Note: To start monitoring a new patient, see Sections 2.2 *Starting Use* through 2.5 *Beginning Monitoring*.
- 3 If finished monitoring, press and hold the power button on the Display (Figure 29 ❷).

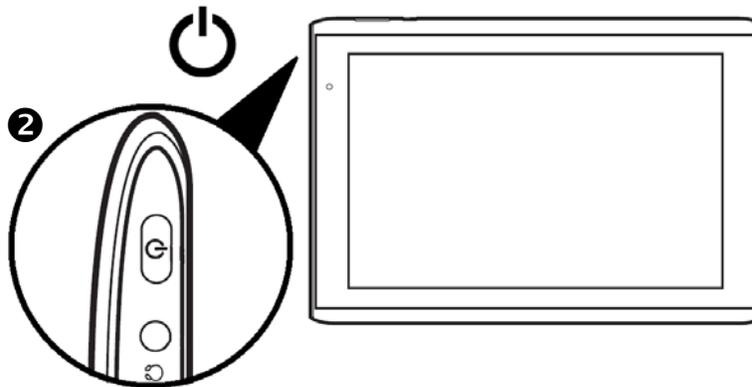


Figure 28. Display Power Button

- 4 Click 'OK' to confirm shut down (Figure 29 ❸).

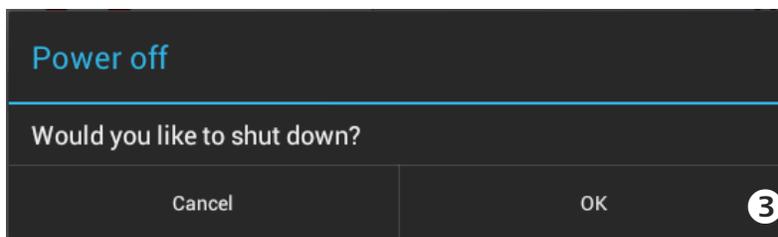


Figure 29. Power Off

3 Care & Maintenance

3.1 Cleaning the Sensor

After use, the Sensor shall be cleaned following the cleaning steps outlined below. Perform these steps immediately after sensor use regardless if there is visible soil or not. An overall figure (Figure 30) of the Multi-Parameter CareGuide 3100 parts to be cleaned for re-use is shown below:

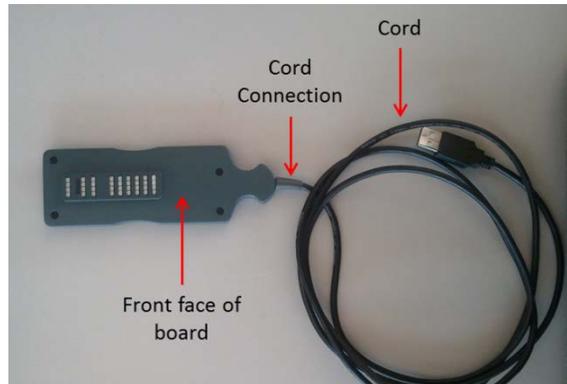


Figure 30. Overview photo including front face of Sensor and cord

Cleaning debris from sensor

Use a Sklar wipe to wipe all areas until all visible debris is removed. If the Sklar wipe becomes visibly dirty, discard and use a new Sklar wipe, until the wipe does not have any debris left on it. Follow the step-by-step directions indicated below:

- 1 Remove one Sklar wipe* from its container
- 2 Wipe the front, back, and sides of the Sensor, and the Sensor cord. Take special care to clean the cord connection.
- 3 Use another wipe to dislodge debris from screw heads on the front face of the Sensor if necessary (Figure 31).
- 4 Use a different wipe to wipe the area between the LED banks to remove debris (Figure 32)

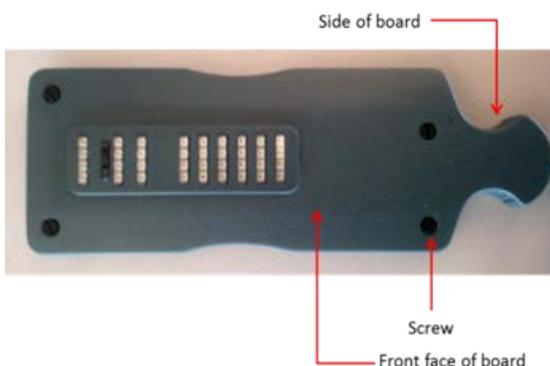


Figure 31. Front face of Sensor

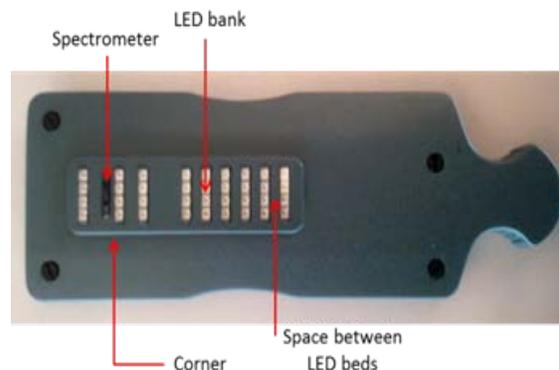


Figure 32. Layout of optical windows including LED banks and spectrometer

- 5 Wipe the spectrometer and surrounding areas
- 6 Wipe each LED from left to right using very light pressure to remove debris from glass
- 7 Once cleaned, allow Sensor to completely dry before moving on to the next step

Removing detergent residue from sensor

- 1 Remove a pre-saturated CleanTex wipe** from its product package.
- 2 Wipe the front, back and side of the Sensor.
- 3 Wipe area between LED banks to remove debris.
- 4 Wipe each LED bank from left to right using very light pressure to avoid streaking on glass casing.
- 5 If CleanTex wipe has noticeable debris on it, repeat the cleaning protocol from the beginning with a fresh Sklar wipe.
- 6 Allow the Sensor to completely air-dry prior to use.
- 7 Visually inspect device for residual soil and repeat this step, if necessary.
- 8 Once cleaned, re-use or store Sensor in original packaging or other clean environment
- 9 Before re-use, examine Sensor to ensure there is no dirt or debris.
- 10 If necessary, repeat the cleaning protocol prior to re-use.

Note: *The Sklar Disinfectant™ Surface Wipes (Sklar Instruments, Part Number 10-1616, EPA Reg# 70144-2-31118) is provided in the packaging, or can be purchased from Sklar Instruments or its distributors:

Sklar Instruments

889 S. Matlack Street
West Chester, PA 19382 U.S.A.
Phone: (800) 221-2166
Fax: (610) 696-9007
www.sklarcorp.com

**The CleanTex wipes (Advantus Corp., Part Number CT 806) is provided in the packaging, or can be purchased from Advantus Corporation distributors:

Specialty Optical Systems

10210 Forest Lane
Dallas, TX 75243
Phone: (800) 443-07101
Fax: (214) 340-5723
Email: Sales@SOSSupply.com
www.SOSSupply.com

3.2 Recharging the Sensor

The Multi-Parameter CareGuide™ 3100 Sensor may be recharged while in use or idle using only the supplied RMI medical-grade battery charger.

The Sensor has an LED (Figure 27 ❶) that indicates charge status by the state of the LED (Figure 28). You can also check the battery charge level using System Tools (see 4.2.3 Battery Charge Level).

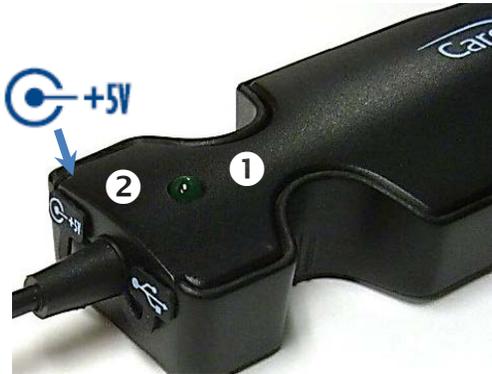


Figure 33. Sensor LED (❶) and Charger Connector (❷)

LED State	Description
LED off	Battery charge is $\leq 5\%$ (<45 minutes) -or- Charger is not plugged in
LED Blinking	Battery charge level is 0-89% and charger is attached and working
LED Solid	Battery charge level is $\geq 90\%$

Figure 34. Sensor Battery Status LED States

To charge the Sensor, connect the DC-in jack to the Sensor (Figure 27 ❷) and plug the Sensor charger (Figure 29 ❸) into any hospital-grade AC 110/220V outlet.



Figure 35. Sensor Charger Connected to Sensor

3.3 Recharging the Display

The Display has a battery charge status icon in the lower right corner of the screen (Figure 30).

To charge the Display, connect the DC-in jack to the Display (Figure 31 ①) and plug the AC adapter into any AC 110/220V outlet (Figure 31 ②).

Icon	Description
	Battery is very low
	Battery is low
	Battery is partially drained
	Battery is full
	Battery is charging

Figure 36. Display Battery Status Icon

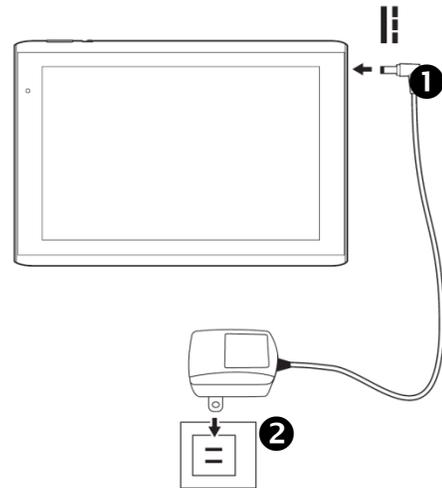


Figure 37. Charging the Display

3.4 Storing the System

- 1 If connected, unplug chargers from wall power and Sensor and Display.
- 2 Disconnect the Sensor from the Display.
- 3 If applicable, remove the Sensor from and discard the used Ray.
- 4 Clean the sensor as described in 3.3 *Cleaning the Sensor*. Place cleaned, dry sensor in storage container or an unused Ray.
- 5 Store display and sensor in a safe, clean location, away from direct sunlight and away from temperature extremes.

Sensor

- Do not exceed 30-90% atmospheric humidity.
- Do not go below 32°F (0°C).
- Do not exceed 104°F (40°C).

Disposable Ray

- Do not exceed 40-60% atmospheric humidity.
- Do not go below 50°F (10°C).
- Do not exceed 80°F (27°C).

Battery Charger

- Do not go below -40°F (-40°C).
- Do not exceed 185°F (85°C).

4 Troubleshooting

4.1 Handling Error Messages

Message	When it happens	Solution
Sensor nearing expiration	Initial setup	Order a replacement sensor soon. Sensor may be used normally for up to one month.
Sensor expired. Please replace.	Initial setup	Order a replacement sensor.
Sensor Check failed	Sensor Check	Check alignment of Ray in Cradle. Check sensor for dirt or soil and clean if necessary. Retry. If error persists, contact Tech Support.
SmO2 shows <10 or >85	During patient monitoring	SmO2 value is beyond the valid measurement range. Such values could be physiologically possible. Check placement on patient if desired.
pHm shows <6.9 or >7.5	During patient monitoring	pHm value is beyond the valid measurement range. Such values could be physiologically possible. Check placement on patient if desired.
Check Sensor. Reposition if needed.	During patient monitoring	Check alignment and adhesion of Ray on patient. If insufficient, use a new Ray and restart. If error persists, contact Tech Support.
Check sensor connection	During patient monitoring	Check sensor cable. Use 'Check Sensor Connection' and/or 'Reset Sensor' tools in System Tools menu. If using a micro-USB to Type A USB adapter cable, check adapter. Remove sensor from adapter; plug adapter cable in by itself; then plug sensor into adapter cable. If error persists, contact Tech Support.
Replace Ray on patient.	During patient monitoring	Ray use has exceeded 72hrs. Pause monitoring, replace Ray in new location on patient, then continue monitoring.
Sensor overheated. Please wait 1 hr.	During patient monitoring	Discontinue use of sensor for at least 1 hour before trying monitoring again. If error persists, contact Tech Support.
Sensor failed. Contact tech support.	Anytime	Contact Tech Support for a replacement sensor.
Battery is low. Please connect charger.	Anytime	Connect battery charger or discontinue use of sensor.

4.2 System Tools

The System Tools menu, accessible by clicking the 'System Tools' button on the Main Screen, has tools that may help in sensor troubleshooting.

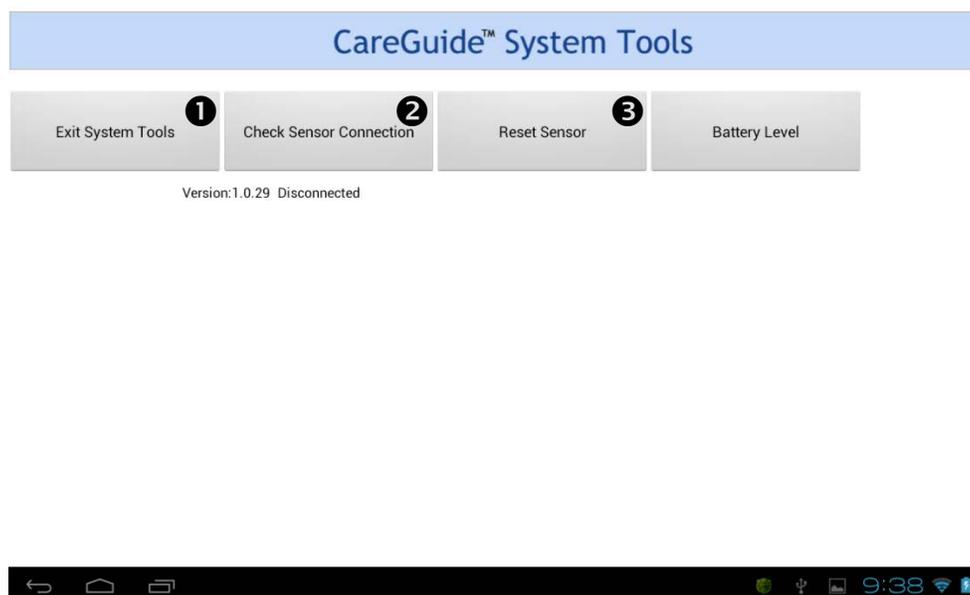


Figure 38. System Tools Screen

4.2.1 Testing the Sensor Connection

To test if the connected Sensor is communicating to the Display properly:

- 1 Click 'Check Sensor Connection' button on the System Tools page (Figure 32 ❶).
- 2 Properly communicating sensors will return the message 'Sensor connected'.
- 3 If you get error 'No sensors connected', check that the Sensor battery is charged. If using a micro-USB to Type A USB adapter cable, remove sensor from adapter; plug adapter cable in by itself; then plug sensor into adapter cable. If error persists, contact RMI Tech Support.

4.2.2 Resetting the Sensor

If errors persist with a communicating Sensor, you can try resetting the Sensor:

- 1 Click 'Reset Sensor' button on the System Tools page (Figure 32 ❷).
- 2 The Sensor should return the message 'Sensor reset successfully'.
- 3 If errors persist after resetting the sensor, contact RMI Tech Support.

4.2.3 Battery Charge Level

You can get a reading of the charge level of the Sensor battery by:

- 1 Click 'Battery Level' button on the System Tools page (Figure 32 ❸).
- 2 The Sensor returns a message 'Battery Level=#', where # is the percent charge.

5 Safety Precautions

5.1 Warnings and Cautions

Before using the Multi-Parameter Mobile CareGuide™ 3100 Oximeter, carefully read this entire manual. Users must fully understand and consistently follow all warnings, precautions, and instructions for safe and effective use of the system.

 **WARNINGS** Alert users about potential serious outcomes for the patient or user (including adverse events, injury, or death).

 **CAUTIONS** Alert users to conditions that may lead to system malfunction or failure.

General Use Warnings

 Use the Multi-Parameter CareGuide™ 3100 with care, as intended, and according to the instructions that shipped with the system. Failure to follow system warnings, precautions, and instructions may cause system malfunction or lead to patient and user injury or and death.

 Do not operate the system near flammable anesthetics. Operating the system near flammable anesthetics may present an explosion that could seriously injure or kill the patient or user.

Cleaning and Maintenance Warnings

 Do not clean the system when it is plugged in, turned on, or connected to a patient. Cleaning the system while it is in use and connected to AC mains power may cause an electrical shock that could seriously injure or kill the patient or user.

 Do not attempt to repair or service any part of the Multi-Parameter CareGuide™ 3100. Attempted repair by untrained, unauthorized individuals may result in serious injury or device malfunction. Contact RMI Technical Support for any repair or service.

CareGuide Sensor Cautions

 The Multi-Parameter CareGuide™ 3100 has a detachable Sensor for monitoring. Use care during operation to avoid soiling or damaging the delicate Sensor. Soiling or damaging the Sensor may cause inaccurate measurements or malfunctions.

 Do not use without first checking and optimizing the Sensor or Ray. Failure to check and optimize the Sensor or Ray may cause inaccurate measurements or malfunction.

 Do not connect any (USB or serial) extension cables to the Sensor cable. Attaching any extension cables will cause the Sensor to time out intermittently and cause malfunction.

 Use only functioning, properly tested, and grounded AC mains electrical outlets to recharge the Sensor. Using faulty, ungrounded outlets may cause failure or malfunction.

CareGuide Ray Cautions

 The Mobile CareGuide™ 2100/3100 Ray is a slight irritant to the skin.

-  Do not place a Sensor and Ray onto skin that is damaged or irritated. Applying Sensors/Rays to skin that is damaged or irritated may cause additional skin damage or irritation. Applying Rays over large, raised veins or onto tattooed, irregularly freckled or discolored skin may result in inaccurate measurements or malfunction.
-  Do not use the same Ray for more than 72 hours. Using a Ray for longer than 72 hours may cause irritation or tissue damage at the site. In addition, use over 72 hour may result in inaccurate measurements or malfunction. If the patient requires monitoring beyond 72 hours, remove the first Ray and attach a new one and place on a different location.
-  Do not apply a Ray to the same site more than three times in a 72-hour period. If additional placements are required, the sensor may be rotated to the contralateral site or used on alternative site (thigh versus deltoid, etc)
-  Do not re-use Rays. The disposable Ray is designed for single-patient, one-time use. Reuse will cause Oximeter malfunction. Dispose used Rays properly.
-  Do not immerse a Ray in water or liquid. Do not expose a Ray to water or moisture. Water, liquid, or moisture will damage the adhesive used to hold the Ray onto the skin. Damaged adhesive may cause gaps between the Ray and patient's skin, which may result in inaccurate measurements. If the Ray gets wet and water damages the adhesive, use a new Ray.

General Use Cautions

-  The Multi-Parameter CareGuide™ 3100 is not defibrillator-proof. It may remain attached to the patient during defibrillation; however readings may be inaccurate during the defibrillation and shortly thereafter. A sensor check should be performed, when convenient, following a defibrillation event.
-  Do not drop Multi-Parameter CareGuide™ 3100 components or subject them to extreme shock. Dropping components or forcefully hitting them against hard objects may damage components and cause Oximeter malfunction.
-  Do not use the Multi-Parameter CareGuide™ 3100 if any component, part, or accessory is damaged or worn. Using damaged or worn equipment may cause failure or malfunction. Contact RMI Technical Support for new equipment if needed.
-  Do not use extension cords or adapters for ungrounded electrical outlets. Using an adapter or extension cord may cause failure or malfunction.
-  Do not use an electrical outlet controlled by a wall switch, or the device may be turned off accidentally.
-  Use only RMI parts and accessories with the Multi-Parameter CareGuide™ 3100 Oximeter. Using non-RMI equipment may cause malfunction. Contact RMI Technical Support to order parts and accessories.
-  Do not use the Multi-Parameter CareGuide™ 3100 in environmental conditions that are:
 - Below 50°F (10°C).
 - Above 104°F (40°C).
 - Outside 30-75% atmospheric humidity.

- Outside 70.0-106.0 kPa atmospheric pressure.

✎ Avoid exposing Multi-Parameter CareGuide™ 3100 components, parts, and equipment to direct sunlight or excessive moisture, heat or cold.

✎ **Cleaning and Maintenance Cautions**

✎ Follow Multi-Parameter CareGuide™ 3100 instructions for cleaning external components (see *Cleaning*, Section 8.1). Never immerse components in water, cleaning solutions, or liquid. This will damage the components, cause malfunction, and void any warranties and service agreements.

✎ Do not use connector cables or other equipment soiled or contaminated with infectious, or potentially infectious, materials. Using soiled or contaminated items may result in a serious infection for the patient or contaminate other patients or users. Soiled or contaminated cables and equipment must be removed from use, and replaced or cleaned according to Multi-Parameter CareGuide™ 3100 instructions, prior to re-use (see *Cleaning*, Section 8.1).

✎ Always follow Multi-Parameter CareGuide™ 3100 instructions for storing and transporting system components and equipment (see *Storage/Transportation*, Section 8.2, for complete device-specific limitations and requirements).

✎ Never attempt to repair Multi-Parameter CareGuide™ 3100 equipment or components. Refer all maintenance and repair to RMI-authorized service technicians. Unauthorized repairs or maintenance may cause user harm or malfunction, and void all warranties and service agreements. Contact RMI Technical Support for details.

5.2 Disposal

Sensor & Display

✎ **WARNING** The Sensor and Display each contain a lithium polymer battery. Please follow local regulations on the disposal or recycling of lithium-containing electronics. Do not throw the Sensor or Display away in the trash.

Disposable Ray

Dispose of used Rays in accordance with local hospital regulations. Unused Rays may be disposed of in regular trash.

Disposable Cradle

The Cradle may be disposed of in regular trash.

Sensor & Display Chargers

Dispose of chargers in accordance with local regulations on electronic waste.

6 Warranty

Reflectance Medical warrants to the original purchaser that the Multi-parameter Mobile CareGuide™ 3100 Sensor (the “Device”) will be free from defects in material and workmanship for a period of one (1) year following delivery of the Device to the original purchaser (the “Warranty Period”). Reflectance Medical does not warrant that operation of the Device will be error-free or uninterrupted. Reflectance Medical shall repair or replace any part or parts of the Device that Reflectance Medical determines is defective within the Warranty Period. At Reflectance Medical’s discretion, it may elect to supply a similar, new or equivalent replacement, or refund the purchase price as of the date of sale of the Device. To qualify for such repair, replacement or refund, the defective Device must a) be returned within thirty (30) days of discovery of the defect by the purchaser and accompanied by proof of date of purchase; b) not have been repaired or altered by any party other than Reflectance Medical or its authorized agents; c) not have been subjected to misuse per the Device Instructions for Use, negligence or accident in Reflectance Medical’s judgment. Purchaser shall be solely responsible for all return freight charges. This warranty does not include Reflectance Medical’s disposable products or non-Reflectance Medical complementary products. Reflectance Medical makes no additional warranty claims for the non-Reflectance Medical Android tablet beyond those provided by the original manufacturer. In no event shall Reflectance Medical be liable for any damages (including, without limitation, lost profits, business interruption, or lost information) arising out of your use of or inability to use the Device, even if Reflectance Medical has been advised of the possibility of such damages.

THIS WARRANTY IS GIVEN IN LIEU OF ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

7 Technical Specifications

Multi-Parameter Mobile CareGuide™ Oximeter 3100		
SmO₂	Range	10% - 85%
	Resolution	1%
	Measurement Rate	30 seconds
	Accuracy	3.8 SmO ₂ units (%)
	Drift	None
pHm	Range	6.90 – 7.50
	Resolution	0.01 pHm units
	Measurement Rate	30 seconds
	Accuracy	0.05 pHm units
	Drift	None
Packaging	System Packaging	<ul style="list-style-type: none"> 1 Multi-Parameter Mobile CareGuide 3100 Sensor 1 sensor battery charger 1 Android display with CareGuide software 1 display charger 1 Micro-USB to Type A adapter (if required) 1 tub of 100 Sklar™ wipes 1 box of 80 CleanTex™ wipes 1 case of 8 Mobile CareGuide™ Ray & cradle sets (boxed individually)
	Packaging for Reorders	<ul style="list-style-type: none"> 1 Multi-Parameter Mobile CareGuide™ 3100 Sensor and 1 battery charger 1 case of 8 Mobile CareGuide™ Ray & cradle sets (boxed individually)
Mobile CareGuide Ray	Size	<ul style="list-style-type: none"> • 155 x 146 x 27 mm (5.9 x 5.4 x 1.06 in) • One size fits shoulder, calf, or thigh.
	Weight	560.3g (2.13oz)
	Material	<ul style="list-style-type: none"> • Latex free • Biocompatible adhesive
	Attachment to patient	<ul style="list-style-type: none"> • Adhesive placement on shoulder, calf or thigh • Intact skin only • Single Use per patient
	Shelf Life	18 months post manufacturing date
	Use Life	72 hours (single use patient)
Multi-Parameter CareGuide Sensor	Size	• 139 x 47 x 23 mm (5.5 x 1.9 x 0.90 inches)
	Weight	177.2g (6.25 oz)
	Sensor Cable Length	• 2.74 m (9 ft)
	Auxiliary USB Cable	• mini-USB to USB
	Connectors	<ul style="list-style-type: none"> • Battery charger • Auxiliary USB

Multi-Parameter Mobile CareGuide™ Oximeter 3100

	Battery	Rechargeable, Lithium-polymer, sealed, not replaceable
	Typical Battery Life	12 hours (60 sec sample rate) 9 hours (30 sec sample rate)
	Battery Charge Time	5 hours to charge from <5% to 100%
	Attachment to Patient	<ul style="list-style-type: none"> • Insert into Mobile CareGuide™ Ray • Clean with CleanTex™ and Sklar™ wipes between patients
	Shelf Life	2 years post manufacturing date
	Use Life	1 year post first use
Battery charger	Voltage required	• Input: 100-240V 0.3A Max 50/60 Hz
	Cable	• Cable length: 2.74 m (9 feet)
Alarms	Audiovisual	Via CareGuide display
	Audible Alarm	Via sensor
	Error Conditions	See Troubleshooting above.
Product Classification	Medical Device	US: Class II Type BF device per section 870.2700 of 21 CFR and IEC 60601-1 3 rd Edition v2005
Standards	Electrical and Constructional Safety	IEC 60601-1-1:2005 (includes former PEMS IEC 60601-1-4)
	Electromagnetic Compatibility	IEC 60601-1-2: 2001/2006 (Class A emissions)
	Laser Safety	Class 1 laser device per IEC 60825-1: Edition 2.0 (2007)
	Enclosure	PC/UABS HT Cycloy C2950; Impact, rough handling, mold stress relief per IEC 60601-1 3 rd edition
	Shipping and Packaging	ISTA 1A
	Risk Analysis/Risk Management	ISO 14971
	Usability	IEC 60601-1-6
	Battery	IEC 62133; UN T1-T8; ED 93/86/EEC; ED 2006/66/EC
	Biocompatibility	Cytotoxicity: ISO 10993-5: v2009 Irritation and Sensitization: ISO 10993-10 v2010
	Cleaning	AAMI TIR 12:2010; AAMI TIR 30:2003
Electromagnetic Emissions and Immunity	This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1 3 rd Edition v2005. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not	

Multi-Parameter Mobile CareGuide™ Oximeter 3100

	<p>occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:</p> <ul style="list-style-type: none"> • Reorient or relocate the devices. • Increase the separation between the devices. • Connect the equipment to an outlet on a different circuit. • Contact the Service Center. 	
<p>Operating Conditions</p>	<p>Temperature</p>	<p>10°C – 40°C (50°F-104°F)</p>
	<p>Humidity</p>	<p>30-75% ATM non-condensing</p>
	<p>Pressure</p>	<p>70-106 kPa</p>

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Multi-Parameter Mobile 3100 OXIMETER

USER MANUAL

Instructions for Using the Multi-Parameter Mobile CareGuide™ 3100 Oximeter

CAUTION: Investigational device.
Limited by Federal law to investigational use



R_x Only

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IFU-0005/Rev. A

Multi-Parameter Mobile CareGuide™

Model Number: 3100

Serial Number: _____
(user records)

License Number: _____
(user records)

Manufactured by:



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IFU-0005/Rev. A

Multi-Parameter Mobile CareGuide™ 3100 Oximeter

IFU-0005/Rev. A Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (301)-796-8118 Page 97 of 361

Table of Contents

1	Introduction.....	4
1.1	Features	4
1.2	Indications for Use	5
1.3	Contraindications.....	5
1.4	Instructions Prior to Use	5
1.5	Components.....	6
2	Patient Monitoring.....	7
2.1	Setup	7
2.2	Starting Use.....	8
2.3	Checking Sensors & Rays.....	9
2.4	Placing Sensor & Ray on Patient.....	10
2.4.1	Shoulder Placement.....	11
2.4.2	Thigh Placement.....	12
2.4.3	Calf Placement.....	13
2.5	Beginning Monitoring.....	14
2.6	Other Operations	15
2.6.1	Display Options	15
2.6.2	Pausing & Resuming for the Same Patient.....	17
2.6.3	Changing to a New Patient.....	17
2.7	Ending Monitoring	18
3	Care & Maintenance	19
3.1	Cleaning the Sensor.....	19
3.2	Recharging the Sensor	21
3.3	Recharging the Display.....	22
3.4	Storing the System	22
4	Troubleshooting	23
4.1	Handling Error Messages	23
4.2	System Tools.....	24
4.2.1	Testing the Sensor Connection.....	24
4.2.2	Resetting the Sensor.....	24
4.2.3	Battery Charge Level	24
5	Safety Precautions	25
5.1	Warnings and Cautions	25
5.2	Disposal.....	27
6	Warranty.....	28
7	Technical Specifications.....	29

Table of Figures

Figure 1. System Components.....	6
Figure 2. Display Power Button and USB port, Connected to Sensor for Use	7
Figure 3. USB Access Prompt.....	7
Figure 4. Main Screen	8
Figure 5. Patient ID Screen.....	8
Figure 6. Patient ID Entered	8
Figure 7. Sensor Check Screen.....	9
Figure 8. Sensor Check In Progress.....	9
Figure 9. Placement Instructions Screen.....	10
Figure 10. Peeling Liner Off Ray	10
Figure 11. Optimal Shoulder Location	11
Figure 12. Ray Placed on Shoulder	11
Figure 13. Optimal Thigh Location.....	12
Figure 14. Ray Placed on Thigh	12
Figure 15. Optimal Calf Location	13
Figure 16. Ray Placed on Calf	13
Figure 17. Placement Instructions Screen	14
Figure 18. Sensor Optimizing	14
Figure 19. Monitoring Screen.....	14
Figure 20. Monitoring Screen- SmO ₂ Trend.....	15
Figure 21. Monitoring Screen- pHm Trend.....	15
Figure 22. Monitoring Screen- Graph Area for Accessing Options	16
Figure 23. Graphing Options Screen- Using On-Screen Keyboard.....	16
Figure 24. Graphing Options Screen	16
Figure 25. Example Monitoring Screen.....	17
Figure 26. Paused Monitoring Screen	17
Figure 27. Example Monitoring Screen.....	18
Figure 28. Display Power Button.....	18
Figure 29. Power Off	18
Figure 30. Overview photo including front face of Sensor and cord	19
Figure 31. Front face of Sensor	19
Figure 32. Layout of optical windows including LED banks and spectrometer.....	19
Figure 33. Sensor LED and Charger Connector	21
Figure 34. Sensor Battery Status LED States.....	21
Figure 35. Sensor Charger Connected to Sensor	21
Figure 36. Display Battery Status Icon.....	22
Figure 37. Charging the Display	22
Figure 38. System Tools Screen	24

1 Introduction

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter provides non-invasive assessment of hemoglobin-oxygen saturation (SmO₂) and pH (pHm) of microvascular blood in a region of skeletal muscle tissues beneath the oximeter sensor. It displays the most recent value of SmO₂ and pHm, as well as a graphical trend of previous measurements.

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is:

- Non-invasive, for acute use, and poses no significant safety questions.
- Uses infrared energy in a way that does not introduce excessive heat (i.e., no safety issue).
- Used in the clinical environment, in an *adjunctive* fashion, where clinicians also use other monitors, patient symptoms, and tests to guide decision-making.
- Not used for screening, nor does it provide diagnosis or determine patient treatment.

1.1 Features

Measurement Features

- SmO₂ and pHm measurements are automatically performed at the set measurement interval.
- Measurements require no individual patient learning or calibration
- SmO₂ and pHm measurements are absolute numbers representing the percentage of oxygen saturation of the muscle tissue and pH of the muscle tissue, respectively
- Sensor can accurately measure SmO₂ and pHm independent of skin pigmentation

Usability Features

- Operation is plug and play into the respective patient monitor or smart display device
- No configuration or calibration steps required
- Disposable Ray comes with cradle sensor check to perform a 1 minute integrity check on both ray and sensor
- Reusable sensor never touches the patient and can be easily cleaned
- Disposable Ray has simple, peel and stick operation to attach to the patient
- Disposable Ray is easily conformable to fit most size adult patients at six different body locations

1.2 Indications for Use

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy.

Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

1.3 Contraindications

The Multi-Parameter CareGuide™ 3100 should not be used for on patients with body temperatures below 34 degrees Celsius.

Do not place a Ray onto skin with nevi, bruises, burns, scars, tattoos, irregular freckling, discoloration, or large raised veins.

The Multi-Parameter CareGuide™ 3100 is not recommended for patients with a BMI <19 or >40.

1.4 Instructions Prior to Use

✱WARNING

Before using the Multi-Parameter Mobile CareGuide™ 3100 Oximeter, carefully read this entire manual. Users must fully understand and consistently follow all warnings, precautions, and instructions for safe and effective use of the system.

Failure to follow instructions for use may result in potentially serious outcomes for the patient or user (including adverse events, injury, or death), or may lead to system malfunction or failure.

For a full list of warnings and cautions when using this device, see Section 5.1 *Warnings and Cautions*.

1.5 Components

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter has three main components and a charger:

- 1 **Mobile CareGuide™ 2100 Ray** A single-use, latex-free disposable Ray (Figure 1 ❶) has a pocket to receive the Multi-Parameter CareGuide™ 3100 Sensor, providing a barrier between the reusable Sensor and the patient. The Ray is designed to adhere onto the skin of the patient's shoulder, thigh, or calf. A single Ray can remain in the same location for up to 72 hours. During this time, the inserted Sensor may be removed from the Ray (e.g., if the patient needs to be relocated for testing or procedures). Later, the Sensor can be re-inserted to resume monitoring (e.g., when the patient returns to his or her room).
- 2 **Multi-Parameter CareGuide™ 3100 Sensor** When inserted into a Ray placed on a patient and connected to the Display via the Sensor cable, the reusable Sensor (Figure 1 ❷) transmits pHm and SmO₂ measurements from the patient to the monitoring display.
- 3 **Display** Measurements from the Multi-Parameter CareGuide 3100 Sensor can be displayed as the Sensor communicates with an Android display containing CareGuide display software using a USB interface (Figure 1 ❸).
- 4 **Battery Charger** The Multi-Parameter CareGuide™ 3100 Sensor operates on enclosed rechargeable Lithium-polymer battery. The Sensor may be recharged (while in use or idle) using only the supplied Reflectance Medical medical-grade battery charger.



Figure 1. System Components

2 Patient Monitoring

2.1 Setup

Prior to use, ensure the Sensor and Display are charged (see 3.2 *Recharging the Sensor* & 3.3 *Recharging the Display*). Both components may be charged during monitoring, if needed.

- 1 Power on the Display by holding down the power button for ~6 seconds (Figure 2 ❶).
- 2 Connect the Sensor cable to the Display USB port (Figure 2 ❷) to ready the system for use (Figure 2 ❸).

Note: If using a Display with only a micro-USB port, plug the supplied micro-USB to Type A USB adapter cable into the Display first, then plug Sensor cable into the adapter cable.

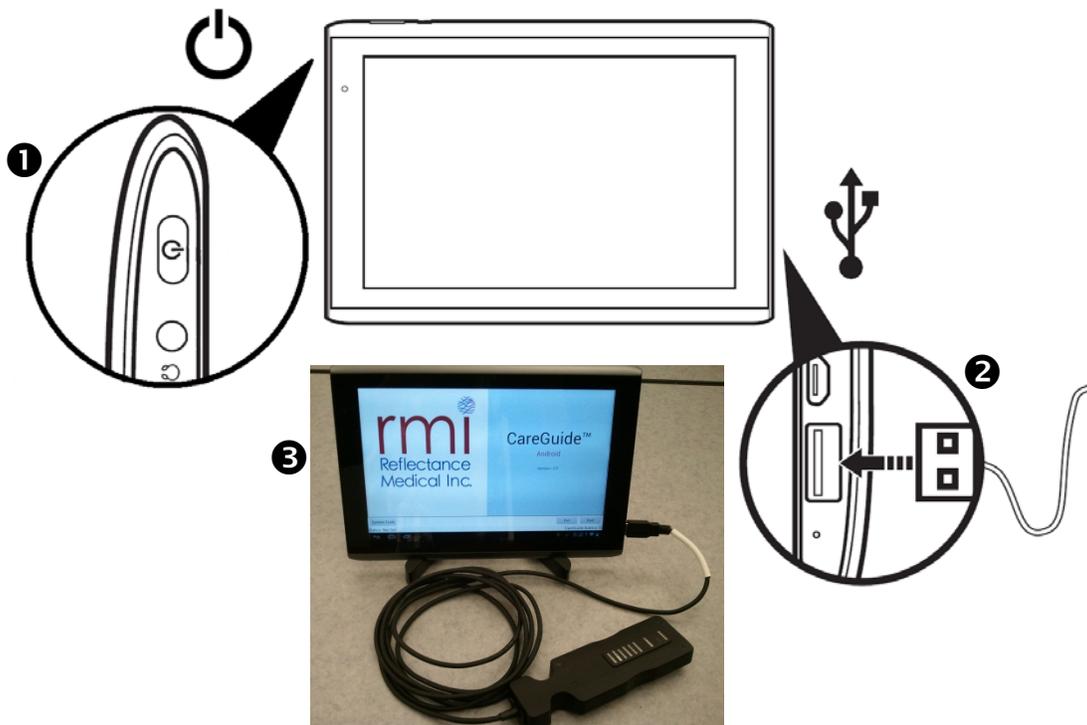


Figure 2. Display Power Button and USB port, Connected to Sensor for Use

- 3 If not already launched, click the CareGuide icon to launch the software.
- 4 Click 'OK' when prompted 'Allow the app CareGuide to access the USB device?' (Figure 3 ❹).

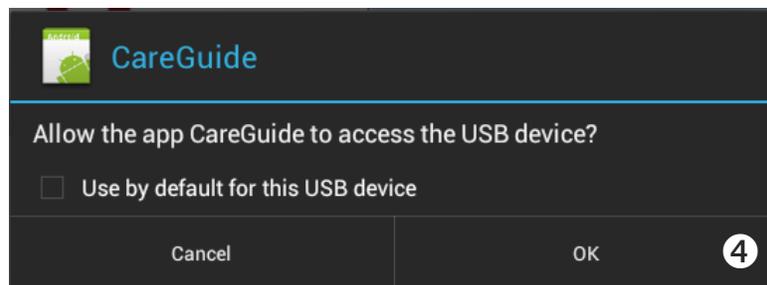


Figure 3. USB Access Prompt

2.2 Starting Use

- 1 Click 'Start' on the Main Screen to begin (Figure 4 ❶).



Figure 4. Main Screen

- 2 If needed, click the Patient ID box to bring up the on-screen keyboard (Figure 5 ❷).
- 3 Enter the patient ID (up to 50 characters), then hide the keyboard (Figure 5 ❸).

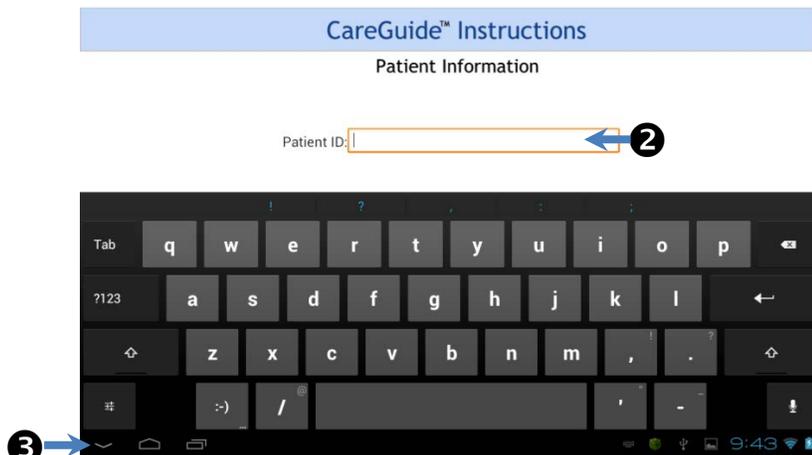


Figure 5. Patient ID Screen

- 4 Click 'Continue' (Figure 6 ❹).

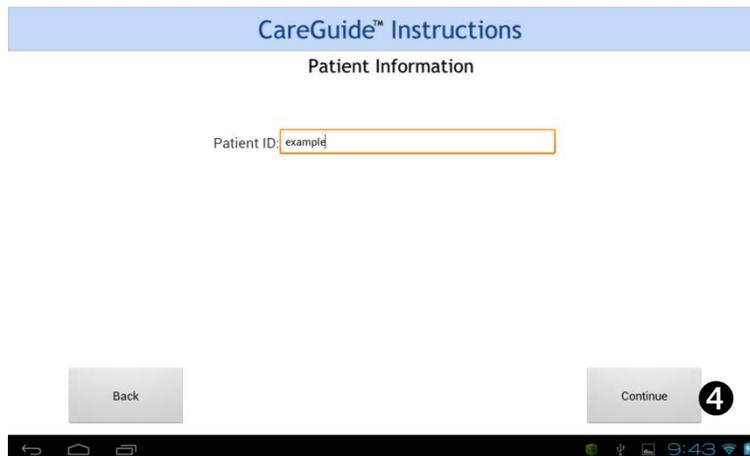


Figure 6. Patient ID Entered

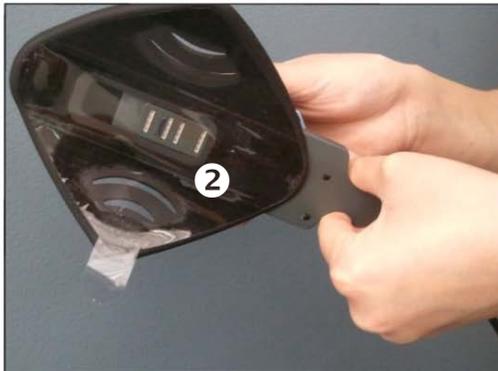
2.3 Checking Sensors & Rays

If it has been 24 hours since the last Sensor Check, you will see the Sensor Check prompt (Figure 7). Otherwise, go straight to Sensor placement (see 2.4 *Placing Sensor & Ray on Patient*).

- 1 Remove the Ray from Cradle and insert Sensor fully (Figure 7 ❶).
- 2 Use the window of the Ray to check Sensor insertion (Figure 7 ❷).
- 3 Replace the Sensor in Ray onto the Cradle, ensuring a snug fit (Figure 7 ❸).
- 4 Verify the arrow on the Ray aligns with the arrow on the Cradle (Figure 7 ❹).
- 5 On the Display, click 'Begin Sensor Check' (Figure 7 ❺).

CareGuide™ Ray Instructions

❶ 1. Insert Sensor into Ray



❸ 2. Place Ray on Cradle

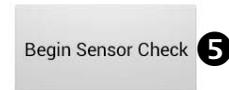
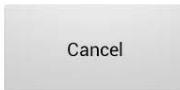


Figure 7. Sensor Check Screen

- 6 Checking takes about 45-50 seconds (Figure 8 ❻).

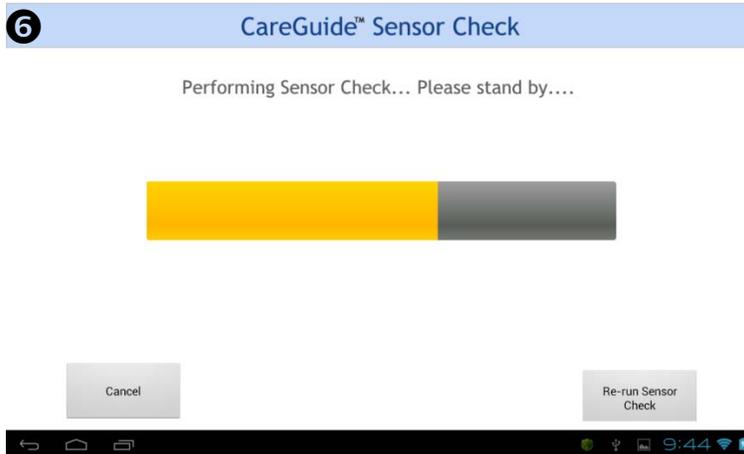


Figure 8. Sensor Check In Progress

- 7 If the Sensor Check passes, the Display will prompt you to place the Sensor & Ray on the patient (Figure 9 ⑦).

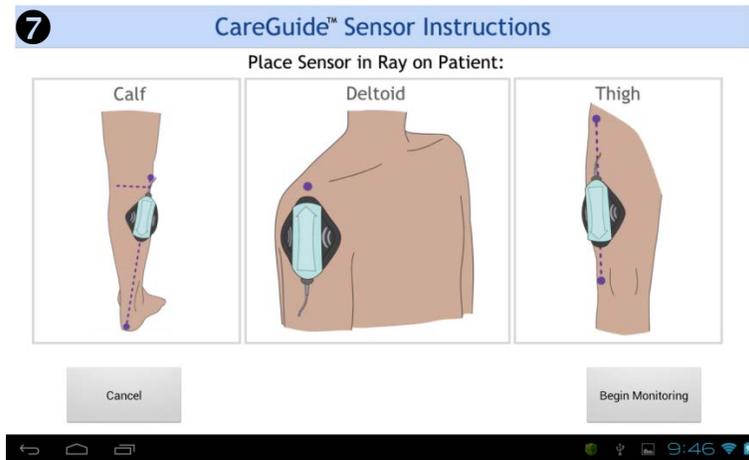


Figure 9. Placement Instructions Screen

- 8 If Sensor Check fails, see 4 Troubleshooting.

2.4 Placing Sensor & Ray on Patient

Recommended placement locations for the Ray are:

- Shoulder
- Thigh
- Calf

Preparing skin:

For the best results, skin at the Ray placement site should be clean and dry. If needed, use an alcohol prep pad to clean the skin. Do not place the Ray until skin has dried.

Note: For excessively hairy patients, consider shaving the placement location.

Preparing Ray:

- 1 Without withdrawing the Sensor from the Ray, remove the Ray from the Cradle.
- 2 Expose Ray adhesive by using the pull tab to peel off the clear liner (Figure 10).



Figure 10. Peeling Liner Off Ray

2.4.1 Shoulder Placement

Recommended for use when:

- Patient is supine or prone, if lying down
- No blood pressure cuff is present
- Shoulder is large enough so that the tips of the Ray do not go beyond half way around the circumference of the upper arm
- No large, raised veins are present
- No nevi, bruises, burns, scars, tattoos or uneven freckling are present

To place the Ray on the shoulder (deltoid):

- 1 Locate the deltoid as you would to for an IM injection (Figure 11 ❶).
- 2 Palpate the acromion process (Figure 11 ❷).
- 3 Align the Ray so the arrow is pointing towards the shoulder joint with the tip of the Ray one fingers' width inferior to the acromion process along the deltoid (Figure 12 ❸).
- 4 Ensure the Ray is centered dorsoventrally over the deltoid muscle before pressing it onto the patient's skin (Figure 12 ❹).

Note: To minimize gaps between the Ray and the patient, press the center (blue) section of the Ray onto the skin first, then smooth down the black foam onto the skin.

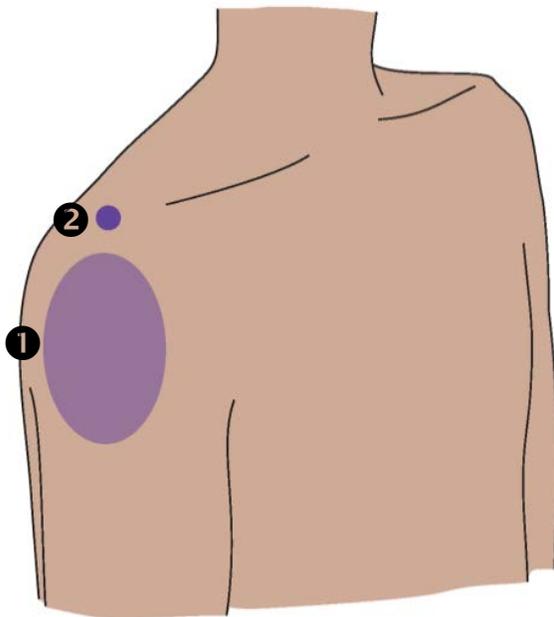


Figure 11. Optimal Shoulder Location

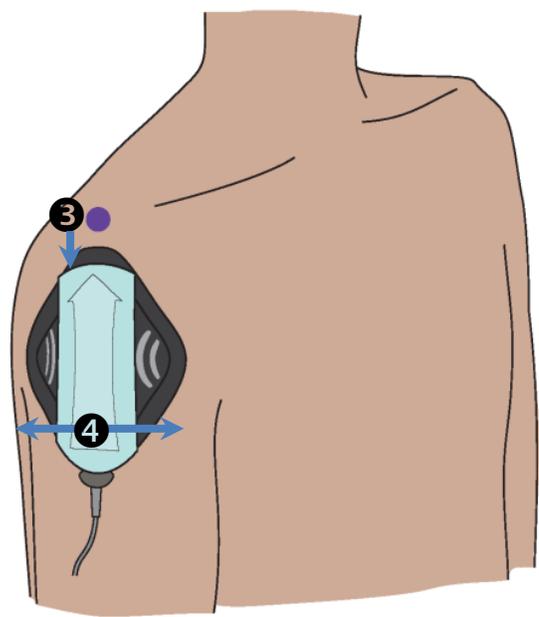


Figure 12. Ray Placed on Shoulder

2.4.2 Thigh Placement

Recommended for use when:

- Patient is supine, if lying down
- Blood pressure cuff or other instruments present on both shoulders
- Ray is too big for shoulder placement
- No large, raised veins are present
- No nevi, bruises, burns, scars, tattoos or uneven freckling are present

To place the Ray on the thigh (vastus lateralis):

- 1 Locate the vastus lateralis, as you would for an IM injection (Figure 13 ❶).
- 2 Use the lateral femoral condyle and point of hip as landmarks to draw an imaginary line along the thigh (Figure 13 ❷).
- 3 Align the Ray so the arrow is pointing towards the lateral femoral condyle, with the tip of the Ray a hand's breadth superior to the lateral femoral condyle (Figure 14 ❸).
- 4 Ensure the length of the blue part of the Ray aligns with the length of the imaginary line before pressing it onto the patient's skin (Figure 14 ❹).

Note: To minimize gaps between the Ray and the patient, press the center (blue) section of the Ray onto the skin first, then smooth down the black foam onto the skin.

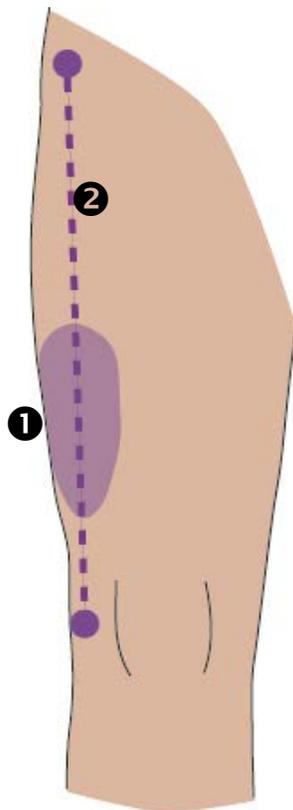


Figure 13. Optimal Thigh Location

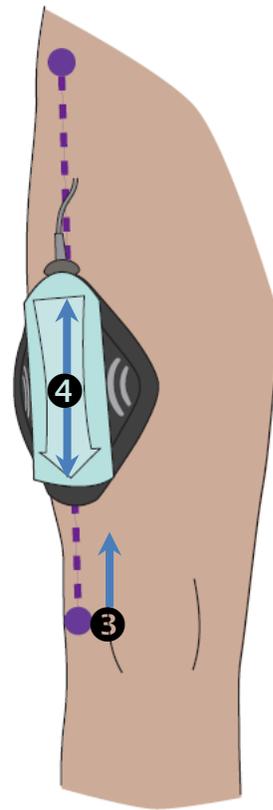


Figure 14. Ray Placed on Thigh

2.4.3 Calf Placement

Recommended for use when:

- Patient is prone, if lying down
- Blood pressure cuff or other instruments present on both shoulders
- Ray is too big for shoulder placement
- No large, raised veins are present
- No nevi, bruises, burns, scars, tattoos or uneven freckling are present

To place the Ray on the calf (lateral gastrocnemius):

- 1 The target muscle for calf placement is the lateral gastrocnemius (Figure 15 ❶).
- 2 Use the lateral femoral condyle and heel as landmarks to draw an imaginary line along the calf (Figure 15 ❷).
- 3 Align the Ray so the arrow is pointing towards the heel, with the cable end of the sensor two fingers' widths inferior to the line of the knee joint (Figure 16 ❸).
- 4 Ensure the length of the blue part of the Ray is aligned with the length of the imaginary line before pressing it onto the patient's skin (Figure 16 ❹).

Note: For ambulatory patients, consider angling the cable end of the sensor slightly toward the fibular head to allow for better range of motion.

Note: To minimize gaps between the Ray and the patient, press the center (blue) section of the Ray onto the skin first, then smooth down the black foam onto the skin.

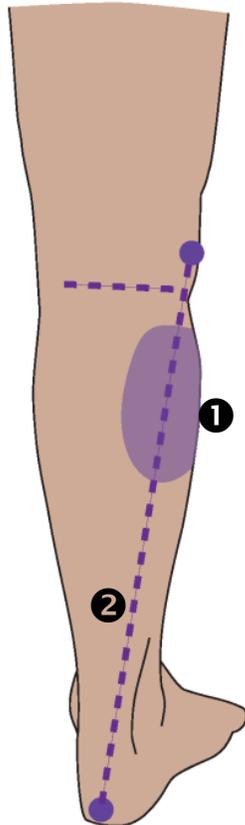


Figure 15. Optimal Calf Location

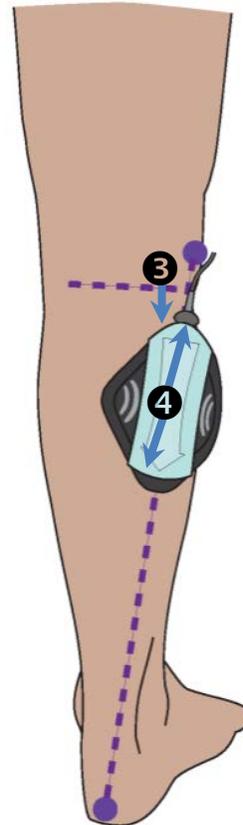


Figure 16. Ray Placed on Calf

2.5 Beginning Monitoring

- 1 Once the Ray is placed on the patient, click 'Begin Monitoring' (Figure 17 ①).

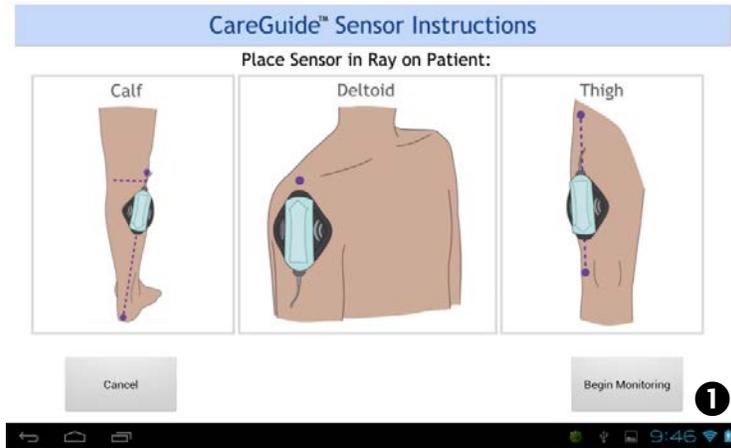


Figure 17. Placement Instructions Screen

- 2 The Sensor optimizes to the patient, which can take 60-90 seconds (Figure 18 ②).

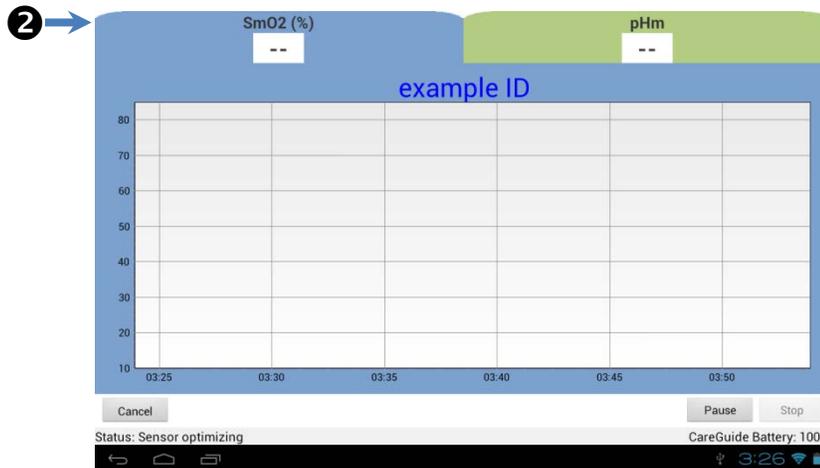


Figure 18. Sensor Optimizing

- 3 Monitoring begins, and SmO₂ and pHm data are displayed (Figure 19 ③).

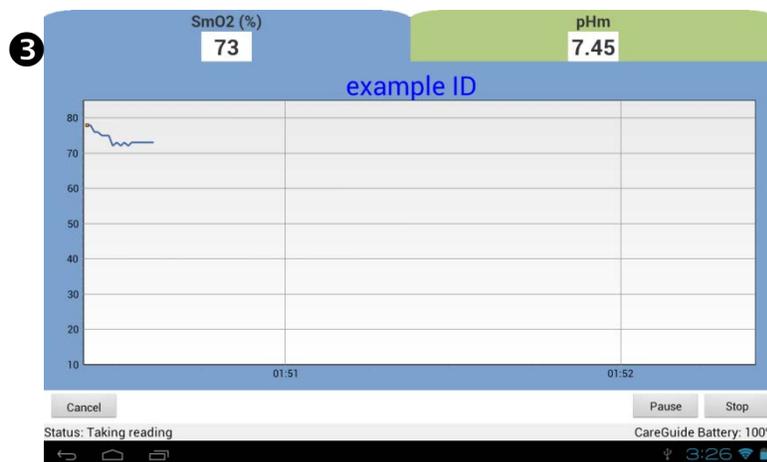


Figure 19. Monitoring Screen

2.6 Other Operations

2.6.1 Display Options

To select which parameter displays on the trend graph:

- 1 Click on the parameter button below the values for the desired trend. Example: to change from SmO₂ trend to pHm, click the green 'pHm' tab (Figure 20 ①).



Figure 20. Monitoring Screen- SmO₂ Trend

- 2 The color of the graph surround will match the parameter currently selected for trend display (Figure 21 ②).



Figure 21. Monitoring Screen- pHm Trend

To adjust the scale of the current parameter's trend graph:

- 1 Touch anywhere on the graph on the Monitoring Screen (Figure 22 ①).

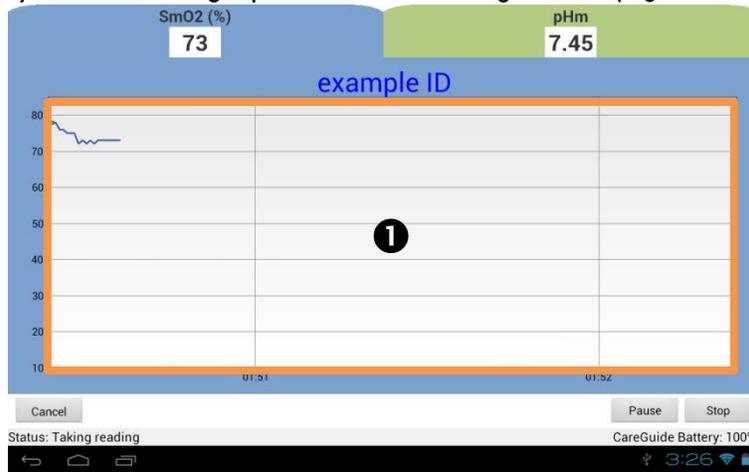


Figure 22. Monitoring Screen- Graph Area for Accessing Options

- 2 Adjust X and Y Axes values using + and – buttons (Figure 23 ②)
- 3 If desired, click the value box to bring up the on-screen keyboard for editing (Figure 23 ③) Hide the on-screen keyboard when adjustments are complete (Figure 23 ④).

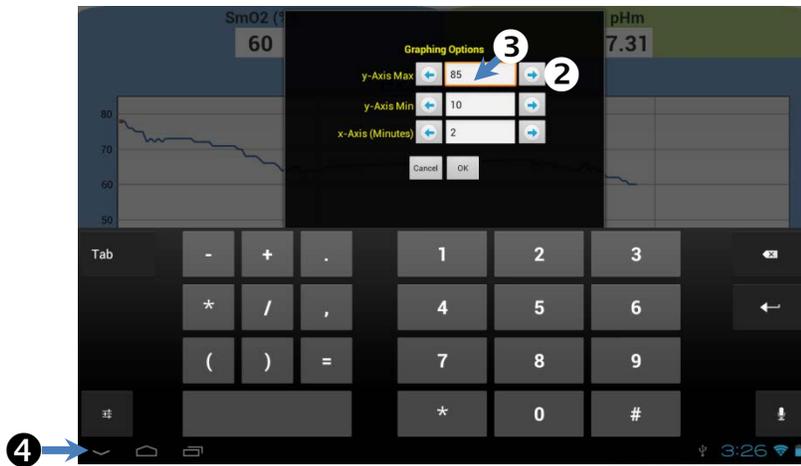


Figure 23. Graphing Options Screen- Using On-Screen Keyboard

- 4 Click 'OK' to save changes and return to Monitoring Screen (Figure 24 ⑤)

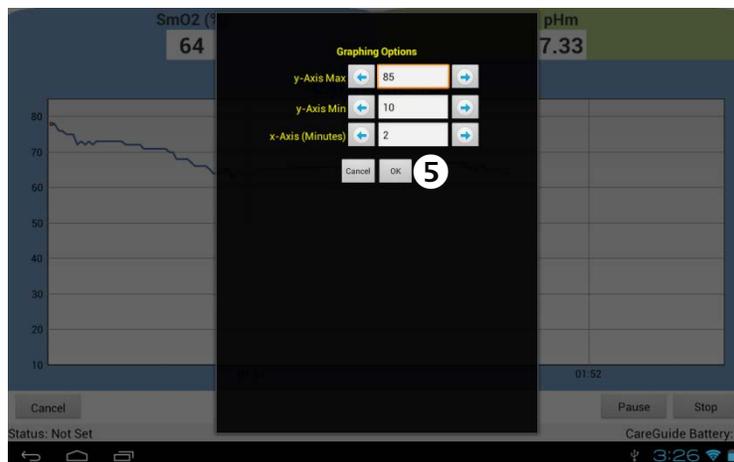


Figure 24. Graphing Options Screen

2.6.2 Pausing & Resuming for the Same Patient

To temporarily pause monitoring (e.g., for testing or procedures):

- 1 Click the 'Pause' button on the Monitoring screen (Figure 25 ❶).

Note: The Multi-Parameter CareGuide 3100 Sensor does contain metal and must be removed from the Ray prior to a patient entering the MRI or similar imaging environment. The Ray may remain attached to the patient during these procedures.

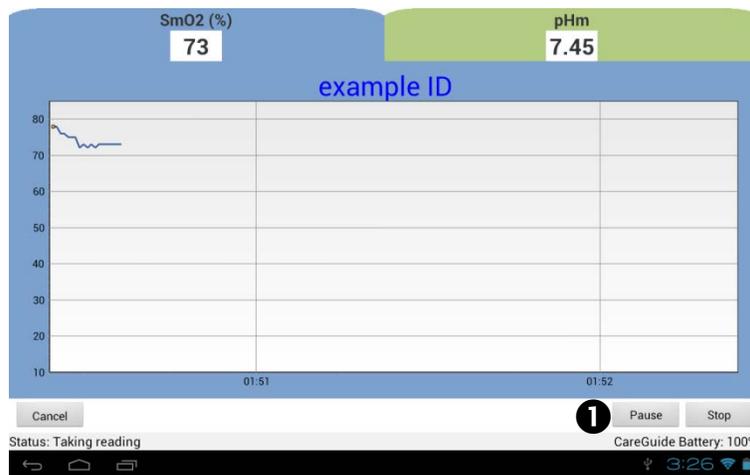


Figure 25. Example Monitoring Screen

- 2 If it had been removed, reinsert the Sensor into the Ray on the patient.
- 3 Click the 'Restart' button on the paused Monitoring screen (Figure 26 ❷) to resume monitoring for the current patient.

Note: If not resumed after 2 hrs of being paused, the system returns to the main screen.



Figure 26. Paused Monitoring Screen

2.6.3 Changing to a New Patient

To change from monitoring the current patient to monitoring a new patient:

- 1 Click the 'Stop' button on the Monitoring Screen (Figure 25) to end current monitoring.
- 2 Once at the Main Screen, see Sections 2.2 *Starting Use* through 2.5 *Beginning Monitoring*.

2.7 Ending Monitoring

- 1 To end monitoring for the current patient, click the 'Stop' button on the Monitoring Screen (Figure 27 ❶).

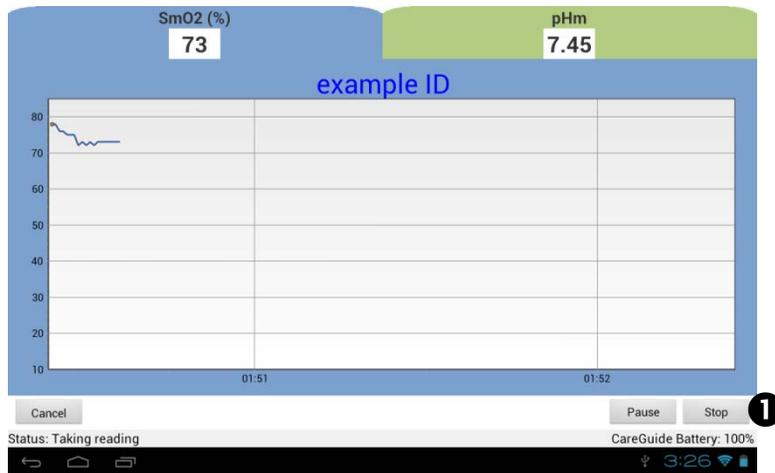


Figure 27. Example Monitoring Screen

- 2 The system returns to the Main screen.
Note: To start monitoring a new patient, see Sections 2.2 *Starting Use* through 2.5 *Beginning Monitoring*.
- 3 If finished monitoring, press and hold the power button on the Display (Figure 29 ❷).

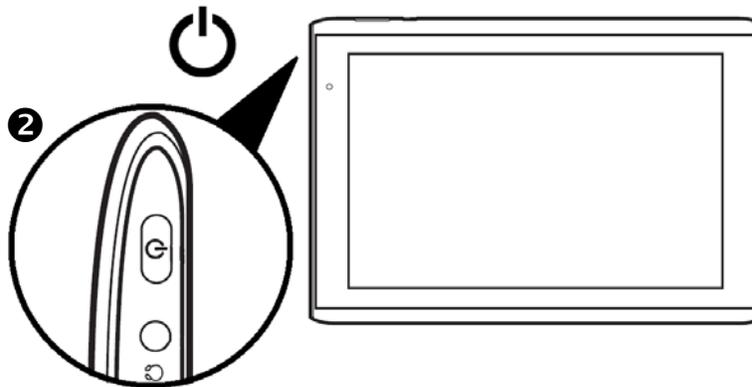


Figure 28. Display Power Button

- 4 Click 'OK' to confirm shut down (Figure 29 ❸).

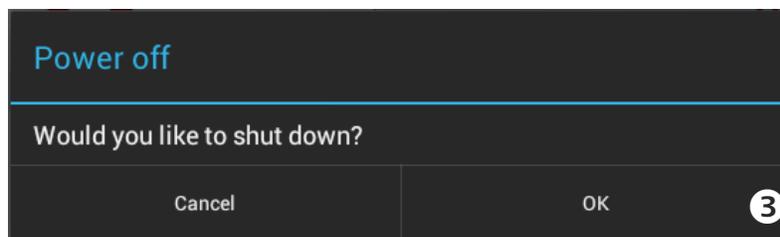


Figure 29. Power Off

3 Care & Maintenance

3.1 Cleaning the Sensor

After use, the Sensor shall be cleaned following the cleaning steps outlined below. Perform these steps immediately after sensor use regardless if there is visible soil or not. An overall figure (Figure 30) of the Multi-Parameter CareGuide 3100 parts to be cleaned for re-use is shown below:

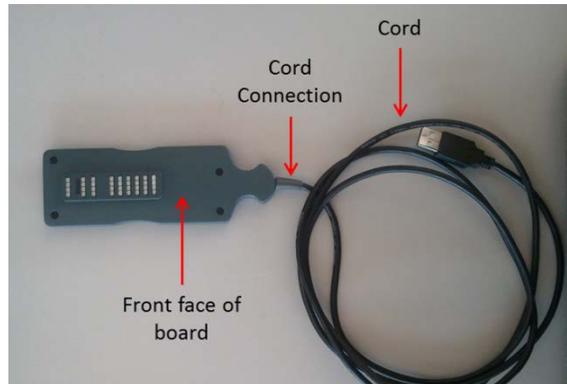


Figure 30. Overview photo including front face of Sensor and cord

Cleaning debris from sensor

Use a Sklar wipe to wipe all areas until all visible debris is removed. If the Sklar wipe becomes visibly dirty, discard and use a new Sklar wipe, until the wipe does not have any debris left on it. Follow the step-by-step directions indicated below:

- 1 Remove one Sklar wipe* from its container
- 2 Wipe the front, back, and sides of the Sensor, and the Sensor cord. Take special care to clean the cord connection.
- 3 Use another wipe to dislodge debris from screw heads on the front face of the Sensor if necessary (Figure 31).
- 4 Use a different wipe to wipe the area between the LED banks to remove debris (Figure 32)

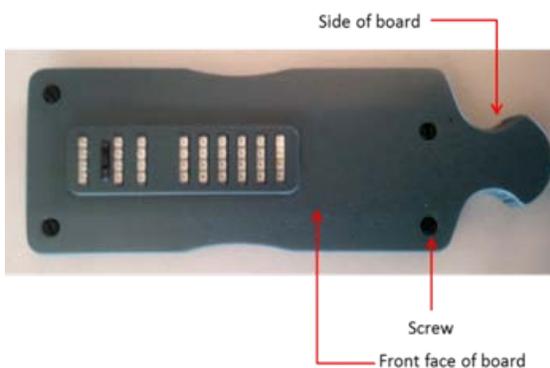


Figure 31. Front face of Sensor

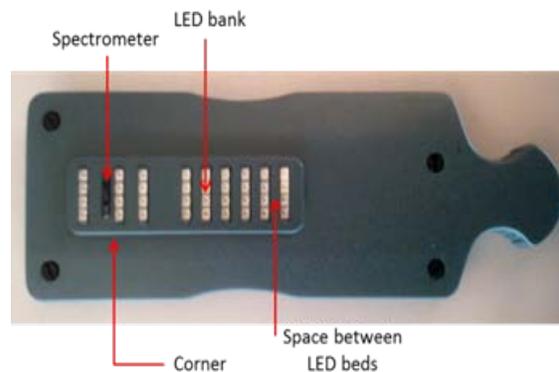


Figure 32. Layout of optical windows including LED banks and spectrometer

- 5 Wipe the spectrometer and surrounding areas
- 6 Wipe each LED from left to right using very light pressure to remove debris from glass
- 7 Once cleaned, allow Sensor to completely dry before moving on to the next step

Removing detergent residue from sensor

- 1 Remove a pre-saturated CleanTex wipe** from its product package.
- 2 Wipe the front, back and side of the Sensor.
- 3 Wipe area between LED banks to remove debris.
- 4 Wipe each LED bank from left to right using very light pressure to avoid streaking on glass casing.
- 5 If CleanTex wipe has noticeable debris on it, repeat the cleaning protocol from the beginning with a fresh Sklar wipe.
- 6 Allow the Sensor to completely air-dry prior to use.
- 7 Visually inspect device for residual soil and repeat this step, if necessary.
- 8 Once cleaned, re-use or store Sensor in original packaging or other clean environment
- 9 Before re-use, examine Sensor to ensure there is no dirt or debris.
- 10 If necessary, repeat the cleaning protocol prior to re-use.

Note: *The Sklar Disinfectant™ Surface Wipes (Sklar Instruments, Part Number 10-1616, EPA Reg# 70144-2-31118) is provided in the packaging, or can be purchased from Sklar Instruments or its distributors:

Sklar Instruments

889 S. Matlack Street
West Chester, PA 19382 U.S.A.
Phone: (800) 221-2166
Fax: (610) 696-9007
www.sklarcorp.com

**The CleanTex wipes (Advantus Corp., Part Number CT 806) is provided in the packaging, or can be purchased from Advantus Corporation distributors:

Specialty Optical Systems

10210 Forest Lane
Dallas, TX 75243
Phone: (800) 443-07101
Fax: (214) 340-5723
Email: Sales@SOSSupply.com
www.SOSSupply.com

3.2 Recharging the Sensor

The Multi-Parameter CareGuide™ 3100 Sensor may be recharged while in use or idle using only the supplied RMI medical-grade battery charger.

The Sensor has an LED (Figure 27 ❶) that indicates charge status by the state of the LED (Figure 28). You can also check the battery charge level using System Tools (see 4.2.3 Battery Charge Level).



Figure 33. Sensor LED (❶) and Charger Connector (❷)

LED State	Description
LED off	Battery charge is $\leq 5\%$ (<45 minutes) -or- Charger is not plugged in
LED Blinking	Battery charge level is 0-89% and charger is attached and working
LED Solid	Battery charge level is $\geq 90\%$

Figure 34. Sensor Battery Status LED States

To charge the Sensor, connect the DC-in jack to the Sensor (Figure 27 ❷) and plug the Sensor charger (Figure 29 ❸) into any hospital-grade AC 110/220V outlet.

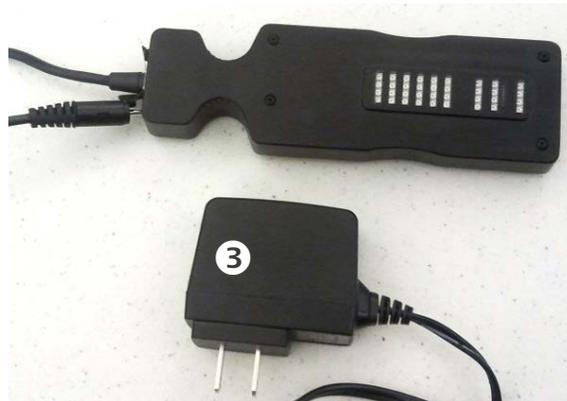


Figure 35. Sensor Charger Connected to Sensor

3.3 Recharging the Display

The Display has a battery charge status icon in the lower right corner of the screen (Figure 30).

To charge the Display, connect the DC-in jack to the Display (Figure 31 ①) and plug the AC adapter into any AC 110/220V outlet (Figure 31 ②).

Icon	Description
	Battery is very low
	Battery is low
	Battery is partially drained
	Battery is full
	Battery is charging

Figure 36. Display Battery Status Icon

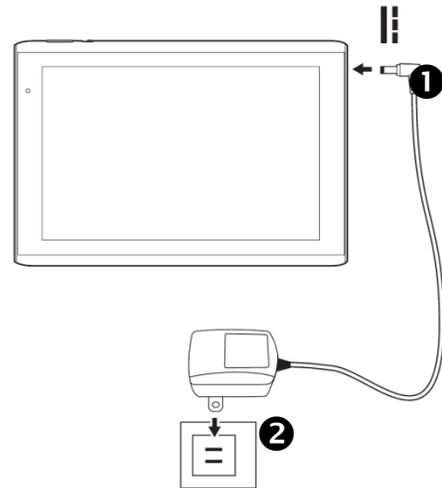


Figure 37. Charging the Display

3.4 Storing the System

- 1 If connected, unplug chargers from wall power and Sensor and Display.
- 2 Disconnect the Sensor from the Display.
- 3 If applicable, remove the Sensor from and discard the used Ray.
- 4 Clean the sensor as described in 3.3 *Cleaning the Sensor*. Place cleaned, dry sensor in storage container or an unused Ray.
- 5 Store display and sensor in a safe, clean location, away from direct sunlight and away from temperature extremes.

Sensor

- Do not exceed 30-90% atmospheric humidity.
- Do not go below 32°F (0°C).
- Do not exceed 104°F (40°C).

Disposable Ray

- Do not exceed 40-60% atmospheric humidity.
- Do not go below 50°F (10°C).
- Do not exceed 80°F (27°C).

Battery Charger

- Do not go below -40°F (-40°C).
- Do not exceed 185°F (85°C).

4 Troubleshooting

4.1 Handling Error Messages

Message	When it happens	Solution
Sensor nearing expiration	Initial setup	Order a replacement sensor soon. Sensor may be used normally for up to one month.
Sensor expired. Please replace.	Initial setup	Order a replacement sensor.
Sensor Check failed	Sensor Check	Check alignment of Ray in Cradle. Check sensor for dirt or soil and clean if necessary. Retry. If error persists, contact Tech Support.
SmO2 shows <10 or >85	During patient monitoring	SmO2 value is beyond the valid measurement range. Such values could be physiologically possible. Check placement on patient if desired.
pHm shows <6.9 or >7.5	During patient monitoring	pHm value is beyond the valid measurement range. Such values could be physiologically possible. Check placement on patient if desired.
Check Sensor. Reposition if needed.	During patient monitoring	Check alignment and adhesion of Ray on patient. If insufficient, use a new Ray and restart. If error persists, contact Tech Support.
Check sensor connection	During patient monitoring	Check sensor cable. Use 'Check Sensor Connection' and/or 'Reset Sensor' tools in System Tools menu. If using a micro-USB to Type A USB adapter cable, check adapter. Remove sensor from adapter; plug adapter cable in by itself; then plug sensor into adapter cable. If error persists, contact Tech Support.
Replace Ray on patient.	During patient monitoring	Ray use has exceeded 72hrs. Pause monitoring, replace Ray in new location on patient, then continue monitoring.
Sensor overheated. Please wait 1 hr.	During patient monitoring	Discontinue use of sensor for at least 1 hour before trying monitoring again. If error persists, contact Tech Support.
Sensor failed. Contact tech support.	Anytime	Contact Tech Support for a replacement sensor.
Battery is low. Please connect charger.	Anytime	Connect battery charger or discontinue use of sensor.

4.2 System Tools

The System Tools menu, accessible by clicking the 'System Tools' button on the Main Screen, has tools that may help in sensor troubleshooting.

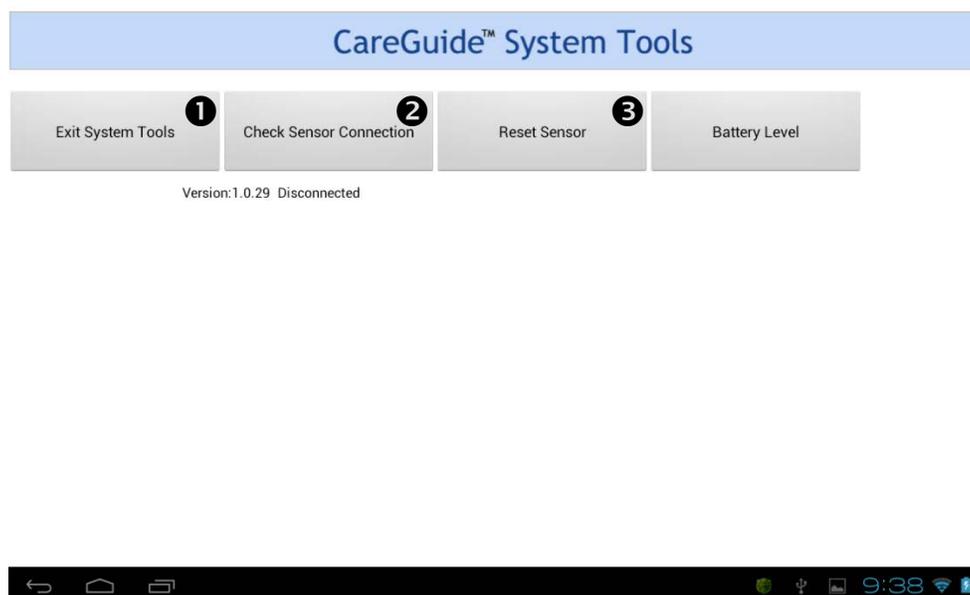


Figure 38. System Tools Screen

4.2.1 Testing the Sensor Connection

To test if the connected Sensor is communicating to the Display properly:

- 1 Click 'Check Sensor Connection' button on the System Tools page (Figure 32 1).
- 2 Properly communicating sensors will return the message 'Sensor connected'.
- 3 If you get error 'No sensors connected', check that the Sensor battery is charged. If using a micro-USB to Type A USB adapter cable, remove sensor from adapter; plug adapter cable in by itself; then plug sensor into adapter cable. If error persists, contact RMI Tech Support.

4.2.2 Resetting the Sensor

If errors persist with a communicating Sensor, you can try resetting the Sensor:

- 1 Click 'Reset Sensor' button on the System Tools page (Figure 32 2).
- 2 The Sensor should return the message 'Sensor reset successfully'.
- 3 If errors persist after resetting the sensor, contact RMI Tech Support.

4.2.3 Battery Charge Level

You can get a reading of the charge level of the Sensor battery by:

- 1 Click 'Battery Level' button on the System Tools page (Figure 32 3).
- 2 The Sensor returns a message 'Battery Level=#', where # is the percent charge.

5 Safety Precautions

5.1 Warnings and Cautions

Before using the Multi-Parameter Mobile CareGuide™ 3100 Oximeter, carefully read this entire manual. Users must fully understand and consistently follow all warnings, precautions, and instructions for safe and effective use of the system.

 **WARNINGS** Alert users about potential serious outcomes for the patient or user (including adverse events, injury, or death).

 **CAUTIONS** Alert users to conditions that may lead to system malfunction or failure.

General Use Warnings

 Use the Multi-Parameter CareGuide™ 3100 with care, as intended, and according to the instructions that shipped with the system. Failure to follow system warnings, precautions, and instructions may cause system malfunction or lead to patient and user injury or and death.

 Do not operate the system near flammable anesthetics. Operating the system near flammable anesthetics may present an explosion that could seriously injure or kill the patient or user.

Cleaning and Maintenance Warnings

 Do not clean the system when it is plugged in, turned on, or connected to a patient. Cleaning the system while it is in use and connected to AC mains power may cause an electrical shock that could seriously injure or kill the patient or user.

 Do not attempt to repair or service any part of the Multi-Parameter CareGuide™ 3100. Attempted repair by untrained, unauthorized individuals may result in serious injury or device malfunction. Contact RMI Technical Support for any repair or service.

CareGuide Sensor Cautions

 The Multi-Parameter CareGuide™ 3100 has a detachable Sensor for monitoring. Use care during operation to avoid soiling or damaging the delicate Sensor. Soiling or damaging the Sensor may cause inaccurate measurements or malfunctions.

 Do not use without first checking and optimizing the Sensor or Ray. Failure to check and optimize the Sensor or Ray may cause inaccurate measurements or malfunction.

 Do not connect any (USB or serial) extension cables to the Sensor cable. Attaching any extension cables will cause the Sensor to time out intermittently and cause malfunction.

 Use only functioning, properly tested, and grounded AC mains electrical outlets to recharge the Sensor. Using faulty, ungrounded outlets may cause failure or malfunction.

CareGuide Ray Cautions

 The Mobile CareGuide™ 2100/3100 Ray is a slight irritant to the skin.

-  Do not place a Sensor and Ray onto skin that is damaged or irritated. Applying Sensors/Rays to skin that is damaged or irritated may cause additional skin damage or irritation. Applying Rays over large, raised veins or onto tattooed, irregularly freckled or discolored skin may result in inaccurate measurements or malfunction.
-  Do not use the same Ray for more than 72 hours. Using a Ray for longer than 72 hours may cause irritation or tissue damage at the site. In addition, use over 72 hour may result in inaccurate measurements or malfunction. If the patient requires monitoring beyond 72 hours, remove the first Ray and attach a new one and place on a different location.
-  Do not apply a Ray to the same site more than three times in a 72-hour period. If additional placements are required, the sensor may be rotated to the contralateral site or used on alternative site (thigh versus deltoid, etc)
-  Do not re-use Rays. The disposable Ray is designed for single-patient, one-time use. Reuse will cause Oximeter malfunction. Dispose used Rays properly.
-  Do not immerse a Ray in water or liquid. Do not expose a Ray to water or moisture. Water, liquid, or moisture will damage the adhesive used to hold the Ray onto the skin. Damaged adhesive may cause gaps between the Ray and patient's skin, which may result in inaccurate measurements. If the Ray gets wet and water damages the adhesive, use a new Ray.

General Use Cautions

-  The Multi-Parameter CareGuide™ 3100 is not defibrillator-proof. It may remain attached to the patient during defibrillation; however readings may be inaccurate during the defibrillation and shortly thereafter. A sensor check should be performed, when convenient, following a defibrillation event.
-  Do not drop Multi-Parameter CareGuide™ 3100 components or subject them to extreme shock. Dropping components or forcefully hitting them against hard objects may damage components and cause Oximeter malfunction.
-  Do not use the Multi-Parameter CareGuide™ 3100 if any component, part, or accessory is damaged or worn. Using damaged or worn equipment may cause failure or malfunction. Contact RMI Technical Support for new equipment if needed.
-  Do not use extension cords or adapters for ungrounded electrical outlets. Using an adapter or extension cord may cause failure or malfunction.
-  Do not use an electrical outlet controlled by a wall switch, or the device may be turned off accidentally.
-  Use only RMI parts and accessories with the Multi-Parameter CareGuide™ 3100 Oximeter. Using non-RMI equipment may cause malfunction. Contact RMI Technical Support to order parts and accessories.
-  Do not use the Multi-Parameter CareGuide™ 3100 in environmental conditions that are:
 - Below 50°F (10°C).
 - Above 104°F (40°C).
 - Outside 30-75% atmospheric humidity.

- Outside 70.0-106.0 kPa atmospheric pressure.

✎ Avoid exposing Multi-Parameter CareGuide™ 3100 components, parts, and equipment to direct sunlight or excessive moisture, heat or cold.

✎ **Cleaning and Maintenance Cautions**

✎ Follow Multi-Parameter CareGuide™ 3100 instructions for cleaning external components (see *Cleaning*, Section 8.1). Never immerse components in water, cleaning solutions, or liquid. This will damage the components, cause malfunction, and void any warranties and service agreements.

✎ Do not use connector cables or other equipment soiled or contaminated with infectious, or potentially infectious, materials. Using soiled or contaminated items may result in a serious infection for the patient or contaminate other patients or users. Soiled or contaminated cables and equipment must be removed from use, and replaced or cleaned according to Multi-Parameter CareGuide™ 3100 instructions, prior to re-use (see *Cleaning*, Section 8.1).

✎ Always follow Multi-Parameter CareGuide™ 3100 instructions for storing and transporting system components and equipment (see *Storage/Transportation*, Section 8.2, for complete device-specific limitations and requirements).

✎ Never attempt to repair Multi-Parameter CareGuide™ 3100 equipment or components. Refer all maintenance and repair to RMI-authorized service technicians. Unauthorized repairs or maintenance may cause user harm or malfunction, and void all warranties and service agreements. Contact RMI Technical Support for details.

5.2 Disposal

Sensor & Display

✎ **WARNING** The Sensor and Display each contain a lithium polymer battery. Please follow local regulations on the disposal or recycling of lithium-containing electronics. Do not throw the Sensor or Display away in the trash.

Disposable Ray

Dispose of used Rays in accordance with local hospital regulations. Unused Rays may be disposed of in regular trash.

Disposable Cradle

The Cradle may be disposed of in regular trash.

Sensor & Display Chargers

Dispose of chargers in accordance with local regulations on electronic waste.

6 Warranty

Reflectance Medical warrants to the original purchaser that the Multi-parameter Mobile CareGuide™ 3100 Sensor (the “Device”) will be free from defects in material and workmanship for a period of one (1) year following delivery of the Device to the original purchaser (the “Warranty Period”). Reflectance Medical does not warrant that operation of the Device will be error-free or uninterrupted. Reflectance Medical shall repair or replace any part or parts of the Device that Reflectance Medical determines is defective within the Warranty Period. At Reflectance Medical’s discretion, it may elect to supply a similar, new or equivalent replacement, or refund the purchase price as of the date of sale of the Device. To qualify for such repair, replacement or refund, the defective Device must a) be returned within thirty (30) days of discovery of the defect by the purchaser and accompanied by proof of date of purchase; b) not have been repaired or altered by any party other than Reflectance Medical or its authorized agents; c) not have been subjected to misuse per the Device Instructions for Use, negligence or accident in Reflectance Medical’s judgment. Purchaser shall be solely responsible for all return freight charges. This warranty does not include Reflectance Medical’s disposable products or non-Reflectance Medical complementary products. Reflectance Medical makes no additional warranty claims for the non-Reflectance Medical Android tablet beyond those provided by the original manufacturer. In no event shall Reflectance Medical be liable for any damages (including, without limitation, lost profits, business interruption, or lost information) arising out of your use of or inability to use the Device, even if Reflectance Medical has been advised of the possibility of such damages.

THIS WARRANTY IS GIVEN IN LIEU OF ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

7 Technical Specifications

Multi-Parameter Mobile CareGuide™ Oximeter 3100		
SmO₂	Range	10% - 85%
	Resolution	1%
	Measurement Rate	30 seconds
	Accuracy	3.8 SmO ₂ units (%)
	Drift	None
pHm	Range	6.90 – 7.50
	Resolution	0.01 pHm units
	Measurement Rate	30 seconds
	Accuracy	0.05 pHm units
	Drift	None
Packaging	System Packaging	<ul style="list-style-type: none"> 1 Multi-Parameter Mobile CareGuide 3100 Sensor 1 sensor battery charger 1 Android display with CareGuide software 1 display charger 1 Micro-USB to Type A adapter (if required) 1 tub of 100 Sklar™ wipes 1 box of 80 CleanTex™ wipes 1 case of 8 Mobile CareGuide™ Ray & cradle sets (boxed individually)
	Packaging for Reorders	1 Multi-Parameter Mobile CareGuide™ 3100 Sensor and 1 battery charger
		1 case of 8 Mobile CareGuide™ Ray & cradle sets (boxed individually)
Mobile CareGuide Ray	Size	<ul style="list-style-type: none"> • 155 x 146 x 27 mm (5.9 x 5.4 x 1.06 in) • One size fits shoulder, calf, or thigh.
	Weight	560.3g (2.13oz)
	Material	<ul style="list-style-type: none"> • Latex free • Biocompatible adhesive
	Attachment to patient	<ul style="list-style-type: none"> • Adhesive placement on shoulder, calf or thigh • Intact skin only • Single Use per patient
	Shelf Life	18 months post manufacturing date
	Use Life	72 hours (single use patient)
Multi-Parameter CareGuide Sensor	Size	• 139 x 47 x 23 mm (5.5 x 1.9 x 0.90 inches)
	Weight	177.2g (6.25 oz)
	Sensor Cable Length	• 2.74 m (9 ft)
	Auxiliary USB Cable	• mini-USB to USB
	Connectors	<ul style="list-style-type: none"> • Battery charger • Auxiliary USB

Multi-Parameter Mobile CareGuide™ Oximeter 3100

	Battery	Rechargeable, Lithium-polymer, sealed, not replaceable
	Typical Battery Life	12 hours (60 sec sample rate) 9 hours (30 sec sample rate)
	Battery Charge Time	5 hours to charge from <5% to 100%
	Attachment to Patient	<ul style="list-style-type: none"> • Insert into Mobile CareGuide™ Ray • Clean with CleanTex™ and Sklar™ wipes between patients
	Shelf Life	2 years post manufacturing date
	Use Life	1 year post first use
Battery charger	Voltage required	• Input: 100-240V 0.3A Max 50/60 Hz
	Cable	• Cable length: 2.74 m (9 feet)
Alarms	Audiovisual	Via CareGuide display
	Audible Alarm	Via sensor
	Error Conditions	See Troubleshooting above.
Product Classification	Medical Device	US: Class II Type BF device per section 870.2700 of 21 CFR and IEC 60601-1 3 rd Edition v2005
Standards	Electrical and Constructional Safety	IEC 60601-1-1:2005 (includes former PEMS IEC 60601-1-4)
	Electromagnetic Compatibility	IEC 60601-1-2: 2001/2006 (Class A emissions)
	Laser Safety	Class 1 laser device per IEC 60825-1: Edition 2.0 (2007)
	Enclosure	PC/UABS HT Cycloy C2950; Impact, rough handling, mold stress relief per IEC 60601-1 3 rd edition
	Shipping and Packaging	ISTA 1A
	Risk Analysis/Risk Management	ISO 14971
	Usability	IEC 60601-1-6
	Battery	IEC 62133; UN T1-T8; ED 93/86/EEC; ED 2006/66/EC
	Biocompatibility	Cytotoxicity: ISO 10993-5: v2009 Irritation and Sensitization: ISO 10993-10 v2010
	Cleaning	AAMI TIR 12:2010; AAMI TIR 30:2003
Electromagnetic Emissions and Immunity	This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1 3 rd Edition v2005. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not	

Multi-Parameter Mobile CareGuide™ Oximeter 3100

	<p>occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:</p> <ul style="list-style-type: none"> • Reorient or relocate the devices. • Increase the separation between the devices. • Connect the equipment to an outlet on a different circuit. • Contact the Service Center. 	
Operating Conditions	Temperature	10°C – 40°C (50°F-104°F)
	Humidity	30-75% ATM non-condensing
	Pressure	70-106 kPa

Manufactured by:



Reflectance Medical, Inc. (RMI)
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Mobile CareGuide™ 2100 Ray

Instructions for Using the Mobile CareGuide™ 2100 Ray

Manufactured by



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R_x Only

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IFU Sensor-0002/Rev. A/Nov 20, 2012

Mobile CareGuide™ 2100 Ray
Instructions for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (301)-796-8118 Page 129 of 361

Contents:

One (1) Mobile CareGuide™ 2100 Disposable Ray

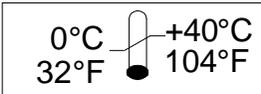
One (1) Mobile CareGuide™ 2100 Disposable Cradle



It is important to read the instructions for use with careful attention to all cautions, notes, and warnings prior to using this product.



This device is intended for single use for one patient within 72 hours. Do not clean and reuse.



This device is to be used within the temperature ranges indicated here, 0-40°C (32-104°F).



Fragile, handle with care.



Keep dry, do not immerse in water.

REF

Product Order Code

LOT

Manufacture Identification Number



Expiration Date (Shelf Life)



Manufactured by



Date of Manufacture

1. Description

Mobile CareGuide™ 2100 Ray A single-use, latex-free Ray is placed onto the skin of the patient's shoulder, thigh, or calf, using a durable, biocompatible, skin adhesive.

2. General Instructions

The Mobile CareGuide™ 2100 Ray weighs 55.9g. A pocket inside the Ray receives a detachable, reusable Mobile CareGuide™ 2100 Sensor. The skin-facing side of the Ray has a protective “window” through which the Sensor detects and measures local tissue oxygenation levels. A single Ray can remain in the same location for up to 72 hours. During this time, the inserted Sensor may be removed from the Ray (e.g., if the patient needs to be relocated for testing or procedures). Later, the Sensor can be re-inserted to resume monitoring (e.g., when the patient returns to his or her room).

3. Storage and Transport

Short Term Storage

Remove the Mobile CareGuide™ 2100 Sensor from the Mobile CareGuide™ 2100 Ray. Use a new Ray with every patient and every time you monitor after removal from the patient.

When ready to use the System with a new patient:

- a Retrieve the stored Sensor.
- b Obtain a new Ray.
- c Set up the System for monitoring a new patient.

Long Term Storage (Shelf Life)

Do not open product packaging or unpack Mobile CareGuide™ 2100 Ray and cradle until ready for use. While awaiting use, follow these storage guidelines for Mobile CareGuide™ 2100 Ray:

- Keep the Ray in the original package until use on patient.
- Do not exceed 40-60% atmospheric humidity.
- Do not go below 50°F (10°C).
- Do not exceed 80°F (27°C).

4. Indications for Use

The Mobile CareGuide™ 2100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Mobile CareGuide 2100 Oximeter is intended to allow for display of SmO₂ data on a third party device, which would interface with the Mobile CareGuide 2100 Oximeter via USB or CAN connection. The Mobile CareGuide 2100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Mobile CareGuide 2100 Oximeter provides output of the most recent value of SmO₂, as well as operational device information. The Mobile CareGuide 2100 Oximeter should not be used as the sole basis for diagnosis or therapy.

Note: The prospective clinical value of data from the Mobile CareGuide™ 2100 Oximeter has not been demonstrated in disease states.

5. Contraindications

The Mobile CareGuide™ 2100 Oximeter should not be used for on patients with body temperatures below 34 degrees Celsius.

Do not place a Ray onto skin with nevi, bruises, burns, scars, tattoos, irregular freckling, discoloration, or large raised veins.

Mobile CareGuide™ 2100 Oximeter is not recommended for patients with BMI <19 or >30.

6. Safety

WARNINGS

- Use the Mobile CareGuide™ 2100 Ray with care, as intended, and according to the instructions that shipped with the System. Failure to follow system warnings, precautions, and instructions may cause system malfunction or lead to patient and user injury or and death.
- Do not operate the System near flammable anesthetics. Operating the System near flammable anesthetics may present an explosion that could seriously injure or kill the patient or user.
- Do not clean the System when it is plugged in, turned on, or connected to a patient. Cleaning the System while it is in use and connected to AC mains power may cause an electrical shock that could seriously injure or kill the patient or user.

PRECAUTIONS

- Do not place a Mobile CareGuide™ 2100 Ray onto skin that is damaged or irritated. Do not place a Ray onto skin with tattoos, irregular freckling, discoloration, or large raised veins. Applying Rays to skin that is damaged or irritated may cause additional skin damage or irritation. Applying Rays over large, raised veins or onto tattooed, irregularly freckled or discolored skin may result in inaccurate measurements or system malfunction.
- Do not re-use Mobile CareGuide™ 2100 Rays. The disposable Ray is designed for single-patient, one-time use. Reuse will cause Oximeter malfunction. Dispose used Rays properly.
- Follow Mobile CareGuide instructions for cleaning external system components (see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use: Cleaning*, Section 8.1). Never immerse components in water, cleaning solutions, or liquid. This will damage the components, cause system malfunction, and void any warranties and service agreements.
- Do not immerse a Mobile CareGuide™ 2100 Ray in water or liquid. Do not expose a Mobile CareGuide™ 2100 Ray to water or moisture. Water, liquid, or moisture will damage the adhesive used to hold the Ray onto the skin. Damaged adhesive may cause gaps between the Ray and patient's skin, which may result in inaccurate measurements. If the Ray gets wet and water damages the adhesive, use a new Ray.
- Do not use the Mobile CareGuide™ 2100 Ray if is damaged or worn. Using damaged or worn equipment may cause system failure or malfunction. Contact Mobile CareGuide Technical Support for new equipment if needed.
- Use only Mobile CareGuide™ 2100 Ray and accessories with the Mobile CareGuide™ 2100 Oximeter. Using non-Mobile CareGuide equipment may cause system malfunction. Contact CareGuide Technical Support to order parts and accessories.
- Do not use the CareGuide™ 2100 Ray in environmental conditions that are:

- Below 50°F (10°C).
- Above 104°F (40°C).
- Above 30-75% atmospheric humidity.
- Above 70.0-106.0 kPa atmospheric pressure.
- Avoid exposing Mobile CareGuide™ 2100 Ray to direct sunlight or excessive moisture, heat or cold.
- Always follow Mobile CareGuide instructions for storing and transporting System components and equipment (see *Storage/Transportation*, Section 3).
- Do not use the System without first checking and optimizing the Ray. Failure to check and optimize the Ray may cause inaccurate measurements or system malfunction.

7. Cleaning

DO NOT CLEAN. RAY IS DISPOSABLE, SINGLE USE ONLY.

8. Assembly

NO ASSEMBLY IS REQUIRED.

9. Directions for Use

Every Care Guide™ 2100 Ray is placed on a protective cradle and packaged together.

- The arrow from the top blue part of the Mobile CareGuide™ 2100 Ray should be aligned with the arrows drawn on each side of the cradle such that they will be pointing in the same way.
- Remove the protective cradle with the Mobile CareGuide™ 2100 Ray from the packaging. When prompted by the System, insert fully the sensor with the logo facing up.
- Remove the Ray from the cradle.

Note: Hold the Ray in one hand with the opening window facing up while inserting the Mobile CareGuide™ 2100 Sensor into the Ray. Mobile CareGuide™ 2100 Ray arrow should be aligned with the arrows printed on the cradle for proper Sensor check.

- When correctly inserted, Sensor Check is performed. Checking takes about 35-40 seconds. On-screen messages display the Sensor check status
- If the Sensor passes the check, remove the Mobile CareGuide™ 2100 Ray with the Sensor inserted from the cradle, remove the liner to expose the adhesive.
- The new Ray and Sensor are ready for patient use (see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use*, which came with the initial system package).
- For Ray and Sensor placement on patient see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use*, which came with the initial system package.

Note: For any problems at any of the above steps or error messages displayed see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use: Troubleshooting*, Section 7.

More details on the instructions are found in the see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use* provided with the system.



Mobile CareGuide™ 2100 Ray

Instructions for Using the Mobile CareGuide™ 2100 Ray

Manufactured by



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R_x Only

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IFU Sensor-0002/Rev. A/Nov 20, 2012

Mobile CareGuide™ 2100 Ray
Instructions for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (301)-796-8118 Page 129 of 361

Contents:

One (1) Mobile CareGuide™ 2100 Disposable Ray

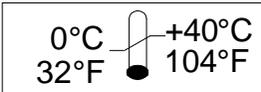
One (1) Mobile CareGuide™ 2100 Disposable Cradle



It is important to read the instructions for use with careful attention to all cautions, notes, and warnings prior to using this product.



This device is intended for single use for one patient within 72 hours. Do not clean and reuse.



This device is to be used within the temperature ranges indicated here, 0-40°C (32-104°F).



Fragile, handle with care.



Keep dry, do not immerse in water.

REF

Product Order Code

LOT

Manufacture Identification Number



Expiration Date (Shelf Life)



Manufactured by



Date of Manufacture

1. Description

Mobile CareGuide™ 2100 Ray A single-use, latex-free Ray is placed onto the skin of the patient's shoulder, thigh, or calf, using a durable, biocompatible, skin adhesive.

2. General Instructions

The Mobile CareGuide™ 2100 Ray weighs 55.9g. A pocket inside the Ray receives a detachable, reusable Mobile CareGuide™ 2100 Sensor. The skin-facing side of the Ray has a protective "window" through which the Sensor detects and measures local tissue oxygenation levels. A single Ray can remain in the same location for up to 72 hours. During this time, the inserted Sensor may be removed from the Ray (e.g., if the patient needs to be relocated for testing or procedures). Later, the Sensor can be re-inserted to resume monitoring (e.g., when the patient returns to his or her room).

3. Storage and Transport

Short Term Storage

Remove the Mobile CareGuide™ 2100 Sensor from the Mobile CareGuide™ 2100 Ray. Use a new Ray with every patient and every time you monitor after removal from the patient.

When ready to use the System with a new patient:

- a Retrieve the stored Sensor.
- b Obtain a new Ray.
- c Set up the System for monitoring a new patient.

Long Term Storage (Shelf Life)

Do not open product packaging or unpack Mobile CareGuide™ 2100 Ray and cradle until ready for use. While awaiting use, follow these storage guidelines for Mobile CareGuide™ 2100 Ray:

- Keep the Ray in the original package until use on patient.
- Do not exceed 40-60% atmospheric humidity.
- Do not go below 50°F (10°C).
- Do not exceed 80°F (27°C).

4. Indications for Use

The Mobile CareGuide™ 2100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Mobile CareGuide 2100 Oximeter is intended to allow for display of SmO₂ data on a third party device, which would interface with the Mobile CareGuide 2100 Oximeter via USB or CAN connection. The Mobile CareGuide 2100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Mobile CareGuide 2100 Oximeter provides output of the most recent value of SmO₂, as well as operational device information. The Mobile CareGuide 2100 Oximeter should not be used as the sole basis for diagnosis or therapy.

Note: The prospective clinical value of data from the Mobile CareGuide™ 2100 Oximeter has not been demonstrated in disease states.

5. Contraindications

The Mobile CareGuide™ 2100 Oximeter should not be used for on patients with body temperatures below 34 degrees Celsius.

Do not place a Ray onto skin with nevi, bruises, burns, scars, tattoos, irregular freckling, discoloration, or large raised veins.

Mobile CareGuide™ 2100 Oximeter is not recommended for patients with BMI <19 or >30.

6. Safety

WARNINGS

- Use the Mobile CareGuide™ 2100 Ray with care, as intended, and according to the instructions that shipped with the System. Failure to follow system warnings, precautions, and instructions may cause system malfunction or lead to patient and user injury or and death.
- Do not operate the System near flammable anesthetics. Operating the System near flammable anesthetics may present an explosion that could seriously injure or kill the patient or user.
- Do not clean the System when it is plugged in, turned on, or connected to a patient. Cleaning the System while it is in use and connected to AC mains power may cause an electrical shock that could seriously injure or kill the patient or user.

PRECAUTIONS

- Do not place a Mobile CareGuide™ 2100 Ray onto skin that is damaged or irritated. Do not place a Ray onto skin with tattoos, irregular freckling, discoloration, or large raised veins. Applying Rays to skin that is damaged or irritated may cause additional skin damage or irritation. Applying Rays over large, raised veins or onto tattooed, irregularly freckled or discolored skin may result in inaccurate measurements or system malfunction.
- Do not re-use Mobile CareGuide™ 2100 Rays. The disposable Ray is designed for single-patient, one-time use. Reuse will cause Oximeter malfunction. Dispose used Rays properly.
- Follow Mobile CareGuide instructions for cleaning external system components (see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use: Cleaning*, Section 8.1). Never immerse components in water, cleaning solutions, or liquid. This will damage the components, cause system malfunction, and void any warranties and service agreements.
- Do not immerse a Mobile CareGuide™ 2100 Ray in water or liquid. Do not expose a Mobile CareGuide™ 2100 Ray to water or moisture. Water, liquid, or moisture will damage the adhesive used to hold the Ray onto the skin. Damaged adhesive may cause gaps between the Ray and patient's skin, which may result in inaccurate measurements. If the Ray gets wet and water damages the adhesive, use a new Ray.
- Do not use the Mobile CareGuide™ 2100 Ray if is damaged or worn. Using damaged or worn equipment may cause system failure or malfunction. Contact Mobile CareGuide Technical Support for new equipment if needed.
- Use only Mobile CareGuide™ 2100 Ray and accessories with the Mobile CareGuide™ 2100 Oximeter. Using non-Mobile CareGuide equipment may cause system malfunction. Contact CareGuide Technical Support to order parts and accessories.
- Do not use the CareGuide™ 2100 Ray in environmental conditions that are:

- Below 50°F (10°C).
- Above 104°F (40°C).
- Above 30-75% atmospheric humidity.
- Above 70.0-106.0 kPa atmospheric pressure.
- Avoid exposing Mobile CareGuide™ 2100 Ray to direct sunlight or excessive moisture, heat or cold.
- Always follow Mobile CareGuide instructions for storing and transporting System components and equipment (see *Storage/Transportation*, Section 3).
- Do not use the System without first checking and optimizing the Ray. Failure to check and optimize the Ray may cause inaccurate measurements or system malfunction.

7. Cleaning

DO NOT CLEAN. RAY IS DISPOSABLE, SINGLE USE ONLY.

8. Assembly

NO ASSEMBLY IS REQUIRED.

9. Directions for Use

Every Care Guide™ 2100 Ray is placed on a protective cradle and packaged together.

- The arrow from the top blue part of the Mobile CareGuide™ 2100 Ray should be aligned with the arrows drawn on each side of the cradle such that they will be pointing in the same way.
- Remove the protective cradle with the Mobile CareGuide™ 2100 Ray from the packaging. When prompted by the System, insert fully the sensor with the logo facing up.
- Remove the Ray from the cradle.

Note: Hold the Ray in one hand with the opening window facing up while inserting the Mobile CareGuide™ 2100 Sensor into the Ray. Mobile CareGuide™ 2100 Ray arrow should be aligned with the arrows printed on the cradle for proper Sensor check.

- When correctly inserted, Sensor Check is performed. Checking takes about 35-40 seconds. On-screen messages display the Sensor check status
- If the Sensor passes the check, remove the Mobile CareGuide™ 2100 Ray with the Sensor inserted from the cradle, remove the liner to expose the adhesive.
- The new Ray and Sensor are ready for patient use (see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use*, which came with the initial system package).
- For Ray and Sensor placement on patient see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use*, which came with the initial system package.

Note: For any problems at any of the above steps or error messages displayed see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use: Troubleshooting*, Section 7.

More details on the instructions are found in the see *Mobile CareGuide™ 2100 Oximeter, Instruction for Use* provided with the system.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 14: Sterilization and Shelf Life

CONFIDENTIAL

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 14

Packaging-Shipping, Cleaning and Shelf Life

14.1 FINISHED DEVICE PERFORMANCE CLEANING TESTING SUMMARY: Standards compliance

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Documents
NA	AAMI TIR 12:2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	Pass	None	Predicate filing (K130079) and on file at RMI: N122218 Cleaning equivalency statement; K113656 Cleaning Summary N122059
NA	AAMI TIR 30:2003	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	Pass	None	Predicate filing (K130079) and on file at RMI: N122218 Cleaning equivalency statement; K113656 Cleaning Summary N122059

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

14.2 FINISHED DEVICE PERFORMANCE PACKAGING-SHIPPING TESTING SUMMARY: RMI generated

RMI #	Name	Description	Results	Exceptions	Reference Documents
--	Packaging and Shipping Test Results	Test results of packaging and shipping test by 3 rd party to validate compliance to ISTA 1A test with final product and boxes	Pass	None	Predicate filing (K130079) and on file at RMI: K113656 Packing and Shipping test results; K113656 Fixed Vibration and Drop
--	Shelf Life	A scientific analysis to set the initial stated shelf life for the disposable Ray at time of commercialization. Protocol to perform real-time testing of actual finished devices in their original packing containers is being deployed starting before commercialization and continued post-shipment.	Pass	None	Predicate filing (K130079) and on file at RMI: K113656 Shelf life assessment of CareGuide_Ray rev_A; RSLV-001 Ray Shelf Life VV Protocol Rev A 110911

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

14.3 RMI test methodology Overview

14.3.1 Cleaning:

Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the same cleaning procedures (see Instructions for Use document) as the Mobile CareGuide 3100 Oximeter predicate (K130079). The sensor housing materials, usage and clinical environment are the same as the predicate.

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(b) (4)

(b)(4)

The AAMI TIR30:2011 benchmark levels for protein and hemoglobin are $<6.4 \mu\text{g}/\text{cm}^2$ and $<2.2 \mu\text{g}/\text{cm}^2$, respectively; therefore, the results met the protocol acceptance criteria. The visual presence of soil on the CareGuide Reusable Sensor devices after cleaning was not observed.

It is the assessment of Reflectance Medical that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet components are conformant with AAMI TIR 12:2010 and AAMI TIR 30:2003 standards.

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

14.3.2 Packaging and Shipping:

Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the same packaging material from the same vendor as the Mobile CareGuide 3100 Oximeter predicate (K130079) to ship: the Multi-Parameter Mobile CareGuide 3100 Oximeter sensor including the Mobile CareGuide 2100 Oximeter battery charger and the Mobile CareGuide ray/cradle assembly.

The CareGuide predicate passed conformance to ISTA 1A standard for vibration and shock. It is the assessment of Reflectance Medical that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet components in their respective packaging are conformant with the ISTA 1A standard.

14.3.3 Shelf-life (from K130079):

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the previously cleared (K122645) Mobile CareGuide 2100 Oximeter disposable Ray. Reflectance Medical declares that the stated shelf life for the Mobile CareGuide 2100 Oximeter Ray: 1.5 years (18 months) when stored at 10-24°C (50-75°F) @ 40-60% relative humidity. Use after this period is possible, but is not recommended nor supported within warranty. Effectiveness of the Ray if stored at temperatures or humidity outside the stated range is not guaranteed. In addition, there are mediations in the system that minimizes the potential use of a failed Ray.

Real-time aging tests are being performed with 6 individually packaged Mobile CareGuide 2100 Oximeter Ray-Cradles subjected to inspection, sensor check, wearing on subjects and actual measurements. The process is conducted after 6 months, 1 year, 18 months and 2 years of controlled storage in original shipping containers for a total of 24 samples.

The Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet sensor uses identical components as the Mobile CareGuide 3100 Oximeter predicate (K130079) sensor. Therefore, Reflectance Medical declares that the stated shelf life for the Multi-Parameter Mobile CareGuide 3100 with Tablet sensor is the same as the predicate device: 2 years when stored at 0-40°C (32-104°F) @ 30-90% relative humidity. Use after this period is not possible and is blocked by the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet sensor software. In addition, there are mediations in the system that minimizes the potential use of a failed sensor.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 14: Sterilization and Shelf Life

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Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 14

Packaging-Shipping, Cleaning and Shelf Life

14.1 FINISHED DEVICE PERFORMANCE CLEANING TESTING SUMMARY: Standards compliance

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Documents
NA	AAMI TIR 12:2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	Pass	None	Predicate filing (K130079) and on file at RMI: N122218 Cleaning equivalency statement; K113656 Cleaning Summary N122059
NA	AAMI TIR 30:2003	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	Pass	None	Predicate filing (K130079) and on file at RMI: N122218 Cleaning equivalency statement; K113656 Cleaning Summary N122059

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

14.2 FINISHED DEVICE PERFORMANCE PACKAGING-SHIPPING TESTING SUMMARY: RMI generated

RMI #	Name	Description	Results	Exceptions	Reference Documents
--	Packaging and Shipping Test Results	Test results of packaging and shipping test by 3 rd party to validate compliance to ISTA 1A test with final product and boxes	Pass	None	Predicate filing (K130079) and on file at RMI: K113656 Packing and Shipping test results; K113656 Fixed Vibration and Drop
--	Shelf Life	A scientific analysis to set the initial stated shelf life for the disposable Ray at time of commercialization. Protocol to perform real-time testing of actual finished devices in their original packing containers is being deployed starting before commercialization and continued post-shipment.	Pass	None	Predicate filing (K130079) and on file at RMI: K113656 Shelf life assessment of CareGuide_Ray rev_A; RSLV-001 Ray Shelf Life VV Protocol Rev A 110911

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

14.3 RMI test methodology Overview

14.3.1 Cleaning:

Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the same cleaning procedures (see Instructions for Use document) as the Mobile CareGuide 3100 Oximeter predicate (K130079). The sensor housing materials, usage and clinical environment are the same as the predicate.

(b) (4) (b)(4)

(b) (4) (b)(4) The AAMI TIR30:2011 benchmark levels for protein and hemoglobin are <6.4 µg/cm² and <2.2 µg/cm², respectively; therefore, the results met the protocol acceptance criteria. The visual presence of soil on the CareGuide Reusable Sensor devices after cleaning was not observed.

It is the assessment of Reflectance Medical that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet components are conformant with AAMI TIR 12:2010 and AAMI TIR 30:2003 standards.

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

14.3.2 Packaging and Shipping:

Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the same packaging material from the same vendor as the Mobile CareGuide 3100 Oximeter predicate (K130079) to ship: the Multi-Parameter Mobile CareGuide 3100 Oximeter sensor including the Mobile CareGuide 2100 Oximeter battery charger and the Mobile CareGuide ray/cradle assembly.

The CareGuide predicate passed conformance to ISTA 1A standard for vibration and shock. It is the assessment of Reflectance Medical that the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet components in their respective packaging are conformant with the ISTA 1A standard.

14.3.3 Shelf-life (from K130079):

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet uses the previously cleared (K122645) Mobile CareGuide 2100 Oximeter disposable Ray. Reflectance Medical declares that the stated shelf life for the Mobile CareGuide 2100 Oximeter Ray: 1.5 years (18 months) when stored at 10-24°C (50-75°F) @ 40-60% relative humidity. Use after this period is possible, but is not recommended nor supported within warranty. Effectiveness of the Ray if stored at temperatures or humidity outside the stated range is not guaranteed. In addition, there are mediations in the system that minimizes the potential use of a failed Ray.

Real-time aging tests are being performed with 6 individually packaged Mobile CareGuide 2100 Oximeter Ray-Cradles subjected to inspection, sensor check, wearing on subjects and actual measurements. The process is conducted after 6 months, 1 year, 18 months and 2 years of controlled storage in original shipping containers for a total of 24 samples.

The Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet sensor uses identical components as the Mobile CareGuide 3100 Oximeter predicate (K130079) sensor. Therefore, Reflectance Medical declares that the stated shelf life for the Multi-Parameter Mobile CareGuide 3100 with Tablet sensor is the same as the predicate device: 2 years when stored at 0-40°C (32-104°F) @ 30-90% relative humidity. Use after this period is not possible and is blocked by the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet sensor software. In addition, there are mediations in the system that minimizes the potential use of a failed sensor.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 15: Biocompatibility

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Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 15**Biocompatibility****15.1 Biocompatibility Standards Compliance****Table 1 Biocompatibility standards compliance**

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Documents
2-153	ISO 10993-5 2009	Biological evaluation of medical devices- Part 5: Test for <i>in vitro</i> cytotoxicity	Pass	None	Predicate filing (K122645) and on file at RMI: cytotoxicity_study_NAMSA_full_report_Aug_2012
2-87	ISO 10993-10 2010	Biological evaluation of medical devices- Part 10: Tests for irritation	Pass	None	Predicate filing (K122645) and on file at RMI: skin_irritation_study_NAMSA_full_report_Aug_2012
2-87	ISO 10993-10 2010	Biological evaluation of medical devices- Part 10: Tests for delay-type hypersensitivity	Pass	None	Predicate filing (K122645) and on file at RMI: sensitization_study_NAMSA_full_report_Sep_2012

15.2 Biocompatibility Methodology OverviewPer FDA Guidance Document #C95-1: *Use of International Standard ISO-10993, 'Biological Evaluation of*

Pages 310 through 311 redacted for the following reasons:

(b)(4)-TS/CCI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 15: Biocompatibility

CONFIDENTIAL

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Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 15**Biocompatibility****15.1 Biocompatibility Standards Compliance****Table 1 Biocompatibility standards compliance**

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Documents
2-153	ISO 10993-5 2009	Biological evaluation of medical devices- Part 5: Test for <i>in vitro</i> cytotoxicity	Pass	None	Predicate filing (K122645) and on file at RMI: cytotoxicity_study_NAMSA_full_report_Aug_2012
2-87	ISO 10993-10 2010	Biological evaluation of medical devices- Part 10: Tests for irritation	Pass	None	Predicate filing (K122645) and on file at RMI: skin_irritation_study_NAMSA_full_report_Aug_2012
2-87	ISO 10993-10 2010	Biological evaluation of medical devices- Part 10: Tests for delay-type hypersensitivity	Pass	None	Predicate filing (K122645) and on file at RMI: sensitization_study_NAMSA_full_report_Sep_2012

15.2 Biocompatibility Methodology OverviewPer FDA Guidance Document #C95-1: *Use of International Standard ISO-10993, 'Biological Evaluation of*

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Medical Devices Part 1: Evaluation and Testing' Table 1 Initial Evaluation Tests for Consideration, the intended device, the Mobile CareGuide 2100 Oximeter Ray, comes in contact with the skin for a duration of < 72 hours. No other surfaces, external communicating devices or implantation are applicable. Table 2 Supplementary Evaluation Test for Consideration is not applicable given the device usage. The necessary tests per guidance are: Cytotoxicity, Irritation and Sensitization. These tests were all conducted using a 3rd party testing lab. The Multi-Parameter Mobile CareGuide 3100 uses the identical, previously cleared (K122645) Mobile CareGuide 2100 Oximeter Ray disposable.

For all tests, the device used was multiple samples of production-equivalent Mobile CareGuide 2100 Oximeter Rays. This is the disposable element of Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet that sits on the surface of human skin and protects the reusable Multi-Parameter Mobile CareGuide 3100 Oximeter Sensor from contacting the skin and also minimizes damage of the sensor. The Mobile CareGuide 2100 Oximeter Ray is composed of a foam material (inert polyurethane foam with skinned covering and closed cell interior), adhesive (medical solvent-less acrylic adhesive) and optical sensor adhesive (pressure sensitive acrylate adhesive).

15.2.1 Cytotoxicity

This was an *in vitro* study to evaluate the predicate (K122645) Mobile CareGuide 2100 Oximeter Ray for potential cytotoxic effects following the guidelines of ISO 10993-5. A single preparation of the Ray test article was extracted in single strength Minimum Essential Medium (1X MEM) at 37°C for 24 hours. The negative control, reagent control and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO₂ for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration.

15.2.2 Irritation

This was an *in vivo* study to evaluate the predicate (K122645) Mobile CareGuide 2100 Oximeter Ray for potential primary skin irritation in accordance with the guidelines of ISO 10993-10: Tests for Irritation and Skin Sensitization. Two 25 mm x 25 mm sections of the Ray test article and control were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application.

15.2.3 Hypersensitivity (Irritation and Sensitization test)

Page 315 redacted for the following reason:

(b)(4)-TS/CCI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 16: Software

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510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 16

Software Overview

Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet – Software Description

16.1 Software Overview

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet software contains software for the sensor and for the Android tablet. The sensor software is identical to the predicate device software, Multi-Parameter Mobile CareGuide™ 3100 Oximeter (K130079). The sensor controls the LEDs and detector, checks the sensor, acquires spectral data, calculates SmO2 and pHm, communicates the SmO2 and pHm values and sensor states conditions to the external 3rd party monitoring device (in the case of the predicate K130079) or an Android tablet (in the case of this filing), checks thermistors for safe temperature levels, stores SmO2 and pHm values and spectral data, and communicates with external service software to control settings, downloads stored data and upgrades the device.

Refer to the K130079 filing for further details on the sensor software.

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter Android Tablet software is the major modification for this filing. It is similar in functionality to the software supporting the interface with the sensor and display parameter values and trends as the predicate device: CareGuide™ 1100 Oximeter (K113656). The Android Tablet software consists of Android operating system, CareGuide display software, lock down software and utility tools.

Software language:

<p>Computing Elements</p>	<p>The 3100 sensor software runs on an embedded main processor with algorithms in "C", identical to the 3100 (K130079).</p> <p>The 3100 Tablet software runs on a commercial tablet with USB communications and GUI components in "Java" using Android SDK.</p>
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16.2 Level of concern

The *level of concern* for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is **Moderate** prior to mitigation of hazards (see Section 16 – Risk Analysis and FMEA documents): a failure of the Software Device could result in minor injury, either to a patient or to a user of the

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

device.

Table 1. Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet Level of Concern Assessment

	Question	Response
Major	Does the Software Device qualify as Blood Establishment Computer Software?	No
	Is the Software Device intended to be used in combination with a drug or biologic?	No
	Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
	Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? a. Does the Software Device control a life supporting or life sustaining function? b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	No
Moderate	Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No
	Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	Yes
	Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	No

Risk Analysis and Failure Mode Effect Analysis were conducted consistent with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005), FDA guidance on General Principles of Software Validation, January 11, 2002 and Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, September 9, 1999.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Roadmap to Software documentation: A listing of RMI Software documentation is provided in Section 16.7.

16.3 Software Overview

Software Design:

The Android Tablet software consists of 4 components (further described below):

1. Android operating system: Android OS 4.0 and OS 4.3 have been validated. The OS is used 'as is' from the tablet manufacturer.
2. CareGuide display software: consists of three components: 1. Communication software to interface with the sensor via the USB port; 2. Display software to start/pause/stop the sensor, enter patient identification, perform a sensor check, display real-time SmO₂ and pHm values, display a trend of historical SmO₂ and pHm values and display any fault conditions reported by the sensor; 3. Store historical trend data and fault conditions in a text file.
3. Lock down software: a 3rd party software package: SureLock from 42Gears Mobility Systems Pvt Ltd is installed on the Android tablet. It restricts the user to only be able to run the CareGuide 3100 display software application. It disables the ability to load any new software applications, or any operating system updates to the tablet. It disables all external communications (Wi-Fi, Bluetooth). There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.
4. Utility tools: there are a set of 3rd party tools that are installed as part of the installation process for the Mobile CareGuide Android Tablet. These tools include APK installer, task manager, file explorer, screen shortcut creator, anti-virus software and USB test program. None of these applications are accessible to the end-user and are used only for installation or service purposes.

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter Software design (Section 16: MPMSDD-002 Mobile CareGuide™ Android Software Design Document) high order components including native Android software are shown in Figure 1 below. A more detailed breakdown of the CareGuide Display software is shown in Figure 2.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

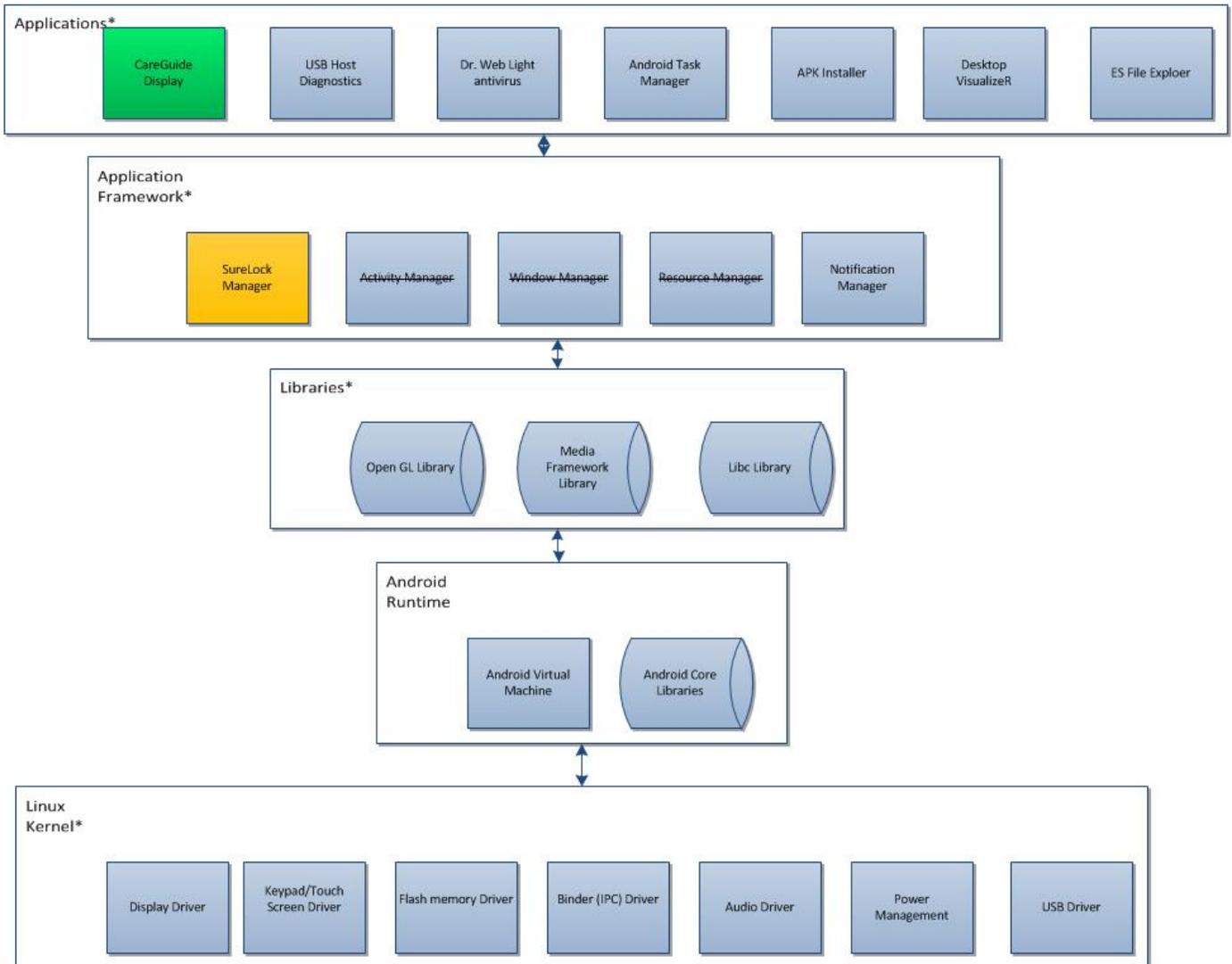


Figure 1. Multi-Parameter Mobile CareGuide™ 3100 Oximeter Android Tablet Software Major Components:

Applications* - additional non-executing applications exist (e.g. Contacts);

Application Framework* - additional non-executing managers exist (e.g. Telephony Manager)

Libraries* - additional non-executing libraries exist (e.g. WebKit);

Linux Kernel* – additional non-executing kernel drivers exist (e.g. Camera).

Note: The corresponding requirement section of the MPMSRS-001 Mobile CareGuide™ Software Requirements Specification document (Section 16) is indicated by the syntax [SRS x.y.z], where x.y.z is the corresponding requirement(s).

Page 321 redacted for the following reason:

(b)(4)-TS/CCI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

- Battery is low. Please connect charger
- Battery xxx%

All of these conditions and the corresponding required user response are shown in the Instructions for Use (Section 13).

- Technical Support (SRS 2.6.4) – allows the end-user or technical staff to test the sensor. Specifically, it allows for:
 - Checking the sensor is connected
 - Resetting the sensor
 - Reporting the battery level

The above functions are described in the Instructions for User (Section 13).

The Android OS, itself, provides technical support to allow qualified service personnel to install/upgrade CareGuide Display software and verify correct installation of that software. Because of the installed SureLock software (see 16.5.2 below), this capability is only accessible in the factory.

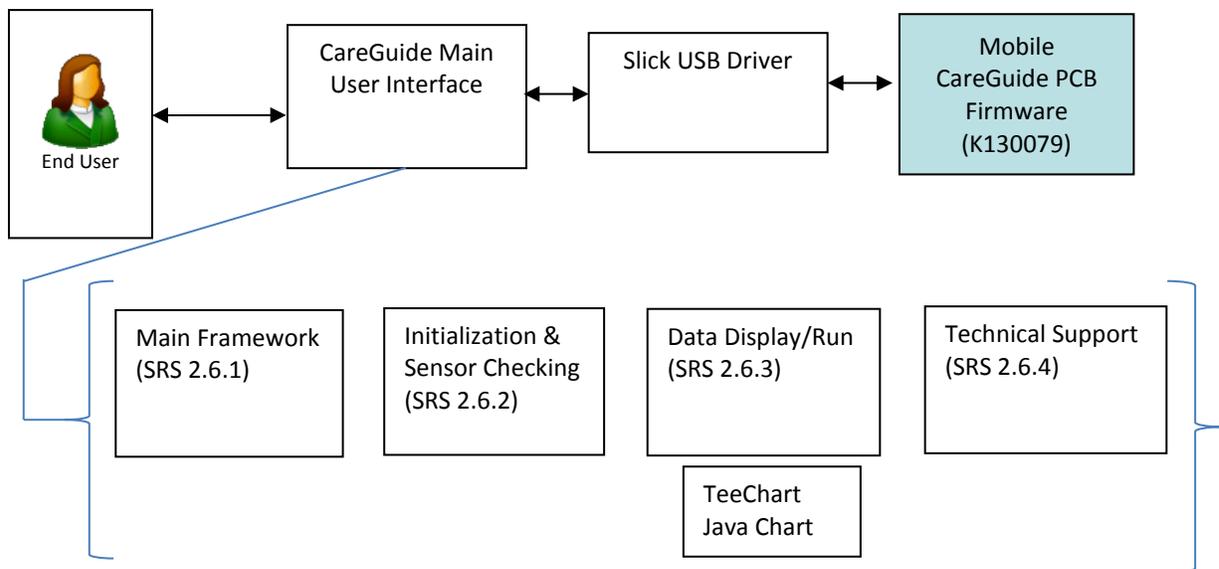


Figure 2. Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet – CareGuide Display Software Major Components

Two off the shelf (OTS) software components are included and installed with the CareGuide Display Software (see Table 2):

1. TeeChart Java Chart for Android – a charting component library used to assist in showing the historical parameter trend data;
2. Slick USB 2 Serial Library – an interface library component that allows communications between the CareGuide Display Software and the Android-Linux Kernel USB driver.

Both of these components are explicitly validated through System V&V testing.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

16.5 Off the Shelf Software

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet software contains off-the-shelf (OTS) software. All of the OTS software that execute during runtime have been validated through unit testing and/or system V&V testing. The components are listed in Table 2 and are described in the sections below.

End users are not required to install nor maintain the OTS software. The same software image is loaded on each production device. This ensures that the same software (including the OTS software) that was validated is on every Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet system. This also mediates the issue of software upgrades and patches at the operating system level since the device is dedicated to the single task of Mobile CareGuide™ and only upgraded by RMI authorized staff. The only documentation or training of OTS software required by the operator is turning on the tablet itself (see Section 13 of this filing).

Table 2. Off the shelf (OTS) software elements for Multi-Parameter Mobile CareGuide™ 3100 Oximeter

OTS Name	Company / Source	Function	Validation
Android OS	Android, Inc. www.android.com (provided through respective tablet manufacturers: Acer and Asus) Release 4.0 and 4.3	Operating System	Unit test; System V&V
Android Task Manager	Smartwho play.google.com/store/apps	OS task manager	For development use only
Android APK Installer	Potente Mobile Apps play.google.com/store/apps	OS application installer	For development use only
ES File Explorer	ES APP Group play.google.com/store/apps	OS file browser	For development use only
Desktop VisualizeR	Bii, Inc. play.google.com/store/apps	Assign icon to application and desktop	For development use only
Dr. Web Light	Doctor Web, Ltd. play.google.com/store/apps	Anti-virus software	System V&V
USB Host Diagnostics	Chainfire play.google.com/store/apps	Service software	For development use only
SureLock Kiosk Mode Lockdown	42Gears Mobility Systems www.42gears.com	Lockdown software	System V&V

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

OTS Name	Company / Source	Function	Validation
TeeChart Java Chart for Android	Steema Software SL www.steema.com	Charting component library	Unit test; System V&V
Slick USB 2 Serial Library	Slickdev Labs www.slickdevlabs.com	USB library	Unit test; System V&V

16.5.1 Android OS

The Android OS is a commercially provided operating system. It is installed by the respective tablet manufacturer. It is not modified by Reflectance Medical and is tested as is. As shown in Figure 1, the Android OS consists of a Linux Kernel layer, the Android runtime layer, runtime libraries, an application framework and a set of applications. The elements in each of these layers that executes with the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet system are called out in Figure 1. There are additional elements which are loaded by the manufacturer and exist on the tablet but do not execute and therefore are not pertinent to the 3100 with Tablet product. For example, there is camera and Wi-Fi software but they are both disabled for the product.

The Android OS is implicitly validated through unit testing and System V&V of the product. Note that only certain releases of the Android OS have been validated (see Table 2) and there are mechanisms in place to prevent the end-user from upgrading or altering the OS (see Section 16.5.2).

16.5.2 Lockdown Software (SRS 2.6.5)

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet contains a software package, “SureLock”, that maintains the system in the same state as when it was installed in the factory. This 3rd party application is installed and enabled by Reflectance Medical at time of factory installation.

As shown in Figure 1, it takes over the functions of Activity Manager, Window Manager and Resource Manager with the Android OS, preventing certain activities. Specifically, SureLock

1. Ensures that only the CareGuide Display software can be executed by the end user; no other application software can be executed;
2. Disables all external communications (Wi-Fi, Bluetooth, Camera) allowing only the USB communications to the sensor to work;
3. Disables the ability to load any new software applications;
4. Disables the ability to make changes or update the operating system software;
5. Disables the ability to change Android settings

There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.

The SureLock software is explicitly validated through System V&V of the product.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

16.5.3 Utility Tools

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet contains software applications that are not used by the end-user but are shipped with the product. These software applications are used by Reflectance Medical for initial configuration or for servicing the product upon failure.

The applications as indicated in Figure 1 and Table 2 are:

1. USB Host Diagnostics – provides diagnostic test of USB port communications; used for service only ;
2. Dr. Web Light – provides anti-virus software to insure no viruses are present before shipping the product to the end-user; used for installation only;
3. Android Task Manager – provides details on applications and drivers executing on the tablet; used for service only;
4. APK Installer – utility to load CareGuide Display application software onto tablet; used for installation only;
5. Desktop Visualizer - utility to assign an icon to the CareGuide Display and create a short-cut for the Android home display; used for installation only;
6. ES File Explorer – an Android file browser; used for service only.

None of these applications run when the sensor is in-use. Therefore they are not included in any unit testing or System V&V testing.

16.5.4 Patient Data Access

While the CareGuide Display software is actively running on the tablet, the current patient id and their most recent history of SmO₂ and pH_m values are visible. It is expected that the clinical site will maintain physical security to only allow authorized personnel to view the display. There is only one protected health information (PHI) identifier accessible: the patient id.

Past patient history stored on the Tablet is not accessible to the end-user because of the SureLock software (Section 16.5.2) which prevents someone from running any other Android application to view the data. Past history is available to authorized end-users by extracting the data from the 3100 sensor itself using an off-line software provided by Reflectance Medical (identical to predicate K130079). The tool runs on a PC under Windows and only provides the end-user with a file containing the patient id and time-stamped values for the SmO₂ and pH_m measurements. There is only one protected health information (PHI) identifier accessible: the patient id.

All sensors and tablets that are returned to RMI after clinical use have all patient data related information erased from their respective storage.

16.6 Software Life Cycle

The Software Life Cycle for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter sensor is described in the predicate filing, K130079.

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Document Number	Document Name	Purpose	Precedent Document	Submittal Location
MPMRA-002	Risk Analysis	Risk Analysis for CareGuide	MPMDIR-001	Section 16: MPMRA-002 Mobile CareGuide™ with Tablet Risk Analysis
MPMFMEA-001	Failure Modes Effect Analysis	FMEA for CareGuide (all failures)	MCGMRD-001; MPMRA-002; MPMSRS-002; MCGHRS-001	Section 16: MPMFMEA-001 Mobile CareGuide™ Failure Modes Effect Analysis
MPMSWV-002	CareGuide™ Clinical Software Validation Protocol	System level testing for clinical software	MPMSRS-002; MPMSDD-002	Section 16: MPMSWV-002 Mobile CareGuide™ 3100 Clinical Tablet Software V&V Test results; There are two documents: 1. test results using a 7” Tablet (OS 4.3) ; 2. test results using a 10” Tablet (OS 4.0) .
MPMUTD-003	Mobile CareGuide™ Android Software Unit Test Document	Unit testing for clinical software	MPMSRS-002; MPMSDD-002	Section 16: MPMUTD-003 Mobile CareGuide™ 3100 Android Software Unit Test results; There are two documents: 1. test results using a 7” Tablet (OS 4.3) ; 2. test results using a 10” Tablet (OS 4.0) .
MCGCMP-001	Mobile CareGuide™ Communications Protocol Document	Interface specification between CareGuide and Display devices	MCGSDD-001; MPMSDD-001	Section 16: MCGCMP-001 Mobile CareGuide™ Communications Protocol Document
MPMTRC-002	Multi-parameter Mobile CareGuide™ 3100 Traceability Matrix	Traceability between all requirements, specifications and testing	--	Section 16 MPMTRC-002 Multi-parameter Mobile CareGuide™ 3100 with Tablet Traceability Matrix Document

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Document Number	Document Name	Purpose	Precedent Document	Submittal Location
MCGSWB-002	Mobile CareGuide™ Clinical Tablet Software Build Process	Process steps to build Mobile CareGuide Tablet display software	MPMSDD-002	Records are available on file at RMI.

16.9 Traceability Matrix

For the Multi-parameter Mobile CareGuide 3100 with Tablet, all requirements were mapped to specifications which were mapped to testing protocols. The document, MPMTRC-002 Multi-parameter Mobile CareGuide™ 3100 with Tablet Traceability Matrix, included in this section shows all of the linkages. A high level roadmap of the linkages is included in the document and also replicated in Figure 3 below. Note that the Multi-parameter Mobile CareGuide™ 3100 had no changes in optics and CPU hardware and the 3100 sensor software from its predecessors K130079 and K122645, so the Traceability Matrix points to hardware and software documents and testing protocols from those respective submissions.

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510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

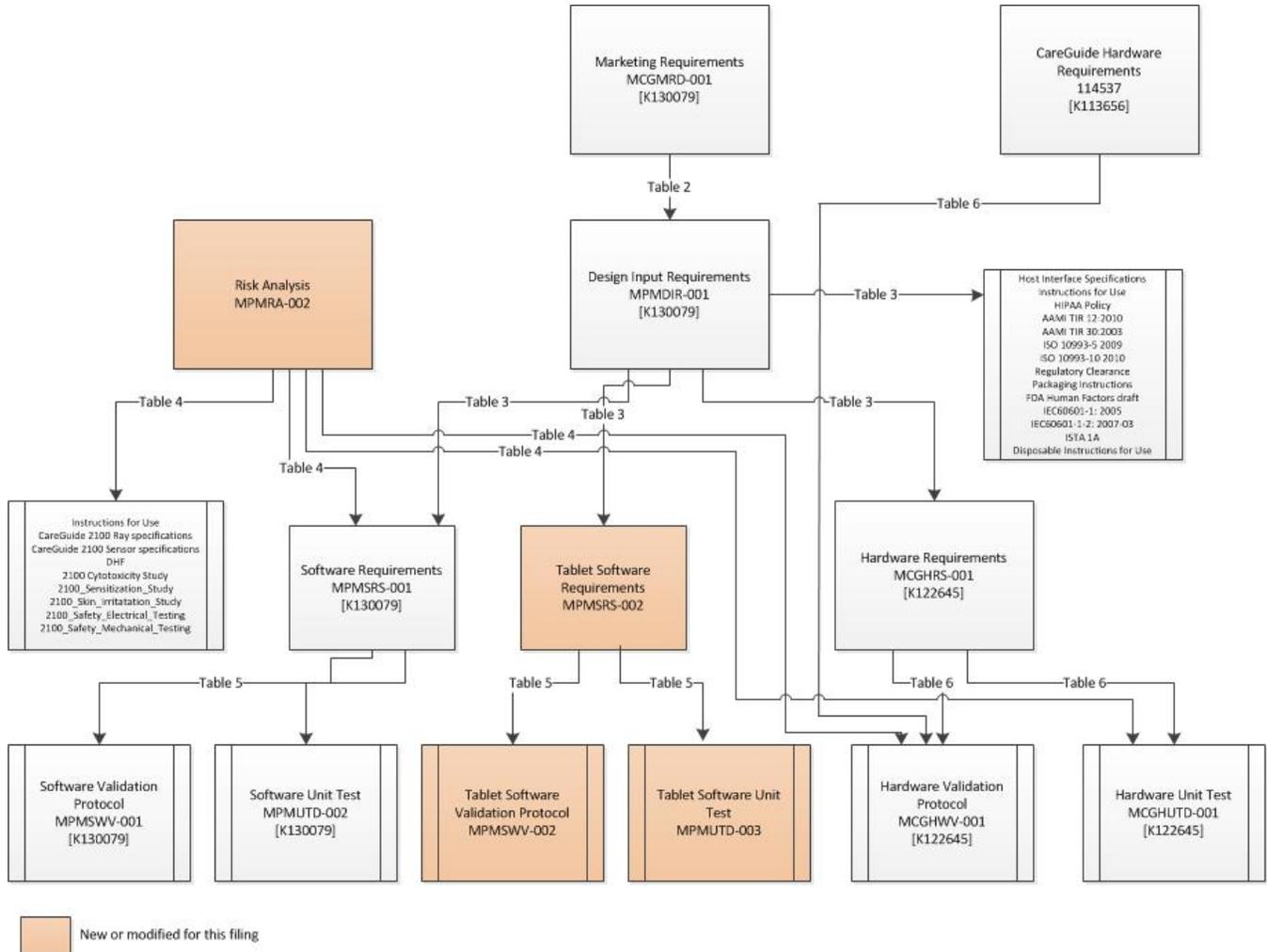


Figure 3. Compatibility Matrix Roadmap

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Section 16: Software

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Section 16

Software Overview

Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet – Software Description

16.1 Software Overview

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet software contains software for the sensor and for the Android tablet. The sensor software is identical to the predicate device software, Multi-Parameter Mobile CareGuide™ 3100 Oximeter (K130079). The sensor controls the LEDs and detector, checks the sensor, acquires spectral data, calculates SmO2 and pHm, communicates the SmO2 and pHm values and sensor states conditions to the external 3rd party monitoring device (in the case of the predicate K130079) or an Android tablet (in the case of this filing), checks thermistors for safe temperature levels, stores SmO2 and pHm values and spectral data, and communicates with external service software to control settings, downloads stored data and upgrades the device.

Refer to the K130079 filing for further details on the sensor software.

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter Android Tablet software is the major modification for this filing. It is similar in functionality to the software supporting the interface with the sensor and display parameter values and trends as the predicate device: CareGuide™ 1100 Oximeter (K113656). The Android Tablet software consists of Android operating system, CareGuide display software, lock down software and utility tools.

Software language:

<p>Computing Elements</p>	<p>The 3100 sensor software runs on an embedded main processor with algorithms in "C", identical to the 3100 (K130079).</p> <p>The 3100 Tablet software runs on a commercial tablet with USB communications and GUI components in "Java" using Android SDK.</p>
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16.2 Level of concern

The *level of concern* for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is **Moderate** prior to mitigation of hazards (see Section 16 – Risk Analysis and FMEA documents): a failure of the Software Device could result in minor injury, either to a patient or to a user of the

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510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

device.

Table 1. Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet Level of Concern Assessment

	Question	Response
Major	Does the Software Device qualify as Blood Establishment Computer Software?	No
	Is the Software Device intended to be used in combination with a drug or biologic?	No
	Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
	Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? a. Does the Software Device control a life supporting or life sustaining function? b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	No
Moderate	Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No
	Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	Yes
	Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	No

Risk Analysis and Failure Mode Effect Analysis were conducted consistent with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005), FDA guidance on General Principles of Software Validation, January 11, 2002 and Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, September 9, 1999.

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510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Roadmap to Software documentation: A listing of RMI Software documentation is provided in Section 16.7.

16.3 Software Overview

Software Design:

The Android Tablet software consists of 4 components (further described below):

1. Android operating system: Android OS 4.0 and OS 4.3 have been validated. The OS is used 'as is' from the tablet manufacturer.
2. CareGuide display software: consists of three components: 1. Communication software to interface with the sensor via the USB port; 2. Display software to start/pause/stop the sensor, enter patient identification, perform a sensor check, display real-time SmO2 and pHm values, display a trend of historical SmO2 and pHm values and display any fault conditions reported by the sensor; 3. Store historical trend data and fault conditions in a text file.
3. Lock down software: a 3rd party software package: SureLock from 42Gears Mobility Systems Pvt Ltd is installed on the Android tablet. It restricts the user to only be able to run the CareGuide 3100 display software application. It disables the ability to load any new software applications, or any operating system updates to the tablet. It disables all external communications (Wi-Fi, Bluetooth). There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.
4. Utility tools: there are a set of 3rd party tools that are installed as part of the installation process for the Mobile CareGuide Android Tablet. These tools include APK installer, task manager, file explorer, screen shortcut creator, anti-virus software and USB test program. None of these applications are accessible to the end-user and are used only for installation or service purposes.

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter Software design (Section 16: MPMSDD-002 Mobile CareGuide™ Android Software Design Document) high order components including native Android software are shown in Figure 1 below. A more detailed breakdown of the CareGuide Display software is shown in Figure 2.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

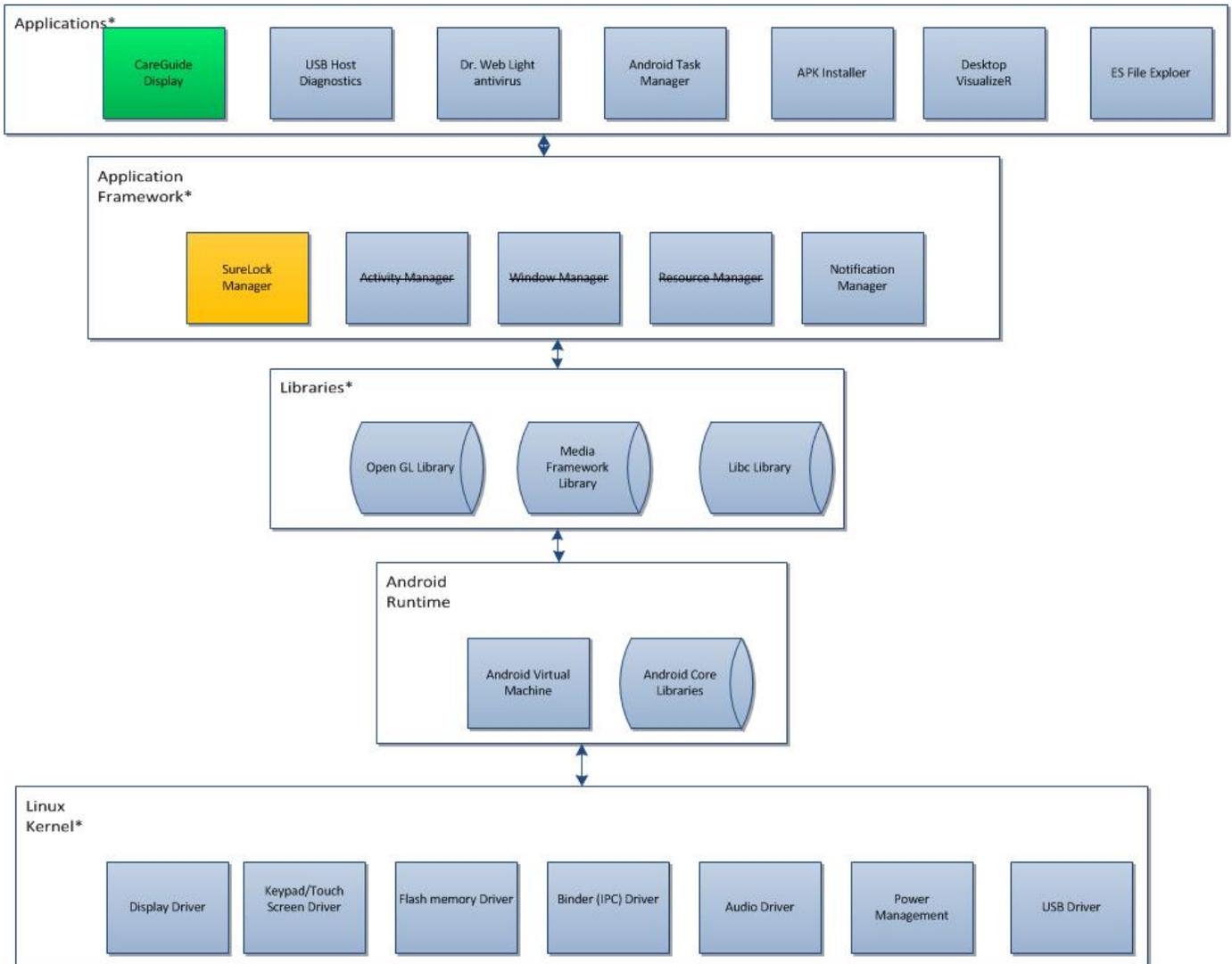


Figure 1. Multi-Parameter Mobile CareGuide™ 3100 Oximeter Android Tablet Software Major Components:

Applications* - additional non-executing applications exist (e.g. Contacts);

Application Framework* - additional non-executing managers exist (e.g. Telephony Manager)

Libraries* - additional non-executing libraries exist (e.g. WebKit);

Linux Kernel* – additional non-executing kernel drivers exist (e.g. Camera).

Note: The corresponding requirement section of the MPMSRS-001 Mobile CareGuide™ Software Requirements Specification document (Section 16) is indicated by the syntax [SRS x.y.z], where x.y.z is the corresponding requirement(s).

Pages 337 through 338 redacted for the following reasons:

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510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

16.5 Off the Shelf Software

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet software contains off-the-shelf (OTS) software. All of the OTS software that execute during runtime have been validated through unit testing and/or system V&V testing. The components are listed in Table 2 and are described in the sections below.

End users are not required to install nor maintain the OTS software. The same software image is loaded on each production device. This ensures that the same software (including the OTS software) that was validated is on every Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet system. This also mediates the issue of software upgrades and patches at the operating system level since the device is dedicated to the single task of Mobile CareGuide™ and only upgraded by RMI authorized staff. The only documentation or training of OTS software required by the operator is turning on the tablet itself (see Section 13 of this filing).

Table 2. Off the shelf (OTS) software elements for Multi-Parameter Mobile CareGuide™ 3100 Oximeter

OTS Name	Company / Source	Function	Validation
Android OS	Android, Inc. www.android.com (provided through respective tablet manufacturers: Acer and Asus) Release 4.0 and 4.3	Operating System	Unit test; System V&V
Android Task Manager	Smartwho play.google.com/store/apps	OS task manager	For development use only
Android APK Installer	Potente Mobile Apps play.google.com/store/apps	OS application installer	For development use only
ES File Explorer	ES APP Group play.google.com/store/apps	OS file browser	For development use only
Desktop VisualizeR	Bii, Inc. play.google.com/store/apps	Assign icon to application and desktop	For development use only
Dr. Web Light	Doctor Web, Ltd. play.google.com/store/apps	Anti-virus software	System V&V
USB Host Diagnostics	Chainfire play.google.com/store/apps	Service software	For development use only
SureLock Kiosk Mode Lockdown	42Gears Mobility Systems www.42gears.com	Lockdown software	System V&V

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

OTS Name	Company / Source	Function	Validation
TeeChart Java Chart for Android	Steema Software SL www.steema.com	Charting component library	Unit test; System V&V
Slick USB 2 Serial Library	Slickdev Labs www.slickdevlabs.com	USB library	Unit test; System V&V

16.5.1 Android OS

The Android OS is a commercially provided operating system. It is installed by the respective tablet manufacturer. It is not modified by Reflectance Medical and is tested as is. As shown in Figure 1, the Android OS consists of a Linux Kernel layer, the Android runtime layer, runtime libraries, an application framework and a set of applications. The elements in each of these layers that executes with the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet system are called out in Figure 1. There are additional elements which are loaded by the manufacturer and exist on the tablet but do not execute and therefore are not pertinent to the 3100 with Tablet product. For example, there is camera and Wi-Fi software but they are both disabled for the product.

The Android OS is implicitly validated through unit testing and System V&V of the product. Note that only certain releases of the Android OS have been validated (see Table 2) and there are mechanisms in place to prevent the end-user from upgrading or altering the OS (see Section 16.5.2).

16.5.2 Lockdown Software (SRS 2.6.5)

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet contains a software package, “SureLock”, that maintains the system in the same state as when it was installed in the factory. This 3rd party application is installed and enabled by Reflectance Medical at time of factory installation.

As shown in Figure 1, it takes over the functions of Activity Manager, Window Manager and Resource Manager with the Android OS, preventing certain activities. Specifically, SureLock

1. Ensures that only the CareGuide Display software can be executed by the end user; no other application software can be executed;
2. Disables all external communications (Wi-Fi, Bluetooth, Camera) allowing only the USB communications to the sensor to work;
3. Disables the ability to load any new software applications;
4. Disables the ability to make changes or update the operating system software;
5. Disables the ability to change Android settings

There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.

The SureLock software is explicitly validated through System V&V of the product.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

16.5.3 Utility Tools

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet contains software applications that are not used by the end-user but are shipped with the product. These software applications are used by Reflectance Medical for initial configuration or for servicing the product upon failure.

The applications as indicated in Figure 1 and Table 2 are:

1. USB Host Diagnostics – provides diagnostic test of USB port communications; used for service only ;
2. Dr. Web Light – provides anti-virus software to insure no viruses are present before shipping the product to the end-user; used for installation only;
3. Android Task Manager – provides details on applications and drivers executing on the tablet; used for service only;
4. APK Installer – utility to load CareGuide Display application software onto tablet; used for installation only;
5. Desktop VisualizerR - utility to assign an icon to the CareGuide Display and create a short-cut for the Android home display; used for installation only;
6. ES File Explorer – an Android file browser; used for service only.

None of these applications run when the sensor is in-use. Therefore they are not included in any unit testing or System V&V testing.

16.5.4 Patient Data Access

While the CareGuide Display software is actively running on the tablet, the current patient id and their most recent history of SmO₂ and pH_m values are visible. It is expected that the clinical site will maintain physical security to only allow authorized personnel to view the display. There is only one protected health information (PHI) identifier accessible: the patient id.

Past patient history stored on the Tablet is not accessible to the end-user because of the SureLock software (Section 16.5.2) which prevents someone from running any other Android application to view the data. Past history is available to authorized end-users by extracting the data from the 3100 sensor itself using an off-line software provided by Reflectance Medical (identical to predicate K130079). The tool runs on a PC under Windows and only provides the end-user with a file containing the patient id and time-stamped values for the SmO₂ and pH_m measurements. There is only one protected health information (PHI) identifier accessible: the patient id.

All sensors and tablets that are returned to RMI after clinical use have all patient data related information erased from their respective storage.

16.6 Software Life Cycle

The Software Life Cycle for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter sensor is described in the predicate filing, K130079.

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510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Document Number	Document Name	Purpose	Precedent Document	Submittal Location
MPMRA-002	Risk Analysis	Risk Analysis for CareGuide	MPMDIR-001	Section 16: MPMRA-002 Mobile CareGuide™ with Tablet Risk Analysis
MPMFMEA-001	Failure Modes Effect Analysis	FMEA for CareGuide (all failures)	MCGMRD-001; MPMRA-002; MPMSRS-002; MCGHRS-001	Section 16: MPMFMEA-001 Mobile CareGuide™ Failure Modes Effect Analysis
MPMSWV-002	CareGuide™ Clinical Software Validation Protocol	System level testing for clinical software	MPMSRS-002; MPMSDD-002	Section 16: MPMSWV-002 Mobile CareGuide™ 3100 Clinical Tablet Software V&V Test results; There are two documents: 1. test results using a 7” Tablet (OS 4.3) ; 2. test results using a 10” Tablet (OS 4.0) .
MPMUTD-003	Mobile CareGuide™ Android Software Unit Test Document	Unit testing for clinical software	MPMSRS-002; MPMSDD-002	Section 16: MPMUTD-003 Mobile CareGuide™ 3100 Android Software Unit Test results; There are two documents: 1. test results using a 7” Tablet (OS 4.3) ; 2. test results using a 10” Tablet (OS 4.0) .
MCGCMP-001	Mobile CareGuide™ Communications Protocol Document	Interface specification between CareGuide and Display devices	MCGSDD-001; MPMSDD-001	Section 16: MCGCMP-001 Mobile CareGuide™ Communications Protocol Document
MPMTRC-002	Multi-parameter Mobile CareGuide™ 3100 Traceability Matrix	Traceability between all requirements, specifications and testing	--	Section 16 MPMTRC-002 Multi-parameter Mobile CareGuide™ 3100 with Tablet Traceability Matrix Document

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Document Number	Document Name	Purpose	Precedent Document	Submittal Location
MCGSWB-002	Mobile CareGuide™ Clinical Tablet Software Build Process	Process steps to build Mobile CareGuide Tablet display software	MPMSDD-002	Records are available on file at RMI.

16.9 Traceability Matrix

For the Multi-parameter Mobile CareGuide 3100 with Tablet, all requirements were mapped to specifications which were mapped to testing protocols. The document, MPMTRC-002 Multi-parameter Mobile CareGuide™ 3100 with Tablet Traceability Matrix, included in this section shows all of the linkages. A high level roadmap of the linkages is included in the document and also replicated in Figure 3 below. Note that the Multi-parameter Mobile CareGuide™ 3100 had no changes in optics and CPU hardware and the 3100 sensor software from its predecessors K130079 and K122645, so the Traceability Matrix points to hardware and software documents and testing protocols from those respective submissions.

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510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

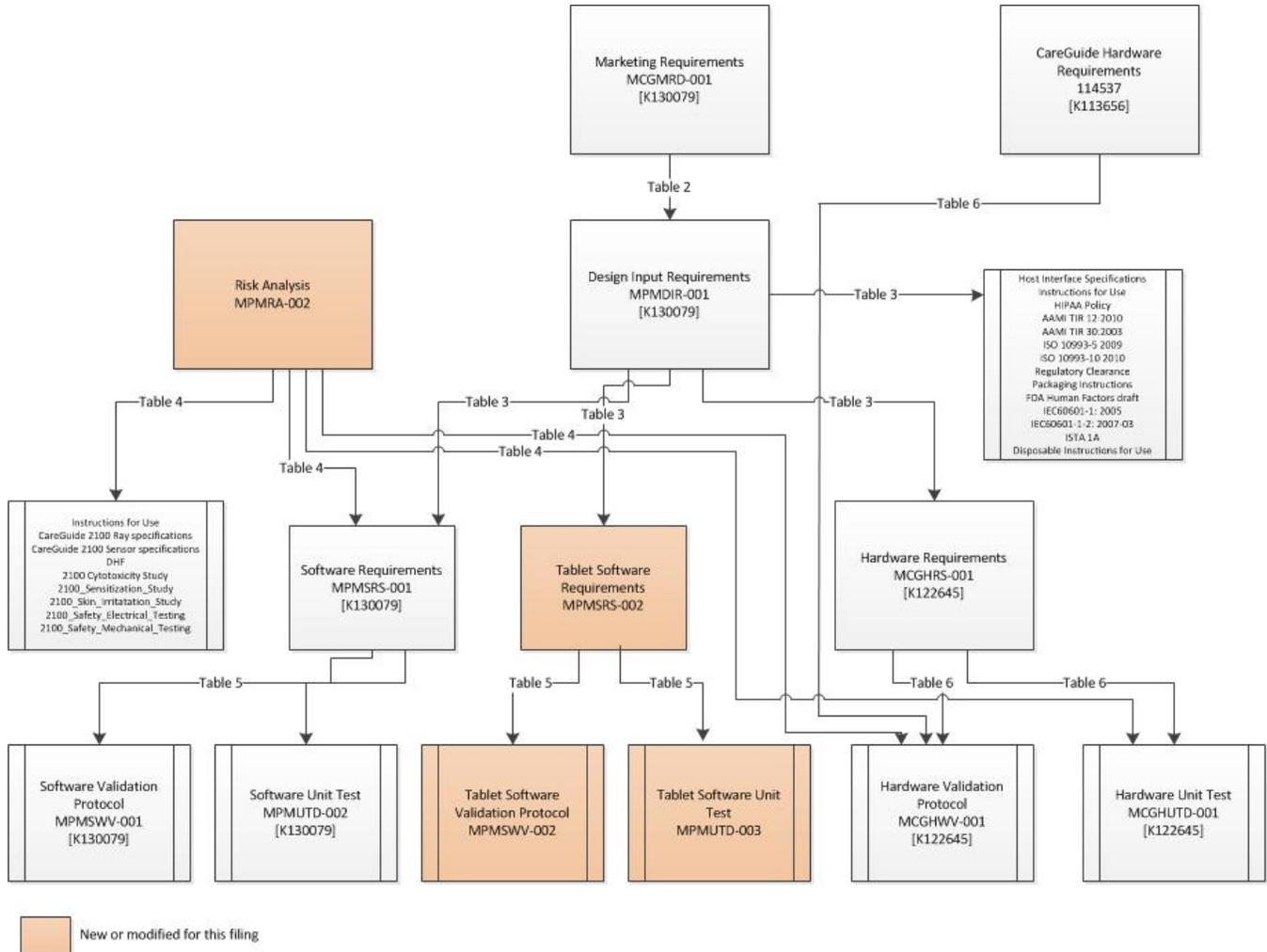


Figure 3. Compatibility Matrix Roadmap

Page 348 redacted for the following reason:

(b)(6)-Personal Privacy Information

Table of Contents

1. INTRODUCTION.....	3
1.1. PURPOSE	3
1.2. SCOPE	3
1.3. REFERENCES DOCUMENTS	4
1.3.1. General Documents	4
1.3.2. Project Specific Documents	4
2. FUNCTIONAL AND PHYSICAL INTERFACE REQUIREMENTS.....	4
3. SOFTWARE AND USER INTERFACE REQUIREMENTS.....	6
4. PERFORMANCE REQUIREMENTS	8
4.1. CALIBRATION AND SENSOR CHECK	9
4.2. COMMUNICATIONS AND STATE MACHINE.....	9
5. ACCESSORIES, SUPPLIES AND EQUIPMENT	10
6. MATERIAL CONSIDERATIONS	10
7. CLINICAL DESCRIPTION.....	10
7.1. PRIMARY MARKET.....	10
7.2. USER PROFILE.....	10
7.3. DURATION OF USE	10
8. INDUSTRIAL DESIGN REQUIREMENTS	11
9. PHYSICAL REQUIREMENTS.....	11
10. SHELF LIFE REQUIREMENTS	11
11. LABELING AND PACKAGING REQUIREMENTS	11
12. REGULATIONS AND STANDARDS REQUIREMENTS.....	12
12.1. TARGET GEOGRAPHIC MARKET.....	12
12.2. ANTICIPATED REGULATORY FILINGS.....	12
13. HUMAN FACTORS REQUIREMENTS	12
14. SAFETY REQUIREMENTS.....	13
16. ENVIRONMENT & STORAGE REQUIREMENTS.....	14
17. TRANSPORTATION/SHIPPING/HANDLING REQUIREMENTS.	15
18. INSTALLATION REQUIREMENTS	15
19. PRODUCT SUPPORT REQUIREMENTS	15

1. Introduction

1.1. Purpose

This document defines the expected performance and functionality of the software and hardware of the Multi-parameter Mobile CareGuide™ 3100 Oximeter.

These requirements are derived from the top level, end user requirements, as defined by the Marketing Requirements Document (MCGMRD) and numerous meetings. This document is intended to serve as a guide for the engineering, development and implementation of the associated system architecture and design.

This project described in this document is to take the existing Mobile CareGuide 2100 Oximeter software, and add to it, a software algorithm to calculate muscle pH “pHm”. The Multi-parameter Mobile CareGuide 3100 hardware, battery charger and disposable Ray/Cradle are identical to the Mobile CareGuide 2100.

1.2. Scope

This scope of the project will include the following:

- a) Analyzing the software algorithms in the existing Mobile CareGuide 2100 Oximeter.
- b) Creating, testing and integrated algorithms to derive pHm from the acquired spectral data.
- c) Formalizing, documenting, and validating the software and firmware requirements to meet all FDA regulatory and other target country regulatory requirements, as applicable, including traceability.
- d) Systems integration and testing of software aspects of the display unit(s), which will include a multi-parameter monitoring device, an Android tablet, and a Windows PC or tablet.

Specific acronyms and abbreviations used in this document are:

Acronym	Description
CE	Conformité Européene
LED	Light Emitting Diode
MCG	Mobile CareGuide
MPM	Multi-parameter Mobile CareGuide
PC	Personal Computer

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- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information

Table of Contents

1. INTRODUCTION.....	3
1.1. PURPOSE	3
1.2. SCOPE	3
1.3. REFERENCES DOCUMENTS	4
1.3.1. General Documents	4
1.3.2. Project Specific Documents	4
2. FUNCTIONAL AND PHYSICAL INTERFACE REQUIREMENTS.....	4
3. SOFTWARE AND USER INTERFACE REQUIREMENTS.....	6
4. PERFORMANCE REQUIREMENTS	8
4.1. CALIBRATION AND SENSOR CHECK	9
4.2. COMMUNICATIONS AND STATE MACHINE.....	9
5. ACCESSORIES, SUPPLIES AND EQUIPMENT	10
6. MATERIAL CONSIDERATIONS	10
7. CLINICAL DESCRIPTION.....	10
7.1. PRIMARY MARKET.....	10
7.2. USER PROFILE.....	10
7.3. DURATION OF USE	10
8. INDUSTRIAL DESIGN REQUIREMENTS	11
9. PHYSICAL REQUIREMENTS.....	11
10. SHELF LIFE REQUIREMENTS	11
11. LABELING AND PACKAGING REQUIREMENTS.....	11
12. REGULATIONS AND STANDARDS REQUIREMENTS.....	12
12.1. TARGET GEOGRAPHIC MARKET.....	12
12.2. ANTICIPATED REGULATORY FILINGS.....	12
13. HUMAN FACTORS REQUIREMENTS	12
14. SAFETY REQUIREMENTS.....	13
16. ENVIRONMENT & STORAGE REQUIREMENTS.....	14
17. TRANSPORTATION/SHIPPING/HANDLING REQUIREMENTS.	15
18. INSTALLATION REQUIREMENTS.....	15
19. PRODUCT SUPPORT REQUIREMENTS	15

1. Introduction

1.1. Purpose

This document defines the expected performance and functionality of the software and hardware of the Multi-parameter Mobile CareGuide™ 3100 Oximeter.

These requirements are derived from the top level, end user requirements, as defined by the Marketing Requirements Document (MCGMRD) and numerous meetings. This document is intended to serve as a guide for the engineering, development and implementation of the associated system architecture and design.

This project described in this document is to take the existing Mobile CareGuide 2100 Oximeter software, and add to it, a software algorithm to calculate muscle pH “pHm”. The Multi-parameter Mobile CareGuide 3100 hardware, battery charger and disposable Ray/Cradle are identical to the Mobile CareGuide 2100.

1.2. Scope

This scope of the project will include the following:

- a) Analyzing the software algorithms in the existing Mobile CareGuide 2100 Oximeter.
- b) Creating, testing and integrated algorithms to derive pHm from the acquired spectral data.
- c) Formalizing, documenting, and validating the software and firmware requirements to meet all FDA regulatory and other target country regulatory requirements, as applicable, including traceability.
- d) Systems integration and testing of software aspects of the display unit(s), which will include a multi-parameter monitoring device, an Android tablet, and a Windows PC or tablet.

Specific acronyms and abbreviations used in this document are:

Acronym	Description
CE	Conformité Européene
LED	Light Emitting Diode
MCG	Mobile CareGuide
MPM	Multi-parameter Mobile CareGuide
PC	Personal Computer

Pages 366 through 378 redacted for the following reasons:

- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information



Table of Contents

1. Introduction	3
1.1. Purpose	3
1.2. Scope	3
1.3. Acronyms and Definition of Terms	4
1.4. References Documents	4
1.4.1 General Documents.....	4
1.4.2 Project Specific Documents	4
1.5. Document Overview	4
1.6. Notation	5
1.6.1 Requirements	5
2. Overall description	5
2.1. Product Perspective	5
2.1.1 System Interfaces	5
2.1.2 User Interfaces	6
2.1.3 Hardware Interfaces	6
2.1.4 Software Interfaces	6
2.1.5 Communications Interfaces	6
2.1.6 Memory Constraints.....	6
2.1.7 Operations.....	6
2.1.8 Site adaptation requirements	7
2.2. Product Functions	7
2.3. User Characteristics	7
2.4. Constraints	7
2.5. Assumptions and Dependencies	7
2.6. Mode/Function	8
2.6.1 Overall framework	8
2.6.2 Initialization and Sensor Check.....	8
2.6.3 Displaying Data	9
2.6.4 Tech Support.....	10
2.6.5 Lock Down	11

1. INTRODUCTION

1.1. Purpose

This document defines the expected performance and functionality of the software that will comprise the Android display software component of the Multi-parameter Mobile CareGuide™ 3100 Oximeter project.

The intended audiences for this SRS are personnel with the responsibility of specifying, designing, coding, testing, verifying, validating, or managing the development of the software. This document is intended to serve as a guide for the engineering, development and implementation of this software.

The requirements set forth in the following pages are derived from top level, end- user requirements that have been defined in the Mobile CareGuide Marketing Requirements Document (MCGMRD).

The main focus of the project described in this document is to describe software that will receive and display values generated by the Multi-parameter Mobile CareGuide 3100 Oximeter. There are no changes in the sensor hardware, sensor software, algorithms and the disposable ray/cradle.

1.2. Scope

This document will define the Android display software requirements for the Reflectance Medical Multi-parameter Mobile CareGuide 3100 Oximeter. The scope of this document will include the following:

- a) Formalizing, documenting, and validating the software requirements to meet all FDA regulatory requirements, including traceability;
- b) Design, implementation and test of the Android display software;
- c) Systems integration and testing of the Android display software with the Multi-parameter Mobile CareGuide 3100 Oximeter and its embedded software.

The Multi-parameter Mobile CareGuide 3100 Oximeter shall be designed and manufactured to comply with US FDA 21 CFR 820, 21 CFR 1040 subchapter J, and Council Directive 93/42/EEC with classification of:

United States: Class II (per 21 CFR, Part 860) [NTS00e:SRS:ef2],

European Union: Class IIb (per93/42/EEC, Annex IX)

United States: Class IV (per 21 CFR, Part 1040.10)

European Union: Class IV (per IEC 60825-1,8)

1.3. Acronyms and Definition of Terms

Term/Acronym	Description
LED	Light Emitting Diode
MPM	Multi-parameter Mobile CareGuide
pHm	Muscle tissue pH
SmO ₂	Oxygen Saturation of Muscle
Sensor	Combination of optics board and processing board
Tablet	Commercial Android Tablet
USB	Universal Serial Bus

1.4. References Documents

1.4.1 General Documents

Document # / Title	Revision
21 CFR, Part 820 U.S. FDA Quality System Regulation (QSR)	4/01/2008
U.S. FDA Design Control Guidance for Medical Device Manufacturers	3/11/1997
IEEE Recommended Practice for Software Requirements Specifications	Std 830-1998
Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	5/11/2005

1.4.2 Project Specific Documents

Document #	Title
MPMDIR-001	Multi-parameter Mobile CareGuide 3100 Design Input Requirements (referred to as MPM:DIR)
MPMRA-002	Multi-parameter Mobile CareGuide 3100 with Tablet Risk Analysis (referred to as MPMT:RA)
MCGCMP-001	Mobile CareGuide Communications Protocol

1.5. Document Overview

This document is organized according to the IEEE recommended practice for writing an SRS (see reference documents).

Section 1 – Introduction (brief introduction with purpose of the document & references).

Section 2 – Overall Description (product description & software description, is the platform for creating the specific requirements).

Section 3 – Specific Software Requirements (these are the testable requirements, and should adhere to the following IEEE recommendations for writing requirements: Concise, Complete, Unambiguous, Verifiable, Modifiable, and Traceable).

1.6. Notation

1.6.1 Requirements

Each statement of requirement is identified by a unique requirement number using the format <NAME>:SRS:#, where <Name> is the code name of the project. Parent requirements from parent documents (XXX) are marked as [NAME:XXX:#].

2. OVERALL DESCRIPTION

2.1. Product Perspective

The Multi-parameter Mobile CareGuide 3100 Oximeter will continuously and noninvasively determine values for muscle oxygen saturation (SmO₂) and muscle tissue ph (pHm). The Multi-parameter Mobile CareGuide 3100 Oximeter uses near infrared spectroscopy to determine hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. SmO₂ is an indication of tissue perfusion. The Multi-parameter Mobile CareGuide 3100 Oximeter will be operated by nurses and other trained medical staff.

2.1.1 System Interfaces

2.1.1.1 Ray

The Ray is the disposable interface between the Oximeter and the patient. The Ray provides an enclosure for the reusable Sensor and adhesive for attaching the Sensor to the patient. The Ray's flexible foam is designed to allow for a semi-custom fit to each patient's unique morphology at the shoulder, calf, or thigh.

2.1.1.2 Cradle

The Cradle provides a housing for a Sensor once it is inserted into a Ray at a controlled height above a known reflective surface. The Ray Cradle is used perform check of the Sensor within a Ray prior to each use, or after 72 hours form the last Sensor Check, when continually used on a patient. This check allows the Software to determine if all parts are still functioning properly

2.1.2 User Interfaces

The Android Display is a 3rd party computing device containing software which can display the generated data, user controls and error messages. It must be conformant with the Mobile CareGuide communications protocol (MCGCMP). It is referred to generically in this document as “Android Display”.

2.1.3 Hardware Interfaces

USB cable will be used to communicate between the Android Display and the Multi-parameter Mobile CareGuide 3100 Oximeter.

2.1.4 Software Interfaces

The Multi-parameter Mobile CareGuide 3100 Android Software turns on and off the Sensor. The Software receives and reports the patient data. All data analysis is performed by the Sensor itself. The Android Software directs the user through the use of the Oximeter and automates most functions. The software monitors the Oximeter for errors and provides advisories and instructions to the user if it cannot resolve the error through automation. Errors are logged for troubleshooting.

The Android Tablet contains 3rd party software that ‘locks down’ the Tablet. The device has a factory-installed version of the Android operating system, a limited set of Android applications, the CareGuide 3100 display software and a software locking application. The locking application only allows a single application, the CareGuide 3100 display application, to run. The user cannot load any new software applications, or any operating system updates to the tablet. There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.

2.1.5 Communications Interfaces

The Android Software communicates with the Sensor through a defined protocol across the Android tablet’s primary USB port. Based on user requests via the display interface, the Android Software commands the Sensor to initialize, perform sensor check, start an assay, stop/pause/restart an assay.

All external communications (Wi-Fi, Bluetooth) are disabled. The only communication channel enabled is the USB connection to the Sensor.

2.1.6 Memory Constraints

2.1.7 Operations

The software will support the following 2 operating modes:

- Normal user (default mode)

Pages 384 through 389 redacted for the following reasons:

- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information



Table of Contents

1. Introduction	3
1.1. Purpose	3
1.2. Scope	3
1.3. Acronyms and Definition of Terms	4
1.4. References Documents	4
1.4.1 General Documents.....	4
1.4.2 Project Specific Documents	4
1.5. Document Overview	4
1.6. Notation	5
1.6.1 Requirements	5
2. Overall description	5
2.1. Product Perspective	5
2.1.1 System Interfaces	5
2.1.2 User Interfaces	6
2.1.3 Hardware Interfaces	6
2.1.4 Software Interfaces	6
2.1.5 Communications Interfaces	6
2.1.6 Memory Constraints.....	6
2.1.7 Operations.....	6
2.1.8 Site adaptation requirements	7
2.2. Product Functions	7
2.3. User Characteristics	7
2.4. Constraints	7
2.5. Assumptions and Dependencies	7
2.6. Mode/Function	8
2.6.1 Overall framework	8
2.6.2 Initialization and Sensor Check.....	8
2.6.3 Displaying Data	9
2.6.4 Tech Support.....	10
2.6.5 Lock Down	11

1. INTRODUCTION

1.1. Purpose

This document defines the expected performance and functionality of the software that will comprise the Android display software component of the Multi-parameter Mobile CareGuide™ 3100 Oximeter project.

The intended audiences for this SRS are personnel with the responsibility of specifying, designing, coding, testing, verifying, validating, or managing the development of the software. This document is intended to serve as a guide for the engineering, development and implementation of this software.

The requirements set forth in the following pages are derived from top level, end- user requirements that have been defined in the Mobile CareGuide Marketing Requirements Document (MCGMRD).

The main focus of the project described in this document is to describe software that will receive and display values generated by the Multi-parameter Mobile CareGuide 3100 Oximeter. There are no changes in the sensor hardware, sensor software, algorithms and the disposable ray/cradle.

1.2. Scope

This document will define the Android display software requirements for the Reflectance Medical Multi-parameter Mobile CareGuide 3100 Oximeter. The scope of this document will include the following:

- a) Formalizing, documenting, and validating the software requirements to meet all FDA regulatory requirements, including traceability;
- b) Design, implementation and test of the Android display software;
- c) Systems integration and testing of the Android display software with the Multi-parameter Mobile CareGuide 3100 Oximeter and its embedded software.

The Multi-parameter Mobile CareGuide 3100 Oximeter shall be designed and manufactured to comply with US FDA 21 CFR 820, 21 CFR 1040 subchapter J, and Council Directive 93/42/EEC with classification of:

United States: Class II (per 21 CFR, Part 860) [NTS00e:SRS:ef2],

European Union: Class IIb (per93/42/EEC, Annex IX)

United States: Class IV (per 21 CFR, Part 1040.10)

European Union: Class IV (per IEC 60825-1,8)

1.3. Acronyms and Definition of Terms

Term/Acronym	Description
LED	Light Emitting Diode
MPM	Multi-parameter Mobile CareGuide
pHm	Muscle tissue pH
SmO ₂	Oxygen Saturation of Muscle
Sensor	Combination of optics board and processing board
Tablet	Commercial Android Tablet
USB	Universal Serial Bus

1.4. References Documents

1.4.1 General Documents

Document # / Title	Revision
21 CFR, Part 820 U.S. FDA Quality System Regulation (QSR)	4/01/2008
U.S. FDA Design Control Guidance for Medical Device Manufacturers	3/11/1997
IEEE Recommended Practice for Software Requirements Specifications	Std 830-1998
Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	5/11/2005

1.4.2 Project Specific Documents

Document #	Title
MPMDIR-001	Multi-parameter Mobile CareGuide 3100 Design Input Requirements (referred to as MPM:DIR)
MPMRA-002	Multi-parameter Mobile CareGuide 3100 with Tablet Risk Analysis (referred to as MPMT:RA)
MCGCMP-001	Mobile CareGuide Communications Protocol

1.5. Document Overview

This document is organized according to the IEEE recommended practice for writing an SRS (see reference documents).

Section 1 – Introduction (brief introduction with purpose of the document & references).

Section 2 – Overall Description (product description & software description, is the platform for creating the specific requirements).

Section 3 – Specific Software Requirements (these are the testable requirements, and should adhere to the following IEEE recommendations for writing requirements: Concise, Complete, Unambiguous, Verifiable, Modifiable, and Traceable).

1.6. Notation

1.6.1 Requirements

Each statement of requirement is identified by a unique requirement number using the format <NAME>:SRS:#, where <Name> is the code name of the project. Parent requirements from parent documents (XXX) are marked as [NAME:XXX:#].

2. OVERALL DESCRIPTION

2.1. Product Perspective

The Multi-parameter Mobile CareGuide 3100 Oximeter will continuously and noninvasively determine values for muscle oxygen saturation (SmO₂) and muscle tissue ph (pHm). The Multi-parameter Mobile CareGuide 3100 Oximeter uses near infrared spectroscopy to determine hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. SmO₂ is an indication of tissue perfusion. The Multi-parameter Mobile CareGuide 3100 Oximeter will be operated by nurses and other trained medical staff.

2.1.1 System Interfaces

2.1.1.1 Ray

The Ray is the disposable interface between the Oximeter and the patient. The Ray provides an enclosure for the reusable Sensor and adhesive for attaching the Sensor to the patient. The Ray's flexible foam is designed to allow for a semi-custom fit to each patient's unique morphology at the shoulder, calf, or thigh.

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The Android Display is a 3rd party computing device containing software which can display the generated data, user controls and error messages. It must be conformant with the Mobile CareGuide communications protocol (MCGCMP). It is referred to generically in this document as “Android Display”.

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The Android Software communicates with the Sensor through a defined protocol across the Android tablet’s primary USB port. Based on user requests via the display interface, the Android Software commands the Sensor to initialize, perform sensor check, start an assay, stop/pause/restart an assay.

All external communications (Wi-Fi, Bluetooth) are disabled. The only communication channel enabled is the USB connection to the Sensor.

2.1.6 Memory Constraints

2.1.7 Operations

The software will support the following 2 operating modes:

- Normal user (default mode)

Pages 395 through 400 redacted for the following reasons:

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(b)(6)-Personal Privacy Information

1. Table of Contents

2.	DOCUMENT DETAILS.....	4
2.1	Modification Log.....	4
2.2	Related Software & Documents	4
3.	SUMMARY.....	5
3.1	Document objectives	5
3.2	Acronyms and Definition of Terms	5
4.	ARCHITECTURE AND MAJOR MODULES	6
4.1	Graphic Overview	6
4.2	CareGuide Main UI Software.....	6
4.2.1	Overview.....	6
5.	DETAILED-LEVEL DESIGN	7
5.1	CareGuide Main UI Software.....	7
5.2	Overall Main Framework (SRS 2.6.1).....	7
5.2.1	MPM:SRS:2.6.1.1	7
5.2.2	MPM:SRS:2.6.1.2	8
5.2.3	MPM:SRS:2.6.1.3	8
5.2.4	MPM:SRS:2.6.1.4	8
5.2.5	MPM:SRS:2.6.1.5	8
5.2.6	MPM:SRS:2.6.1.6	9
5.2.7	MPM:SRS:2.6.1.7	9
5.2.8	MPM:SRS:2.6.1.8	9
5.2.9	MPM:SRS:2.6.1.9	9
5.2.10	MPM:SRS:2.6.1.10	9
5.2.11	Applicable Modules & Functions	9
5.3	Initialization & Sensor Checking (SRS 2.6.2)	10
5.3.1	MPM:SRS:2.6.2.1	10
5.3.2	MPM:SRS:2.6.2.2	10
5.3.3	MPM:SRS:2.6.2.3	12
5.3.4	MPM:SRS:2.6.2.4	12
5.3.5	MPM:SRS:2.6.2.5	12
5.3.6	MPM:SRS:2.6.2.6	13
5.3.7	Applicable Modules & Functions	14
5.4	Data Display/Run (SRS 2.6.3).....	14
5.4.1	MPM:SRS:2.6.3.1	14
5.4.2	MPM:SRS:2.6.3.2-5	14
5.4.3	MPM:SRS:2.6.3.6	15
5.4.4	MPM:SRS:2.6.3.7-8	15
5.4.5	MPM:SRS:2.6.3.9	16
5.4.6	MPM:SRS:2.6.3.10	16
5.4.7	MPM:SRS:2.6.3.11	16
5.4.8	MPM:SRS:2.6.3.12-13	16
5.4.9	MPM:SRS:2.6.3.14	17
5.4.10	Applicable Modules & Functions	17



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Title: Multi-parameter Mobile Care Guide™ 3100 with Tablet Software Design Document

Doc Number: MPMSDD-002

Originator: Steve Weisner

Revision: A

Date: 10/1/13

ECO: N.A.

5.5 Tech Support (SRS 2.6.4)..... 17

5.5.1 MPM:SRS:2.6.4.1-2 17

5.5.2 MPM:SRS:2.6.4.3 18

5.5.3 MPM:SRS:2.6.4.4 18

5.6 Lockdown (SRS 2.6.5) 18

5.6.1 MPM:SRS:2.6.5.1-5 18

2. DOCUMENT DETAILS

2.1 Modification Log

Version	Date	Comment	Updated By
A	10/1/2013	Initial Version	RD

2.2 Related Software & Documents

Description	Latest Revision
MPMDIR-001 Mobile CareGuide™ Design Input Requirements Document	Rev B
MPMSRS-002 Mobile CareGuide™ Android Software Requirements	Rev A
MPMFMEA-001 Mobile CareGuide™ Failure Modes Effect Analysis	Rev B
MPMRA-002 Mobile CareGuide™ with Tablet Risk Analysis	Rev A
MCGCMP-001 Mobile CareGuide™ Communications Protocol Document	Rev D

3. SUMMARY

3.1 Document objectives

This software design document serves two purposes:

Architecture & Major Modules is to depict the relationships among the *major* functional units in the Mobile CareGuide Android Display Software (CareGuide) including relationships to hardware and to data flows. A summary for each major functional unit is included.

Detailed Design expresses the representation of the major software components within each major module and contains more detailed information of each component including module or class descriptions and how each interconnects.

3.2 Acronyms and Definition of Terms

Acronym	Description
pHm	Muscle blood pH (acid/base balance)
SmO ₂	Muscle oxygen saturation
UI	Graphical User Interface
USB	Universal Serial Bus

Pages 405 through 418 redacted for the following reasons:

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1. Table of Contents

2.	DOCUMENT DETAILS.....	4
2.1	Modification Log.....	4
2.2	Related Software & Documents	4
3.	SUMMARY.....	5
3.1	Document objectives	5
3.2	Acronyms and Definition of Terms	5
4.	ARCHITECTURE AND MAJOR MODULES	6
4.1	Graphic Overview	6
4.2	CareGuide Main UI Software.....	6
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5.	DETAILED-LEVEL DESIGN	7
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5.2.2	MPM:SRS:2.6.1.2	8
5.2.3	MPM:SRS:2.6.1.3	8
5.2.4	MPM:SRS:2.6.1.4	8
5.2.5	MPM:SRS:2.6.1.5	8
5.2.6	MPM:SRS:2.6.1.6	9
5.2.7	MPM:SRS:2.6.1.7	9
5.2.8	MPM:SRS:2.6.1.8	9
5.2.9	MPM:SRS:2.6.1.9	9
5.2.10	MPM:SRS:2.6.1.10	9
5.2.11	Applicable Modules & Functions	9
5.3	Initialization & Sensor Checking (SRS 2.6.2)	10
5.3.1	MPM:SRS:2.6.2.1	10
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5.3.3	MPM:SRS:2.6.2.3	12
5.3.4	MPM:SRS:2.6.2.4	12
5.3.5	MPM:SRS:2.6.2.5	12
5.3.6	MPM:SRS:2.6.2.6	13
5.3.7	Applicable Modules & Functions	14
5.4	Data Display/Run (SRS 2.6.3).....	14
5.4.1	MPM:SRS:2.6.3.1	14
5.4.2	MPM:SRS:2.6.3.2-5	14
5.4.3	MPM:SRS:2.6.3.6	15
5.4.4	MPM:SRS:2.6.3.7-8	15
5.4.5	MPM:SRS:2.6.3.9	16
5.4.6	MPM:SRS:2.6.3.10	16
5.4.7	MPM:SRS:2.6.3.11	16
5.4.8	MPM:SRS:2.6.3.12-13	16
5.4.9	MPM:SRS:2.6.3.14	17
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5.5.1 MPM:SRS:2.6.4.1-2 17

5.5.2 MPM:SRS:2.6.4.3 18

5.5.3 MPM:SRS:2.6.4.4 18

5.6 Lockdown (SRS 2.6.5) 18

5.6.1 MPM:SRS:2.6.5.1-5 18

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Detailed Design expresses the representation of the major software components within each major module and contains more detailed information of each component including module or class descriptions and how each interconnects.

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Acronym	Description
pHm	Muscle blood pH (acid/base balance)
SmO ₂	Muscle oxygen saturation
UI	Graphical User Interface
USB	Universal Serial Bus

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sensor. Medical personnel are interested in the patient's SmO₂ and pH level because they are indications of tissue perfusion.

The Android Tablet is a 3rd party computing device containing software which can display the generated data, user controls and error messages. The Multi-parameter Mobile CareGuide 3100 Android Software turns on and off the Sensor. The Software receives and reports the patient data. All data analysis is performed by the Sensor itself. The Android Software directs the user through the use of the Oximeter and automates most functions. The software monitors the Oximeter for errors and provides advisories and instructions to the user if it cannot resolve the error through automation. Errors are logged for troubleshooting.

The Android Tablet contains 3rd party software that 'locks down' the Tablet. The device has a factory-installed version of the Android operating system, a limited set of Android applications, the CareGuide 3100 display software and a software locking application. The locking application only allows a single application, the CareGuide 3100 display application, to run. The user cannot load any new software applications, or any operating system updates to the tablet. There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.

References

Document # / Title
MCGMRD-001 Mobile CareGuide Marketing Requirements
ISO 14971:2007(E) Medical devices — Application of risk management to medical devices

2.0 Fault Tree



AND: This symbol represents multiple conditions that must exist simultaneously in order to create the described result



OR: This symbol suggests that any of multiple inputs could create the described result. Generally, the more AND conditions, then the better controlled the system is. However, all controls are not displayed in the chart and some controls are more effective than others. Therefore, the severity, probability and detectability are further defined in the risk analysis below.

Page 439 redacted for the following reason:

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3.0 Estimating Risk

The risk index associated with each identified fault or potential failure of the system is evaluated using the following three determinants described in the corresponding tables: severity, probability, and detectability. The final risk associated with the fault is defined as the product of the severity, probability and detectability and is listed as the RPN (risk probability number) in the risk analysis table.

The potential severity of the failure (weighing consequence of use or failure) based on the following scale:

SEVERITY (S)		
1	Negligible	Does not result in injury or product damage. May cause minor nuisance
2	Slight	Little or no potential of injury. Medical attention limited to self-care.
3	Marginal	Potential for injury requiring physician intervention.
4	Critical	Potential for death or serious injury that can be mitigated by physician intervention.
5	Catastrophic	Potential for death that cannot be readily mitigated by physician intervention.

The probability (likelihood) of the fault resulting in a hazardous condition of the severity described is estimated based on the following scale:

Probability (P)		
Probability Level	Description	Rate in events/device
1	Incredible	<1/100,000
2	Improbable	1/1000-1/100,000
3	Remote	1/100-1/1000
4	Occasional	1/10-1/100
5	Probable	1-1/10
6	Frequent	>1

The ability to detect and avert the various fault conditions prior to the described hazardous situation and its described effects is estimated using the detectability scale:

DETECTABILITY		
0.1	Very High	>90% of the time detected before hazardous condition
0.25	High	75 to 90% of the time detected before hazardous condition
0.5	Moderate	50 to 75% of the time detected before hazardous condition
0.75	Low	25 to 50% of the time detected before hazardous condition
1.0	Almost certain non-detection	0 to 25% of the time detected before hazardous condition

4.0 Evaluation of Risk

The risk is assigned a risk priority number (RPN) based on the product of the severity, probability and detectability. The table below graphically illustrates the relationships and illustrates the determination of the level of concern.

P					
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25
S	1	2	3	4	5

5.0 Risk Acceptability

The risk acceptability is assigned based on the analysis of the RPN as described above. The worst case RPN represents the risk acceptability for the system. The level of concern that results from evaluation of the mitigated system is assigned based on the table below.

Risk Acceptability	RPN range	Action Required
Acceptable	0.1 to <5	No specific action required.
Acceptable with special review & justification	5 to 9	Requires team review and client representative approval to proceed in development process. Such risk requires reduction of risk to levels as low as reasonably possible and may require risk/benefit analysis.
Substantial Concern	>9	Requires team review and corporate level acceptance of risk prior to proceeding with development. Such risk requires reduction of risk to levels as low as reasonably possible and requires risk/benefit analysis.

6.0 Risk Analysis

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on a third party device, which would interface with the Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a

hospital and during patient transport within the hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO₂ and pH_m, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.

The goals of monitoring as an adjunct to clinical decision-making is to directly or indirectly reduce the incidence of complications. This is based on the premise that unambiguous and accurate information, readily interpretable and available, will assist the physician in deciding on and initiating patient treatment. In such hospital/clinical environments, the physician typically relies on multiple monitors providing information on other physiologic parameters such as blood pressure, heart rate, ECG and arterial oxygen saturation. The physician relies on all these parameters, along with the patient's medical history and results from blood analysis and imaging techniques to treat or monitor the patient.

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sensor. Medical personnel are interested in the patient's SmO₂ and pH level because they are indications of tissue perfusion.

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OR: This symbol suggests that any of multiple inputs could create the described result. Generally, the more AND conditions, then the better controlled the system is. However, all controls are not displayed in the chart and some controls are more effective than others. Therefore, the severity, probability and detectability are further defined in the risk analysis below.

Page 453 redacted for the following reason:

(b)(4)-TS/CCI

3.0 Estimating Risk

The risk index associated with each identified fault or potential failure of the system is evaluated using the following three determinants described in the corresponding tables: severity, probability, and detectability. The final risk associated with the fault is defined as the product of the severity, probability and detectability and is listed as the RPN (risk probability number) in the risk analysis table.

The potential severity of the failure (weighing consequence of use or failure) based on the following scale:

SEVERITY (S)		
1	Negligible	Does not result in injury or product damage. May cause minor nuisance
2	Slight	Little or no potential of injury. Medical attention limited to self-care.
3	Marginal	Potential for injury requiring physician intervention.
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5	Catastrophic	Potential for death that cannot be readily mitigated by physician intervention.

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Probability (P)		
Probability Level	Description	Rate in events/device
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2	Improbable	1/1000-1/100,000
3	Remote	1/100-1/1000
4	Occasional	1/10-1/100
5	Probable	1-1/10
6	Frequent	>1

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DETECTABILITY		
0.1	Very High	>90% of the time detected before hazardous condition
0.25	High	75 to 90% of the time detected before hazardous condition
0.5	Moderate	50 to 75% of the time detected before hazardous condition
0.75	Low	25 to 50% of the time detected before hazardous condition
1.0	Almost certain non-detection	0 to 25% of the time detected before hazardous condition

4.0 Evaluation of Risk

The risk is assigned a risk priority number (RPN) based on the product of the severity, probability and detectability. The table below graphically illustrates the relationships and illustrates the determination of the level of concern.

P					
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25
S	1	2	3	4	5

5.0 Risk Acceptability

The risk acceptability is assigned based on the analysis of the RPN as described above. The worst case RPN represents the risk acceptability for the system. The level of concern that results from evaluation of the mitigated system is assigned based on the table below.

Risk Acceptability	RPN range	Action Required
Acceptable	0.1 to <5	No specific action required.
Acceptable with special review & justification	5 to 9	Requires team review and client representative approval to proceed in development process. Such risk requires reduction of risk to levels as low as reasonably possible and may require risk/benefit analysis.
Substantial Concern	>9	Requires team review and corporate level acceptance of risk prior to proceeding with development. Such risk requires reduction of risk to levels as low as reasonably possible and requires risk/benefit analysis.

6.0 Risk Analysis

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on a third party device, which would interface with the Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a

hospital and during patient transport within the hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO₂ and pH_m, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.

The goals of monitoring as an adjunct to clinical decision-making is to directly or indirectly reduce the incidence of complications. This is based on the premise that unambiguous and accurate information, readily interpretable and available, will assist the physician in deciding on and initiating patient treatment. In such hospital/clinical environments, the physician typically relies on multiple monitors providing information on other physiologic parameters such as blood pressure, heart rate, ECG and arterial oxygen saturation. The physician relies on all these parameters, along with the patient's medical history and results from blood analysis and imaging techniques to treat or monitor the patient.

Pages 457 through 464 redacted for the following reasons:

- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information

.Table Of Contents

1. INTRODUCTION.....2

2. RESPONSIBILITIES3

3. REFERENCES.....3

4. ESTIMATING RISK.....3

5. EVALUATION OF RISK5

6. LEVEL OF RISK.....5

7. FMEA.....6

8. LEVEL OF RISK.....23

TABLE OF TABLES

TABLE 1. SEVERITY (S)4

TABLE 2. PROBABILITY (P)4

TABLE 3. DETECTABILITY (D).....5

TABLE 4. RISK PRIORITY EVALUATION5

TABLE 5. LEVEL OF RISK6

TABLE 6. FMEA7

1. Introduction

The focus of this document will be to review the risk in a bottom up approach from a device perspective, and is intended to be a design Failure Modes and Effects Analysis (FMEA). The intent of this document is to evaluate the system based on design features as identified in the current design phase. It begins with those features identified in the requirements documents. A FMEA table evaluates each potential fault and the level of associated risk. A value is then assigned for severity, probability and the ability to detect (detectability) each fault identified. Mitigating controls are proposed and the resulting severity, probability and detectability of the mitigated fault condition leading to a hazardous device condition are assessed. The final result is an updated description of the level of risk of the device.

The device that is being analyzed in this document is the Multi-parameter Mobile CareGuide 3100 Oximeter. Please note that this device is nearly identical to the Mobile CareGuide 2100 Oximeter, described in an earlier set of documents. The only new variant is the addition of software algorithms to measure muscle pH (“pHm”).

The Multi-parameter Mobile CareGuide 3100 Oximeter, like its predecessor, will monitor patient levels of SmO2 continuously and noninvasively. It will also determine and display values for muscle oxygen saturation (SmO2) which is an indication of tissue perfusion. The device will include a monitoring system, composed of a display device, sensor and patient disposable. The Multi-parameter Mobile CareGuide 3100 Oximeter will use near infrared

spectroscopy to determine hemoglobin oxygen saturation and pH in a region of skeletal muscle tissue beneath the sensor.

The Multi-parameter Mobile CareGuide 3100 Oximeter will include a processor board that will receive the raw data from the sensor and then conduct complex calculations to determine the patient's SMO2 and pHm levels. It will also be powered by a battery and will therefore be portable for potential use in the field, at the site of an accident, and during the transport of a patient to and within a medical facility.

The Multi-parameter Mobile CareGuide 3100 Oximeter is almost identical to the predecessor Mobile CareGuide 2100 Oximeter. As a result, the FMEA for this device will include many of the same potential failure points as the Mobile CareGuide 2100 Oximeter device, plus the additional ones that deal with pHm.

The device is classified as having a Moderate level of concern.

2. Responsibilities

Review responsibilities include the following:

Clinical
Regulatory
Quality
Risk Management
Technical (Engineering)

(b) (6)

(b)(6)

3. References

MPMRA-001 Mobile CareGuide Risk Analysis
MPMDIR-001 Mobile CareGuide Design Input Requirements
MCGHRS-001 Mobile CareGuide Hardware Requirements Specification
MPMSRS-001 Mobile CareGuide Software Requirements Specification
114536, Design Input Document, CareGuide
ISO 14971:2007 Medical devices — Application of risk management to medical devices
SOP 07300300—Risk Analysis Procedure

4. Estimating Risk

The risk index associated with each identified fault or potential failure of the system is evaluated using the following three determinants described in the corresponding tables: severity, probability, and detectability. The final risk associated with the fault is defined as the

product of the severity, probability and detectability and is listed as the RPN (risk probability number) in the risk analysis table.

The potential severity of the failure (weighing consequence of use or failure) based on the following scale:

Table 1. Severity (S)

SEVERITY		
1	Insignificant	Does not result in injury or product damage. May cause minor nuisance
2	Slight	Little or no potential of injury. Medical attention limited to self care.
3	Moderate	Potential for injury requiring physician intervention.
4	Critical	Potential for death or serious injury requiring physician intervention.
5	Catastrophic	Potential for death that cannot be readily mitigated by physician intervention.

The probability (likelihood) of the fault resulting in a hazardous condition of the severity described is estimated based on the following scale:

Table 2. Probability (P)

PROBABILITY		
1	Improbable	$\leq 10^{-5}$
2	Remote	$10^{-3} - 10^{-5}$
3	Occasional	$10^{-2} - 10^{-3}$
4	Probable	$10^{-1} - 10^{-2}$
5	Frequent	Up to 10^{-1}

The ability to detect and avert the various fault conditions prior to the described hazardous situation and its described effects is estimated using the detectability scale:

Table 3. Detectability (D)

DETECTABILITY		
0.1	Very High	>90% of the time detected before hazardous condition
0.25	High	75 to 90% of the time detected before hazardous condition
0.5	Moderate	50 to 75% of the time detected before hazardous condition
0.75	Low	25 to 50% of the time detected before hazardous condition
1.0	Almost certain non-detection	0 to 25% of the time detected before hazardous condition

5. Evaluation of Risk

The risk is assigned a risk priority number (RPN) based on the product of the severity, probability and detectability. The table below graphically illustrates the relationships and illustrates the determination of the level of risk.

Table 4. Risk Priority Evaluation

P						
1	1	2	3	4	5	
2	2	4	6	8	10	
3	3	6	9	12	15	
4	4	8	12	16	20	
5	5	10	15	20	25	
S	1	2	3	4	5	

6. Level of Risk

The level of risk is assigned based on the analysis of the RPN as described above. The worst case RPN represents the level of risk for the system. The level of risk that results from evaluation of the mitigated system is assigned based on the table below.

Table 5. Level of Risk

Risk Acceptability	RPN range	Action Required
Acceptable	1 to <5	No specific action required.
Acceptable with special review & justification	5 to 10	Requires team review and approval to proceed in development process. Such risk requires reduction of risk to levels as low as reasonably possible and may require risk/benefit analysis.
Substantial Concern	>10	Requires team review and formal acceptance of risk prior to proceeding with development. Such risk requires reduction of risk to levels as low as reasonably possible and requires risk/benefit analysis.

7. FMEA

Table 6 presents the FMEA for the Multi-parameter Mobile CareGuide 3100 Oximeter devices. Recommended mitigations are tabulated in detail in Table 7 and can be used for reference purposes.

Pages 470 through 487 redacted for the following reasons:

- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information

.Table Of Contents

1. INTRODUCTION.....2

2. RESPONSIBILITIES3

3. REFERENCES.....3

4. ESTIMATING RISK.....3

5. EVALUATION OF RISK5

6. LEVEL OF RISK.....5

7. FMEA.....6

8. LEVEL OF RISK.....23

TABLE OF TABLES

TABLE 1. SEVERITY (S)4

TABLE 2. PROBABILITY (P)4

TABLE 3. DETECTABILITY (D).....5

TABLE 4. RISK PRIORITY EVALUATION5

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1. Introduction

The focus of this document will be to review the risk in a bottom up approach from a device perspective, and is intended to be a design Failure Modes and Effects Analysis (FMEA). The intent of this document is to evaluate the system based on design features as identified in the current design phase. It begins with those features identified in the requirements documents. A FMEA table evaluates each potential fault and the level of associated risk. A value is then assigned for severity, probability and the ability to detect (detectability) each fault identified. Mitigating controls are proposed and the resulting severity, probability and detectability of the mitigated fault condition leading to a hazardous device condition are assessed. The final result is an updated description of the level of risk of the device.

The device that is being analyzed in this document is the Multi-parameter Mobile CareGuide 3100 Oximeter. Please note that this device is nearly identical to the Mobile CareGuide 2100 Oximeter, described in an earlier set of documents. The only new variant is the addition of software algorithms to measure muscle pH (“pHm”).

The Multi-parameter Mobile CareGuide 3100 Oximeter, like its predecessor, will monitor patient levels of SmO2 continuously and noninvasively. It will also determine and display values for muscle oxygen saturation (SmO2) which is an indication of tissue perfusion. The device will include a monitoring system, composed of a display device, sensor and patient disposable. The Multi-parameter Mobile CareGuide 3100 Oximeter will use near infrared

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The device is classified as having a Moderate level of concern.

2. Responsibilities

Review responsibilities include the following:

Clinical	Babs Soller	Reflectance Medical Inc.
Regulatory	Nandini Murthy	ENEM Consulting
Quality	Sandeep Lad	Source Scientific LLC
Risk Management	Sandeep Lad	Source Scientific, LLC
Technical (Engineering)	Eric D'Ipollito Babs Soller Gwenn Ellerby	Source Scientific, LLC Reflectance Medical Inc. Reflectance Medical Inc.

3. References

MPMRA-001 Mobile CareGuide Risk Analysis
 MPMDIR-001 Mobile CareGuide Design Input Requirements
 MCGHRS-001 Mobile CareGuide Hardware Requirements Specification
 MPMSRS-001 Mobile CareGuide Software Requirements Specification
 114536, Design Input Document, CareGuide
 ISO 14971:2007 Medical devices — Application of risk management to medical devices
 SOP 07300300—Risk Analysis Procedure

4. Estimating Risk

The risk index associated with each identified fault or potential failure of the system is evaluated using the following three determinants described in the corresponding tables: severity, probability, and detectability. The final risk associated with the fault is defined as the

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The potential severity of the failure (weighing consequence of use or failure) based on the following scale:

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Table 4. Risk Priority Evaluation

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1	1	2	3	4	5	
2	2	4	6	8	10	
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4	4	8	12	16	20	
5	5	10	15	20	25	
S	1	2	3	4	5	

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The level of risk is assigned based on the analysis of the RPN as described above. The worst case RPN represents the level of risk for the system. The level of risk that results from evaluation of the mitigated system is assigned based on the table below.

Table 5. Level of Risk

Risk Acceptability	RPN range	Action Required
Acceptable	1 to <5	No specific action required.
Acceptable with special review & justification	5 to 10	Requires team review and approval to proceed in development process. Such risk requires reduction of risk to levels as low as reasonably possible and may require risk/benefit analysis.
Substantial Concern	>10	Requires team review and formal acceptance of risk prior to proceeding with development. Such risk requires reduction of risk to levels as low as reasonably possible and requires risk/benefit analysis.

7. FMEA

Table 6 presents the FMEA for the Multi-parameter Mobile CareGuide 3100 Oximeter devices. Recommended mitigations are tabulated in detail in Table 7 and can be used for reference purposes.

Pages 493 through 510 redacted for the following reasons:

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Records processed under FOIA Request # 2014-3652; Released by CDRH on 02/18/2016

Title: Mobile CareGuide 3100 Clinical Tablet Software Validation Testing Protocol
Doc Number: MPMSWV-003 **Originator:** Steve Weisner
Revision: A **Date:** 10/7/13
ECO: NA

1.0 Introduction

1.1 Purpose

This document defines the testing protocol for validation of the Mobile CareGuide 3100 Android Tablet Software.

The intended audiences for this V&V testing protocol are personnel with the responsibility of specifying, designing, coding, testing, verifying, validating or managing the development of the software.

1.2 Scope

This document specifies the requirements to perform and expected outcomes of testing to validate the Mobile CareGuide 3100 Oximeter Software against its SRS (MPMSRS-002 Multi-Parameter Mobile CareGuide Android Software Requirements). This document also serves as the form to be completed during validation testing.

Note: the Multi-Parameter Mobile CareGuide 3100 Oximeter sensor is validated through a separate protocol.

1.3 Acronyms and Definition of Terms

Acronym	Description
hrs	Hours
IT	Integration Time
LED	Light emitting diode
NVM	Non-Volatile Memory
pH	Muscle pH (hydrogen ion concentration)
RMI	Reflectance Medical Inc.
SmO ₂	Muscle oxygen saturation
SRS	Software Requirement Specifications
USB	Universal Serial Bus

1.4 Reference Documents

MPMSRS-002 Multi-Parameter Mobile CareGuide Android Software Requirements (**MPM:SRS**)

Pages 512 through 519 redacted for the following reasons:

(b)(4)-TS/CCI



Title: Mobile CareGuide 3100 Clinical Tablet Software Validation Testing Protocol
Doc Number: MPMSWV-003 **Originator:** Steve Weisner
Revision: A **Date:** 10/7/13
ECO: NA

Mobile CareGuide 3100 Clinical Tablet Software Validation Testing Protocol

REVIEWED AND APPROVED BY:

Gwenn Ellerby *[Signature]* 10/7/13
 Project Manager Signature Date

Peter Scott *[Signature]* 10/7/13
 Engineering Signature Date

Steve Weisner *[Signature]* 10/7/13
 Quality Signature Date

CHANGE HISTORY			
Rev.	Date	Description	CO #
A	10/07/13	Original document	N/A



Records processed under FOIA Request # 2014-3652; Released by CDRH on 02/18/2016

Title: Mobile CareGuide 3100 Clinical Tablet Software Validation Testing Protocol
Doc Number: MPMSWV-003 **Originator:** Steve Weisner
Revision: A **Date:** 10/7/13
ECO: NA

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SRS	Software Requirement Specifications
USB	Universal Serial Bus

1.4 Reference Documents

MPMSRS-002 Multi-Parameter Mobile CareGuide Android Software Requirements (**MPM:SRS**)

Pages 522 through 529 redacted for the following reasons:

(b)(4)-TS/CCI



Title: Mobile CareGuide 3100 Clinical Tablet Software Validation Testing Protocol
Doc Number: MPMSWV-003 **Originator:** Steve Weisner
Revision: A **Date:** 10/7/13
ECO: NA

Mobile CareGuide 3100 Clinical Tablet Software Validation Testing Protocol

REVIEWED AND APPROVED BY:

Gwenn Ellerby [Signature] 10/7/13
Project Manager Signature Date

Peter Scott [Signature] 10/7/13
Engineering Signature Date

Steve Weisner [Signature] 10/7/13
Quality Signature Date

CHANGE HISTORY			
Rev.	Date	Description	CO #
A	10/07/13	Original document	N/A



Title: Mobile CareGuide 3100 Clinical Tablet Software Validation Testing Protocol
Doc Number: MPMSWV-003 **Originator:** Steve Weisner
Revision: A **Date:** 10/7/13
ECO: NA

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pH	Muscle pH (hydrogen ion concentration)
RMI	Reflectance Medical Inc.
SmO ₂	Muscle oxygen saturation
SRS	Software Requirement Specifications
USB	Universal Serial Bus

1.4 Reference Documents

MPMSRS-002 Multi-Parameter Mobile CareGuide Android Software Requirements (**MPM:SRS**)

Pages 532 through 539 redacted for the following reasons:

(b)(4)-TS/CCI



Title: Mobile CareGuide 3100 Clinical Tablet Software Validation Testing Protocol
Doc Number: MPMSWV-003 **Originator:** Steve Weisner
Revision: A **Date:** 10/7/13
ECO: NA

Mobile CareGuide 3100 Clinical Tablet Software Validation Testing Protocol

REVIEWED AND APPROVED BY:

Gwenn Ellerby *[Signature]* 10/7/13
 Project Manager Signature Date

Peter Scott *[Signature]* 10/7/13
 Engineering Signature Date

Steve Weisner *[Signature]* 10/7/13
 Quality Signature Date

CHANGE HISTORY			
Rev.	Date	Description	CO #
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RMI	Reflectance Medical Inc.
SmO ₂	Muscle oxygen saturation
SRS	Software Requirement Specifications
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1.4 Reference Documents

MPMSRS-002 Multi-Parameter Mobile CareGuide Android Software Requirements (**MPM:SRS**)

Pages 542 through 550 redacted for the following reasons:

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Title: Mobile Care Guide 3100 Android Software Unit Test Document
Doc Number: MPMUTD-004
Revision: A
ECO: NA
Originator: Steve Weisner
Date: 10/7/13

Table of Contents

1. General Approach..... 3
2. Test Procedure Overview 3
 2.1.1 *MPM:SRS:2.6.1.7 Verify power on self-test from sensor 4*
 2.1.2 *MPM:SRS: 2.6.1.8 Verify use of checksums in communications with sensor 5*
 2.1.3 *MPM:SRS: 2.6.1.10 Verify failed communications with sensor..... 6*
 2.1.4 *MPM:SRS: 2.6.2.1 Synchronize time stamps..... 8*
 2.1.5 *MPM:SRS: 2.6.3.9 Handle SmO2/pHm error returns..... 9*
 2.1.6 *MPM:SRS: 2.6.3.11 SmO2 and pHm Out-of-Range indicators..... 10*



Title: Mobile CareGuide 3100 Android Software Unit Test Document
Doc Number: MPMUTD-004
Revision: A
ECO: NA
Originator: Steve Weisner
Date: 10/7/13

1. General Approach

The testing procedures in this document formally tests and document any specific requirement as listed in MPMSRS-002 Multi-parameter Mobile CareGuide 3100 Android Software Requirements that cannot be tested, is difficult to test, or is impractical to test in a system-testing environment. For each test, the requirement is listed along with various test scenarios.

2. Test Procedure Overview

Each function being tested contains the following sections:

- X. Requirement Name and Number
- X.1 Requirement Description
- X.2 Test Description:
 - a) Applicable Software & Modules
 - b) Details
- X.3 Test Results

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Title: Mobile Care Guide 3100 Android Software Unit Test Document
Doc Number: MPMUTD-004
Revision: A
ECO: NA
Originator: Steve Weisner
Date: 10/7/13

Table of Contents

1. General Approach..... 3
2. Test Procedure Overview 3
 2.1.1 *MPM:SRS:2.6.1.7 Verify power on self-test from sensor 4*
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 2.1.4 *MPM:SRS: 2.6.2.1 Synchronize time stamps..... 8*
 2.1.5 *MPM:SRS: 2.6.3.9 Handle SmO2/pHm error returns..... 9*
 2.1.6 *MPM:SRS: 2.6.3.11 SmO2 and pHm Out-of-Range indicators..... 10*

Pages 563 through 573 redacted for the following reasons:

- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information



Title: Mobile CareGuide 3100 Android Software Unit Test Document
Doc Number: MPMUTD-004
Revision: A
ECO: NA
Originator: Steve Weisner
Date: 10/7/13

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The testing procedures in this document formally tests and document any specific requirement as listed in MPMSRS-002 Multi-parameter Mobile CareGuide 3100 Android Software Requirements that cannot be tested, is difficult to test, or is impractical to test in a system-testing environment. For each test, the requirement is listed along with various test scenarios.

2. Test Procedure Overview

Each function being tested contains the following sections:

- X. Requirement Name and Number
- X.1 Requirement Description
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 - a) Applicable Software & Modules
 - b) Details
- X.3 Test Results

Pages 575 through 584 redacted for the following reasons:

- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information



Title: Mobile CareGuide 3100 Android Software Unit Test Document
Doc Number: MPMUTD-004
Revision: A
ECO: NA
Originator: Steve Weisner
Date: 10/7/13

1. General Approach

The testing procedures in this document formally tests and document any specific requirement as listed in MPMSRS-002 Multi-parameter Mobile CareGuide 3100 Android Software Requirements that cannot be tested, is difficult to test, or is impractical to test in a system-testing environment. For each test, the requirement is listed along with various test scenarios.

2. Test Procedure Overview

Each function being tested contains the following sections:

- X. Requirement Name and Number
- X.1 Requirement Description
- X.2 Test Description:
 - a) Applicable Software & Modules
 - b) Details
- X.3 Test Results

Pages 586 through 648 redacted for the following reasons:

- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information



Records processed under FOIA Request # 2014-3652; Released by CDRH on 02/18/2016

Title: Mobile Multi-parameter Mobile CareGuide 3100 with Tablet Traceability Matrix
Doc Number: MPMTRC-002 **Originator:** Steve Weisner
Revision: A **Date:** 12/4/2013
ECO: n/a

1.0 Introduction

1.1 Purpose

This document defines the traceability matrix for the Multi-parameter Mobile CareGuide 3100 with Tablet.

The intended audiences for this document are personnel with the responsibility of specifying, designing, coding, testing, verifying, validating or managing the development of the software.

1.2 Scope

This document provides a linkage between all product requirements, specifications and verification/validation documentation for the Multi-parameter Mobile CareGuide 3100 with Tablet. Mapping is through the following tables:

- Table 2 Marketing Requirements mapped to Design Input Requirements;
- Table 3 Design Input Requirements mapped to Software Requirements and Hardware Requirements;
- Table 4 Risk Analysis mapped to Specifications and Verification/Validation;
- Table 5 Software Requirements mapped to Verification/Validation and Unit Testing;
- Table 6 Hardware Requirements mapped to Verification/Validation and Unit Testing.

1.3 Acronyms and Definition of Terms

Acronym	Description
CAN	Serial interface bus
LED	Light emitting diode
MCG	Mobile CareGuide 2100
MPM	Multi-parameter Mobile CareGuide 3100
pHm	Muscle pH (hydrogen ion concentration)
RMI	Reflectance Medical Inc.
SmO ₂	Muscle oxygen saturation
USB	Universal Serial Bus

Pages 650 through 691 redacted for the following reasons:

- (b)(4)-TS/CCI
(b)(6)-Personal Privacy Information



Records processed under FOIA Request # 2014-3652; Released by CDRH on 02/18/2016

Title: Mobile Multi-parameter Mobile CareGuide 3100 with Tablet Traceability Matrix
Doc Number: MPMTRC-002 **Originator:** Steve Weisner
Revision: A **Date:** 12/4/2013
ECO: n/a

1.0 Introduction

1.1 Purpose

This document defines the traceability matrix for the Multi-parameter Mobile CareGuide 3100 with Tablet.

The intended audiences for this document are personnel with the responsibility of specifying, designing, coding, testing, verifying, validating or managing the development of the software.

1.2 Scope

This document provides a linkage between all product requirements, specifications and verification/validation documentation for the Multi-parameter Mobile CareGuide 3100 with Tablet. Mapping is through the following tables:

- Table 2 Marketing Requirements mapped to Design Input Requirements;
- Table 3 Design Input Requirements mapped to Software Requirements and Hardware Requirements;
- Table 4 Risk Analysis mapped to Specifications and Verification/Validation;
- Table 5 Software Requirements mapped to Verification/Validation and Unit Testing;
- Table 6 Hardware Requirements mapped to Verification/Validation and Unit Testing.

1.3 Acronyms and Definition of Terms

Acronym	Description
CAN	Serial interface bus
LED	Light emitting diode
MCG	Mobile CareGuide 2100
MPM	Multi-parameter Mobile CareGuide 3100
pHm	Muscle pH (hydrogen ion concentration)
RMI	Reflectance Medical Inc.
SmO ₂	Muscle oxygen saturation
USB	Universal Serial Bus

Pages 693 through 733 redacted for the following reasons:

(b)(4)-TS/CCI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 17: EMC & Electrical Safety

CONFIDENTIAL

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 17**Electromagnetic Compatibility (EMC) and Safety****17.1 EMC and Safety Standards Compliance**

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Documents
5-27	IEC 60601-1-1: 2005	Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standards: Safety requirements for medical electrical systems	Pass	None	Predicate filing (K122645) and on file at RMI: Mobile CareGuide USB Harmonics and Flicker; Mobile CareGuide USB Immunity; Mobile CareGuide Mechanical Safety
5-35	IEC 60601-1-2: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Pass	None	Predicate filing (K122645) and on file at RMI: Mobile CareGuide USB Emissions

Page 736 redacted for the following reason:

(b)(4)-TS/CCI

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

17.4 EMC & Safety Testing Mitigations

Section 13 Instructions for Use document Section 9.0 Electromagnetic Emissions and Immunity indicates the following:

“This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1 3rd Edition v2005. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices.
- Increase the separation between the devices.
- Connect the equipment to an outlet on a different circuit.
- Contact the Service Center. “

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 17: EMC & Electrical Safety

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Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 17**Electromagnetic Compatibility (EMC) and Safety****17.1 EMC and Safety Standards Compliance**

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5-27	IEC 60601-1-1: 2005	Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standards: Safety requirements for medical electrical systems	Pass	None	Predicate filing (K122645) and on file at RMI: Mobile CareGuide USB Harmonics and Flicker; Mobile CareGuide USB Immunity; Mobile CareGuide Mechanical Safety
5-35	IEC 60601-1-2: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Pass	None	Predicate filing (K122645) and on file at RMI: Mobile CareGuide USB Emissions

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

17.2 EMC & Safety Testing Methodology Overview

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet sensor uses the identical hardware including optical, electrical and mechanical components as the predicate (K122645) Mobile CareGuide 2100 Oximeter sensor. The ray (disposable) and battery charger are the same respective products: Mobile CareGuide 2100 Oximeter ray and Mobile CareGuide 2100 Oximeter battery charger. A summary of the predicate device safety and EMC testing and results are described below.

Safety Testing on predicate device: A certified 3rd party testing agency performed compliance test with production equivalent Mobile CareGuide 2100 Oximeter sensor, ray and battery charger. Both the CAN and USB versions of the Mobile CareGuide 2100 Oximeter were tested. Only the USB version is applicable to the Multi-parameter Mobile CareGuide 3100 Oximeter with Tablet. As appropriate, the sensor was tested during charging and without the charger. Testing agency also received relevant production equivalent product documentation and labeling. The following safety tests were performed: dielectric test; power input; residual voltage and leakage current. The following mechanical tests were performed: mechanical strength; impact test; drop impact test and mold strength relief test.

EMC Testing on predicate device: A certified 3rd party testing agency performed compliance test with production equivalent Mobile CareGuide 2100 Oximeter sensor, ray and battery charger. Both the CAN and USB versions of the Mobile CareGuide 2100 Oximeter were tested. Only the USB version is applicable to the Multi-parameter Mobile CareGuide 3100 Oximeter with Tablet. As appropriate, the sensor was tested during charging and without the charger. Testing agency also received relevant production equivalent product documentation and labeling. The following EMC tests were performed: radiated emissions; AC mains conducted emissions; harmonics; flicker; electrostatic discharge immunity (IEC 61000-4-2); radiated, radio-frequency, electromagnetic immunity (IEC 61000-4-3); electrical fast transient/burst immunity (IEC 61000-4-4); immunity to surge (IEC 61000-4-5); conducted, radio-frequency, electromagnetic field immunity (IEC 61000-4-6); power frequency magnetic field immunity (IEC 61000-4-8); voltage dips/interruptions immunity (IEC 61000-4-11).

17.3 EMC & Safety Testing Results

Safety Testing: All tests passed; the product is declared compliant with the standard.

EMC Testing: All tests are passed and the product is declared compliant with the standard.

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

17.4 EMC & Safety Testing Mitigations

Section 13 Instructions for Use document Section 9.0 Electromagnetic Emissions and Immunity indicates the following:

“This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1 3rd Edition v2005. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices.
- Increase the separation between the devices.
- Connect the equipment to an outlet on a different circuit.
- Contact the Service Center. “

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 18: Bench Performance Tests

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Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 18

PERFORMANCE TESTING - BENCH

18.1 FINISHED DEVICE PERFORMANCE BENCH TESTING SUMMARY: Standards compliance

Table 1 Finished device performance bench testing: standards compliance

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Documents
12-168	IEC60825-1 Ed 2.0 (2007)	Safety of laser products - Part 1: Equipment classification, and requirements	Pass as Class 1 Laser Device	None	Predicate filing (K113656) and on file at RMI: iec60825-1_compliance

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

18.2 FINISHED DEVICE PERFORMANCE BENCH TESTING SUMMARY: System Hardware testing RMI generated**Table 2 Finished device performance bench testing: system hardware testing**

RMI #	Name	Description	Results	Exceptions	Reference Documents
MCGHRS-001	Mobile CareGuide 2100 Hardware Requirements Specifications, CareGuide	Input requirements for hardware (electrical, mechanical and disposable) components of Mobile CareGuide 2100 Oximeter	See Predicate K122645 Mobile CareGuide 2100 Hardware Validation Results	NA	Predicate filing (K122645) and on file at RMI: MCGHRS-001 Mobile CareGuide Hardware Requirements Specification
MCGHWV-001	Mobile CareGuide 2100 Hardware Validation Results	Validation System test results for the Mobile CareGuide 2100 Sensor, Disposable Ray and Sensor Check packaging and demonstrate traceability to hardware-related product requirements.	Pass	2.2.5, 2.2.6, 8.1-8.9, 9.3, 9.4	Predicate filing (K122645) and on file at RMI: MCGHWV-001 Mobile CareGuide 2100 Hardware Validation

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Page 2 of 5

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

RMI #	Name	Description	Results	Exceptions	Reference Documents
MCGHUTD-001	Mobile CareGuide 2100 Hardware Unit Test Results	Validation unit test results for the Mobile CareGuide 2100 Sensor, Disposable Ray and Sensor Check packaging to demonstrate traceability to hardware-related product requirements.	Pass	4	Predicate filing (K122645) and on file at RMI: MCGHUTD-001 Mobile CareGuide Hardware Unit Test Document
RMIHWV-005	CareGuide Optics Testing-SYSTEM	Confirm the overall optical system performance of Mobile CareGuide Sensor meets design specifications.	Pass	None	On file at RMI.

18.3 RMI test methodology Overview

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet hardware (optical and CPU components) are equivalent to the predicate device Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079) which is equivalent to its predicate device Mobile CareGuide 2100 Oximeter (K122645).

RMI performed overall system testing on the predicate device (K122645) complete Mobile CareGuide 2100 Oximeter. The tests, as specified in Section 18.2 above, were performed on one or more production-equivalent product samples to demonstrate adherence to requirement document (MCGHRS-001 Mobile CareGuide Hardware Requirements Specification) and relevant standards (see also Section 9). All tests were performed by trained RMI employees or authorized contractors under RMI's standard operating procedures with calibrated equipment.

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Page 3 of 5

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

RMI performs individual board testing on all Mobile CareGuide sensors. The tests (RMITP-001 through RMITP-016) as specified in Section 18.4 below, are performed on each production-equivalent Mobile CareGuide 3100 Oximeter sensor to validate that it will perform as specified. A sensor board must pass all acceptance criteria for each test below to be used for commercial or clinical use.

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Page 4 of 5

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: CareGuide Oximeter

18.4 FINISHED DEVICE BENCH TESTING RESULTS - Component Hardware testing RMI generated

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet continued to be bench tested with the existing bench test suite from the predicate K122645 Mobile CareGuide 2100 Oximeter bench tests.

Note: A sensor board must pass all acceptance criteria for each test to be used for clinical use. Any board that fails one or more acceptance criteria is rejected for commercial or clinical use. There are multiple test procedures with corresponding test forms. All test procedures and test forms are on file and available at RMI.

18.5 Conclusions:

All bench testing of hardware with associated bench-test software against applicable regulatory standards, RMI system hardware tests and RMI component hardware tests have been completed successfully on the predicate devices K130079 and K122645. Since the hardware of the Multi-Parameter Mobile CareGuide 3100 with Tablet sensor is equivalent to the hardware of the predicates K130079 and K122645 devices, these aspects of the 3100 with Tablet product are declared conformant.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 18: Bench Performance Tests

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Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 18

PERFORMANCE TESTING - BENCH

18.1 FINISHED DEVICE PERFORMANCE BENCH TESTING SUMMARY: Standards compliance

Table 1 Finished device performance bench testing: standards compliance

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Documents
12-168	IEC60825-1 Ed 2.0 (2007)	Safety of laser products - Part 1: Equipment classification, and requirements	Pass as Class 1 Laser Device	None	Predicate filing (K113656) and on file at RMI: iec60825-1_compliance

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

18.2 FINISHED DEVICE PERFORMANCE BENCH TESTING SUMMARY: System Hardware testing RMI generated**Table 2 Finished device performance bench testing: system hardware testing**

RMI #	Name	Description	Results	Exceptions	Reference Documents
MCGHRS-001	Mobile CareGuide 2100 Hardware Requirements Specifications, CareGuide	Input requirements for hardware (electrical, mechanical and disposable) components of Mobile CareGuide 2100 Oximeter	See Predicate K122645 Mobile CareGuide 2100 Hardware Validation Results	NA	Predicate filing (K122645) and on file at RMI: MCGHRS-001 Mobile CareGuide Hardware Requirements Specification
MCGHWV-001	Mobile CareGuide 2100 Hardware Validation Results	Validation System test results for the Mobile CareGuide 2100 Sensor, Disposable Ray and Sensor Check packaging and demonstrate traceability to hardware-related product requirements.	Pass	2.2.5, 2.2.6, 8.1-8.9, 9.3, 9.4	Predicate filing (K122645) and on file at RMI: MCGHWV-001 Mobile CareGuide 2100 Hardware Validation

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Page 2 of 5

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

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MCGHUTD-001	Mobile CareGuide 2100 Hardware Unit Test Results	Validation unit test results for the Mobile CareGuide 2100 Sensor, Disposable Ray and Sensor Check packaging to demonstrate traceability to hardware-related product requirements.	Pass	4	Predicate filing (K122645) and on file at RMI: MCGHUTD-001 Mobile CareGuide Hardware Unit Test Document
RMIHWV-005	CareGuide Optics Testing-SYSTEM	Confirm the overall optical system performance of Mobile CareGuide Sensor meets design specifications.	Pass	None	On file at RMI.

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RMI performed overall system testing on the predicate device (K122645) complete Mobile CareGuide 2100 Oximeter. The tests, as specified in Section 18.2 above, were performed on one or more production-equivalent product samples to demonstrate adherence to requirement document (MCGHRS-001 Mobile CareGuide Hardware Requirements Specification) and relevant standards (see also Section 9). All tests were performed by trained RMI employees or authorized contractors under RMI's standard operating procedures with calibrated equipment.

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Page 3 of 5

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

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Page 4 of 5

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: CareGuide Oximeter

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K133923/5001

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



FDA CDRH DMC

MAR 13 2014

Received

Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Phone: 508.366.4700
Fax: 508.366.4770

03/07/2014

Office of Device Evaluation [510(k)]
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Craig Nichols, Biomedical Engineer
FDA / CDRH / ODE / DCD

Re: K133923 – Supplement 1, Traditional 510(k) Premarket Notification for
Multi-parameter Mobile CareGuide 3100 Oximeter with Tablet

Dear Craig,

Reflectance Medical Inc. (RMI) filed a traditional 510(k) for the Multi-parameter Mobile CareGuide 3100 Oximeter with Tablet, received by the FDA on December 30, 2013. The company received FDA letter dated 02/27/2014 with three comments/questions. The formal response to these three questions is in this Supplement 1, including the recommended changes to the formal filing.

Please find enclosed one (1) paper copy and two (2) CDs with the eCopy version of Supplement 1 to 510(k), K133923. Please note that the eCopy is an exact duplicate of the paper copy.

We request that the FDA regard the contents of this submission as subject to protection from public disclosure to the extent permitted by the provisions of 21 C.F.R. § 807.95(b).

If you should have any questions or require further information, please contact

(b)(6) (b)(6)

(b)(6) (b)(6)

Sincerely,

(b)(6)

(b)(6)

13

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet – Supplement 1

TRADITIONAL 510(k) PREMARKET NOTIFICATION SUBMISSION

Mobile CareGuide™ 3100 Oximeter with Tablet

K133923 - Supplement 1

TABLE OF CONTENTS

Attachments	Contents	Page
2	Cover Letter	1
3	Supplement 1 (Response to FDA questions of February 27, 2014)	2
4	Section 11 Updated Device Description	12
5	Section 12 Updated Substantial Equivalence Summary	24
6	Section 13 Updated Proposed Labeling Summary	34
7	Section 13 Final Labeling – Mobile CareGuide 3100 Oximeter with Tablet	43
8	Section 17 Updated Electromagnetic Compatibility and Safety	76

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
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03/07/2014

Office of Device Evaluation [510(k)]
Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Craig Nichols, Biomedical Engineer
FDA / CDRH / ODE / DCD

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We request that the FDA regard the contents of this submission as subject to protection from public disclosure to the extent permitted by the provisions of 21 C.F.R. § 807.95(b).

If you should have any questions or require further information, please contact (b)(6) (b)(6)
(b)(6) (b)(6)

Sincerely,

(b)(6)
(b)(6)

Response to Comments for K133923:

Please find our response to your questions below. Each question is reproduced in blue and the answer below it in black. The questions are answered in the order that they were received. Corresponding updates to original submission sections are attached following this summary.

I. *There is no electromagnetic compatibility (EMC) testing provided in the submission. Please provide testing for the proposed device (Multi-Parameter Care Guide 3100 with Tablet) that accounts for the entire system, including both Android tablets. Alternatively, you may provide sound scientific justification for why further EMC testing is not necessary.*

RMI response:

The two tablets specified in the submittal (Acer A500 and Asus Google Nexus 7) are commercial off-the-shelf (OTS) computer tablets.

Acer A500 Android tablet:

RMI has chosen the Acer A500 Android tablet for use with the CareGuide 3100 based on the vendor's certification.

The tablet manufacturer's documentation states that the tablet is classified as Class B based on: "EN 55022:2006/A1:2007" titled 'Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement'.

The tablet is also compliant with "EN 55024:1198/A1:2001/A2:2003" titled 'Information technology equipment – Immunity characteristics – Limits and methods of measurement'.

Asus Google Nexus 7 tablet:

RMI has chosen the Asus Google Nexus 7 (Model ME370T) Android tablet for use with the CareGuide 3100 based on the vendor's certification.

The tablet manufacturer's documentation states that the tablet is compliant with: "EN 55022:2010" titled 'Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement'.

The tablet is also compliant with "EN 55024:2010" titled 'Information technology equipment – Immunity characteristics – Limits and methods of measurement'.

The above references to EN 55022 for classification and EN 55024 for EMC compliance qualify the device for use with a medical device. The Medical Device Directive (MDD) and IEC 60601-1-2: 2001/2006 reference in relevant part: "equipment are to be classified per CISPR 22 (EN 55022) as Class A or Class B" and, "with respect to EMC immunity: equipment are to be classified per CISPR 24 (EN 55024)".

In addition, the wireless LAN and Bluetooth communications are intentionally disabled on this tablet per Reflectance Medical loading procedure (see Section 16.5.2 Lockdown Software). This should further limit EMC exposure.

Reflectance Medical therefore believes that additional EMC testing is not required for the Acer A500 tablets. We have modified the Instructions for Use document Section 7 Electromagnetic Emissions and Immunity to add "The Acer A500 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2006/A1:2007 Class B and EN 55024:1198/A1:2001/A2:2003. The Asus Google Nexus 7 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2010 and EN 55024:2010. Refer to Tablet Manufacturer's documentation." The cover pages and Declarations of Conformity from the Acer ICONIA TAB User Guide Model A500 2011 and the Asus Google Nexus 7 are included below in this response.

We have modified Section 17.2 EMC & Safety Testing Methodology Overview to add the following:
“EMC Testing on Tablet: The Acer A500 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2006/A1:2007 Class B and EN 55024:1198/A1:2001/A2:2003. The Asus Google Nexus 7 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2010 and EN 55024:2010.”

We have modified Section 17.4 EMC & Safety Testing Mitigations to “This sensor has been tested and found to comply with the limits for medical devices to IEC 60601-1 3rd Edition v2005. The Acer A500 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2006/A1:2007 Class B and EN 55024:1198/A1:2001/A2:2003. The Asus Google Nexus 7 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2010 and EN 55024:2010. Refer to Tablet Manufacturer’s documentation.”

acer

User Guide



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Acer ICONIA TAB User Guide

Model: A500

First issue: 03/2011

ICONIA TAB

Downloaded from www.Manualslib.com manuals search engine

CE 0682 Ⓢ

Acer Incorporated
Date: March 2, 2011

Declaration of Conformity

We, Acer Incorporated,
of 8F., No. 88, Sec. 1, Xintai 5th Rd., Xizhi Dist, New Taipei City, 22181, Taiwan

Declare under sole responsibility that the product:

Model: A500

Description: Tablet Computer

To which this declaration relates, is in conformity with the following standards
and/or other normative documents:

- EN 300 328 V1.7.1
- EN 300 440-1 V1.6.1 ; EN300 440-2 V1.4.1
- EN 301 489-1 V1.8.1 ; EN 301489-3 V1.4.1 ; EN 301489-17 V2.1.1
- EN 55022:2006/A1:2007 Class B ; EN 55024:1998/A1:2001/A2:2003
- EN 60950-1: 2006+A11:2009
- EN 50332-2: 2003
- EN62311:2008; EN62209-2:2010

We hereby declare that the above named product is in conformance to all the
essential requirements of the R&TTE Directive (99/5/EC) issued by the Commission
of the European Community.

The conformity assessment procedure referred to in Article 10 and detailed in
Annex [IV] of directive 1999/5/EC has been followed related to Articles:

- R&TTE Article 3.1 (a) Health and Safety
- R&TTE Article 3.1 (b) EMC
- R&TTE Article 3.2 Spectrum Usage

with the involvement of the following Notified Body:

CETECOM, Untertuerkheimer Str. 6 – 10 66117 Saarbruecken

Identification mark: **0682** (Notified Body) CE

The technical documentation relevant to the above equipment will be held at:

Acer Incorporated

8F., No. 88, Sec. 1, Xintai 5th Rd., Xizhi Dist, New Taipei City, 22181, Taiwan

Authorized person:



Name: Harriot SL Lee

nexus

7

Guidebook

For Android™
mobile technology
platform 4.2

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EC Declaration of Conformity



We, the undersigned,

Manufacturer:	ASUSTeK COMPUTER INC.
Address, City:	4F, No. 150, LI-TE Rd., PEITOU, TAIPEI 112, TAIWAN
Country:	TAIWAN
Authorized representative in Europe:	ASUS COMPUTER GmbH
Address, City:	HARKORT STR. 21-23, 40880 RATINGEN
Country:	GERMANY

declare the following apparatus:

Product name :	ASUS Pad
Model name :	ME370T

conform with the essential requirements of the following directives:

2004/108/EC-EMC Directive

<input checked="" type="checkbox"/> EN 55022:2010	<input checked="" type="checkbox"/> EN 55024:2010
<input checked="" type="checkbox"/> EN 61000-3-2:2006+A2:2009	<input checked="" type="checkbox"/> EN 61000-3-3:2008
<input type="checkbox"/> EN 55013:2001+A1:2003+A2:2006	<input type="checkbox"/> EN 55020:2007+A11:2011

1999/5/EC-R &TTE Directive

<input checked="" type="checkbox"/> EN 300 328 V1.7.1(2006-10)	<input checked="" type="checkbox"/> EN 301 489-1 V1.9.2(2011-09)
<input checked="" type="checkbox"/> EN 300 440-1 V1.6.1(2010-08)	<input checked="" type="checkbox"/> EN 301 489-3 V1.4.1(2002-08)
<input checked="" type="checkbox"/> EN 300 440-2 V1.4.1(2010-08)	<input type="checkbox"/> EN 301 489-4 V1.4.1(2009-05)
<input type="checkbox"/> EN 301 511 V9.0.2(2003-03)	<input type="checkbox"/> EN 301 489-7 V1.3.1(2005-11)
<input type="checkbox"/> EN 301 908-1 V5.2.1(2011-05)	<input type="checkbox"/> EN 301 489-9 V1.4.1(2007-11)
<input type="checkbox"/> EN 301 908-2 V5.2.1(2011-07)	<input checked="" type="checkbox"/> EN 301 489-17 V2.1.1(2009-05)
<input type="checkbox"/> EN 301 893 V1.6.1(2011-11)	<input type="checkbox"/> EN 301 489-24 V1.5.1(2010-09)
<input type="checkbox"/> EN 302 544-2 V1.1.1(2009-01)	<input checked="" type="checkbox"/> EN 300 330-1 V1.7.1(2010-02)
<input type="checkbox"/> EN 302 623 V1.1.1(2009-01)	<input checked="" type="checkbox"/> EN 300 330-2 V1.5.1(2010-02)
<input type="checkbox"/> EN 300 330-1 V1.7.1(2010-02)	<input checked="" type="checkbox"/> EN 62311 Jan 2008
<input type="checkbox"/> EN 300 330-2 V1.5.1(2010-02)	<input checked="" type="checkbox"/> EN 62209-2 Jun 2010
<input type="checkbox"/> EN 50360:2001	
<input type="checkbox"/> EN 62479:2010	

2006/95/EC-LVD Directive

<input type="checkbox"/> EN 60950-1 / A11:2009	<input type="checkbox"/> EN 60065:2002 / A2:2010
<input checked="" type="checkbox"/> EN 60950-1 / A12:2011	<input type="checkbox"/> EN 60065:2002 / A12:2011

2009/125/EC-ErP Directive

<input type="checkbox"/> Regulation (EC) No. 1275/2008	<input checked="" type="checkbox"/> Regulation (EC) No. 278/2009
<input type="checkbox"/> Regulation (EC) No. 642/2009	

2011/65/EU-RoHS Directive

Ver. 121001

CE marking



(EC conformity marking)

Position : **CEO**

Name : **Jerry Shen**

Declaration Date: **Nov. 28, 2012**

Year to begin affixing CE marking:**2012**

Signature : _____

2. According to pg. 11 of 12 in the Device Description, your proposed device contains a number of alarms that will be displayed on the two proposed Android tablets. There appears to be no further description of the alarms in the submission (including labeling) or whether the proposed device complies with the collateral alarms standard, IEC 60601-1-8: "Medical electrical equipment-- Part 1-8: General requirements for basic safety and essential performance-- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems." Please further describe the alarm operation and characteristics and specify whether the proposed device declares compliance to IEC 60601-1-8 and if so provide a completed Form 3654. Alternatively, please discuss how the alarms have been equivalently validated to address the issues described in the standard for the proposed device.

RMI response:

There are no alarms generated by the CareGuide 3100 sensor. The term "alarms" was used in error. The Section 11 – Device Description has been changed to:

"Detected device inoperative conditions are communicated to and indicated by the Tablet as alerts so that the clinician can respond. The device inoperative conditions are: sensor check failed; sensor needs to be repositioned; sensor hardware/software failed; sensor near expiration date; sensor exceeded expiration date; sensor exceeded its first use date; sensor has not been factory calibrated; sensor thermistor has exceeded safe range; ray on same patient for 72 hours and must be replaced; sensor has a low battery charge; SmO2 value is out of range; pHm value is out of range."

All of the technical inoperative conditions have been validated through V&V System testing and Unit testing per the Traceability document (Section 16 Mobile CareGuide 3100 with Tablet Traceability Matrix).

3. The predicate device which was approved (K130079) did not appear to have any specific 3rd party displays included in the submission. Please discuss how you've assessed the human factors impact of the two specific Android tablets chosen in the submission. In your response, please provide any testing that was conducted to assess the usability of the two specific Android tablets. Alternatively, please provide a justification for why a human factors assessment of the two specific Android tablets was not necessary.

RMI response:

The usability of the 3100 with Tablet (K133923) is equivalent to the predicate device K113656 CareGuide 1100. The CareGuide 3100 Tablet (K133923) contains a dedicated tablet, which displays parameter and trend data equivalent to the predicate CareGuide 1100 (K113656) display. In addition, the 3100 Tablet's UI features to enter patient id, perform sensor check, start and stop monitoring and adjust trend scales are also equivalent to the device CareGuide 1100. The size and screen resolution is actually larger and better in the K133923 display compared to the K113656 display.

The Risk assessment showed that the risk of use errors in the proposed Android Tablet display was similar to the predicate CareGuide 1100 Display. Therefore, Reflectance Medical believes that additional human factors assessment in the form of usability testing is not required for these tablets.

Section 12 .3.3 Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet Table 2-1
Substantial Equivalence: Comparison of RMI's Multi-Parameter CareGuide 3100 with Tablet to Mobile CareGuide 3100 and CareGuide 1100 has added the highlighted rows:

Characteristics	RMI Multi-Parameter CareGuide Oximeter 3100 with Tablet	RMI Multi-Parameter CareGuide Oximeter 3100 - K130079	RMI CareGuide Oximeter 1100 - K113656
Muscle tissue SmO2 algorithm	Same as CareGuide 1100	Same as CareGuide 1100	SmO2 calculated from preprocessed spectra
Local tissue pH algorithm	Same as CareGuide 3100	pHm calculated from preprocessed spectra	N.A.
Monitoring Application	Yes (general intended use)	Yes (general intended use)	Yes (general intended use)
Cardiovascular product code MUD, 21 C.F.R. § 870.2700	Yes	Yes	Yes

Pages 765 through 766 redacted for the following reasons:

(b)(4)-TS/CCI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Section 11

Device Description

**Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet–
Device Description Product Description**

Background from 510(k)-cleared K130079:

The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is a noninvasive optical sensor that monitors two physiological parameters, SmO₂ and pHm, and reports them to the User via a display device. Light sources in the sensor illuminate the skin with near infrared (NIR) light. NIR light passes through the skin and fat, with only some loss to be primarily absorbed by blood vessels in the muscle tissue. Light which is not absorbed is scattered back and analyzed by the spectroscopic detector, also contained in the sensor. The microprocessor in the sensor converts the reflected light to an absorbance spectrum which is then analyzed by two separate algorithms, also stored in the sensor's microprocessor. The two algorithms calculate muscle oxygen saturation (SmO₂), and muscle pH (pHm).

The sensor is attached to the patient using the CareGuide Ray. The Ray is an adhesive-backed sleeve that isolates the sensor optics from direct contact with the patient's skin, keeping the sensor firmly attached to the skin. The Ray also provides a light shield to prevent ambient light from reaching the sensor spectrometer. One Ray is used per patient, but the CareGuide Sensor is reusable. Prior to use on each patient the Multi-Parameter Mobile CareGuide sensor is placed in a new ray and the assembly is placed on the cradle, which is packaged with the Ray. Software in the sensor performs an optical sensor check to determine that the sensor optics remain within specification. The result of the sensor check is communicated to the user. Once the sensor check is passed, the adhesive liner is removed from the Ray and the sensor, within the Ray, is adhered to the patient's skin over either the deltoid, calf or thigh muscle.

When the sensor is first placed on the patient software in the sensor automatically performs an initialization routine which sets up the spectral data collection parameters for the individual patient. Once conditions are established the sensor begins collecting spectra and reporting parameter values.

The Multi-Parameter Mobile CareGuide 3100 with Tablet's sensor measures and provides for output of SmO₂ and pHm data. There is no change in hardware or software from the previous version of the device, RMI's Multi-Parameter Mobile CareGuide 3100. The Multi-Parameter Mobile CareGuide 3100 with Tablet uses the same disposable and battery charger as the Multi-Parameter Mobile CareGuide 3100. The Multi-Parameter Mobile CareGuide 3100 with Tablet also had no changes in the algorithm by which SmO₂ and pHm are calculated.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Addition of Android Tablet display {subject of this 510(k)}:

The main differences between the 3100 with Tablet and 3100 is the addition of qualified display devices (Android Tablet) and software on the Tablet to display real-time and historical trend data. This section describes these changes in detail.

The Multi-Parameter Mobile CareGuide 3100 sensor communicates with the Multi-Parameter Mobile CareGuide 3100, which is compliant with the Mobile CareGuide communications protocol. SmO₂ and pH_m values suitable for display and trending are sent via the Mobile CareGuide communications protocol to the Tablet as well as battery level, error information and device states. The Mobile CareGuide communications protocol can be found as part of the predicate K130079 submission.

Table 1. Key difference between RMI's Multi-Parameter Mobile CareGuide 3100 with Tablet and the Multi-Parameter CareGuide 3100

Tablet	Qualified two tablets hardware platforms:
Tablet software	Software on tablet: a. Android operating system; b. CareGuide display software; c. Utility tools; d. Lockdown software

Table 2. Key similarities between RMI's Multi-parameter Mobile CareGuide 3100 with Tablet and the Multi-Parameter CareGuide 3100

Optics	The optical circuit board is unchanged.
Power	The power (rechargeable battery and battery charger) is unchanged
Computing Element	The embedded main processor is unchanged.
Interface	The USB interface is unchanged.
Communications Protocol	The communications protocol between the sensor and the Tablet is unchanged.
Mechanical	The size, shape and material of the sensor case is unchanged
Disposable	The ray (disposable) is unchanged
Algorithm	The calculation algorithms for SmO ₂ and pH _m are unchanged.
Flow of Operation	The overall flow of operation from the perspective of the user is unchanged
Safety	Both products contain the same safety check of thermistors to prevent excessive heat exposure on the skin.

Page 769 redacted for the following reason:

(b)(4)-TS/CCI

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

Multi-Parameter Mobile
CareGuide 3100 Sensor
(USB)

Multi-Parameter Mobile
CareGuide 3100 Tablet

Mobile CareGuide 2100
Cradle & Ray



Figure 1. (a) Multi-Parameter Mobile CareGuide 3100 reusable sensor (USB), (b) Multi-Parameter Mobile CareGuide 3100 Tablet, (c) Mobile CareGuide 2100 disposable foam ray, packaged with the disposable Mobile CareGuide Cradle (used in conjunction with the Multi-Parameter Mobile CareGuide 3100 reusable sensor).

Multi-Parameter Mobile CareGuide 3100 Sensor: The Multi-Parameter Mobile CareGuide 3100 reusable battery-powered sensor contains the optical and electronic elements necessary to collect spectra from skin, fat, and muscle. All of these components are identical to the predicate Mobile CareGuide 3100 Sensor (K130079). The sensor has a 3m long cord with a USB connector to connect to the Android Tablet. In addition, there is a separate patient-safe 5V wall-connected power supply to charge the battery which may be using during sensor operation or during idle. Please refer to the predicate (K130079) for additional details.

11.2 Mobile CareGuide Ray

The Multi-Parameter Mobile CareGuide 3100 with Tablet sensor uses the Mobile CareGuide 2100 disposable sleeve or “ray”, which is a disposable sleeve (Figure 11) that isolates the sensor optical elements from the patient’s skin. The ray is made of molded foam coated with adhesive which conforms to the contour of the deltoid, thigh, or calf muscle.



Figure 11. Top view of disposable sleeve (ray).

Biocompatibility testing of the ray is described in Section 15 of this submission. Shelf life assessment of the ray is described in Section 14.

11.7 Mobile CareGuide Cradle

The cradle is a disposable part packaged with the ray (Figure 1c), used for verifying that the optical performance of the Sensor remains constant between uses. The Multi-Parameter Mobile

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

CareGuide 3100 sensor uses the Mobile CareGuide 2100 “cradle”. If the optical characteristics have changed significantly between uses or if the sensor is not properly aligned on the cradle, then the sensor will fail the sensor check and sensor cannot be used.

11.8 Mobile CareGuide Tablet

The Mobile CareGuide Tablet is a commercial Android tablet. For this filing, two devices have been validated: Acer A500 (RMI 3100-3007) and Asus Google Nexus 7 (RMI 3100-3006). The product is used as is from the respective manufacturer with additional software installed by Reflectance Medical. Reflectance Medical makes no additional regulatory claims of this hardware beyond those established by the respective manufacturer.

Mobile CareGuide Android Tablet Software: The Android software consists of 4 components (further described in Section 16 of this filing):

1. Android operating system: Android OS 4.0 and OS 4.3 have been validated. The OS is used ‘as is’ from the tablet manufacturer.
2. CareGuide display software: consists of three components: a. Communication software to interface with the sensor via the USB port; b. Display software to start/pause/stop the sensor, enter patient identification, perform a sensor check, display real-time SmO2 and pHm values, display a trend of historical SmO2 and pHm values and display any fault conditions reported by the sensor; c. Store historical trend data and fault conditions in a text file.
3. Lock down software: a 3rd party software package: SureLock from 42Gears Mobility Systems Pvt Ltd is installed on the Android tablet. It restricts the user to only be able to run the CareGuide 3100 display software application. It disables the ability to load any new software applications, or any operating system updates to the tablet. It disables all external communications (Wi-Fi, Bluetooth). There is a special key sequence and an additional password (set at the factory) required to disable the lockdown functions. This bypass is not provided to the end-user.
4. Utility tools: there are a set of 3rd party tools that are installed as part of the installation process for the Mobile CareGuide Android Tablet. These tools include APK installer, task manager, file explorer, screen shortcut creator, anti-virus software and USB test program. None of these applications are accessible to the end-user and are used only for installation or service purposes.

Pages 772 through 774 redacted for the following reasons:

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

11.10.6 Physical Specifications of the Mobile CareGuide 2100 Battery Charger**Table 15. Mobile CareGuide 2100 battery charger physical specifications**

Item	Specification	Notes
Manufacturer	PEI-Genesis Emerson Model PA-120030-01	UL; cUL; TUV; AS/NZS; CB; CE; PSE
Input	100-240V 0.3A Max 50/60 Hz	Drawing: Section_11 Hardware_Drawings: On file at RMI; <i>see</i> K122645
Output	5V 2.0A Max 10W Max	
Length	58 mm	
Width	25 mm	
Height	52 mm	
Weight	149.7 g	
Cable length	2.74 m	
Cable termination	PP-012: 0.7 mm (ID) x 2.35 mm (OD)	

11.10.7 Physical Specifications of the Mobile CareGuide 3100 Android Tablet**Table 16. Mobile CareGuide 3100 Android Tablet physical specifications**

Item	Specification	Notes
Manufacturer	ASUS Model ME370T	UL; FCC Part 15 Drawing: This is a commercial OEM device.
Type	7" Android Tablet	
Screen resolution	1280 x 800	
Input	5V 2.0A Max 10W Max	
Length	196 mm	
Width	119 mm	
Thickness	9 mm	
Weight	334.8 g	
Power	4325 mAh 16Wh Lithium- polymer battery	
AC Adapter	AD83531 (model number may vary) switching power supply 100-240V AC 50-60Hz; Output Max 5.0V 2.0A UL; CE; NOM	
Manufacturer	ACER Model A500-10S16	UL; FCC Part 15 Drawing: This is a commercial OEM device.
Type	10.1" Android Tablet	
Screen resolution	1366 x 768	
Input	5V 2.0A Max 10W Max	
Length	260 mm	
Width	178 mm	
Thickness	10 mm	
Weight	756.0 g	

Pages 776 through 777 redacted for the following reasons:

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

measurements;

5. Then the numeric values of the SmO₂ and pHm are transmitted to the Tablet and displayed.

Except for #5 above, all of the above sensor functions are identical the FDA-cleared Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079). At the end of the measurement procedure, the clinician will remove the Ray from the patient and discard it. The sensor is returned to the Tablet for use for another patient following the same procedure. Prior to reuse, the sensor is cleaned and checked using a new Ray and cradle. These reuse instructions are also identical the FDA-cleared Multi-Parameter Mobile CareGuide 3100 Oximeter (K130079).

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 12

SUBSTANTIAL EQUIVALENCE DETERMINATION

12.1 Substantial Equivalence – Predicates

Trade name of New Device: Multi-Parameter CareGuide™ Oximeter with Tablet
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc. (RMI)
510(k) Number: N/A
Proposed additional product codes: None

Predicate Device #1: Mobile CareGuide 3100
Trade name of Device: Multi-Parameter CareGuide™ Oximeter 3100
Model Number: 3100
510(k) Holder/Submitter: Reflectance Medical, Inc.
510(k) Number: K130079
Product codes: MUD, 21 CFR 870.2700, Cardiovascular
CBZ, 21 CFR 868.1170, Anesthesiology

Predicate Device #2: CareGuide
Trade Name of Device: Multi-Parameter CareGuide™ Oximeter
Model Number: 1100
510(k) Holder/Submitter: Reflectance Medical Inc.
510(k) Number: K113656
Product code: MUD, 21 C.F.R. § 870.2700, Cardiovascular

12.2 Multi-Parameter Mobile CareGuide 3100 with Tablet Proposed Indications for use:

The proposed indications for use for RMI’s Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet are:

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

12.3 SUBSTANTIAL EQUIVALENCE – REVIEW OF PREDICATES:

The Mobile CareGuide 3100 with Tablet is a multi-parameter oximeter, calculating and displaying SmO₂ and pH_m trends on an Android Tablet. Earlier versions of the device were cleared to monitor and display SmO₂ trends through K113656 (CareGuide 1100) and K130079 (Mobile CareGuide 3100, which cleared monitoring and display of both SmO₂ and pH_m trends through an interface to third party displays). K113656 was cleared under product code MUD, 21 C.F.R. § 870.2700. K130079 was cleared under the product codes MUD, 21 C.F.R. § 870.2700 and CBZ, 21 CFR 868.1170, Anesthesiology.

12.3.1 SmO₂ and pH_m Predicates: Mobile CareGuide 3100 (K130079)

The algorithms for calculating SmO₂ and pH_m are unchanged from the predicate Mobile CareGuide 3100. The hardware platform, including the optical components, described for the Mobile CareGuide 3100 is identical to the hardware platform for the Mobile CareGuide 3100 with Tablet. The software deployed for the Mobile CareGuide 3100 sensor is identical to the software for the Mobile CareGuide 3100 with Tablet. The communications protocol that allows the Mobile CareGuide 3100 sensor to communicate with 3rd party display devices is identical to the protocol used to communicate with the Tablet component of the Mobile CareGuide 3100 with Tablet. The Mobile CareGuide 3100 Oximeter with Tablet is technologically equivalent to the predicate Mobile CareGuide 3100. The Mobile CareGuide 3100 Oximeter with Tablet has the same Indications for Use statement as the predicate Mobile CareGuide 3100.

Mobile CareGuide 3100 Indications for Use Statement (K130079):

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pH_m data on a third party device, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO₂ and pH_m in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.”

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

12.3.2 Predicate (for display component in indications): CareGuide 1100 (K113656)

CareGuide 1100 Indications for Use Statement:

“The CareGuide™ Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The CareGuide displays the most recent value of SmO₂, as well as a graphical trend of previous SmO₂ measurements. The CareGuide System should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the CareGuide™ Oximeter has not been demonstrated in disease states.”

12.3.3 Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet {subject of this 510(k)}:

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

Table 12-1 Substantial Equivalence: Comparison of RMI’s Multi-Parameter CareGuide 3100 with Tablet to Mobile CareGuide 3100 and CareGuide 1100

Characteristics	RMI Multi-Parameter CareGuide Oximeter 3100 with Tablet	RMI Multi-Parameter CareGuide Oximeter 3100 K130079	RMI CareGuide Oximeter 1100 K113656
Muscle tissue SmO ₂ algorithm	Same as CareGuide 1100	Same as CareGuide 1100	SmO ₂ calculated from preprocessed spectra
Local tissue pH algorithm	Same as CareGuide 3100	pHm calculated from preprocessed spectra	N.A.

Pages 782 through 783 redacted for the following reasons:

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Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SmO₂ whereas the Multi-Parameter Mobile CareGuide 3100 with Tablet performs them with both SmO₂ and pHm.

Therefore the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is substantially equivalent to the predicate devices by indications for use and device features and functionality.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

12.4 SUBSTANTIAL EQUIVALENCE DETERMINATION

RMI has addressed the following questions from the FDA Substantial Equivalence flowchart (appended as the last page of this section), available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134783.htm>.

New device is compared to marketed device?

Yes. The Multi-Parameter CareGuide 3100 with Tablet is compared to RMI's CareGuide 1100 Oximeter and Multi-Parameter Mobile CareGuide 3100 Oximeter (K113656, K130079).

Does new Device have same indication statement?

Yes, the RMI Multi-Parameter CareGuide 3100 with Tablet has the same intended use as the predicate devices. The indications for use statement proposed by RMI is:

“The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.”

This indications for use statement draws from the indications for use statements for:

- Multi-Parameter Mobile CareGuide 3100 Oximeter: SmO2 and pHm measurements and USB communications to a display device (K130079)
- CareGuide 1100 Oximeter: display of SmO2 and pHm data (K113656)

There is no change in how the User would use the information generated by the Multi-Parameter Mobile CareGuide 3100 with Tablet relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter Mobile CareGuide 3100 with Tablet nor any of the predicate devices identified by RMI provides any diagnostic output. Please see Section 13 of this submission for Proposed Multi-Parameter Mobile CareGuide 3100 with Tablet Labeling.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

New Device has same intended use and may be “substantially equivalent”

Yes.

This device’s oximetry and pHm features have been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter and pH (21 CFR 868.1170).

The Multi-Parameter Mobile CareGuide 3100 with Tablet has the same intended use as one of the identified predicates, the Multi-Parameter Mobile CareGuide 3100 (K130079).

Does new Device have same Technological Characteristics, e.g. Design, Materials, Etc.?

Yes. The Multi-Parameter Mobile CareGuide 3100 with Tablet has the same principle of operation (an optical technological platform that relies on light absorption) and identical algorithms as both predicate devices. The Multi-Parameter Mobile CareGuide 3100 with Tablet uses the identical hardware, software, mechanical components and disposable sleeve as the Mobile CareGuide 3100 (K130079). The Multi-Parameter Mobile CareGuide 3100 includes a sensor and monitor and, outputs a numeric trend like the CareGuide 1100 predicate device (K113656).

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. The descriptive characteristics of the proposed device are not precise enough to ensure equivalence. However, as explained below, and in additional sections of this submission, performance data demonstrate Substantial Equivalence to the predicate devices. Therefore, the fact that the descriptive characteristics of the Multi-Parameter Mobile CareGuide 3100 with Tablet are not precise enough to ensure equivalence do not preclude a determination of Substantial Equivalence under FDA’s laws, regulations and guidance.

Are Performance Data Available to Assess Equivalence?

Yes. Please see the following sections of this submission:

- Section 14: Packaging/Shipping/Shelf life (there are no sterile components)
- Section 15: Biocompatibility
- Section 16: Software
- Section 17: Electrical Safety and EMC
- Section 18: Bench tests

Performance Data Demonstrate Equivalence?

Yes.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

The Multi-Parameter Mobile CareGuide 3100 with Tablet meets relevant consensus and FDA recognized standards for Oximeters, which support substantial equivalence. Biocompatibility, Electrical safety and EMC testing from the predicate device (K130079) were successfully completed. Validation of performance in the form of an Animal study, and a Clinical study for the predicate device (K130079) was successful. Bench Testing is summarized in Sections 18 of this submission.

Substantial Equivalence Determination:

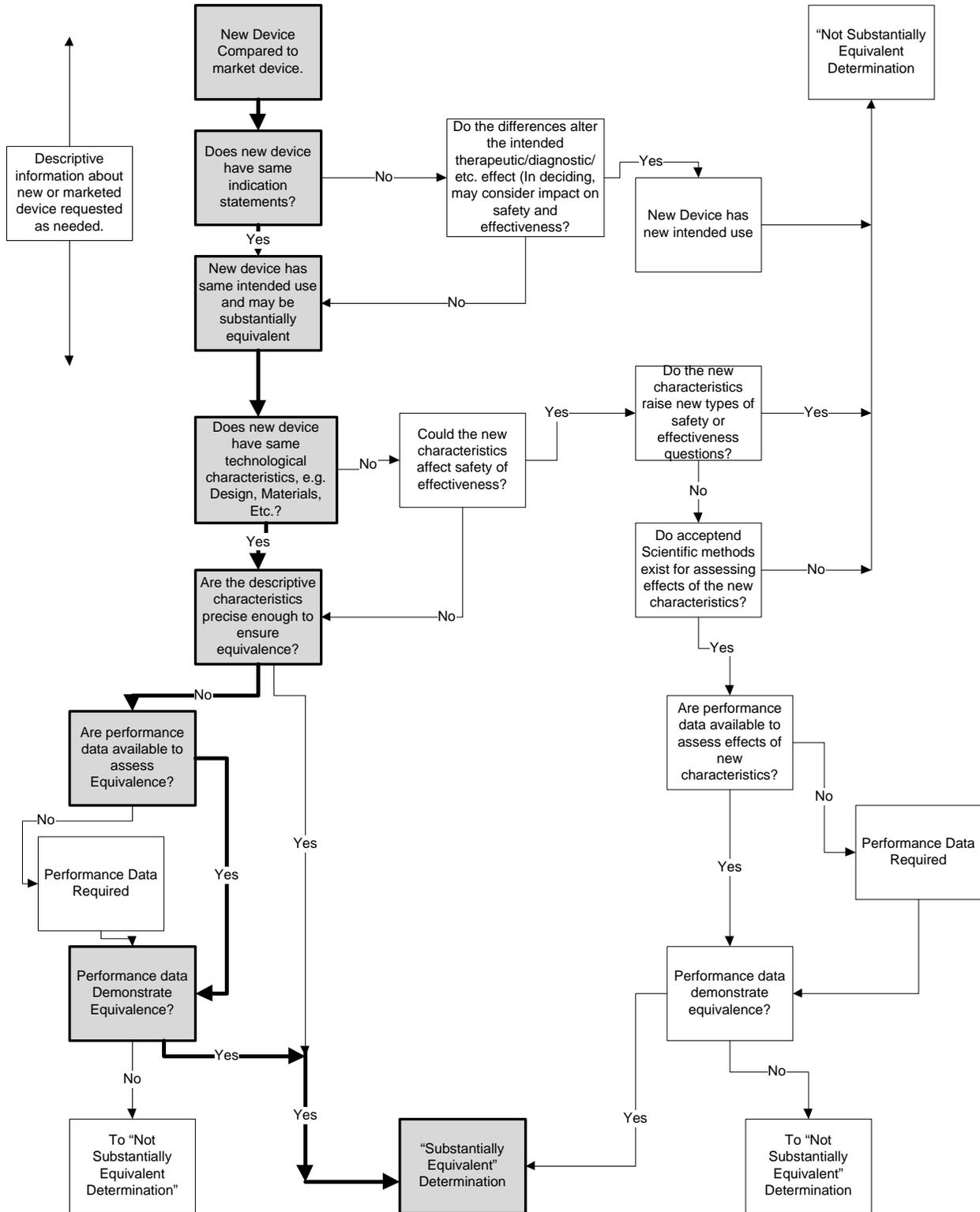
The Multi-Parameter Mobile CareGuide 3100 with Tablet is substantially equivalent to the predicate devices:

- The Indications for use for SmO₂ and pHm are identical with that of the predicates. They are all monitors.
- The reference to multiple classification codes in this 510(k) is identical with that of the predicates.
- Technologically, the Multi-Parameter Mobile CareGuide 3100 with Tablet is similar to the predicates.
- There is no change in the algorithm for monitoring of SmO₂ and pHm. Therefore, the accuracy of the Multi-Parameter Mobile CareGuide 3100 with Tablet is identical to the accuracy of the predicates.

Therefore, the Multi-Parameter Mobile CareGuide Oximeter 3100 with Tablet is Substantially Equivalent to the predicate devices.

Reflectance Medical, Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet



Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 13

PROPOSED LABELING

13.1 DRAFT PRODUCT LABELING

Labeling for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet consists of:

- Primary packaging label
- Secondary packaging label
- Device labeling
- Instructions for Use (Operator's Manual)

Draft labeling is included in this section. The product labels support compliance to requirements Section 16: DIR 11.1 through 11.16.

13.2 PRIMARY PACKAGING (immediate packaging) LABEL

Draft primary packaging labeling for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet components are provided in Figures 13.1, 13.2, 13.3, 13.4 and 13.5.

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

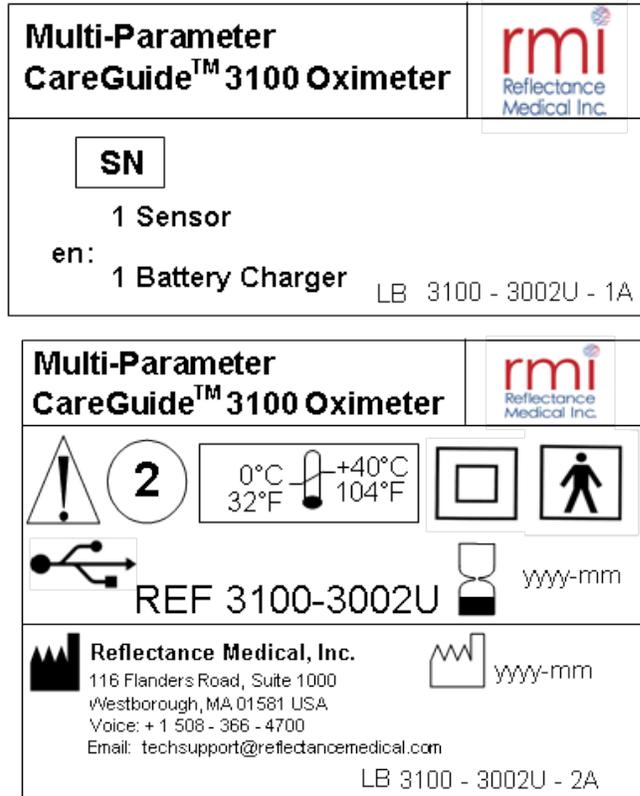


Figure 13.1: Sensor for USB interface Primary Packaging label:
Part 3002U-1A and Part 3002U-2A
(unchanged from predicate K130079)

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

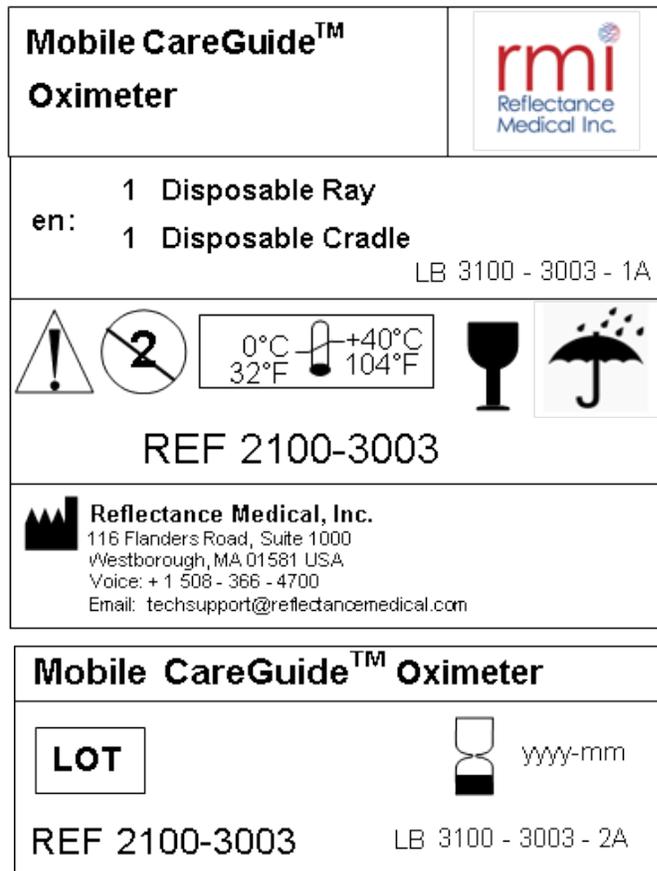


Figure 13.2: Disposable (Ray/Cradle) Primary packaging label:
 Part 3003-1A and Part 3003-2A
 (unchanged from predicate K130079)

Reflectance Medical Inc.

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Figure 13.3: Battery Charger Primary packaging label:
Part 3004-1A and Part 3004-2A
(unchanged from predicate K130079)

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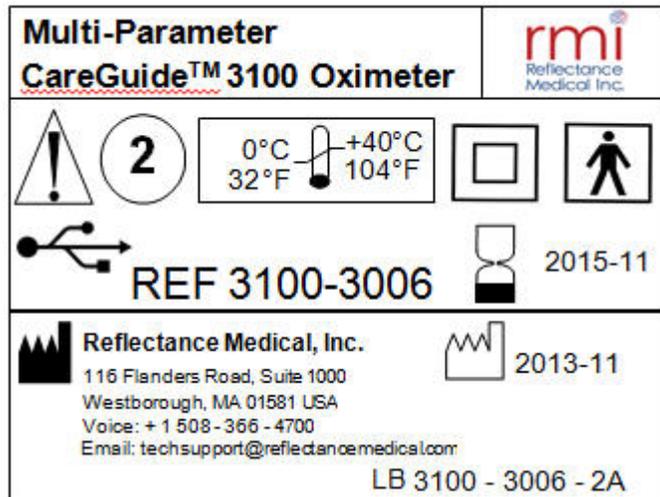
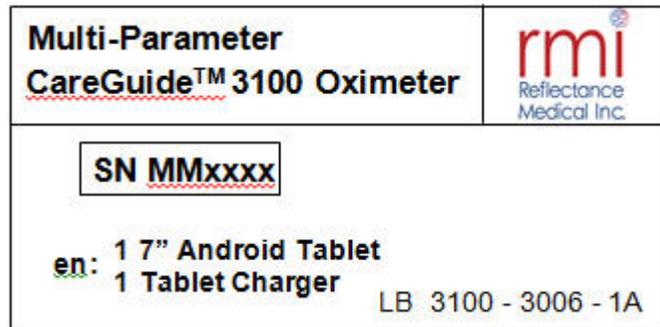


Figure 13.4: 7" Android Tablet Primary Packaging label:
Part 3006-1A and Part 3006-2A

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

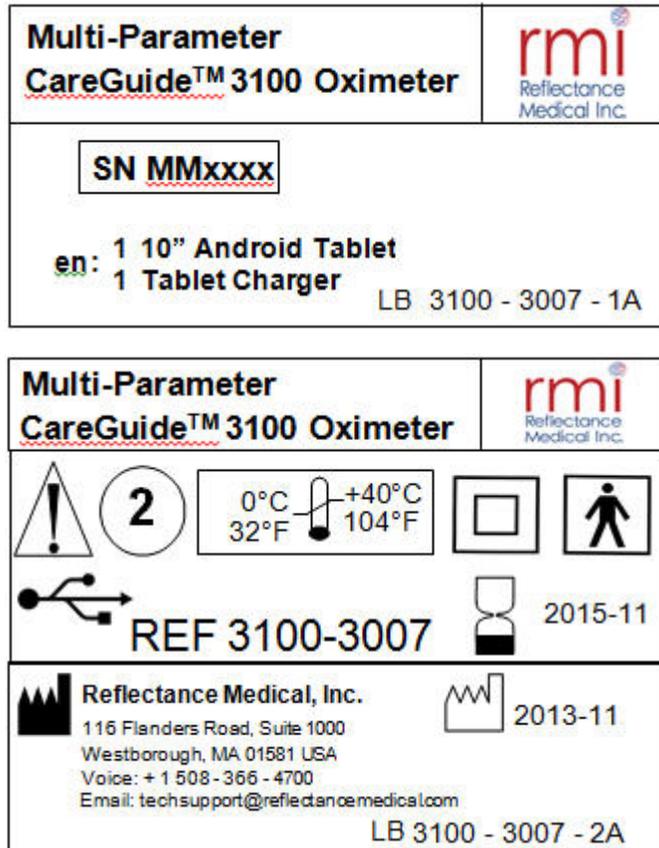


Figure 13.5: 10" Android Tablet Primary Packaging label:
Part 3007-1A and Part 3007-2A

Reflectance Medical Inc.

510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

13.3 SECONDARY PACKAGING (outside shipping container) LABEL

Draft secondary packaging labeling for the Mobile CareGuide™ 3100 Oximeter with Tablet components are provided in Figure 13.6.



Figure 13.6: Disposable (“Ray”) Secondary Packaging label
(unchanged from predicate K130079)

Reflectance Medical Inc.

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13.4 DEVICE LABELING

The following labeling is included directly on the Mobile CareGuide device. Device labelling is unchanged from predicate K130079.

- “CareGuide” is printed on the exterior of the Ray (Figure 13.7).



Figure 13.7: “CareGuide” logo printed on the exterior of the Ray

- Sensor with USB connector label (Figure 13.8) is printed on the cable of the Sensor (Figure 13.9).



Figure 13.8: Sensor with USB connector device label (Part 3002U-3A)

Reflectance Medical Inc.

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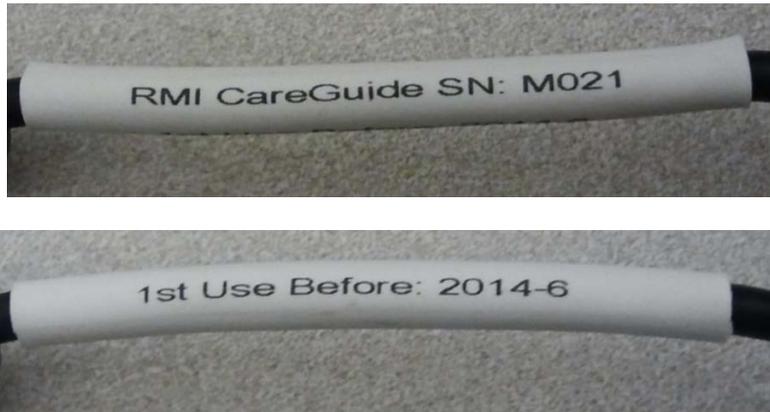


Figure 13.9: Sensor device label on the cable of the sensor

13.5 INSTRUCTIONS FOR USE (OPERATOR'S MANUAL)

The following draft Instructions for Use (IFU) for the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet are included in Section 13:

1. Multi-Parameter Mobile CareGuide™ 3100 Oximeter instructions for use – 5MAR2014 IFU REV B.

Multi-Parameter Mobile CareGuide™ 3100 Oximeter IFU will accompany the Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet system when shipped as a unit.

2. Mobile CareGuide™ Ray instructions for use - Instructions for Use - Ray Mars v5.0 20NOV2012 (unchanged from predicate K130079)

Mobile CareGuide™ Ray IFU will accompany the box of 8 Mobile CareGuide™ Ray when shipped as separate order.



Multi-Parameter Mobile 3100 OXIMETER

USER MANUAL

Instructions for Using the Multi-Parameter Mobile CareGuide™ 3100 Oximeter



R_x Only

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IFU-0005/Rev. B

Multi-Parameter Mobile CareGuide™

Model Number: 3100

Serial Number: _____
(user records)

License Number: _____
(user records)

Manufactured by:



Reflectance Medical, Inc. (RMI)
116 Flanders Road, Suite 1000
Westborough, MA 01581 USA
Voice: +1.508.366.4700
Fax: +1.508.366.4770
Email: techsupport@reflectancemedical.com
Website: www.reflectancemedical.com

Technical Support:



Voice: +1.508.475.9366
Email: techsupport@reflectancemedical.com

R_x Only

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IFU-0005/Rev. B

Multi-Parameter Mobile CareGuide™ 3100 Oximeter

IFU-0005/Rev. B

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (301)-796-8118 Page 44 of 78

Table of Contents

1	Introduction.....	4
1.1	Features	4
1.2	Indications for Use	5
1.3	Contraindications.....	5
1.4	Instructions Prior to Use	5
1.5	Components.....	6
2	Patient Monitoring.....	7
2.1	Setup	7
2.2	Starting Use.....	8
2.3	Checking Sensors & Rays.....	9
2.4	Placing Sensor & Ray on Patient.....	10
2.4.1	Shoulder Placement.....	11
2.4.2	Thigh Placement.....	12
2.4.3	Calf Placement.....	13
2.5	Beginning Monitoring.....	14
2.6	Other Operations	15
2.6.1	Display Options	15
2.6.2	Pausing & Resuming for the Same Patient.....	17
2.6.3	Changing to a New Patient.....	17
2.7	Ending Monitoring	18
3	Care & Maintenance	19
3.1	Cleaning the Sensor.....	19
3.2	Recharging the Sensor	21
3.3	Recharging the Display.....	22
3.4	Storing the System	22
4	Troubleshooting	23
4.1	Handling Error Messages	23
4.2	System Tools.....	24
4.2.1	Testing the Sensor Connection.....	24
4.2.2	Resetting the Sensor.....	24
4.2.3	Battery Charge Level	24
5	Safety Precautions	25
5.1	Warnings and Cautions	25
5.2	Disposal.....	27
6	Warranty.....	28
7	Technical Specifications.....	29

Table of Figures

Figure 1. System Components.....	6
Figure 2. Display Power Button and USB port, Connected to Sensor for Use	7
Figure 3. USB Access Prompt.....	7
Figure 4. Main Screen	8
Figure 5. Patient ID Screen.....	8
Figure 6. Patient ID Entered	8
Figure 7. Sensor Check Screen.....	9
Figure 8. Sensor Check In Progress.....	9
Figure 9. Placement Instructions Screen.....	10
Figure 10. Peeling Liner Off Ray	10
Figure 11. Optimal Shoulder Location	11
Figure 12. Ray Placed on Shoulder	11
Figure 13. Optimal Thigh Location.....	12
Figure 14. Ray Placed on Thigh	12
Figure 15. Optimal Calf Location	13
Figure 16. Ray Placed on Calf	13
Figure 17. Placement Instructions Screen	14
Figure 18. Sensor Optimizing	14
Figure 19. Monitoring Screen.....	14
Figure 20. Monitoring Screen- SmO ₂ Trend.....	15
Figure 21. Monitoring Screen- pHm Trend.....	15
Figure 22. Monitoring Screen- Graph Area for Accessing Options	16
Figure 23. Graphing Options Screen- Using On-Screen Keyboard.....	16
Figure 24. Graphing Options Screen	16
Figure 25. Example Monitoring Screen.....	17
Figure 26. Paused Monitoring Screen	17
Figure 27. Example Monitoring Screen.....	18
Figure 28. Display Power Button.....	18
Figure 29. Power Off	18
Figure 30. Overview photo including front face of Sensor and cord	19
Figure 31. Front face of Sensor	19
Figure 32. Layout of optical windows including LED banks and spectrometer.....	19
Figure 33. Sensor LED and Charger Connector	21
Figure 34. Sensor Battery Status LED States.....	21
Figure 35. Sensor Charger Connected to Sensor	21
Figure 36. Display Battery Status Icon.....	22
Figure 37. Charging the Display	22
Figure 38. System Tools Screen	24

1 Introduction

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter provides non-invasive assessment of hemoglobin-oxygen saturation (SmO₂) and pH (pHm) of microvascular blood in a region of skeletal muscle tissues beneath the oximeter sensor. It displays the most recent value of SmO₂ and pHm, as well as a graphical trend of previous measurements.

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is:

- Non-invasive, for acute use, and poses no significant safety questions.
- Uses infrared energy in a way that does not introduce excessive heat (i.e., no safety issue).
- Used in the clinical environment, in an *adjunctive* fashion, where clinicians also use other monitors, patient symptoms, and tests to guide decision-making.
- Not used for screening, nor does it provide diagnosis or determine patient treatment.

1.1 Features

Measurement Features

- SmO₂ and pHm measurements are automatically performed at the set measurement interval.
- Measurements require no individual patient learning or calibration
- SmO₂ and pHm measurements are absolute numbers representing the percentage of oxygen saturation of the muscle tissue and pH of the muscle tissue, respectively
- Sensor can accurately measure SmO₂ and pHm independent of skin pigmentation

Usability Features

- Operation is plug and play into the respective patient monitor or smart display device
- No configuration or calibration steps required
- Disposable Ray comes with cradle sensor check to perform a 1 minute integrity check on both ray and sensor
- Reusable sensor never touches the patient and can be easily cleaned
- Disposable Ray has simple, peel and stick operation to attach to the patient
- Disposable Ray is easily conformable to fit most size adult patients at six different body locations

1.2 Indications for Use

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO₂ and pHm data on an Android Tablet display, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet provides display of the most recent values of SmO₂ and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet should not be used as the sole basis for diagnosis or therapy.

Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter with Tablet has not been demonstrated in disease states.

1.3 Contraindications

The Multi-Parameter CareGuide™ 3100 should not be used for on patients with body temperatures below 34 degrees Celsius.

Do not place a Ray onto skin with nevi, bruises, burns, scars, tattoos, irregular freckling, discoloration, or large raised veins.

The Multi-Parameter CareGuide™ 3100 is not recommended for patients with a BMI <19 or >40.

1.4 Instructions Prior to Use

✱WARNING

Before using the Multi-Parameter Mobile CareGuide™ 3100 Oximeter, carefully read this entire manual. Users must fully understand and consistently follow all warnings, precautions, and instructions for safe and effective use of the system.

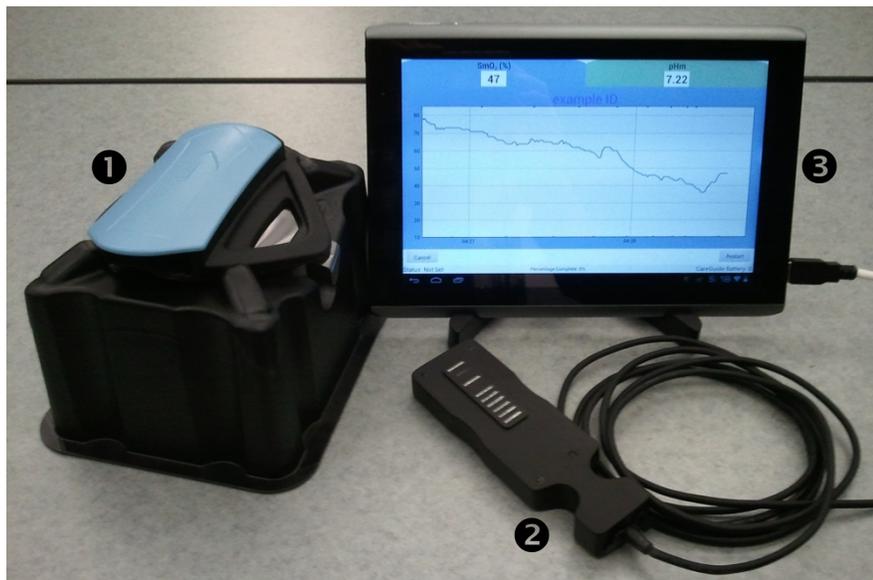
Failure to follow instructions for use may result in potentially serious outcomes for the patient or user (including adverse events, injury, or death), or may lead to system malfunction or failure.

For a full list of warnings and cautions when using this device, see Section 5.1 *Warnings and Cautions*.

1.5 Components

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter has three main components and a charger:

- 1 **Mobile CareGuide™ 2100 Ray** A single-use, latex-free disposable Ray (Figure 1 ①) has a pocket to receive the Multi-Parameter CareGuide™ 3100 Sensor, providing a barrier between the reusable Sensor and the patient. The Ray is designed to adhere onto the skin of the patient's shoulder, thigh, or calf. A single Ray can remain in the same location for up to 72 hours. During this time, the inserted Sensor may be removed from the Ray (e.g., if the patient needs to be relocated for testing or procedures). Later, the Sensor can be re-inserted to resume monitoring (e.g., when the patient returns to his or her room).
- 2 **Multi-Parameter CareGuide™ 3100 Sensor** When inserted into a Ray placed on a patient and connected to the Display via the Sensor cable, the reusable Sensor (Figure 1 ②) transmits pHm and SmO₂ measurements from the patient to the monitoring display.
- 3 **Display** Measurements from the Multi-Parameter CareGuide 3100 Sensor can be displayed as the Sensor communicates with an Acer A500 or Google Nexus 7 Android display containing CareGuide display software using a USB interface (Figure 1 ③).
- 4 **Battery Charger** The Multi-Parameter CareGuide™ 3100 Sensor operates on enclosed rechargeable Lithium-polymer battery. The Sensor may be recharged (while in use or idle) using only the supplied Reflectance Medical medical-grade battery charger.



- ① Ray on Cradle
- ② Sensor
- ③ Display

Figure 1. System Components

2 Patient Monitoring

2.1 Setup

Prior to use, ensure the Sensor and Display are charged (see 3.2 *Recharging the Sensor* & 3.3 *Recharging the Display*). Both components may be charged during monitoring, if needed.

- 1 Power on the Display by holding down the power button for ~6 seconds (Figure 2 ❶).
- 2 Connect the Sensor cable to the Display USB port (Figure 2 ❷) to ready the system for use (Figure 2 ❸).

Note: If using a Display with only a micro-USB port, plug the supplied micro-USB to Type A USB adapter cable into the Display first, then plug Sensor cable into the adapter cable.

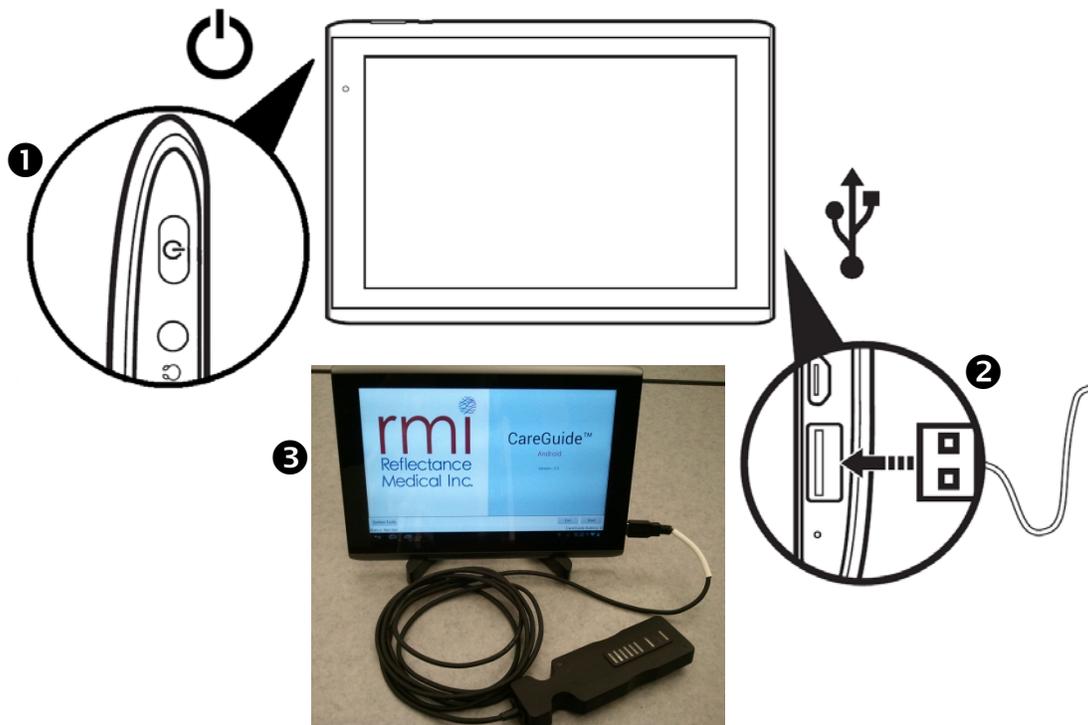


Figure 2. Display Power Button and USB port, Connected to Sensor for Use

- 3 If not already launched, click the CareGuide icon to launch the software.
- 4 Click 'OK' when prompted 'Allow the app CareGuide to access the USB device?' (Figure 3 ❹).

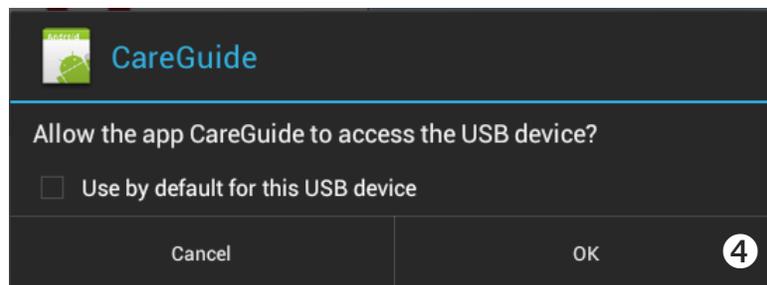


Figure 3. USB Access Prompt

2.2 Starting Use

- 1 Click 'Start' on the Main Screen to begin (Figure 4 ①).



Figure 4. Main Screen

- 2 If needed, click the Patient ID box to bring up the on-screen keyboard (Figure 5 ②).
- 3 Enter the patient ID (up to 50 characters), then hide the keyboard (Figure 5 ③).

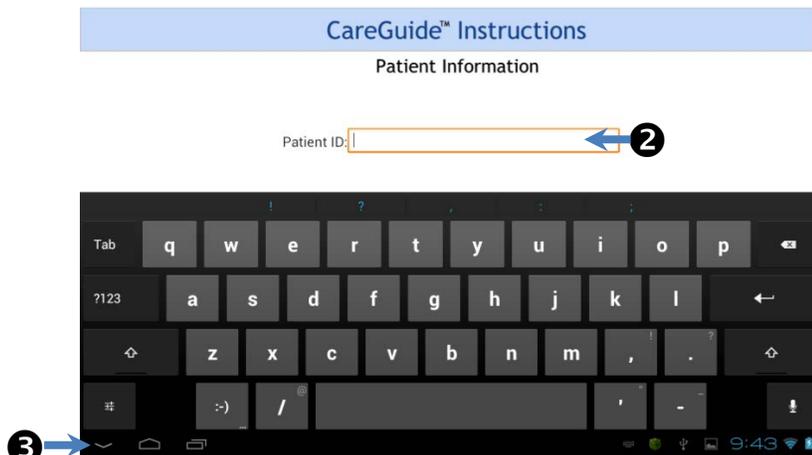


Figure 5. Patient ID Screen

- 4 Click 'Continue' (Figure 6 ④).

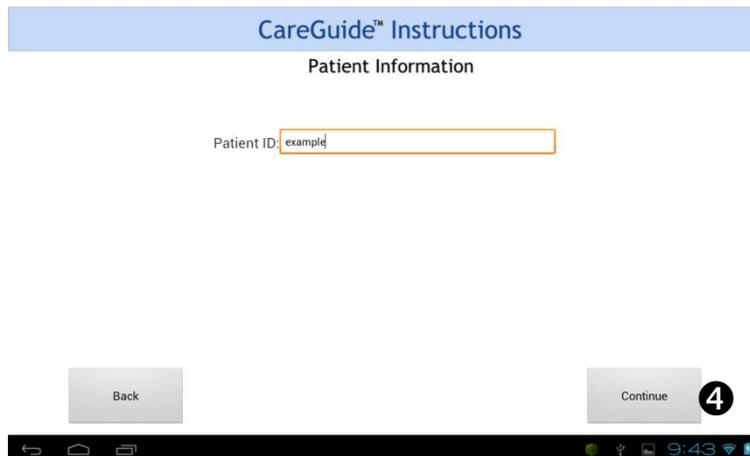


Figure 6. Patient ID Entered

2.3 Checking Sensors & Rays

If it has been 24 hours since the last Sensor Check, you will see the Sensor Check prompt (Figure 7). Otherwise, go straight to Sensor placement (see 2.4 *Placing Sensor & Ray on Patient*).

- 1 Remove the Ray from Cradle and insert Sensor fully (Figure 7 ❶).
- 2 Use the window of the Ray to check Sensor insertion (Figure 7 ❷).
- 3 Replace the Sensor in Ray onto the Cradle, ensuring a snug fit (Figure 7 ❸).
- 4 Verify the arrow on the Ray aligns with the arrow on the Cradle (Figure 7 ❹).
- 5 On the Display, click 'Begin Sensor Check' (Figure 7 ❺).

CareGuide™ Ray Instructions

❶ 1. Insert Sensor into Ray



❸ 2. Place Ray on Cradle

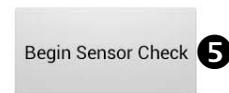
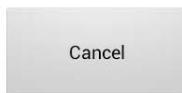


Figure 7. Sensor Check Screen

- 6 Checking takes about 45-50 seconds (Figure 8 ❻).

❻ CareGuide™ Sensor Check

Performing Sensor Check... Please stand by....

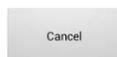


Figure 8. Sensor Check In Progress

- 7 If the Sensor Check passes, the Display will prompt you to place the Sensor & Ray on the patient (Figure 9 ⑦).

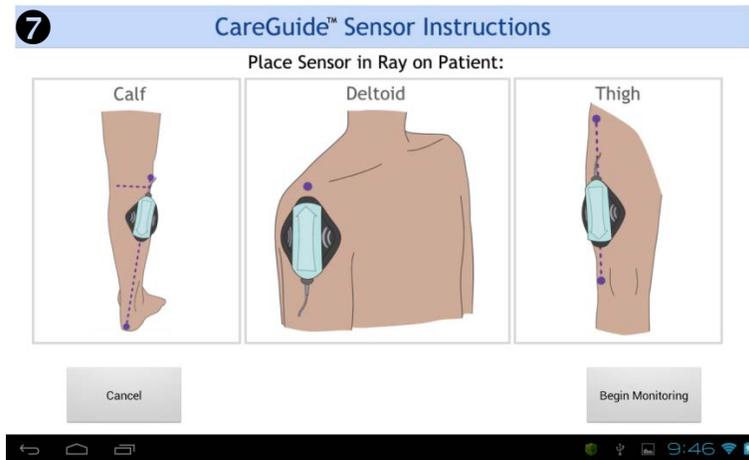


Figure 9. Placement Instructions Screen

- 8 If Sensor Check fails, see 4 Troubleshooting.

2.4 Placing Sensor & Ray on Patient

Recommended placement locations for the Ray are:

- Shoulder
- Thigh
- Calf

Preparing skin:

For the best results, skin at the Ray placement site should be clean and dry. If needed, use an alcohol prep pad to clean the skin. Do not place the Ray until skin has dried.

Note: For excessively hairy patients, consider shaving the placement location.

Preparing Ray:

- 1 Without withdrawing the Sensor from the Ray, remove the Ray from the Cradle.
- 2 Expose Ray adhesive by using the pull tab to peel off the clear liner (Figure 10).



Figure 10. Peeling Liner Off Ray

2.4.1 Shoulder Placement

Recommended for use when:

- Patient is supine or prone, if lying down
- No blood pressure cuff is present
- Shoulder is large enough so that the tips of the Ray do not go beyond half way around the circumference of the upper arm
- No large, raised veins are present
- No nevi, bruises, burns, scars, tattoos or uneven freckling are present

To place the Ray on the shoulder (deltoid):

- 1 Locate the deltoid as you would to for an IM injection (Figure 11 ❶).
- 2 Palpate the acromion process (Figure 11 ❷).
- 3 Align the Ray so the arrow is pointing towards the shoulder joint with the tip of the Ray one fingers' width inferior to the acromion process along the deltoid (Figure 12 ❸).
- 4 Ensure the Ray is centered dorsoventrally over the deltoid muscle before pressing it onto the patient's skin (Figure 12 ❹).

Note: To minimize gaps between the Ray and the patient, press the center (blue) section of the Ray onto the skin first, then smooth down the black foam onto the skin.

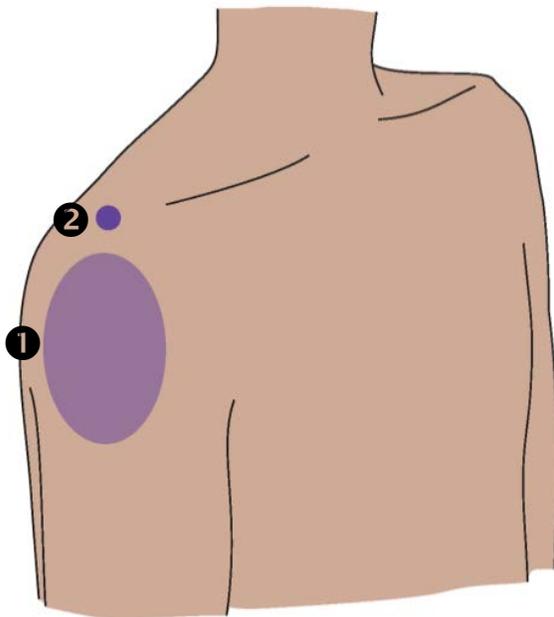


Figure 11. Optimal Shoulder Location

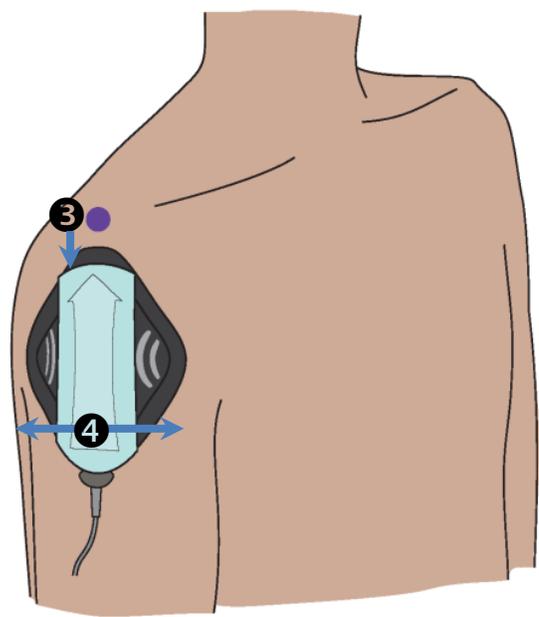


Figure 12. Ray Placed on Shoulder

2.4.2 Thigh Placement

Recommended for use when:

- Patient is supine, if lying down
- Blood pressure cuff or other instruments present on both shoulders
- Ray is too big for shoulder placement
- No large, raised veins are present
- No nevi, bruises, burns, scars, tattoos or uneven freckling are present

To place the Ray on the thigh (vastus lateralis):

- 1 Locate the vastus lateralis, as you would for an IM injection (Figure 13 ❶).
- 2 Use the lateral femoral condyle and point of hip as landmarks to draw an imaginary line along the thigh (Figure 13 ❷).
- 3 Align the Ray so the arrow is pointing towards the lateral femoral condyle, with the tip of the Ray a hand's breadth superior to the lateral femoral condyle (Figure 14 ❸).
- 4 Ensure the length of the blue part of the Ray aligns with the length of the imaginary line before pressing it onto the patient's skin (Figure 14 ❹).

Note: To minimize gaps between the Ray and the patient, press the center (blue) section of the Ray onto the skin first, then smooth down the black foam onto the skin.

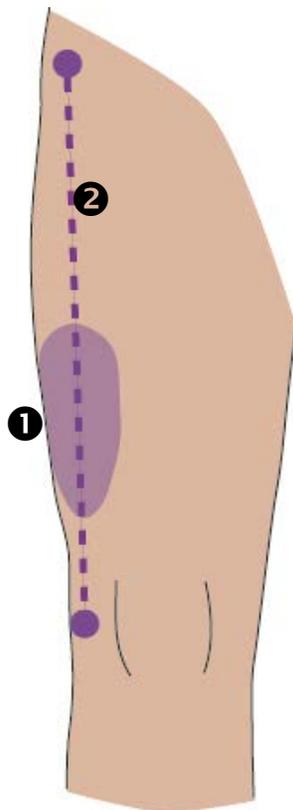


Figure 13. Optimal Thigh Location

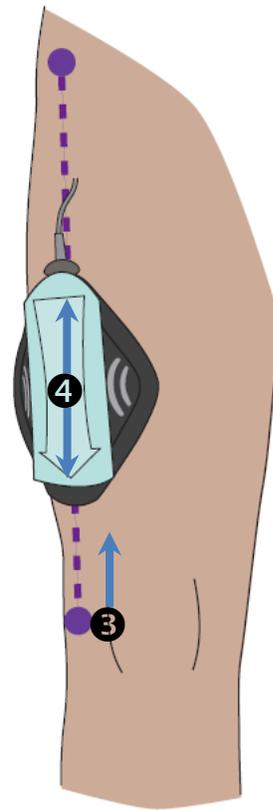


Figure 14. Ray Placed on Thigh

2.4.3 Calf Placement

Recommended for use when:

- Patient is prone, if lying down
- Blood pressure cuff or other instruments present on both shoulders
- Ray is too big for shoulder placement
- No large, raised veins are present
- No nevi, bruises, burns, scars, tattoos or uneven freckling are present

To place the Ray on the calf (lateral gastrocnemius):

- 1 The target muscle for calf placement is the lateral gastrocnemius (Figure 15 ❶).
- 2 Use the lateral femoral condyle and heel as landmarks to draw an imaginary line along the calf (Figure 15 ❷).
- 3 Align the Ray so the arrow is pointing towards the heel, with the cable end of the sensor two fingers' widths inferior to the line of the knee joint (Figure 16 ❸).
- 4 Ensure the length of the blue part of the Ray is aligned with the length of the imaginary line before pressing it onto the patient's skin (Figure 16 ❹).

Note: For ambulatory patients, consider angling the cable end of the sensor slightly toward the fibular head to allow for better range of motion.

Note: To minimize gaps between the Ray and the patient, press the center (blue) section of the Ray onto the skin first, then smooth down the black foam onto the skin.

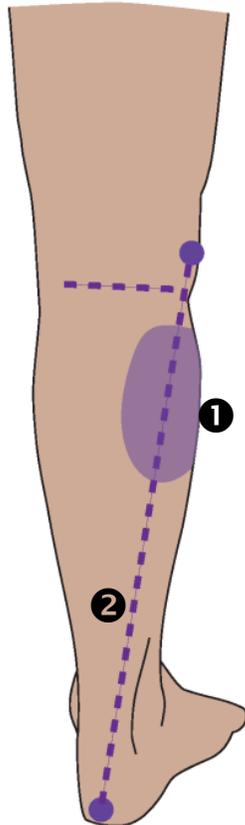


Figure 15. Optimal Calf Location

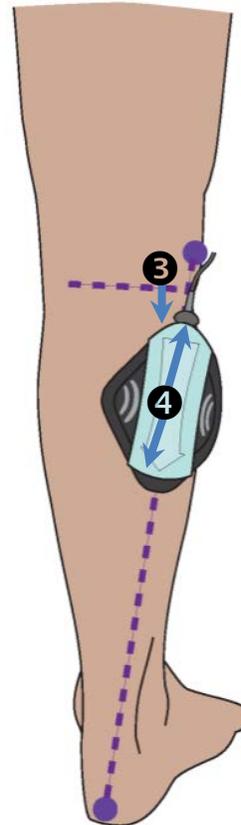


Figure 16. Ray Placed on Calf

2.5 Beginning Monitoring

- 1 Once the Ray is placed on the patient, click 'Begin Monitoring' (Figure 17 ①).

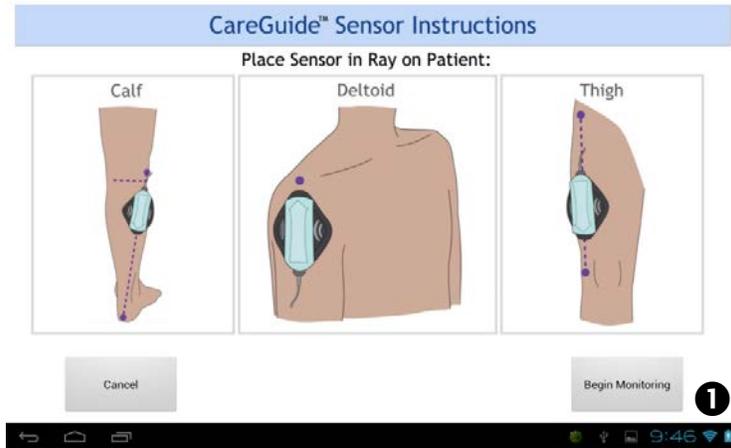


Figure 17. Placement Instructions Screen

- 2 The Sensor optimizes to the patient, which can take 60-90 seconds (Figure 18 ②).

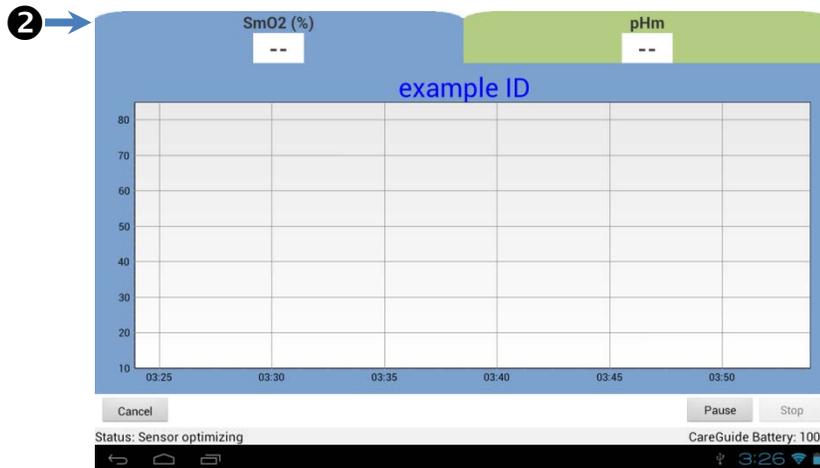


Figure 18. Sensor Optimizing

- 3 Monitoring begins, and SmO₂ and pHm data are displayed (Figure 19 ③).

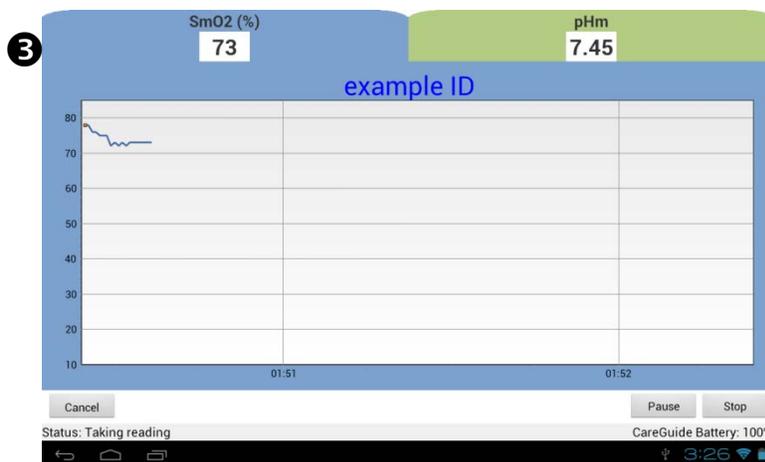


Figure 19. Monitoring Screen

2.6 Other Operations

2.6.1 Display Options

To select which parameter displays on the trend graph:

- 1 Click on the parameter button below the values for the desired trend. Example: to change from SmO₂ trend to pHm, click the green 'pHm' tab (Figure 20 ①).



Figure 20. Monitoring Screen- SmO₂ Trend

- 2 The color of the graph surround will match the parameter currently selected for trend display (Figure 21 ②).



Figure 21. Monitoring Screen- pHm Trend

To adjust the scale of the current parameter's trend graph:

- 1 Touch anywhere on the graph on the Monitoring Screen (Figure 22 ①).

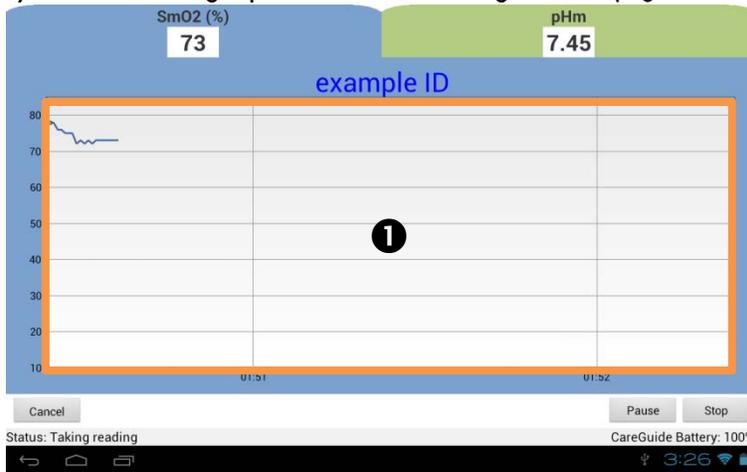


Figure 22. Monitoring Screen- Graph Area for Accessing Options

- 2 Adjust X and Y Axes values using + and – buttons (Figure 23 ②)
- 3 If desired, click the value box to bring up the on-screen keyboard for editing (Figure 23 ③) Hide the on-screen keyboard when adjustments are complete (Figure 23 ④).

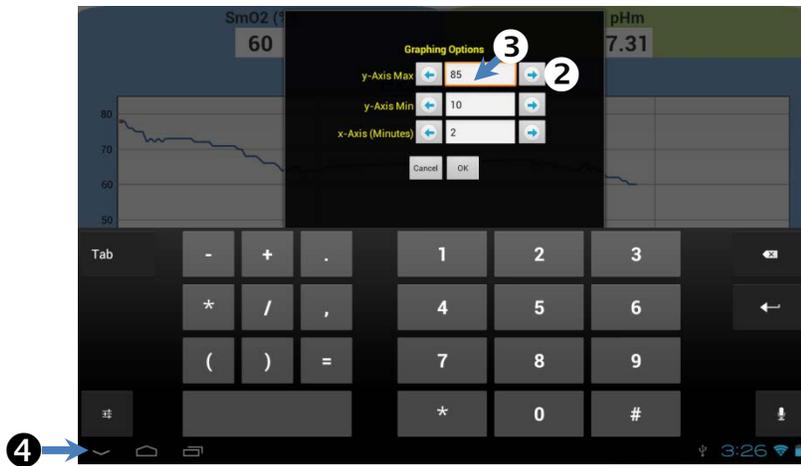


Figure 23. Graphing Options Screen- Using On-Screen Keyboard

- 4 Click 'OK' to save changes and return to Monitoring Screen (Figure 24 ⑤)

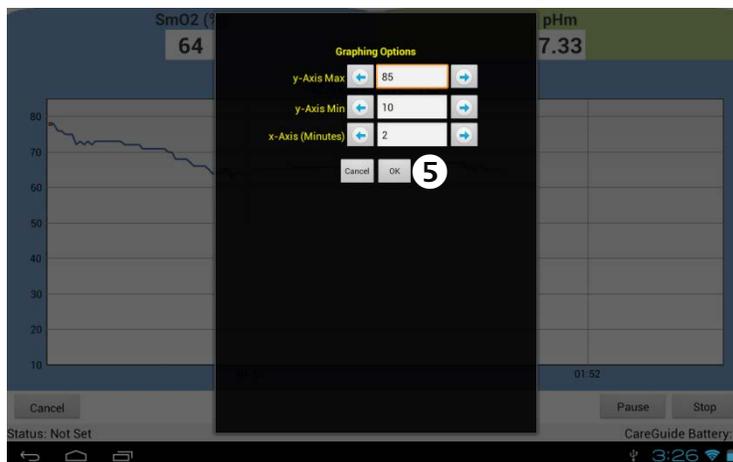


Figure 24. Graphing Options Screen

2.6.2 Pausing & Resuming for the Same Patient

To temporarily pause monitoring (e.g., for testing or procedures):

- 1 Click the 'Pause' button on the Monitoring screen (Figure 25 ❶).

Note: The Multi-Parameter CareGuide 3100 Sensor does contain metal and must be removed from the Ray prior to a patient entering the MRI or similar imaging environment. The Ray may remain attached to the patient during these procedures.

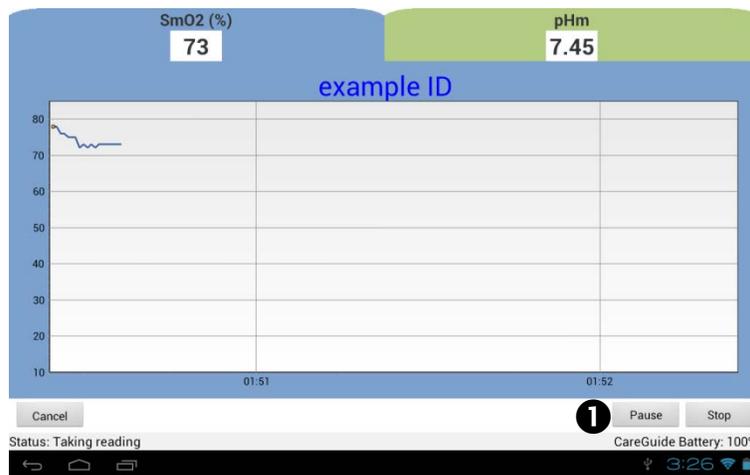


Figure 25. Example Monitoring Screen

- 2 If it had been removed, reinsert the Sensor into the Ray on the patient.
- 3 Click the 'Restart' button on the paused Monitoring screen (Figure 26 ❷) to resume monitoring for the current patient.

Note: If not resumed after 2 hrs of being paused, the system returns to the main screen.



Figure 26. Paused Monitoring Screen

2.6.3 Changing to a New Patient

To change from monitoring the current patient to monitoring a new patient:

- 1 Click the 'Stop' button on the Monitoring Screen (Figure 25) to end current monitoring.
- 2 Once at the Main Screen, see Sections 2.2 *Starting Use* through 2.5 *Beginning Monitoring*.

2.7 Ending Monitoring

- 1 To end monitoring for the current patient, click the 'Stop' button on the Monitoring Screen (Figure 27 ❶).

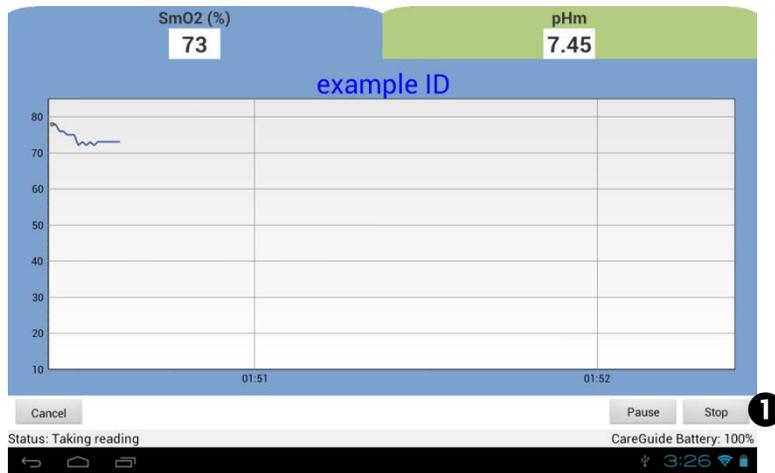


Figure 27. Example Monitoring Screen

- 2 The system returns to the Main screen.
Note: To start monitoring a new patient, see Sections 2.2 *Starting Use* through 2.5 *Beginning Monitoring*.
- 3 If finished monitoring, press and hold the power button on the Display (Figure 29 ❷).

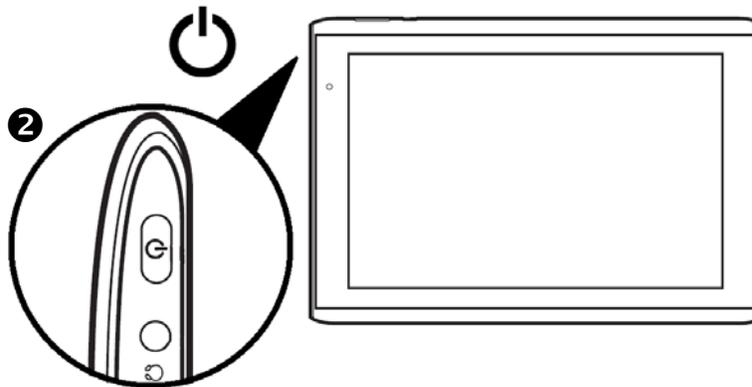


Figure 28. Display Power Button

- 4 Click 'OK' to confirm shut down (Figure 29 ❸).

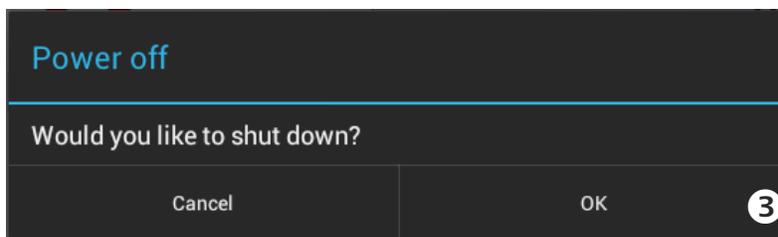


Figure 29. Power Off

3 Care & Maintenance

3.1 Cleaning the Sensor

After use, the Sensor shall be cleaned following the cleaning steps outlined below. Perform these steps immediately after sensor use regardless if there is visible soil or not. An overall figure (Figure 30) of the Multi-Parameter CareGuide 3100 parts to be cleaned for re-use is shown below:

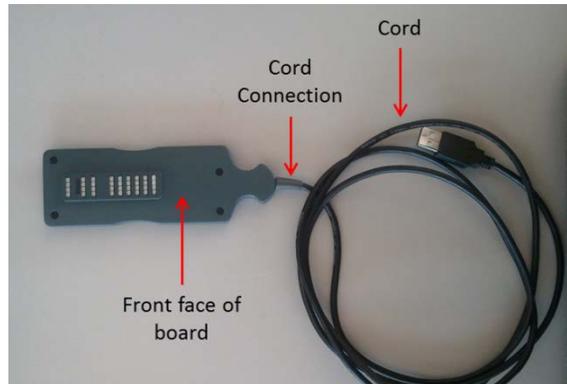


Figure 30. Overview photo including front face of Sensor and cord

Cleaning debris from sensor

Use a Sklar wipe to wipe all areas until all visible debris is removed. If the Sklar wipe becomes visibly dirty, discard and use a new Sklar wipe, until the wipe does not have any debris left on it. Follow the step-by-step directions indicated below:

- 1 Remove one Sklar wipe* from its container
- 2 Wipe the front, back, and sides of the Sensor, and the Sensor cord. Take special care to clean the cord connection.
- 3 Use another wipe to dislodge debris from screw heads on the front face of the Sensor if necessary (Figure 31).
- 4 Use a different wipe to wipe the area between the LED banks to remove debris (Figure 32)

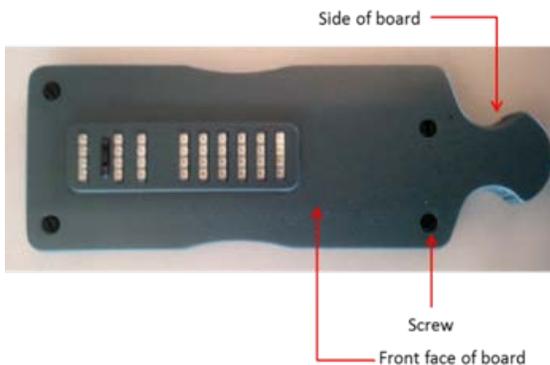


Figure 31. Front face of Sensor

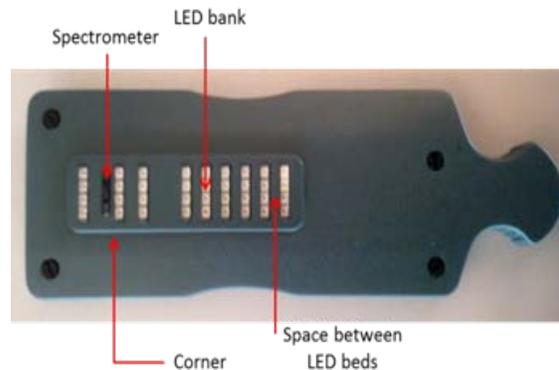


Figure 32. Layout of optical windows including LED banks and spectrometer

- 5 Wipe the spectrometer and surrounding areas
- 6 Wipe each LED from left to right using very light pressure to remove debris from glass
- 7 Once cleaned, allow Sensor to completely dry before moving on to the next step

Removing detergent residue from sensor

- 1 Remove a pre-saturated CleanTex wipe** from its product package.
- 2 Wipe the front, back and side of the Sensor.
- 3 Wipe area between LED banks to remove debris.
- 4 Wipe each LED bank from left to right using very light pressure to avoid streaking on glass casing.
- 5 If CleanTex wipe has noticeable debris on it, repeat the cleaning protocol from the beginning with a fresh Sklar wipe.
- 6 Allow the Sensor to completely air-dry prior to use.
- 7 Visually inspect device for residual soil and repeat this step, if necessary.
- 8 Once cleaned, re-use or store Sensor in original packaging or other clean environment
- 9 Before re-use, examine Sensor to ensure there is no dirt or debris.
- 10 If necessary, repeat the cleaning protocol prior to re-use.

Note: *The Sklar Disinfectant™ Surface Wipes (Sklar Instruments, Part Number 10-1616, EPA Reg# 70144-2-31118) is provided in the packaging, or can be purchased from Sklar Instruments or its distributors:

Sklar Instruments

889 S. Matlack Street
West Chester, PA 19382 U.S.A.
Phone: (800) 221-2166
Fax: (610) 696-9007
www.sklarcorp.com

**The CleanTex wipes (Advantus Corp., Part Number CT 806) is provided in the packaging, or can be purchased from Advantus Corporation distributors:

Specialty Optical Systems

10210 Forest Lane
Dallas, TX 75243
Phone: (800) 443-07101
Fax: (214) 340-5723
Email: Sales@SOSSupply.com
www.SOSSupply.com

3.2 Recharging the Sensor

The Multi-Parameter CareGuide™ 3100 Sensor may be recharged while in use or idle using only the supplied RMI medical-grade battery charger.

The Sensor has an LED (Figure 27 ❶) that indicates charge status by the state of the LED (Figure 28). You can also check the battery charge level using System Tools (see 4.2.3 Battery Charge Level).



Figure 33. Sensor LED (❶) and Charger Connector (❷)

LED State	Description
LED off	Battery charge is $\leq 5\%$ (<45 minutes) -or- Charger is not plugged in
LED Blinking	Battery charge level is 0-89% and charger is attached and working
LED Solid	Battery charge level is $\geq 90\%$

Figure 34. Sensor Battery Status LED States

To charge the Sensor, connect the DC-in jack to the Sensor (Figure 27 ❷) and plug the Sensor charger (Figure 29 ❸) into any hospital-grade AC 110/220V outlet.



Figure 35. Sensor Charger Connected to Sensor

3.3 Recharging the Display

The Display has a battery charge status icon in the lower right corner of the screen (Figure 30).

To charge the Display, connect the DC-in jack to the Display (Figure 31 ①) and plug the AC adapter into any AC 110/220V outlet (Figure 31 ②).

Icon	Description
	Battery is very low
	Battery is low
	Battery is partially drained
	Battery is full
	Battery is charging

Figure 36. Display Battery Status Icon

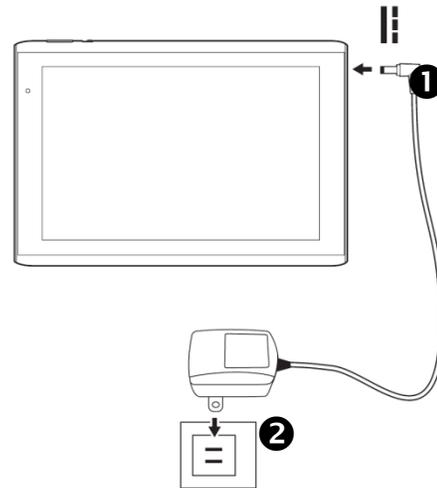


Figure 37. Charging the Display

3.4 Storing the System

- 1 If connected, unplug chargers from wall power and Sensor and Display.
- 2 Disconnect the Sensor from the Display.
- 3 If applicable, remove the Sensor from and discard the used Ray.
- 4 Clean the sensor as described in 3.3 *Cleaning the Sensor*. Place cleaned, dry sensor in storage container or an unused Ray.
- 5 Store display and sensor in a safe, clean location, away from direct sunlight and away from temperature extremes.

Sensor

- Do not exceed 30-90% atmospheric humidity.
- Do not go below 32°F (0°C).
- Do not exceed 104°F (40°C).

Disposable Ray

- Do not exceed 40-60% atmospheric humidity.
- Do not go below 50°F (10°C).
- Do not exceed 80°F (27°C).

Battery Charger

- Do not go below -40°F (-40°C).
- Do not exceed 185°F (85°C).

4 Troubleshooting

4.1 Handling Error Messages

Message	When it happens	Solution
Sensor nearing expiration	Initial setup	Order a replacement sensor soon. Sensor may be used normally for up to one month.
Sensor expired. Please replace.	Initial setup	Order a replacement sensor.
Sensor Check failed	Sensor Check	Check alignment of Ray in Cradle. Check sensor for dirt or soil and clean if necessary. Retry. If error persists, contact Tech Support.
SmO2 shows <10 or >85	During patient monitoring	SmO2 value is beyond the valid measurement range. Such values could be physiologically possible. Check placement on patient if desired.
pHm shows <6.9 or >7.5	During patient monitoring	pHm value is beyond the valid measurement range. Such values could be physiologically possible. Check placement on patient if desired.
Check Sensor. Reposition if needed.	During patient monitoring	Check alignment and adhesion of Ray on patient. If insufficient, use a new Ray and restart. If error persists, contact Tech Support.
Check sensor connection	During patient monitoring	Check sensor cable. Use 'Check Sensor Connection' and/or 'Reset Sensor' tools in System Tools menu. If using a micro-USB to Type A USB adapter cable, check adapter. Remove sensor from adapter; plug adapter cable in by itself; then plug sensor into adapter cable. If error persists, contact Tech Support.
Replace Ray on patient.	During patient monitoring	Ray use has exceeded 72hrs. Pause monitoring, replace Ray in new location on patient, then continue monitoring.
Sensor overheated. Please wait 1 hr.	During patient monitoring	Discontinue use of sensor for at least 1 hour before trying monitoring again. If error persists, contact Tech Support.
Sensor failed. Contact tech support.	Anytime	Contact Tech Support for a replacement sensor.
Battery is low. Please connect charger.	Anytime	Connect battery charger or discontinue use of sensor.

4.2 System Tools

The System Tools menu, accessible by clicking the 'System Tools' button on the Main Screen, has tools that may help in sensor troubleshooting.

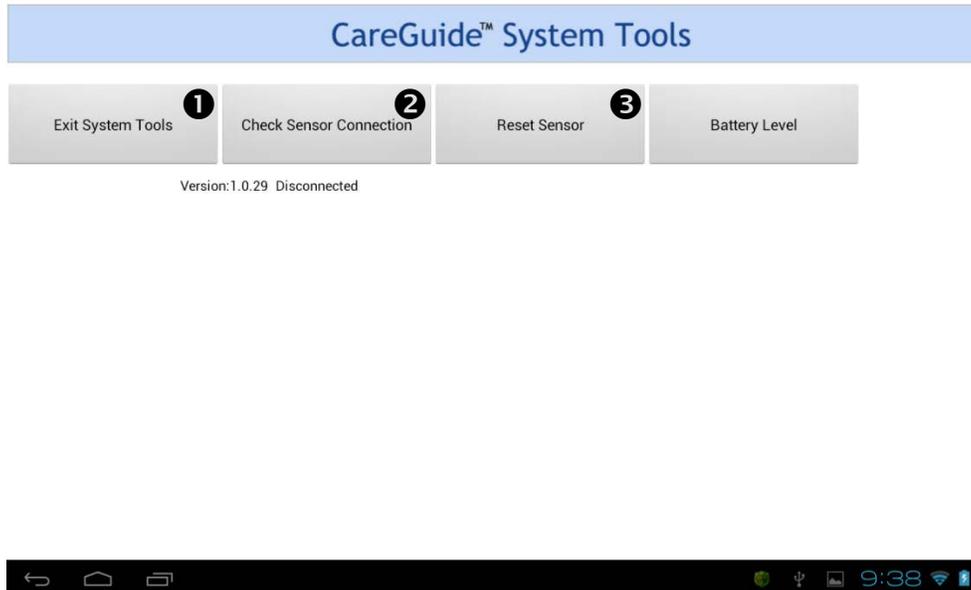


Figure 38. System Tools Screen

4.2.1 Testing the Sensor Connection

To test if the connected Sensor is communicating to the Display properly:

- 1 Click 'Check Sensor Connection' button on the System Tools page (Figure 32 ①).
- 2 Properly communicating sensors will return the message 'Sensor connected'.
- 3 If you get error 'No sensors connected', check that the Sensor battery is charged. If using a micro-USB to Type A USB adapter cable, remove sensor from adapter; plug adapter cable in by itself; then plug sensor into adapter cable. If error persists, contact RMI Tech Support.

4.2.2 Resetting the Sensor

If errors persist with a communicating Sensor, you can try resetting the Sensor:

- 1 Click 'Reset Sensor' button on the System Tools page (Figure 32 ②).
- 2 The Sensor should return the message 'Sensor reset successfully'.
- 3 If errors persist after resetting the sensor, contact RMI Tech Support.

4.2.3 Battery Charge Level

You can get a reading of the charge level of the Sensor battery by:

- 1 Click 'Battery Level' button on the System Tools page (Figure 32 ③).
- 2 The Sensor returns a message 'Battery Level=#', where # is the percent charge.

5 Safety Precautions

5.1 Warnings and Cautions

Before using the Multi-Parameter Mobile CareGuide™ 3100 Oximeter, carefully read this entire manual. Users must fully understand and consistently follow all warnings, precautions, and instructions for safe and effective use of the system.

 **WARNINGS** Alert users about potential serious outcomes for the patient or user (including adverse events, injury, or death).

 **CAUTIONS** Alert users to conditions that may lead to system malfunction or failure.

General Use Warnings

 Use the Multi-Parameter CareGuide™ 3100 with care, as intended, and according to the instructions that shipped with the system. Failure to follow system warnings, precautions, and instructions may cause system malfunction or lead to patient and user injury or and death.

 Do not operate the system near flammable anesthetics. Operating the system near flammable anesthetics may present an explosion that could seriously injure or kill the patient or user.

Cleaning and Maintenance Warnings

 Do not clean the system when it is plugged in, turned on, or connected to a patient. Cleaning the system while it is in use and connected to AC mains power may cause an electrical shock that could seriously injure or kill the patient or user.

 Do not attempt to repair or service any part of the Multi-Parameter CareGuide™ 3100. Attempted repair by untrained, unauthorized individuals may result in serious injury or device malfunction. Contact RMI Technical Support for any repair or service.

CareGuide Sensor Cautions

 The Multi-Parameter CareGuide™ 3100 has a detachable Sensor for monitoring. Use care during operation to avoid soiling or damaging the delicate Sensor. Soiling or damaging the Sensor may cause inaccurate measurements or malfunctions.

 Do not use without first checking and optimizing the Sensor or Ray. Failure to check and optimize the Sensor or Ray may cause inaccurate measurements or malfunction.

 Do not connect any (USB or serial) extension cables to the Sensor cable. Attaching any extension cables will cause the Sensor to time out intermittently and cause malfunction.

 Use only functioning, properly tested, and grounded AC mains electrical outlets to recharge the Sensor. Using faulty, ungrounded outlets may cause failure or malfunction.

CareGuide Ray Cautions

 The Mobile CareGuide™ 2100/3100 Ray is a slight irritant to the skin.

-  Do not place a Sensor and Ray onto skin that is damaged or irritated. Applying Sensors/Rays to skin that is damaged or irritated may cause additional skin damage or irritation. Applying Rays over large, raised veins or onto tattooed, irregularly freckled or discolored skin may result in inaccurate measurements or malfunction.
-  Do not use the same Ray for more than 72 hours. Using a Ray for longer than 72 hours may cause irritation or tissue damage at the site. In addition, use over 72 hour may result in inaccurate measurements or malfunction. If the patient requires monitoring beyond 72 hours, remove the first Ray and attach a new one and place on a different location.
-  Do not apply a Ray to the same site more than three times in a 72-hour period. If additional placements are required, the sensor may be rotated to the contralateral site or used on alternative site (thigh versus deltoid, etc)
-  Do not re-use Rays. The disposable Ray is designed for single-patient, one-time use. Reuse will cause Oximeter malfunction. Dispose used Rays properly.
-  Do not immerse a Ray in water or liquid. Do not expose a Ray to water or moisture. Water, liquid, or moisture will damage the adhesive used to hold the Ray onto the skin. Damaged adhesive may cause gaps between the Ray and patient's skin, which may result in inaccurate measurements. If the Ray gets wet and water damages the adhesive, use a new Ray.

General Use Cautions

-  The Multi-Parameter CareGuide™ 3100 is not defibrillator-proof. It may remain attached to the patient during defibrillation; however readings may be inaccurate during the defibrillation and shortly thereafter. A sensor check should be performed, when convenient, following a defibrillation event.
-  Do not drop Multi-Parameter CareGuide™ 3100 components or subject them to extreme shock. Dropping components or forcefully hitting them against hard objects may damage components and cause Oximeter malfunction.
-  Do not use the Multi-Parameter CareGuide™ 3100 if any component, part, or accessory is damaged or worn. Using damaged or worn equipment may cause failure or malfunction. Contact RMI Technical Support for new equipment if needed.
-  Do not use extension cords or adapters for ungrounded electrical outlets. Using an adapter or extension cord may cause failure or malfunction.
-  Do not use an electrical outlet controlled by a wall switch, or the device may be turned off accidentally.
-  Use only RMI parts and accessories with the Multi-Parameter CareGuide™ 3100 Oximeter. Using non-RMI equipment may cause malfunction. Contact RMI Technical Support to order parts and accessories.
-  Do not use the Multi-Parameter CareGuide™ 3100 in environmental conditions that are:
 - Below 50°F (10°C).
 - Above 104°F (40°C).
 - Outside 30-75% atmospheric humidity.

- Outside 70.0-106.0 kPa atmospheric pressure.

- ✎ Avoid exposing Multi-Parameter CareGuide™ 3100 components, parts, and equipment to direct sunlight or excessive moisture, heat or cold.

✎ **Cleaning and Maintenance Cautions**

- ✎ Follow Multi-Parameter CareGuide™ 3100 instructions for cleaning external components (see *Cleaning*, Section 8.1). Never immerse components in water, cleaning solutions, or liquid. This will damage the components, cause malfunction, and void any warranties and service agreements.

- ✎ Do not use connector cables or other equipment soiled or contaminated with infectious, or potentially infectious, materials. Using soiled or contaminated items may result in a serious infection for the patient or contaminate other patients or users. Soiled or contaminated cables and equipment must be removed from use, and replaced or cleaned according to Multi-Parameter CareGuide™ 3100 instructions, prior to re-use (see *Cleaning*, Section 8.1).

- ✎ Always follow Multi-Parameter CareGuide™ 3100 instructions for storing and transporting system components and equipment (see *Storage/Transportation*, Section 8.2, for complete device-specific limitations and requirements).

- ✎ Never attempt to repair Multi-Parameter CareGuide™ 3100 equipment or components. Refer all maintenance and repair to RMI-authorized service technicians. Unauthorized repairs or maintenance may cause user harm or malfunction, and void all warranties and service agreements. Contact RMI Technical Support for details.

5.2 Disposal

Sensor & Display

- ✎ **WARNING** The Sensor and Display each contain a lithium polymer battery. Please follow local regulations on the disposal or recycling of lithium-containing electronics. Do not throw the Sensor or Display away in the trash.

Disposable Ray

Dispose of used Rays in accordance with local hospital regulations. Unused Rays may be disposed of in regular trash.

Disposable Cradle

The Cradle may be disposed of in regular trash.

Sensor & Display Chargers

Dispose of chargers in accordance with local regulations on electronic waste.

6 Warranty

Reflectance Medical warrants to the original purchaser that the Multi-parameter Mobile CareGuide™ 3100 Sensor (the “Device”) will be free from defects in material and workmanship for a period of one (1) year following delivery of the Device to the original purchaser (the “Warranty Period”). Reflectance Medical does not warrant that operation of the Device will be error-free or uninterrupted. Reflectance Medical shall repair or replace any part or parts of the Device that Reflectance Medical determines is defective within the Warranty Period. At Reflectance Medical’s discretion, it may elect to supply a similar, new or equivalent replacement, or refund the purchase price as of the date of sale of the Device. To qualify for such repair, replacement or refund, the defective Device must a) be returned within thirty (30) days of discovery of the defect by the purchaser and accompanied by proof of date of purchase; b) not have been repaired or altered by any party other than Reflectance Medical or its authorized agents; c) not have been subjected to misuse per the Device Instructions for Use, negligence or accident in Reflectance Medical’s judgment. Purchaser shall be solely responsible for all return freight charges. This warranty does not include Reflectance Medical’s disposable products or non-Reflectance Medical complementary products. Reflectance Medical makes no additional warranty claims for the non-Reflectance Medical Android tablet beyond those provided by the original manufacturer. In no event shall Reflectance Medical be liable for any damages (including, without limitation, lost profits, business interruption, or lost information) arising out of your use of or inability to use the Device, even if Reflectance Medical has been advised of the possibility of such damages.

THIS WARRANTY IS GIVEN IN LIEU OF ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

7 Technical Specifications

Multi-Parameter Mobile CareGuide™ Oximeter 3100		
SmO₂	Range	10% - 85%
	Resolution	1%
	Measurement Rate	30 seconds
	Accuracy	3.8 SmO ₂ units (%)
	Drift	None
pHm	Range	6.90 – 7.50
	Resolution	0.01 pHm units
	Measurement Rate	30 seconds
	Accuracy	0.05 pHm units
	Drift	None
Packaging	System Packaging	<ul style="list-style-type: none"> 1 Multi-Parameter Mobile CareGuide 3100 Sensor 1 sensor battery charger 1 Android display with CareGuide software 1 display charger 1 Micro-USB to Type A adapter (if required) 1 tub of 100 Sklar™ wipes 1 box of 80 CleanTex™ wipes 1 case of 8 Mobile CareGuide™ Ray & cradle sets (boxed individually)
	Packaging for Reorders	<ul style="list-style-type: none"> 1 Multi-Parameter Mobile CareGuide™ 3100 Sensor and 1 battery charger 1 case of 8 Mobile CareGuide™ Ray & cradle sets (boxed individually)
Mobile CareGuide Ray	Size	<ul style="list-style-type: none"> • 155 x 146 x 27 mm (5.9 x 5.4 x 1.06 in) • One size fits shoulder, calf, or thigh.
	Weight	560.3g (2.13oz)
	Material	<ul style="list-style-type: none"> • Latex free • Biocompatible adhesive
	Attachment to patient	<ul style="list-style-type: none"> • Adhesive placement on shoulder, calf or thigh • Intact skin only • Single Use per patient
	Shelf Life	18 months post manufacturing date
	Use Life	72 hours (single use patient)
Multi-Parameter CareGuide Sensor	Size	• 139 x 47 x 23 mm (5.5 x 1.9 x 0.90 inches)
	Weight	177.2g (6.25 oz)
	Sensor Cable Length	• 2.74 m (9 ft)
	Auxiliary USB Cable	• mini-USB to USB
	Connectors	<ul style="list-style-type: none"> • Battery charger • Auxiliary USB

Multi-Parameter Mobile CareGuide™ Oximeter 3100

	Battery	Rechargeable, Lithium-polymer, sealed, not replaceable
	Typical Battery Life	12 hours (60 sec sample rate) 9 hours (30 sec sample rate)
	Battery Charge Time	5 hours to charge from <5% to 100%
	Attachment to Patient	<ul style="list-style-type: none"> • Insert into Mobile CareGuide™ Ray • Clean with CleanTex™ and Sklar™ wipes between patients
	Shelf Life	2 years post manufacturing date
	Use Life	1 year post first use
Battery charger	Voltage required	• Input: 100-240V 0.3A Max 50/60 Hz
	Cable	• Cable length: 2.74 m (9 feet)
Alarms	Audiovisual	Via CareGuide display
	Audible Alarm	Via sensor
	Error Conditions	See Troubleshooting above.
Product Classification	Medical Device	US: Class II Type BF device per section 870.2700 of 21 CFR and IEC 60601-1 3 rd Edition v2005
Standards	Electrical and Constructional Safety	IEC 60601-1-1:2005 (includes former PEMS IEC 60601-1-4)
	Electromagnetic Compatibility	IEC 60601-1-2: 2001/2006 (Class A emissions)
	Laser Safety	Class 1 laser device per IEC 60825-1: Edition 2.0 (2007)
	Enclosure	PC/UABS HT Cycloy C2950; Impact, rough handling, mold stress relief per IEC 60601-1 3 rd edition
	Shipping and Packaging	ISTA 1A
	Risk Analysis/Risk Management	ISO 14971
	Usability	IEC 60601-1-6
	Battery	IEC 62133; UN T1-T8; ED 93/86/EEC; ED 2006/66/EC
	Biocompatibility	Cytotoxicity: ISO 10993-5: v2009 Irritation and Sensitization: ISO 10993-10 v2010
	Cleaning	AAMI TIR 12:2010; AAMI TIR 30:2003
Electromagnetic Emissions and Immunity	This sensor has been tested and found to comply with the limits for medical devices to IEC 60601-1 3 rd Edition v2005. The Acer A500 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2006/A1:2007 Class B and EN 55024:1198/A1:2001/A2:2003. The	

Multi-Parameter Mobile CareGuide™ Oximeter 3100

	<p>Asus Google Nexus 7 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2010 and EN 55024:2010. Refer to Tablet Manufacturer's documentation.</p> <p>This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:</p> <ul style="list-style-type: none"> • Reorient or relocate the devices. • Increase the separation between the devices. • Connect the equipment to an outlet on a different circuit. • Contact the Service Center. 	
Operating Conditions	Temperature	10°C – 40°C (50°F-104°F)
	Humidity	30-75% ATM non-condensing
	Pressure	70-106 kPa

Manufactured by:



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Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

SECTION 17

Electromagnetic Compatibility (EMC) and Safety

17.1 EMC and Safety Standards Compliance

FDA Recognition number	Standard #	Standard Name	Results	Exceptions	Reference Documents
5-27	IEC 60601-1-1: 2005	Medical electrical equipment -- Part 1-1: General requirements for safety – Collateral standards: Safety requirements for medical electrical systems	Pass	None	Predicate filing (K122645) and on file at RMI: Mobile CareGuide USB Harmonics and Flicker; Mobile CareGuide USB Immunity; Mobile CareGuide Mechanical Safety
5-35	IEC 60601-1-2: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests	Pass	None	Predicate filing (K122645) and on file at RMI: Mobile CareGuide USB Emissions

Page 832 redacted for the following reason:

(b)(4)-TS/CCI

Reflectance Medical Inc.

Traditional 510(k) Premarket Notification Submission: Multi-Parameter Mobile CareGuide™ 3100 Oximeter with Tablet

17.3 EMC & Safety Testing Results

Safety Testing: All tests passed; the product is declared compliant with the standard.

EMC Testing: All tests are passed and the product is declared compliant with the standard.

17.4 EMC & Safety Testing Mitigations

Section 13 Instructions for Use document Section 9.0 Electromagnetic Emissions and Immunity indicates the following:

“This sensor has been tested and found to comply with the limits for medical devices to IEC 60601-1 3rd Edition v2005. The Acer A500 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2006/A1:2007 Class B and EN 55024:1198/A1:2001/A2:2003. The Asus Google Nexus 7 tablet has been tested by the manufacturer as compliant with the requirements of EN 55022:2010 and EN 55024:2010. Refer to Tablet Manufacturer’s documentation. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices.
- Increase the separation between the devices.
- Connect the equipment to an outlet on a different circuit.
- Contact the Service Center. “