

Rad-G®
with temperature



Not for Sale in the USA - For Export Only

These operating instructions provide the necessary information for proper operation of the Rad-G. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of Rad-G are prerequisites for its proper use. Do not operate Rad-G without completely reading and understanding these instructions. If you encounter any serious incident with the product, please notify the competent authority in your country and the manufacturer.

Note: Cleared Use Only: The device and related accessories are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

Notice: Purchase or possession of this device does not carry any expressed or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

CAUTION: Use of this device must follow the order of a physician.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

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About This Manual

This manual explains how to set up and use the Rad-G®. Important safety information relating to general use of Rad-G appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Features and Indications for Use

Product Description

The Rad-G® is intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (PR), perfusion index (Pi), pleth variability index (PVi) and pleth respiration rate (RRp) and spot-check temperature measurement.

The following key features are available for Rad-G®:

- Masimo SET® technology performance.
- Noninvasive functional saturation of arterial oxygen hemoglobin (SpO₂) and pulse rate (PR), Pleth Variability Index (PVi), and Respiration Rate determined by plethysmographic waveform (RRp).
- Non-contact surface temperature measurement.

Indications for Use

The Rad-G® and Accessories are intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), Pulse Rate (PR), and Pleth Respiration Rate (RRp).

The Rad-G® and Accessories are indicated for noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and Pulse Rate (PR) of adult, pediatric, infant, and neonate patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, transport, and home environments.

The Rad-G® and Accessories are indicated for the noninvasive spot-checking or continuous monitoring of Respiration Rate from the photoplethysmogram (RRp) of adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, transport, and home environments.

The Rad-G® and Accessories are indicated for the noninvasive spot-checking of Temperature of adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, transport, and home environments.

Contraindications

The Rad-G device is not intended for use as an apnea monitor.

Safety Information, Warnings, and Cautions

CAUTION: Rad-G is to be operated by, or under the supervision of, qualified personnel only. Read the manual, accessories directions for use, all precautionary information, and specifications before use.

Safety Warnings and Cautions

WARNING: Do not use Rad-G if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.

WARNING: Do not adjust, repair, open, disassemble, or modify the Rad-G. Damage to the device may result in degraded performance and/or patient injury.

WARNING: Do not start or operate the Rad-G unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.

WARNING: Do not place the Rad-G or accessories in any position that might cause it to fall on the patient.

WARNING: Only use Masimo authorized devices with Rad-G. Using unauthorized devices with Rad-G may result in damage to the device and/or patient injury.

WARNING: All sensors and cables are designed for use with specific devices. Verify the compatibility of the device, cable, and sensor before use; otherwise degraded performance and/or patient injury can result.

WARNING: Do not use the Rad-G in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide to avoid risk of explosion.

WARNING: Do not use the Rad-G during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: Rad-G may be used during defibrillation. However, to reduce the risk of electric shock, the operator should not touch the Rad-G during defibrillation.

WARNING: To protect against electrical shock injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this Operator's Manual.
- Do not attempt to clean the Rad-G while monitoring patient.

WARNING: To ensure safety, avoid placing anything on the device during operation.

WARNING: As with all medical equipment, carefully route patient cables to reduce the possibility of patient entanglement or strangulation.

CAUTION: Do not place the Rad-G where the controls can be changed by the patient.

CAUTION: Do not place Rad-G where the AC power supply cannot be readily disconnected when used on AC power.

CAUTION: Only use the AC power adapter provided by Masimo. Using a different AC power adapter could cause damage to the Rad-G. Check the power adapter to ensure that it is intact and undamaged.

CAUTION: To ensure patient electrical isolation, all external device connections to the output interface connector must be done using only authorized data cables.

Note: Disconnect the device from AC mains by unplugging the AC power supply from the Rad-G.

Note: Use and store the Rad-G in accordance with specifications. See the Specifications section in this manual.

Performance Warnings and Cautions

WARNING: Rad-G should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: The Rad-G and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

WARNING: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check Rad-G for proper functioning.

WARNING: Rad-G is not an apnea monitor.

WARNING: Rad-G should not be used as a replacement or substitute for ECG-based arrhythmia analysis.

WARNING: Always ensure settings including alarm limits and alarm speaker volume are appropriate for each patient and facility's protocol and environment prior to use. Devices in which the alarm speaker is not working or the alarm speaker volume setting is not distinguishable from the facilities ambient noise should not be used.

WARNING: When using the Rad-G for spot-check monitoring, no physiological alarms are provided.

WARNING: PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.

WARNING: Rad-G may be used during defibrillation. However, this may temporarily affect the accuracy or availability of the parameters.

WARNING: Rad-G may be used during electrocautery. However, this may temporarily affect the accuracy or availability of the parameters.

WARNING: Properly apply sensors according to sensor's directions for use. Misapplied sensor or sensors that become partially dislodged may cause no or incorrect readings.

WARNING: Select a well perfused site for monitoring, very low perfusion at the monitored site may result in no or incorrect readings.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Rad-G, including cables specified. Otherwise, degradation of the performance of this equipment could result.

WARNING: Displayed parameter(s) may not be accurate when a low SIQ message is provided. Clinicians should consider additional information to supplement values to completely understand the patient's condition.

WARNING: If SpO₂ values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

WARNING: SpO₂ is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

WARNING: Optical, pleth-based measurements (e.g. SpO₂, PVi and RRp) can be affected by the following:

- Improper sensor application or use of use of incorrect sensor.
- Blood pressure cuff applied to the same arm as the sensor site.
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous congestion.
- Abnormal venous pulsations (e.g. tricuspid valve regurgitation, Trendelenburg position).
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Moisture, birthmarks, skin discoloration, nail aberration, deformed fingers, or foreign objects in the light path.
- Elevated levels of bilirubin.
- Physiological conditions that can significantly shift the oxygen disassociation curve.
- A physiological condition that may affect vasomotor tone or changes in vasomotor tone.

WARNING: No or inaccurate SpO₂ readings may be caused by:

- Improper sensor application.
- Blood pressure cuff applied to the same arm as the sensor site.
- Arterial catheter
- Elevated levels of COHb and/or MetHb. Note: High levels of COHb or MetHb may occur with a seemingly normal SpO₂.
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous congestion.
- Excessive venous pulsations (e.g. tricuspid valve regurgitation, Trendelenburg position).
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Moisture, birthmarks, skin discoloration, or foreign objects in the light path.
- Elevated levels of bilirubin.
- Severe anemia.

- Very low arterial perfusion.
- Hypocapnic or Hypercapnic conditions.
- Excessive motion.
- Vasospastic disease such as Raynaud's.
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Peripheral vascular disease.
- EMI radiation interference.

WARNING: PVi may not accurately reflect fluid responsiveness due to the following conditions:

- When not on mechanical ventilation.
- Under mechanical ventilation with a tidal volume less than 8 mL/kg.
- Venous congestion.
- Abnormal venous pulsations (e.g. tricuspid valve regurgitation, Trendelenburg position).
- Conditions which may affect peripheral arterial blood flow (e.g., Hypotension, severe vasoconstriction, severe anemia, or hypothermia.)
- When applied to a site other than a finger.
- Low perfusion.
- Motion.

WARNING: Inaccurate RRp readings may be caused by:

- Low arterial perfusion.
- Motion induced artifact.
- Severe anemia.
- Arrhythmia.

CAUTION: The RRp value may be inaccurate under conditions where the pulse rate is less than two times the respiration rate. The following conditions may include, but it's not limited to: patients with high respiration rate and low heart rate, or patients with specific medical conditions such as sick sinus syndrome, bradycardia due to any primary cardiac conditions as well as secondary condition from beta blockers, digoxin, etc.

CAUTION: Respiration rate provides an indicator of central ventilatory drive and not a direct indication that air is moving through the upper airway.

CAUTION: If using Rad-G during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.

CAUTION: When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

CAUTION: High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor.

CAUTION: To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

CAUTION: When Silence Duration is set to All Mute, there will be no audible alarms on Rad-G; however, there will be visual alarms displayed on Rad-G.

CAUTION: If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

CAUTION: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to Rad-G.

CAUTION: To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the Rad-G is used.

CAUTION: Do not place the Rad-G near electrical equipment that may affect the device, preventing it from working properly.

CAUTION: Failure to charge Rad-G promptly after a Low Battery alarm may result in the device shutting down.

CAUTION: Do not connect the AC power supply to an electrical outlet controlled by a wall switch or dimmer.

CAUTION: Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing the low SIQ troubleshooting steps listed in the troubleshooting section.

Note: Cables and sensors are provided with X-Cal® technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of patient monitoring time.

Note: Physiological conditions that result in loss of pulsatile signal may result in no SpO₂ or RRP readings.

Note: It is recommended that Rad-G battery is fully charged prior to use.

Note: Always charge Rad-G when it is not in use to ensure that the battery remains fully charged.

Note: All batteries lose capacity with age, thus the amount of run time at Low Battery will vary depending upon the age of the battery.

Note: A functional tester cannot be used to assess the accuracy of Rad-G.

Note: When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the Rad-G is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.

Note: Additional information specific to the Masimo sensors compatible with Rad-G, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).

Integrated Temperature

WARNING: If any measurement seems questionable, repeat the measurement after allowing some additional time for the patient temperature to stabilize or check the patient's vital signs by alternate means and then check Rad-G for proper functioning.

WARNING: No or inaccurate temperature readings may result due to the following:

- Directed to measurement site other than the forehead.
- Obstructed access to skins surface (e.g. perspiration, excess oil, hair, tattoos, piercing, paint, heavy make-up).
- Directed to measurement site with non-uniform blood flow (e.g. scar tissue, compromised tissue due to skin disorder, drug therapies that affect normal body temperature).
- Obstructed temperature sensor opening.
- Use on patients with severe or therapeutic hypothermia due to exposure to external heat/cold sources and/or certain therapies
- Measurement performed in presence of interfering infrared light sources (e.g., direct sunlight or heating lamps).

Cleaning and Service Warnings and Cautions

WARNING: Do not attempt to remanufacture, recondition or recycle the Rad-G as these processes may damage the electrical components, potentially leading to patient harm.

WARNING: To avoid electric shock, do not attempt to replace or remove the Battery from the Rad-G. Service of Rad-G should be done by qualified personnel only.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the Rad-G for servicing.

CAUTION: Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the display.

CAUTION: To avoid permanent damage to the Rad-G, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

CAUTION: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the Rad-G. These substances affect the device's materials and device failure can result.

CAUTION: Do not submerge the Rad-G in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

CAUTION: To prevent damage, do not soak or immerse Rad-G in any liquid solution.

Compliance Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

WARNING: Per RSS-Gen, Section 8.4 This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. Per RSS-Gen, Radio apparatus shall comply with the requirements to include required notices or statements to the user of equipment with each unit of equipment model offered for sale.

CAUTION: Comply with local laws in the disposal of the device and/or its accessories.

CAUTION: Device contains an internal battery. Dispose of the battery according to country or regional requirements.

CAUTION: Use only the recommended patient cable or direct connect sensor provided by Masimo. See Masimo website for details. (www.masimo.com)

Note: Use Rad-G in accordance with the Environmental Specifications section in the Operator's Manual.

Note: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Note: This equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 60601-1-2: 2015. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

Note: In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of manufacturer could void the user's authority to operate this equipment.

Note: To satisfy RF exposure requirements, this device and its antenna must operate with a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Note: This Class B digital apparatus complies with Canadian ICES-003.

Chapter 1: Rad-G Technology Overview

The following chapter contains general descriptions about functional oxygen saturation (SpO_2) and Signal IQ used by Masimo products.

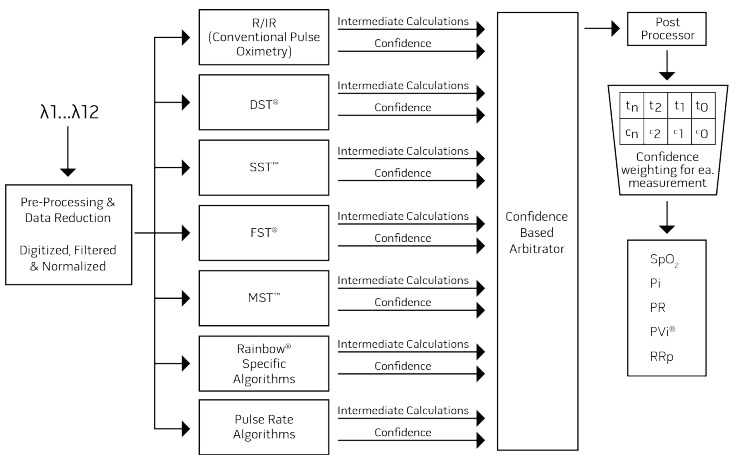
Signal Extraction Technology® (SET®)

Masimo Signal Extraction Technology's signal processing differs from that of conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise).

Masimo SET® pulse oximetry utilizes parallel engines and adaptive filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET® signal processing algorithm, Discrete Saturation Transform® (DST®), in parallel with Fast Saturation Transform (FST®), reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

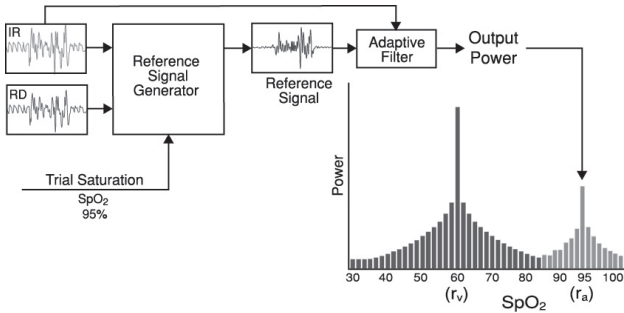
Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.



Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (SpO_2)

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
2. The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Successful Monitoring for SpO_2 , PR and Pi

Stability of the SpO_2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each.

The stability of the readings over time is affected by the averaging time being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer averaging times delay the response of the oximeter and reduce the measured variations of SpO_2 and pulse rate.

Functional Oxygen Saturation (SpO_2)

The Rad-G is calibrated to measure and display functional oxygen saturation (SpO_2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.

Note: Dyshemoglobins are not capable of transporting oxygen, but are recognized as oxygenated hemoglobins by conventional pulse oximetry.

General Description for Pulse Rate (PR)

Pulse rate (PR), measured in beats per minute (BPM) is based on the optical detection of peripheral flow pulse.

General Description for Perfusion Index (Pi)

The Perfusion Index (Pi) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. Pi thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter.

General Description for Pleth Variability Index (PVi)

The Pleth Variability Index (PVi) is a measure of the dynamic changes in the Perfusion Index (Pi) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in Pi over a time interval where one or more complete respiratory cycles have occurred. PVi is displayed as a percentage (0-100%).

PVi may show changes that reflect physiological factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.

The utility of PVi has been evaluated in clinical studies [1-11]. Technical and clinical factors that may affect PVi include probe malposition, probe site, patient motion, skin incision, spontaneous breathing activity, lung compliance, open pericardium, use of vasopressors or vasodilators, low perfusion index, subject age, arrhythmias, left or right heart failure, and tidal volume [12-14].

Citations for Pleth Variability Index (PVi)

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13. Cannesson M. *Arterial pressure variation and goal-directed fluid therapy*. *J Cardiothorac Vasc Anesth*. 2010 Jun; 24(3):487-97.
14. Takeyama M, Matsunaga A, Kakahana Y, Masuda M, Kuniyoshi T, Kanmura Y. *Impact of Skin Incision on the Pleth Variability Index*. *J Clin Monit Comput* 2011 Aug; 25(4):215-21.

General Description for Respiration Rate (RRp)

Respiration rate can be determined by the plethysmographic waveform (RRp). This method measures respirations per minute (rpm) based on cyclic variation in photoplethysmogram (i.e. pleth or PPG) to establish a respiration rate measurement.

Signal IQ

The Signal IQ provides an indicator of the assessment of the confidence in the displayed SpO₂ value. The SpO₂ SIQ can also be used to identify the occurrence of a patient's pulse.

With motion, the plethysmographic waveform is often distorted and may be obscured by noise artifact. Shown as a vertical line, the SpO₂ SIQ coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Signal IQ identifies the timing that the algorithms have determined for the arterial pulsation. The pulse tone (when enabled) coincides with the vertical line of the SpO₂ SIQ.

The height of the vertical line of the SpO₂ SIQ provides an assessment of the confidence in the measurement displayed. A high vertical bar indicates higher confidence in the measurement. A small vertical bar indicates lower confidence in the displayed measurement. When the Signal IQ is very low, this suggests that the accuracy of the displayed measurement may be compromised.

Temperature Technology

Rad-G uses an infrared optical sensor to detect infrared blackbody radiation that is naturally emitted based upon the human body temperature through the skin surface. The infrared radiation detected is processed using a Masimo proprietary algorithm to determine the skin surface temperature that is adjusted to display the approximation of the patient's body or core temperature.

Chapter 2: Description

General System Description

The Rad-G system includes the following:

- Rad-G Device
- Masimo patient cable and/or sensor
- AC/DC Power Supply

* Only use with Masimo supplied AC/DC Power Supply (PN 38602); (Input Rating 100-240V~, 50-60Hz, 0.6A; Output 5V, 1.2A, 6W).

Features

Front View



1. Patient Cable Connector: Allows connection to a direct-connect sensor, patient cable or data cable.

2. Power Button: Powers Rad-G On and Off. See *Powering Rad-G ON and OFF* on page 28.

3. Display and Touchscreen: User interface to view parameters and change settings. See *Using the Touchscreen and Home Button* on page 31.

4. Temperature Window: Displays temperature and provides the icon that provides the ability to perform the temperature measurement. See *Temperature Window* on page 53.

5. Backward Navigation Button: Navigate back from a selection or exit a menu item.

6. Home Button: Multipurpose user interface that allows for navigation to the home screen.

7. Main Menu Button: Access to main menu settings. See *Accessing Main Menu Options* on page 37.

8. Speaker: The speaker supports audible indicators or instructions.

9. DC Input Connector: Connection to an AC power supply for battery charging.

WARNING: Only use the AC power supply provided by Masimo. Using a different AC power supply could result in degraded performance and/or patient injury, and cause damage to Rad-G. Check the power cord and plug to ensure that it is intact and undamaged.

Back View



1. Infrared Optical Sensor

The sensor that is directed to the patient forehead to provide body temperature measurements. See *Temperature Measurement* on page 54.

Chapter 3: Setting Up

Unpacking and Inspection

To unpack and inspect the Rad-G:

1. Remove the Rad-G from the shipping carton and examine it for signs of shipping damage.
2. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.
3. If anything is missing or damaged, contact the Masimo Technical Service Department. See **Return Procedure** on page 83.

Preparation for Use

Prior to setting up the Rad-G, perform the following steps:

1. Confirm that you have all system components:
 - Rad-G Device
 - Masimo patient cable and/or sensor
 - AC/DC Power Supply
2. Read the **Safety Information, Warnings, and Cautions** on page 11.
3. Setup the Rad-G according to the directions provided in this Operator's Manual.

Guidelines for Setting Up

When setting up Rad-G, follow these guidelines:

1. Charge Rad-G's battery fully before use. See **Initial Battery Charging** on page 27.
2. Rad-G should not be operated outside the environmental conditions listed in the specifications section even during charging. See **Environmental** on page 73.

Initial Battery Charging

Before use, the Rad-G battery should be fully charged.

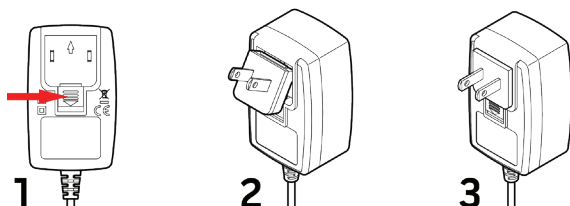
Note: The Rad-G must be ON during recharging if the battery is completely depleted.

To charge Rad-G:

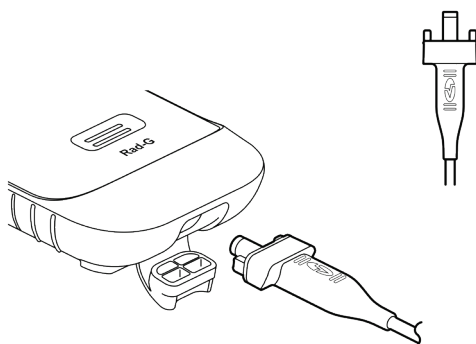
1. Before charging, make sure the plug configuration is appropriate.
 - a) If an incorrect plug insert is included in the AC power supply, then remove it by using a thumb or finger to slide the spring loaded locking key downward (see image 1).
 - b) Attach the correct plug insert by tipping of the blade assembly into the power supply at a 30-60 degree angle (see image 2).

Note: The top edge of the blade assembly is flat and the bottom edge is U shaped. The power supply has the corresponding shapes.

c) Push the blade assembly down until locked in place (see image 3). A clicking sound will be heard when locked in place.



2. Plug the AC power supply into an AC power source. See **AC Power Indicator** on page 37.
3. Plug the DC output connector to the bottom of the Rad-G. Verify the plug orientation is correct during connection (see the images below).



Powering Rad-G ON and OFF

To Power ON Rad-G:

1. Press and hold the Power Button for more than two (2) seconds until one (1) audible tone sounds.



2. The Rad-G powers ON.

To Power OFF Rad-G:

1. Press and hold the Power Button for more than two (2) seconds until one (1) audible tone sounds.
2. The Rad-G powers OFF.

Automatic Power OFF

Auto Power OFF is only available when Rad-G is in *Spot-Check* mode.

By default, after approximately 1 minute without activity, Rad-G powers OFF automatically to save battery life. The duration of no activity until Rad-G automatically powers off can be changed. See **Access Control** on page 47. This feature cannot be disabled.

Note: When *Auto Power Off* is set to 1 minute, and the *Measurement Timeout* setting is set to longer than the 1 minute *Auto Power Off* setting, Rad-G powers OFF **after** the measurement timeout (without activity). See **Additional Settings** on page 44.

Set Mode of Operation

The Rad-G has two modes of operation:

- Continuous
- Spot-Check

The default mode of operation for Rad-G is continuous. To change between continuous and spot-check modes of operation, see **Device Mode** on page 46.

CAUTION: Continuous monitoring will be suspended while in spot check mode.

Chapter 4: Operation

The information in this chapter assumes that Rad-G is set up and ready for use. This chapter provides necessary information for proper operation of the device. Do not operate Rad-G without completely reading and understanding these instructions.

Using the Touchscreen and Home Button



1. Display and Touchscreen: To access settings and other screens, touch a value or icon on the Display View. See **About the Main Screen** on page 34.




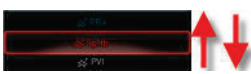


2. Backward Navigation: Navigates to previous or exits a *Main Menu* item.

3. Home Button: Returns display to the *Main Screen*, press the Home button.

4. Main Menu: Access to the main menu settings. See **Accessing Main Menu Options** on page 37.

Using the Touchscreen Interface

Using the gestures described below to interact with Rad-G.

Action	Illustration	Example	Description
Touch			Touch and release. Action performed once finger is released.
Swipe (Touch and Move)			Touch, move (left, right, up or down), and release. Moves an object across the display.
Flick			Touch and quickly swipe (left, right, up or down), and release.

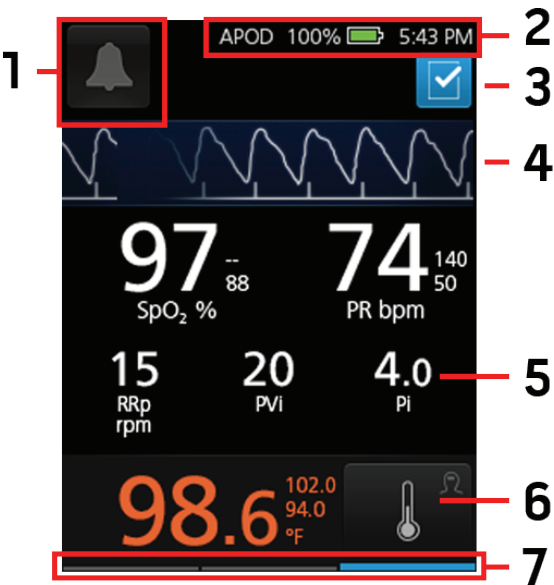
Below is a list of all the different types of controls available on Rad-G and the various ways to interact with each type of control.

Control	Applicable Actions	Description
Toggle	Touch and slide knob	Switches between toggle states
	Touch and slide left or right of toggle	Quickly moves knob left or right
Labeled Toggle	Touch and slide knob	Switches between toggle states
	Touch and slide left or right of toggle	Quickly moves knob left or right
	Touch label	Quickly moves knob left or right
Spinner	Touch center (focused) tile	<ul style="list-style-type: none">When closed, expands spinnerWhen open, collapses spinner
	Swipe up or down	When open, scrolls through spinner tiles
	Touch unfocused tile	When open, scrolls tile into center (focused) position
	Touch anywhere outside spinner	When open, collapses spinner
Slider	Touch and slide knob	Moves knob

Control	Applicable Actions	Description
	Press anywhere along slider path	Quickly moves knob to tap position
Slider Spinner	Touch and slide knob	Moves knob
	Touch anywhere along slider path	Quickly moves knob to tap position
	Touch center (focused) tile	<ul style="list-style-type: none"> • When closed, expands spinner • When open, collapses spinner
	Swipe up/down	When open, scrolls through spinner tiles
	Touch unfocused tile	When open, scrolls tile into center (focused) position
	Touch anywhere outside spinner	When open, collapses spinner
Button	Touch	Performs action (as defined by the button description)
Icon Menu	Touch tile	Opens menu specified by tile
	Swipe left or right (anywhere)	Scrolls icons left or right
	Touch bottom indicator icon	Quickly centers tile corresponding to indicator icon
Alert Silence icon	Touch	Silences all audible alerts
Back Arrow	Touch	Exits menu, abandons any changes

About the Main Screen

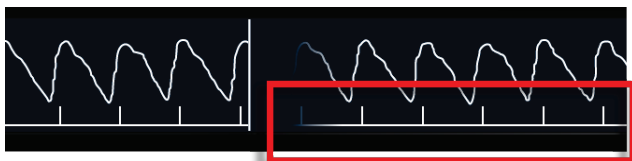
The *Main Screen* consists of different areas.



Item	Feature	Description
1	Alarm Acknowledgment	Displays active alarms and allows silencing of active alarms. See About Alarms on page 56.
2	Status Bar	Displays device status. See About the Status Bar on page 36.
3	Surgical Safety Checklist	Provides access to the checklist. See Surgical Safety Checklist on page 35.
4	Waveform	Displays pleth waveform and signal confidence. See Signal IQ Indicators on page 35.
5	Parameter Display	Displays the parameter readings. See Parameter Settings on page 38.
6	Temperature Window	Displays temperature and contains the icon to take measurements. See Chapter 6: Temperature Operation on page 53.
7	Available Function Bar	Displays which functions below the screen (back, home or main menu) can be accessed while viewing the current screen. See Front View on page 25.

Signal IQ Indicators

Signal IQ (SIQ) indicators are displayed as vertical bars for each individual pulsation. The height of the bar provides an assessment of the confidence in the SpO₂ measurement displayed.





Surgical Safety Checklist

The *Surgical Safety Checklist* is accessed from the Main Screen. See **About the Main Screen** on page 34. The checklist can be enabled and disabled through the device settings. See **Additional Settings** on page 44. When disabled, the icon does not appear on the *Main Screen*.

Items displayed in the checklist include the following:

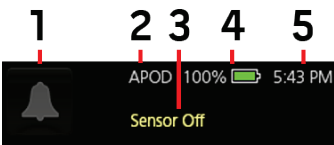
- Patient Identified
- Site Marked
- Procedure Verified
- Medication Check
- Allergy/Airway Check

After checking any or all items, select **OK** to save and return to the *Main Screen*. To clear **All** checked items, select **Clear**.

- When one or more items (but NOT all items) on the checklist are checked off, the icon on the *Main Screen* is Black .
- When **All** items are checked off, the icon on the *Main Screen* changes to Blue .

About the Status Bar

The Status Bar is visible on the top portion of the *Main Screen*.



Item	Feature	Description
1	Alarm Silence	Displays alarm status and mutes all active audible alarms for Rad-G. See Silencing Alarms on page 57.
2	Sensitivity Mode	Displays the sensitivity mode setting. The example shown illustrates that Profiles is currently set to APOD (Normal Sensitivity). See Sensitivity Modes Overview on page 36.
3	Status Message	Messages related to Rad-G operation appear in this area. See Messages on page 57.
4	Rad-G Battery Charge/AC Power Indicator	Displays battery status for Rad-G. The example shows that the battery is fully charged to 100%. See AC Power Indicator on page 37.
5	Current Time	Displays the current time. Time can be set in the <i>Localization</i> screen, which contains settings related to local time and date. See Localization on page 46.

Sensitivity Modes Overview





Three sensitivity levels enable a clinician to tailor the response of Rad-G to the needs of the particular patient situation. See **Additional Settings** on page 44. The sensitivity levels are as follows:

- **NORM (Normal Sensitivity)**
NORM is the recommended sensitivity mode for patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).
- **APOD® (Adaptive Probe Off Detection® Sensitivity)**
APOD is the recommended sensitivity mode for situations which there is a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.
- **MAX (Maximum Sensitivity)**
MAX is the recommended sensitivity mode for patients with low perfusion or when

a *low perfusion* message displays in APOD or NORM mode. MAX mode is not recommended for care areas where patients are not monitored visually, such as medical-surgical floors. It is designed to display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.

AC Power Indicator

When Rad-G is powered ON, the AC Power Indicator icon will be displayed as follows:







Icon	Status
	Battery is connected to an AC power source and currently charging.
	Battery is unplugged from AC power source; the Battery Charge Status Indicator icon provides a visual indication of the current battery charge condition.
	Battery is connected to an AC power source and is fully charged.
	<p>The battery charge reaches a low level:</p> <ul style="list-style-type: none">• The Battery Charge Status Indicator icon will change color (Red).• A "Low Battery" message appears. <p>Connect the battery to AC power to prevent the device from powering OFF and to charge the battery.</p>

Accessing Main Menu Options

To access *Main Menu* options, press the Main Menu button  at the bottom-right corner of the touchscreen. See **Front View** on page 25.

To exit the *Main Menu*, press the Home Button  at the bottom-center of the touchscreen or the Backward Navigation Arrow button  at the bottom-left of the touchscreen.

The *Main Menu* options are:

Display Icon	Main Menu Option	Description	Information
	Parameter Settings*	<ul style="list-style-type: none"> Set alarm limits for all parameters. Additional settings for SpO2, PVi, Pi, and Temperature 	See Parameter Settings on page 38.
	Additional Settings*	<ul style="list-style-type: none"> Set sensitivity mode to Max, Norm, or APOD. Enable/disable the surgery safety checklist. 	See Additional Settings on page 44.
	Sounds	<ul style="list-style-type: none"> Set alarm volume, pulse tone volume, and silence duration. Enable/disable SmartTone. 	See Sounds on page 45.
	Device Settings	<ul style="list-style-type: none"> Set device to local date and time. Set display brightness. Enable/disable all mute. Set mode of operation. Restore factory defaults. 	See Device Settings on page 45.
	About	Shows the device's software version and serial number.	See About on page 48.
	Trends	Allows trend information to be cleared.	See Trends on page 49.

* When Rad-G is set to *Home* mode of operation under **Access Control** on page 47, this setting does not display and cannot be accessed and changed. The *Home* mode option is only available when Rad-G is in *Continuous* mode of operation.

Parameter Settings



Follow the instructions below to access any of the available parameter setting screens. See **Accessing Main Menu Options** on page 37.

1. In the *Parameter Settings* screen, swipe left or right to access the desired parameter.
2. Select the desired parameter icon.
 - See **SpO2 Settings** on page 39.

- See **PR Settings** on page 40.*
- See **PVi Settings** on page 41.
- See **Pi Settings** on page 41.
- See **Respiration Rate (RRp) Settings** on page 42.*
- See **Temperature Settings** on page 43.

* Parameter setting displays only when Rad-G is in *Continuous* mode of operation. See **Device Mode** on page 46.

SpO2 Settings

Allows access to any of the following options:

SpO2 Alarms on page 39*

Additional Settings for SpO2 on page 40

* Parameter alarm settings are available only when Rad-G is in *Continuous* mode of operation. See **Device Mode** on page 46.

SpO2 Alarms

From the *Alarms* screen, change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	2% to 99% in steps of 1%, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	88%	1% to 98% in steps of 1%
Rapid Desat	Sets the Rapid Desat limit threshold to the selected amount below the Low Alarm Limit. When an SpO ₂ value falls below the Rapid Desat limit the audio and visual alarms are immediately triggered without respect to alarm delay.	NA	-10%	Off, -5%, or -10%
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	NA	15 seconds	0, 5, 10, or 15 seconds

Additional Settings for SpO2

From the *Additional Settings* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time*	The length of time over which the system calculates the average of all data points.	8 seconds	2-4, 4-6, 8, 10, 12, 14, or 16 seconds**
FastSat	See FastSat Overview on page 40.	Off	Off or On

* With FastSat the averaging time is dependent on the input signal.

** For the 2 and 4 second settings the averaging time may range from 2-4 and 4-6 seconds, respectively.

FastSat Overview

FastSat enables rapid tracking of arterial oxygen saturation changes. Arterial oxygen saturation data is averaged using pulse oximeter averaging algorithms to smooth the trend.

When Rad-G is set to FastSat *On*, the averaging algorithm evaluates all saturation values, providing an averaged saturation value that is a better representation of the patient's current oxygenation status. With FastSat set to *On*, the averaging time is dependent on the input signal.

PR Settings

From the *PR Settings* screen, change the following option:

PR Alarms on page 40

PR Alarms

From the *PR Alarms* screen, change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	High	140 bpm	35 bpm to 235 bpm, in steps of 5 bpm
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	50 bpm	30 bpm to 230 bpm, in steps of 5 bpm

PVi Settings

From the *PVi Settings* screen, access any of the following options:

PVi Alarms on page 41*

Additional Settings for PVi on page 41

* Parameter alarm settings are available only when Rad-G is in *Continuous* mode of operation. See **Device Mode** on page 46.

PVi Alarms

From the *Alarms* screen, change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	2 to 99, in steps of 1, or Off When set to Off, alarms are disabled.
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	Off or 1 to 98 in steps of 1 When set to Off, alarms are disabled.

Additional Settings for PVi

From the *Additional Settings* screen, change the following option:

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time	The length of time over which the system calculates the average of PVi data points before it is displayed.	Long	Short ¹ or Long

¹ When using the Short averaging time, the displayed PVi will reflect changes in PVi more quickly than the Long setting.

Pi Settings

From the *Pi Settings* screen, access any of the following screens:

Pi Alarms on page 42*

Additional Settings for Pi on page 42

* Parameter alarm settings are available only when Rad-G is in *Continuous* mode of operation. See **Device Mode** on page 46.

Pi Alarms

From the *Alarms* screen, change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	0.04 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 19 in steps of 1, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	0.30	Off, or 0.03 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 18 in steps of 1

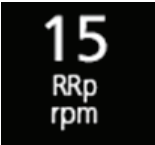
Additional Settings for Pi

From the *Additional Settings* screen, change the following option:

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time	The length of time over which the system calculates the average of all data points.	Long	Short or Long

Respiration Rate (RRp) Settings

When using a pulse oximetry sensor with Rad-G, respiration rate can be determined by the plethysmographic waveform (RRp). This method measures respirations per minute (rpm) based on cyclic variation in photoplethysmogram (i.e. pleth or PPG) to establish a respiration rate measurement. When using a pulse oximetry sensor, RRp alarms and RRp settings are active and the *Main Screen* labels respiratory rate as *RRp*, as shown below.



From the *RRp Settings* screen, access the following screen:

RRp Alarms on page 43.

RRp Alarms

From the *Alarms* screen, change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	High	30 breaths per minute	6 to 69 breaths per minute in steps of 1 breaths per minute, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	6 breaths per minute	Off, or 5 to 68 breaths per minute in steps of 1 breaths per minute

Temperature Settings

From the *Temperature Settings* screen, access any of the following options:

Temperature Alarms on page 43

Additional Settings for Temperature on page 44

Temperature Alarms

From the *Alarms* screen, change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	93.4°F to 109.3°F, in steps of 0.1, or Off 34.2°C to 42.9°C, in steps of 0.1, or Off When set to Off, alarms are disabled.
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	93.3°F to 109.2°F in steps of 0.1, or Off 34.1°C to 42.8°C, in steps of 0.1, or Off When set to Off, alarms are disabled.

Additional Settings for Temperature

From the *Additional Settings* screen, change the following option:

Options	Description	Factory Default Settings	User Configurable Settings
Measurement Timeout*	How long to display the temperature reading after the measurement is taken.	1 minute	1, 2, 3, or 4 minutes
Unit	The unit of measure for temperature.	°F	°F or °C
Surface Temperature**	Displays the measured surface temperature (not the temperature displayed in the temperature window).	NA	NA

* Setting only available for temperature and when Rad-G is in *Continuous* mode of operation.

** This field is read-only and cannot be configured by the user.

Additional Settings



Use the *Additional Settings* screen to configure the following:

Options	Description	Factory Default Settings	User Configurable Settings
Sensitivity Mode	Change Sensitivity Mode. See <i>Sensitivity Modes Overview</i> on page 36.	APOD	MAX, APOD, NORM
Enable Checklist*	Enable or disable the surgery safety checklist. See <i>Surgical Safety Checklist</i> on page 35.	Off	On or Off
Measurement Timeout**	How long to display the parameter readings after the sensor is removed from the patient.	1 minute	1, 2, 3, or 4 minutes

* Setting only available when Rad-G is in *Continuous* mode of operation.

** Setting only available when Rad-G is in *Spot-Check* mode of operation.

Sounds



Use the *Sounds* screen to control the volume of sounds on Rad-G.

Option	Description	Factory Default Settings	User Configurable Settings
Alarm Volume*	Sets the alarm volume level.	High	High, Medium, or Low
Pulse Tone Volume	Sets the pulse tone volume level.	High	High, Medium, or Low
Silence Duration*	Sets the amount of time that the alarm is silenced.	2 minutes	1, 2, 3 minutes, or All Mute**
SmartTone	Allows the audible pulse to continue to beep when the pleth graph shows signs of motion.	Off	On or Off

* Setting only available when Rad-G is in *Continuous* mode of operation. See **Device Mode** on page 46.

** Requires user to have All Mute Enabled turned on in the *Access Control* menu. See **Access Control** on page 47.

Device Settings



The *Device Settings* menu allows the user to view and customize settings for Rad-G. The Device Settings options are:



Localization

See **Localization** on page 46.



Device Mode

See **Device Mode** on page 46.



Brightness

See **Brightness** on page 47.



Access Control

See **Access Control** on page 47.

Localization



Use the *Localization* screen to view the current date and time and configure settings related to local time and date. The user can view the current time on the Status Bar. See **About the Status Bar** on page 36.

Option	Description	Factory Default Settings	User Configurable Settings
Date	Set the current date.	N/A	day/month/year
Time*	Set the current time.	N/A	hours:minutes

* 24hr is the default display mode and cannot be changed.

Device Mode



The *Device Mode* screen allows the user to select the device operating mode. Continuous Monitoring is the default device mode. When the Rad-G is turned off, the device mode is stored. Rad-G will start in the same mode when turned on again. Trend information is stored on the device in either mode. Device and parameter settings differ between *Continuous* and *Spot-Check* mode.

Option	Description	Factory Default Settings	User Configurable Settings
Monitoring	Switch device mode of operation between continuous and spot check.	Continuous	Continuous or Spot Check

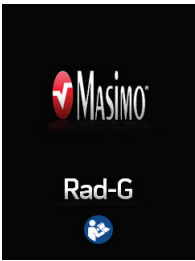
CAUTION: Device mode can only be changed during non-monitoring.

Access to the *Device Mode* screen is password protected.

1. When the *Enter Access Code* screen displays, select **6 2 7**.
2. Press the *OK* key to access the *Device Mode* screen.
3. Select the desired option and select *OK* to set the device mode.

CAUTION: Continuous monitoring will be suspended while in spot-check mode. See **Chapter 5: Spot-Check Operation** on page 51.

In *continuous* mode, the device screen background is black. The device performs continuous measurements and parameter alarms are available.



In *spot-check* mode, the device screen background is white. The device can be used for spot-checking without parameter alarms. See **Chapter 5: Spot-Check Operation** on page 51.



Brightness



Use the *Brightness* screen to adjust the brightness of Rad-G's display.

Option	Description	Factory Default Settings	User Configurable Settings
Brightness	Adjust the brightness level of the display manually.	100%	25% to 100% in steps of 25%

Access Control



The *Access Control* screen contains configurable options and settings that require a password to view or change.

To enter Access Control

1. When the screen requests to *enter access code*, enter the following: **6 2 7**
2. Press *OK* to access the password-protected screen.

Note: The password will have to be entered every time this screen is accessed.

Option	Description	Factory Default Settings	User Configurable Settings
Home Use*	Enables or disables ability to change parameter alarm settings.	Off	On or Off
All Mute Enabled*	Enables parameter Alarm Silence menu option. See Sounds on page 45.	Off	On or Off
Auto Power Off**, ***	Duration of no activity until Rad-G automatically powers off.	1 minute	1, 5 or 10 minutes
Factory Defaults	Options are restored to factory values.	N/A	Press Restore .

* Setting only available when Rad-G is in *Continuous* mode of operation.

** Setting only available when Rad-G is in *Spot-Check* mode of operation.

*** This setting may be affected by the measurement timeout settings. See **Automatic Power OFF** on page 29.

About



Use the *About* screen to view the serial number as well as Rad-G software version information. These details may be helpful during troubleshooting or when contacting Masimo for assistance.

Option *	Description
Serial Number	Displays the serial number for the device.
Software Version	Displays the version number of the device software.
MCU Software Version	Displays the version number of the device board software.

* These fields are read-only and cannot be configured by the user.

Trends



Trend Settings

Use the *Trend Settings* screen to clear trend data stored on Rad-G.

Option	Description	Factory Default Settings	User Configurable Settings
Clear Trends	Deletes all stored trend data.	N/A	Press Clear to delete all stored trend data.

Chapter 5: Spot-Check Operation

The following information discusses performing a spot check using the Rad-G.

Overview

Spot-check mode allows spot-checking of parameters. To change operation modes from continuous to spot-check, see **Device Mode** on page 46. When in spot-check mode, the screen has a white background/theme and the settings options are the same as continuous mode but with no alarms or alarm settings. See **Accessing Main Menu Options** on page 37.

Spot Checking

Perform a pulse oximetry measurement by placing the sensor on the patient's digit. Refer to the Directions for Use for the specific sensor for proper site selection and application.

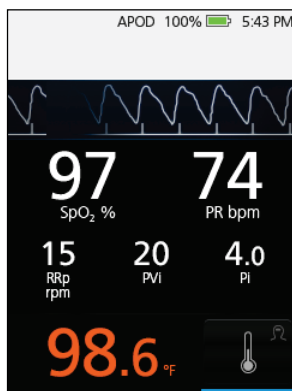
After the sensor is placed, the Rad-G looks for a pulse. Once a pulse is detected, the measurement begins and the Rad-G obtains values.

Perform a temperature measurement using the temperature function (if desired). See **Temperature Measurement** on page 54.

CAUTION: Do not let the sensor or patient cable obstruct the temperature sensor during the temperature measurement.

Connecting a sensor or a patient cable is optional when performing a temperature measurement.

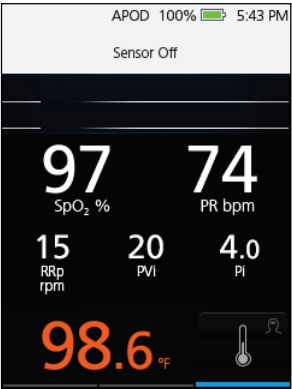
To complete the spot-checking, remove the sensor from the patient and final parameter values will display. See **Spot-Check Values** on page 52.



Spot-Check Values

Note: The spot-check values display for 1 minute after removing the sensor from the patient.

The length of time the values display can be adjusted using the *Measurement Timeout* setting. See **Additional Settings** on page 44.



Chapter 6: Temperature Operation

The following chapter contains information about performing a temperature measurement using Rad-G.

Overview

The non-contact temperature feature uses an infrared detector to measure the infrared blackbody energy that is naturally emitted by the human body based upon temperature at the surface of the skin. The infrared energy detected is processed through Masimo's algorithms to provide an approximation of the body temperature measured from a sublingual temperature measurement.

Temperature Window

The *Temperature Window* displays on the bottom of the Main Screen. See **About the Main Screen** on page 34.



Item	Description
1	Display shows the last temperature measurement taken. Pressing/selecting the <i>Temperature Window</i> on the screen opens the <i>Temperature Settings</i> . See <i>Temperature Settings</i> . The measurement remains displayed until the time out limit has been reached. See <i>Additional Settings</i> on page 44.
2	Measurement Icon. Press/select to take temperature measurement. See <i>Temperature Measurement</i> on page 54.

Temperature Measurement

CAUTION: Do not perform temperature measurements in the path of other infrared sources (e.g., direct sunlight, heat lamps)

CAUTION: Do not let the sensor cable obstruct the temperature sensor during measurement.


1. Turn ON the Rad-G.
2. Select a site at the center of the forehead (*Figure 1*). See Site Selection.
3. Locate and hold the Rad-G parallel to the skin surface with the temperature sensor aligned with the center of the forehead. Maintain approx. 1.5" to 2" (3.8 to 5 cm) away from the skin surface (*Figure 2*).
4. Tap the *Measurement* icon  on the display. Hold the Rad-G steady until a beep is heard and the value displays on the screen.
See Temperature Window.



Figure 1

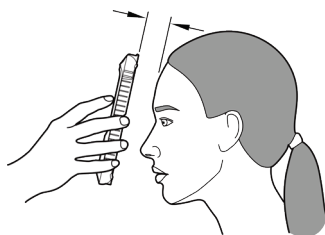


Figure 2

Note: If temperature is suspected to be incorrect, see **Messages** on page 57.

Chapter 7: Alarms and Messages

The following chapter contains information about alerts and messages. For more information, see **Chapter 8: Troubleshooting** on page 59.

Alarm Interface

Rad-G alarms are presented to the user both audibly and visually. Alarms have different priority levels and come from different sources.

Audible Alarms

The following table describes audible alarm behaviors.


Priority	Alarm Sound
High	10-pulse burst
Medium	3-pulse burst

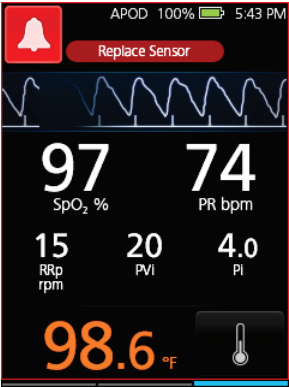
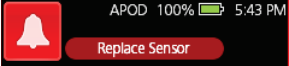
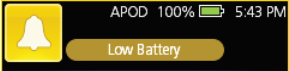
Visual Alarms

Visual alarms are displayed on the Rad-G *Main Screen*.

Main Screen




The following table describes the different visual alarm types.




Alarm Source/Example	Explanation
	Parameter Level: The example shown here is a PR alarm (PR High) as the reading exceeds the upper alarm limit. Note that the PR parameter as well as the Window are illuminated red, and the explanation of the alarm is shown at the top of the Window (PR High).

Alarm Source/Example	Explanation
	<p>System Level: The example shown here is a "Replace Sensor" alarm.</p> <p>Note that the border of the entire Rad-G display is illuminated, and the explanation of the alarm is shown in the Status Bar (Replace Sensor).</p>
	<p>High Priority Alarm The example shown here is a Replace Sensor alarm.</p> <p>Note that the border of the entire Rad-G display is illuminated, and the explanation of the alarm is shown in the Status Bar (Replace Sensor).</p>
	<p>Medium Priority Alarm The example shown here is a Low Battery alarm.</p> <p>Note that the border of the entire Rad-G display is illuminated, and the explanation of the alarm is shown in the Status Bar (Low Battery).</p>

About Alarms

The *Alarm Silence* icon is an indicator as well as a functional button. It always indicates the presence of alarms, and it can be used to temporarily suspend audible alarms for a pre-configured amount of time (Silence Duration). See **Sounds** on page 45.

Icon Appearance	Description	Visual Alarms
	There are currently no active alarms, and no alarms have been silenced.	No
	There are currently no active alarms, but at least one alarm has been and is still silenced.	No
	High Priority Alarm. There is currently at least one active alarm that has not been silenced.	Yes

Icon Appearance	Description	Visual Alarms
	High Priority Alarm - Silenced. There is currently at least one active alarm, but all active alarms are silenced.	Yes
	Medium Priority Alarm. There is currently at least one active alarm that has not been silenced.	Yes
	Medium Priority Alarm - Silenced. There is currently at least one active alarm, but all active alarms are silenced.	Yes

Silencing Alarms

To silence or dismiss alarms:

- Touch the *Alarm Silence* button.
- Audible alarms that are temporarily suspended by pressing the *Alarm Silence* button can be unsuspended by pressing the *Alarm Silence* button again.

Messages

The following section lists common messages, their potential causes, and next steps.

Message	Potential Causes	Next Steps
<i>No Sensor</i>	<ul style="list-style-type: none"> • Sensor or cable is not fully inserted into the device. 	<ul style="list-style-type: none"> • Disconnect and reconnect sensor or cable.
<i>No Cable</i>	<ul style="list-style-type: none"> • An incorrect sensor or cable, defective sensor or cable used. • Sensor latch is not fully closed. 	<ul style="list-style-type: none"> • See <i>Directions for Use</i> for sensor. • Close sensor latch. • If problem still persists, contact Customer Service. See Contacting Masimo on page 83.
<i>Replace the Sensor</i>	<ul style="list-style-type: none"> • Sensor is non-functional. • Defective sensor or cable. 	Replace sensor.
<i>Sensor Off</i>	Sensor has been removed from patient during monitoring.	Place sensor on patient.
<i>Low Battery</i>	Battery charge is low.	Charge battery by powering the device with AC line power.
<i>System Fault</i> <i>Ox##.#</i>	Internal component failure.	Contact Masimo service. See <i>Contacting Masimo</i> .

Message	Potential Causes	Next Steps
<i>Check Ambient Temperature</i>	Environmental temperature conditions may be too high or too low for a temperature measurement.	<ul style="list-style-type: none"> • Verify ambient temperature does not exceed operating specification. See the <i>Specifications</i> chapter. • If problem still persists, contact Customer Service. See Contacting Masimo on page 83.
<i>Temperature Out of Range</i>	Measured temperature is out of supported range (Incorrect measurement site)	<ul style="list-style-type: none"> • Retake measurement. See Temperature Measurement on page 54. • Verify patient temperature is not outside of the Rad-G measurement range. See the <i>Specifications</i> chapter. • If problem still persists, contact Customer Service. See Contacting Masimo on page 83.
<i>Retake Measurement</i>	Unstable measurement	<ul style="list-style-type: none"> • Retake measurement. See Temperature Measurement on page 54. • Hold the device steady during measurements. • Ensure the patient's head is steady during measurements. • If problem still persists, contact Customer Service. See Contacting Masimo on page 83.

Chapter 8: Troubleshooting

The following chapter contains troubleshooting information for the Rad-G.

Troubleshooting Measurements

The following section lists possible measurement symptoms, the potential cause, and next steps. For additional information, see **Safety Information, Warnings, and Cautions** on page 11.

Symptom	Potential Causes	Next Steps
<i>Difficulty obtaining a reading or unexpected readings</i>	<ul style="list-style-type: none">• Inappropriate sensor or sensor size.• Improper sensor type or application.• Sensor displacement.• Low perfusion.• Excessive motion artifact.• Excessive ambient or strobing light.• Low battery/ not plugged into AC power supply.• Interference from line frequency-induced noise.	<ul style="list-style-type: none">• Allow time for parameter reading to stabilize.• Verify sensor type and size and re-apply sensor. See <i>Directions for Use</i> for sensor.• Check if blood flow to the sensor site is restricted.• Check the placement of the sensor. Re-apply sensor or move to a different site.• Replace sensor.• Verify the device and sensor are configured with the parameter.• Verify proper sensor and sensor size for the patient.• Shield the sensor from excessive or strobing light.• Minimize or eliminate motion at the monitoring site.• Connect AC power supply.
<i>Dimly Lit Parameters</i>	<ul style="list-style-type: none">• Low signal quality.	<ul style="list-style-type: none">• Assess the patient.• Verify sensor type and size and re-apply sensor. See <i>Directions for Use</i> for sensor.• Check if blood flow to the sensor site is restricted.• Check the placement of the sensor. Re-apply sensor or move to a different site.• Replace sensor.• Minimize or eliminate motion at the monitoring site.

Symptom	Potential Causes	Next Steps
<i>Difficulty obtaining a temperature measurement reading</i>	<ul style="list-style-type: none"> • Temperature sensor is covered. • Improper measurement distance. • Improper measurement site. • Device is unstable during measurement. 	<ul style="list-style-type: none"> • Ensure the temperature sensor is not covered or blocked. • Check the measurement distance. See Chapter 6: Temperature Operation on page 53. • Check the measurement site. See Chapter 6: Temperature Operation on page 53. • Hold device steady during measurements.

Troubleshooting Rad-G

The following section lists possible Rad-G symptoms, potential causes, and next steps. For more information, see **Messages** on page 57.

Symptom	Potential Causes	Next Steps
<i>Device does not turn on or screen is blank</i>	<ul style="list-style-type: none"> • Depleted Battery. • Internal failure. • EMI (Electro Magnetic Interference). 	<ul style="list-style-type: none"> • Check AC Power connection. • Turn Rad-G OFF and ON. • Contact Masimo service. See Contacting Masimo on page 83.
<i>System failure or device is not working</i>	<ul style="list-style-type: none"> • Internal failure. • EMI (Electro Magnetic Interference). • Device audible settings may be incorrect. 	<ul style="list-style-type: none"> • Turn Rad-G OFF and ON. • If plugged in, check device AC power is properly grounded. • Relocate the device from other devices that may cause electromagnetic interference. • Check that Sounds have not been silenced. • Check Sounds volume settings. • Check that the device speaker is not being muffled. • Contact Masimo service. See Contacting Masimo on page 83.

Symptom	Potential Causes	Next Steps
<i>Speaker does not work</i>	<ul style="list-style-type: none"> • Device audible settings may be incorrect. • Internal failure. 	<ul style="list-style-type: none"> • Turn Rad-G OFF and ON. • Check that <i>Sounds</i> have not been silenced. • Check <i>Sounds</i> volume settings. • Check that the device speaker is not being muffled. • Contact Masimo service. See Contacting Masimo on page 83.
<i>Battery run time significantly reduced</i>	<ul style="list-style-type: none"> • Battery not fully charged. • Battery damaged. • Battery capacity reduced. 	<ul style="list-style-type: none"> • Check battery charge level indicator. • Check battery is fully charged. • Contact Masimo service. See Contacting Masimo on page 83.
<i>Battery not charging after plugged into AC power source</i>	Battery is damaged.	Contact Masimo service. See Contacting Masimo on page 83.

Chapter 9: Specifications

The following chapter contains specifications for the Rad-G.

Display Range and Display Resolution

Measurement	Display Range	Resolution
SpO ₂ (Functional Oxygen Saturation)	0% to 100%	1%
PR (Pulse Rate)	25 bpm to 240 bpm	1 bpm
Pi (Perfusion Index)	0.00 to 20	0.01
PVi (Pleth Variability Index)	0 to 100	1
RRp (Respiration Rate from the Pleth)	4 rpm to 70 rpm	1 rpm
Temperature	93.2°F to 109.4°F	0.1 °F
	34.0°C to 43.0°C	0.1 °C

The emitted wavelengths range from 600 nm to 1000 nm and the peak optical power is less than 15 mW. Information about the wavelength range can be especially useful to clinicians.

Accuracy (ARMS)*

Oxygen Saturation (SpO ₂)		
No Motion [1] (SpO ₂ from 70% to 100%)	Adults, Pediatrics, Infants	2%
	Neonates	3%
Motion [2] (SpO ₂ from 70% to 100%)	All patient populations	3%
Low perfusion [3] (SpO ₂ from 70% to 100%)	All patient populations	2%
Pulse Rate (PR)		
Range	25 bpm to 240 bpm	
No motion	All patient populations	3 bpm
Motion [4]	All patient populations	5 bpm
Low Perfusion	All patient populations	3 bpm

Respiratory Rate (RRp) [5]		
Range	Range of 4 rpm to 70 rpm	
No Motion	Adults, Pediatrics (>2 years of age)	3 rpm A_{RMS}^* , ± 1 rpm mean error
Temperature [7], [8]		
Laboratory Accuracy		
Range (surface temperance)	34.0°C to 43.0°C (93.2°F to 109.4°F)	$\pm 0.3^\circ\text{C}$ (0.54°F)
Clinical Accuracy		
Range	36.0°C to 42.4°C (96.8°F to 108.32°F)	
Adults, Pediatrics (>5 years of age)	Clinical bias: $\pm 0.25^\circ\text{C}$ (0.45°F) LoA: $\leq 1.2^\circ\text{C}$ (2.16°F) Clinical Repeatability: $\leq 0.2^\circ\text{C}$ (0.36°F)	

* A_{RMS} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within $\pm A_{RMS}$ of the reference measurements in a controlled study.

Note: A functional tester cannot be used to assess the accuracy of Rad-G.

SpO2 Performance Specifications

Accuracy testing for SpO₂ was performed on healthy adult subjects. The tables below provides A_{RMS} (Accuracy Root Mean Square) values measured using the Masimo rainbow SET Technology with Masimo Reusable DCI-mini sensors in clinical studies under no motion conditions. The Bland-Altman plots provided in the operator's manual are for the sensors identified in the respective plots. Bland-Altman plots for sensors not listed in the tables below are available in the Directions for Use (DFU) for those sensors. See the sensor DFU for the Bland-Altman plots for the respective compatible sensor.

Measurement A_{RMS} Values for Reusable DCI-mini Sensors	
SpO ₂ Accuracy Range (%)	A_{RMS} (%)
70-80	1.2
80-90	1.7
90-100	1.9
70-100	1.6

The below Bland-Altman plot represents the correlation of the $(SpO_2 - SaO_2)$ versus $(SpO_2 + SaO_2)/2$ under no motion with an upper 95% and lower 95% limits of agreement.

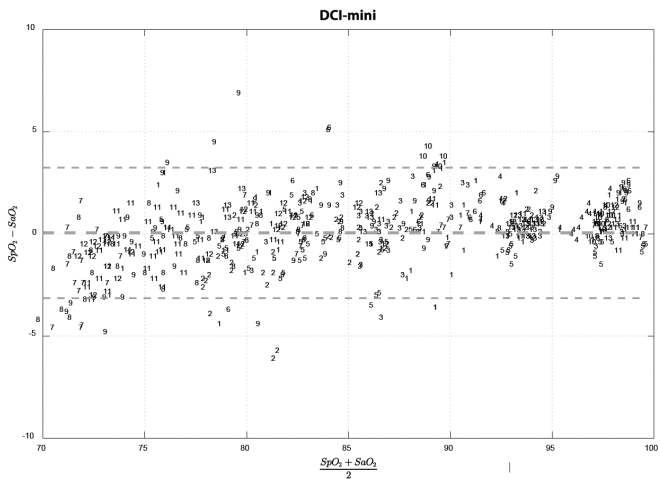


Figure 1: Reusable DCI-mini Sensors (ARMS 70-100%)

RRp Performance Specifications

The below Bland Altman plots represent the correlation of RRp and the reference respiration rate in healthy adult subjects with upper 95% and lower 95% limits of agreement.

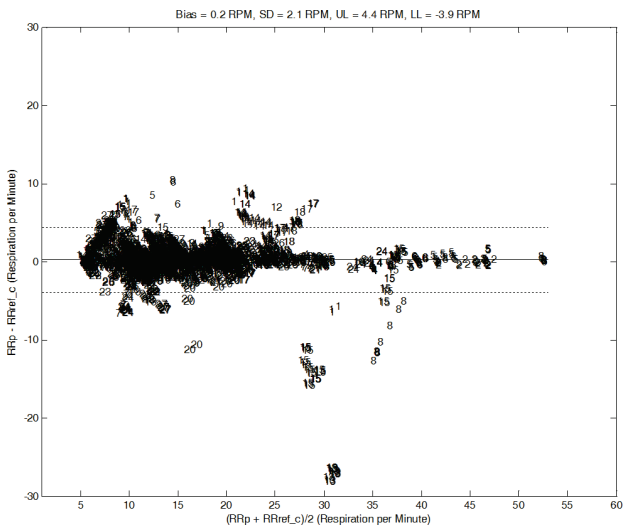


Figure 2: Subject by Subject Bland-Altman plot of RRp with respect to RRref_c

The below Bland Altman plots represent the correlation of RRp and the reference respiration rate in hospitalized adult subjects with upper 95% and lower 95% limits of agreement.

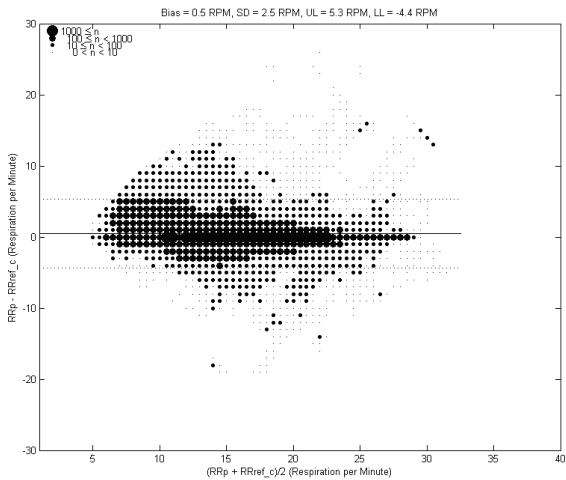


Figure 3: Bland-Altman plot of RRp with respect to RRref_c

The below Bland Altman plots represent the correlation of RRp and the reference respiration rate in hospitalized pediatric subjects with upper 95% and lower 95% limits of agreement.

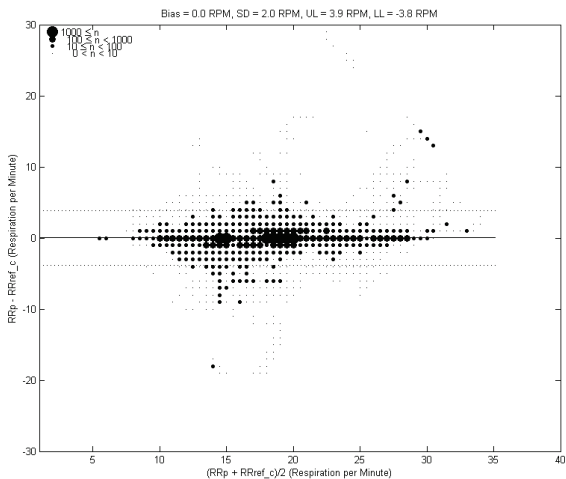


Figure 4: Bland-Altman plot of RRp with respect to RRref_c

Medical Conditions

Adult Medical Conditions

Medical Conditions from Clinical Study of Hospitalized Adult Patients

N		N	
Autoimmune		Musculoskeletal and Connective Tissue (Cont.)	
Psoriasis	1	End stage arthritis and osteonecrosis, bitateral hips	1
Cardiovascular		Fasciotomy wounds of right foot and tibia.	1
Atrial Septal Defect	1	Idiopathic scoliosis and kyphoscoliosis	1
Coronary Disease	1	Left Femur Fracture, surgical treated with intramedullary Rod	1
Hypertension	22	Left Femur tumor	1
Congenital		Left Hip Pathological fracture	1
Arthrogryposis Multiplex Congenita	1	Lower limb length difference (discrepancy)	1
Endocrine/Metabolic		Nonunion of left long finger metacarpal fracture	1
Diabetes	2	Osteoarthritis	4
Hyperlipidemia	8	Right fourth metatarsal fracture	1
Hypomagnesemia	1	Right lower leg and foot compartment syndrome	1
Hypothyroidism	2	Scar contracture left hand	1
Morbid Obesity	6	Traumatic amputation of left thumb with complication	1
Gastrointestinal		NA	
Acid Reflux	1	None Reported	9
Appendicitis	5	Neoplasm	

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Chronic Constipation	1	Hodgkin's lymphoma	1
Constipation	1	Lipoma	1
Crohns Disease	1	Malignant Tumor	1
Emesis	1	Nephrology	
GERD	4	Hydronephrosis	1
Hiatal Hernia	1	Neurological	
Jaundice	1	Peripheral Neuropathy	1
Reflux Disease	1	Autism Spectrum Disorder	1
Genitourinary		Bilateral Hand Tremors	1
Bladder Cancer	1	Head injury	1
Breast Cancer/Breast Cancer History	2	Infantile cerebral palsy, unspecified	1
Cervical Cancer	1	Neuropathy	1
Endometrial Cancer	1	Restless Leg Syndrome	1
Fibroid Uterus	1	Neurological/Orthopedic	
Rectocele	1	Scoliosis, Distal Femoral epiphyseal arrest	1
Urinary tract infection	1	Obstetrics and Gynecology	
Hematology		Left ovarian Endodermal sinus tumor	1
Acute Blood Loss Anemia	1	Pregnancy	1
Anemia	4	Premature Birth (27 weeks)	1
Blood Clotting Disorder/Unspecified	1	Ophthalmology	

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Chronic Thrombocytopenia	1	Glaucoma	2
Hereditary Spherocytosis	1	Ophthalmology	
Leukocytosis	1	Glaucoma	1
Sickle Cell Disease	1	Other	
Hepatobiliary		Lethargy	1
Cholecystitis	1	Subdural Hematoma	1
Cholecystitis with Choledocholithiasis	1	Pain	
Cholelithiasis	5	Acute post-operative pain	1
Chronic Cholecystitis	1	Psychiatric	
Gall Stones	2	ADHD (Attention Deficit Hyperactivity Disorder)	1
Liver Cyst	1	Anxiety	1
Infections		Psychiatric/Developmental	
Cellulitis	1	Learning Disability and Slight Anxiety	1
Muscular		Renal	
Ventral Hernia	2	Kidney Disease	2
Musculoskeletal		Kidney Failure	1
Umbilical Hernia	1	Kidney Stones	1
Musculoskeletal and Connective Tissue		Respiratory	
Bilateral tibial fracture.	1	Asthma	7
Closed Fracture of Left Shaft of Femur	1	Pneumonia	2
Closed fracture of neck of left femur	1	Risk of Sleep Apnea	3

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Complete traumatic metarpophalangeal amputation of left index finger	1	Sleep Apnea	13
Congenital deformity of hip (joint)	1	Urology	
Contracture, Achilles tendon	1	Enuresis	1
Crushing injury of left wrist, hand, and finger (following MVC)	1	Vascular	
Degenerative arthritis of hip	1	Hemangioma - Lower lip	1
Degenerative Joint Disease	1	Raynaud Phenomenon	1
Dupuytrens Contracture (Right Hand)	1		

Pediatric Medical Conditions

Medical Conditions from Clinical Study of Hospitalized Pediatric Patients

N		N	
Congenital		Musculoskeletal and Connective Tissue (Cont.)	
Arthrogyposis Multiplex Congenita	1	Radius and ulna distal fracture, left sequela	1
Congenital/Neurological		Right fourth metatarsal fracture	1
Cerebral Palsy	1	Right Leg Pain	1
Congenital/Orthopedic		Right lower leg and foot compartment syndrome	1
Genu Valgam, and Leg length Discrepancy (Surgically treated)	1	Scar contracture left hand	1
Endocrine/Metabolic		Traumatic amputation of left thumb with complication	1
Hypothyroidism-Congenital	1	Musculoskeletal and Connective Tissue/neoplasm	
Gastrointestinal		Rt. Leg Mass (Tumor), Sarcoma Rt. Femur)	1
Appendicitis	8	Nephrology	

Chronic Constipation	1	Hydronephrosis	1
Constipation	1	Neurological	
GERD	2	Autism Spectrum Disorder	1
Jaundice	1	Congenital Hydrocephalus p/s Shunt	1
General		Head injury	1
Unintentional weight loss	1	Infantile cerebral palsy, unspecified	1
Genitourinary		Sensorineural hearing loss, Bilateral	1
Urinary tract infection	1	Stage IV neuroblastoma S/P, resection Chemotherapy with Stem Cell Transplant	1
Hematology		Neurological/Orthopedic	
Anemia	1	Scoliosis (Spine disorder)	1
Hereditary Spherocytosis	1	Scoliosis, Distal Femoral epiphyseal arrest	1
Hypogammaglobinemia, Thrombocytopenia	1	Obstetrics and Gynecology	
Hepatobiliary		Left ovarian Endodermal sinus tumor	1
Cholecystitis with Choledocholithiasis	1	Premature Birth (27 weeks)	1
Cholelithiasis	2	Ophthalmology	
Musculoskeletal and Connective Tissue		Glaucoma	1
Bilateral tibial fracture.	1	Otolar	
Closed Fracture of Left Shaft of Femur	1	Hearing Impaired	1
Closed fracture of neck of left femur	1	Pain	
Complete traumatic metarpophalangeal amputation of left index finger	1	Acute post-operative pain	1
congenital deformity of hip (joint)	1	Peritoneal/Retroperitoneal	

Congenital dislocation of one hip with subluxation of other hip	1	Peritonitis	1
Contracture, Achilles tendon	1	Psychiatric	
Crushing injury of left wrist, hand, and finger (following MVC)	1	ADHD (attention deficit hyperactivity disorder)	1
Dislocation of hip (bilateral)	1	Anxiety	1
Fasciotomy wounds of right foot and tibia.	1	Psychiatric/Developmental	
Femur fracture, open (right femoral shaft)	1	Learning Disability and Slight Anxiety	1
Hip dysplasia	1	Respiratory	
Idiopathic scoliosis and kyphoscoliosis	1	Asthma	6
Left Femur Fracture, surgical treated with intramedullary Rod	1	Pulmonary Nodule	1
Lower limb length difference (discrepancy)	1	Urology	
Malunion, fracture	1	Enuresis	1
Nonunion of left long finger metacarpal fracture	1	Vascular	
Other congenital deformity of hip	1	Hemangioma - Lower lip	1

Electrical

AC Power Requirements	
AC Power requirements	100-240VAC, 50/60Hz, 0.6A
Power consumption	< 6W

Note: Only use with Masimo AC/DC Power Supply (PN 38602); Input Rating 100-240V~, 50-60Hz, 0.6A; Output 5V, 1.2A, 6W.

Battery	
Type	Lithium ion
Capacity	24 hours [9]

Battery	
Charging Time	8 hours*

*Time to reach 80% capacity at 25°C (77°F) ambient temperature.

Environmental

Rad-G Device Environmental Conditions	
Operating Temperature	10°C to 40°C (50°F to 104°F)
Storage/Transport Temperature	-20°C to 60°C (-4°F to 140°F) [7]
Operating Humidity	10% to 95%, non-condensing
Storage/Transport Humidity	10% to 95%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1060 mbar (540 hPa to 1060 hPa)

Physical Characteristics

Physical Characteristics	
Dimensions	7.4 cm x 19.8 cm x 2.5 cm (2.9" x 7.8" x 1.0")
Weight	0.27 kg. (0.59 lbs.)

Display Indicators

Item	Description
Display Update Rate	1 second
Type	TFT LCD
Pixels	320 dots x 240 dots

Compliance

EMC Compliance
IEC 60601-1-2:2014
EN/ISO 80601-2-61:2017, Clause 202.6.2.3, 20 V/m

Safety Standards Compliance
ANSI/AAMI ES 60601-1 + Am 1
CAN/CSA C22.2 No. 60601-1
IEC 60601-1 + Am 1
IEC 62366
IEC 60601-1-6
IEC 60601-1-8
IEC 60601-1-11
ISO 80601-2-56
EN/ISO 80601-2-61

Equipment Classification per IEC 60601-1	
Type of Protection	Class II (AC power)
	Internally powered (Battery power)
Degree of Protection of Electrical Shock	Defibrillation proof BF-Applied Part
Protection against harm from liquid ingress	IP22, Protection from ingress of particulates > than 12.5 mm and protection against vertically falling water drops when enclosure is tilted at 15 degrees.
Mode of Operation	Continuous operation

Guidance and Manufacturer's Declaration - Electromagnetic Compliance


Electromagnetic Emissions

Electromagnetic Emissions		
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. Suitable for use in all establishments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR 11	Class B	
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power lines	+/- 2 kV for power lines	Mains power quality should be that of a typical commercial or hospital environment.

Electromagnetic Immunity			
	+/- 1 kV for input/ output lines	+/- 1 kV for input/output lines	
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s)	+/- 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT, 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°; 0% UT 1 cycle, and 70% UT 25/30 cycles at 0°	0% UT, 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°; 0% UT 1 cycle, and 70% UT 25/30 cycles at 0°	Mains power quality should be that of a typical commercial or hospital environment.
	0% UT, 250/300 cycle UT: Rated voltage for the equipment	0% UT, 250/300 cycle UT: Rated voltage for the equipment	
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	Performed over 0.15-80 MHz
	6 Vrms in ISM bands	6 Vrms in ISM bands	Performed on the following ISM (industrial, scientific and medical) bands of frequency: The bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz

Electromagnetic Immunity			
Radiated RF IEC 61000-4-3	3 V/m 80 MHZ to 2.7 GHz	20 V/m	
Interference may occur in the vicinity of equipment marked with the following symbol: 			











Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communication Equipment























Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-395	TETRA 400	Pulse modulation (b) 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM (c) +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation (b) 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation (b) 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 35: UMTS	Pulse modulation (b) 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation (b) 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11	Pulse modulation (b)	0.2	0.3	9

Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
5500		a/n	217 Hz			
5785						
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
(a) For some services, only the uplink frequencies are included. (b) The carrier shall be modulated use a 50% duty cycle square wave signal. (c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Symbols

The following symbols may appear on the product or product labeling:

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
	Mark of conformity to European medical device directive 93/42/EEC		Separate collection for electrical and electronic equipment (WEEE)
IP22	Protection from ingress of particulates > than 12.5 mm and protection against vertically falling water drops when enclosure is tilted at 15 degrees		Defibrillation-proof. Type BF applied part
	Recyclable		Caution
	Non-Sterile		Authorized representative in the European community
	Federal Communications Commission (FCC) Licensing	Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

Symbol	Description	Symbol	Description
IC Model:	Industry Canada Identification	FCC ID:	Identifies unit has been registered as a radio device
	Serial number		Lot code
	Manufacturer		Catalog number (model number)
	Date of manufacture YYYY-MM-DD		Masimo reference number
	Not made with natural rubber latex		Electrostatic
	Storage temperature range		Fragile, handle with care
	Keep dry		Do not use if package is damaged
	Storage humidity limitation		Atmospheric pressure limitation
	Class II Equipment		Stand-By
	DC current		AC current
	China Restriction of Hazardous Substances		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual
	Medical Device	-	--
	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eIFU is not available in all countries.		

Citations

[1] The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO₂ against a laboratory CO-Oximeter and ECG monitor.

[2] The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO₂ against a laboratory CO-Oximeter and ECG monitor.

[3] The Rad-G has been validated for low perfusion accuracy in bench-top testing against a Biotek Index 2TM* simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70%-100%.

[4] Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Fluke Biotek Index 2 simulator.

[5] RRp performance has been clinically validated on 28 healthy, adult volunteers, 59 hospitalized adult patients, and 28 hospitalized pediatric patients (> 2 years of age). The clinical testing included non-randomized studies comparing RRp measurements against manual, clinician-scored capnograms. The clinical testing on hospitalized adult and pediatric patients was conducted using convenience sampling and did not necessarily include all patient conditions found in hospitals and hospital-type settings. The clinical testing results may not be generalized to all patient conditions. RRp performance was validated across the entire range of 4 to 70 RPM through bench testing.

[6] This represents typical run time at the default display brightness, indoor lighting conditions, and no audio or alarms.

[7] The laboratory accuracy of the temperature sensor is $\pm 0.1^{\circ}\text{C}$ (0.18°F) for an input surface temperature range of 34°C to 43°C (93.2°F to 109.4°F).

[8] The temperature sensor has been validated on 105 subjects, 5 years of age or older, against a reference sublingual clinical thermometer. Results have shown a clinical bias of -0.24°C (-0.43°F) with limits of agreement 1.12°C (2.02°F).

[9] If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20°C to $+30^{\circ}\text{C}$, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.

*Registered trademark of Fluke Biomedical Corporation, Everett, Washington.

Chapter 10: Service and Maintenance

The following chapter contains information about cleaning, battery operation, performance verification, service, repair, and warranty.

Cleaning

To clean the device:

1. Disconnect the AC Power Supply and ensure the sensor is not applied to the patient.
2. Turn off the device.
3. Wipe the outer surfaces using a dampened soft cloth with a mild detergent and warm water solution or one of the recommended cleaning solutions twice or until the surfaces are free of any visible residue.
CAUTION: Do not allow liquids to enter the interior of the device.
4. Dry the device thoroughly prior to using on a patient.

The surfaces of the Rad-G may be cleaned with the following solvents or cleaning agents:

- 70% Isopropyl Alcohol (IPA)
- Glutaraldehyde (Cidex® Plus)
- 0.5% sodium hypochlorite water solution (10% bleach/water solution)
- Accelerated Hydrogen Peroxide® solutions (Oxivir® TB)
- Quaternary ammonium chloride solution (Up to 55% alcohol/0.5% quaternary ammonium chloride, such as Ecolab Asepti-Wipe® II Germicidal Wipes or PDI Super Sani-Cloth® Germicidal Wipes)

CAUTION: Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the device may occur.

CAUTION: To prevent damage, do not soak or immerse the device in any liquid solution.

CAUTION: Do not sterilize by irradiation, steam, and autoclave or ethylene oxide.

Maintenance

Battery Operation and Maintenance

The Rad-G includes a lithium ion rechargeable battery.

Before using the Rad-G without the AC power connected, check the battery status indicator and ensure that the battery is fully charged. See **AC Power Indicator** on page 37.

To charge the Rad-G battery, refer to **Initial Battery Charging** on page 27.

Note: When battery run time is significantly reduced, it is advisable to completely discharge and fully recharge the battery.

Performance Verification

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

To test the performance of the Rad-G following repairs or during routine maintenance, follow the procedure outlined in this chapter. If the Rad-G fails any of the described tests, discontinue its use and correct the problem before returning the device back to the user.

Before performing the following tests, do the following:

- Connect the Rad-G to AC power and fully charge the battery.
- Disconnect the Rad-G sensor.

Power-On Self-Test

To conduct a Power-On Self-Test:

1. Power ON the device by pressing the power button.
2. Upon powering on, the device should emit a tone and the Rad-G logo should display.

Note: If the Rad-G does not pass the Power-On Self-Test see **Chapter 7: Messages and Troubleshooting** on page 59.

Touchscreen Function Test

To conduct a Touchscreen Function Test:

1. Connect the Rad-G to AC power.
2. Perform the operations outlined in **Chapter 4: Operation** on page 31.

Speaker Test

To conduct a Speaker Test

1. With Rad-G connected to AC power and powered on, enter the *Sounds* settings. See **Sounds** on page 45.
2. Increase and decrease the Alarm Volume and Pulse Tone Volume levels. The speaker should respond and sound in relationship to the adjustment.
 - If the speaker does not sound, see **Chapter 8: Troubleshooting** on page 59.

Repair Policy

Masimo or an authorized service department must perform warranty repair and service. Do not use malfunctioning equipment. Have the device repaired.

Clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in *Cleaning*. Make sure the equipment is fully dry before packing.

To return the device for service, refer to ***Return Procedure*** on page 83.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in *Cleaning*. Make sure the equipment is fully dry before packing. Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number. Package the equipment securely, in the original shipping container if possible, and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the Rad-G. Include the RMA number in the letter.
- Warranty information, a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the Rad-G is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the Rad-G has been decontaminated for bloodborne pathogens.
- Return the Rad-G to the shipping address listed in ***Contacting Masimo*** on page 83 below.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Tel: +1 949 297 7000
Fax: +1 949 297 7001

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product (Rad-G™) and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months and any batteries for six (6) months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo

determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

Limitation of Warranty

Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and software media, and Masimo does not make any other promises, conditions, or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any implied warranty of merchantability, fitness for a particular purpose, satisfactory quality, or as to the use of reasonable skill and care. See the licensing terms for the terms and conditions that apply to and Software accompanying the Product. Additionally, Masimo will not be liable for any incidental, indirect, special, or consequential loss, damage, or expense arising from the use or loss of use of any Products or Software. In no event shall Masimo's liability arising from any Product or Software (under contract, warranty, tort, strict liability, or otherwise) exceed the amount paid by purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

Sales & End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Restrictions

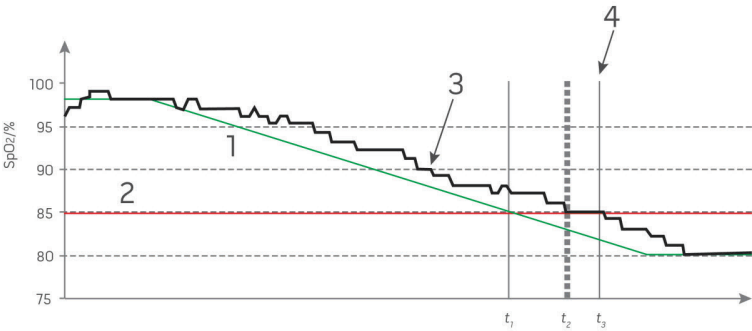
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Appendix: Concepts of Alarm Response Delay

Concepts of Alarm Response Delay

As with any pulse oximeter equipment, the audible and visual alarms are subject to alarm response delay, which is composed of Alarm Condition Delay and Alarm Signal Generation Delay. Alarm Condition Delay is the time from the occurrence of the triggering event to when the alarm system determines the alarm condition exists. While Alarm Signal Generation Delay is the time from the onset of an alarm condition to the generation of its alarm signal. The graphic below is a simplified illustration of the concept of alarm response delay and does not reflect actual lengths of delays.



Reference	Definition	Reference	Definition
1	SaO ₂	4	Alarm Signal Generation
2	Alarm Limit	SpO ₂	Saturation
3	Displayed SpO ₂	t	Time

The Alarm Condition Delay is graphically represented as $t_2 - t_1$ in the figure above to show the delay due to processing and averaging.

The Alarm Signal Generation Delay is graphically represented as $t_3 - t_2$ in the figure above to show the delay due to alarm system strategy and communication time.

The overall alarm system delay time is graphically represented as $t_3 - t_1$.

For more information about alarm response delay, refer to ISO 80601-2-61.

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