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Operators Manual

Rad-G™ Continuous Pulse Oximeter

Masimo

These operating instructions provide the necessary information for proper operation of all models 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 cleared by the Food and Drug Administration (FDA) and 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 express 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: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings and precautions.

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

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IN ACCORDANCE WITH
Conforms to ANSI/AAMI std. ES 60601-1:2005, Certified to CAN/CSA std. C22.2 No. 60601-1:2008, and applicable Particular, (ISO 80601-2-61:2011) and related Collateral (IEC 60601-1-11:2010) Standards for which the product has been found to comply by Intertek.

Patents: ***www.masimo.com/patents.htm***

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About This Manual

This manual explains how to set up and use Rad-G™ Continuous Pulse Oximeter. 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™ Continuous Pulse Oximeter is intended for the noninvasive 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).

The following key features are available for Rad-G:

- Masimo SET® technology performance.
- Noninvasive continuous monitoring of functional saturation of arterial oxygen hemoglobin (SpO_2) and pulse rate (PR), Perfusion Index (Pi), Pleth Variability Index (PVi), and Respiration Rate determined by plethysmographic waveform (RRp).

Indications for Use

The Rad-G™ Continuous Pulse Oximeter is intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), Pulse Rate (PR), Perfusion Index (Pi), and Pleth Respiration Rate (RRp).

The Rad-G™ Continuous Pulse Oximeter is indicated for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), Pulse Rate (PR), and Perfusion Index (Pi) of adult, pediatric, and infant 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™ Continuous Pulse Oximeter is indicated for use 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.

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.

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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: 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: 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: 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 SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

WARNING: SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

WARNING: Optical, pleth-based measurements (e.g. SpO_2 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 value 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 SpO_2 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 SpO_2.
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous congestion.
- Excessive venous pulsations (e.g. tricuspid value 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: 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 on Rad-G, 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 SpO_2, PR, 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).

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.

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.

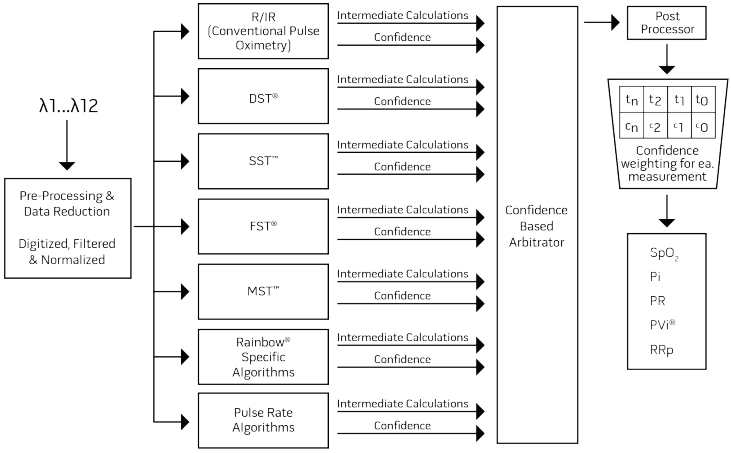
Signal Extraction Technology® (SET®)

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.

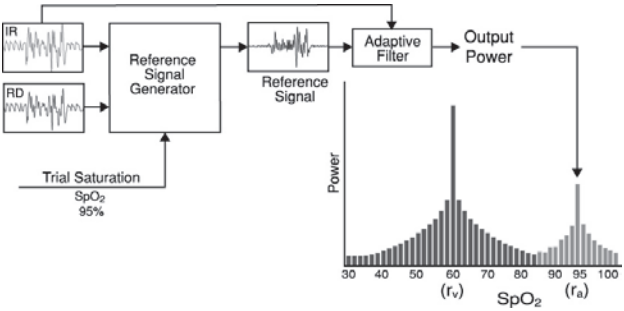
Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.



Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (SpO2)

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 SpO2, 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 (SpO2)

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, Kakihana 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 SpO_2 value. The SpO_2 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 SpO_2 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 SpO_2 SIQ.

The height of the vertical line of the SpO_2 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.

Chapter 2: Description

General System Description

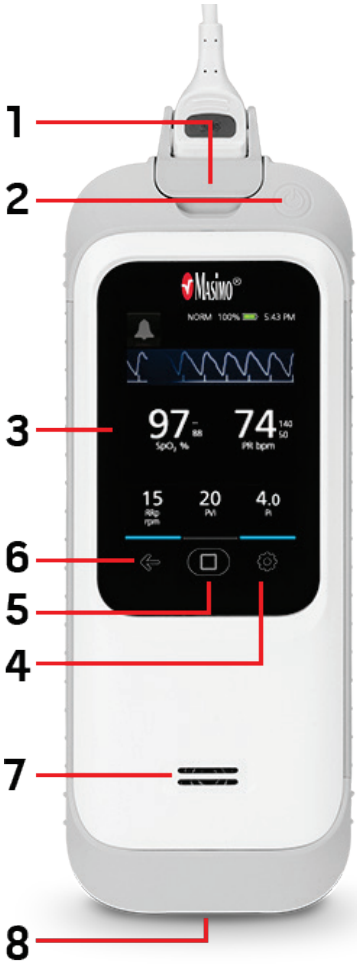
The Rad-G system includes the following:

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

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

Features

Front View



1. Sensor or Patient Cable Connector: Allows connection to a sensor or patient cable.

2. Power Button: Power Rad-G On and Off. See ***Powering Rad-G ON and OFF*** on page 22.

3. Display and Touchscreen: Provides a user interface to view parameters and change settings. Settings can be changed by pressing a parameter.

4. Main Menu: Provides access to main menu settings. See ***Accessing Main Menu Options*** on page 26.

5. Home Button: Provides a multipurpose user interface that allows for navigation to the home screen.

6. Backward Navigation: Provides the ability to navigate backwards or exit a menu item.

7. Speaker: The speaker provides audio instructions. Care should be taken not to cover the speaker.

8. DC Input Connector: Provides a 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.

Note: Rad-G can be used while the power supply is plugged into an outlet

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 59.

Preparation for Use

Prior to setting up the Rad-G for monitoring, 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 9.
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 21.
2. Rad-G should not be operated outside the environmental conditions listed in the specifications section. See ***Environmental*** on page 47.

Initial Battery Charging

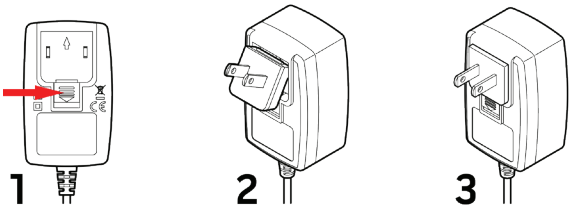
Before use, the Rad-G battery must be fully charged.

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

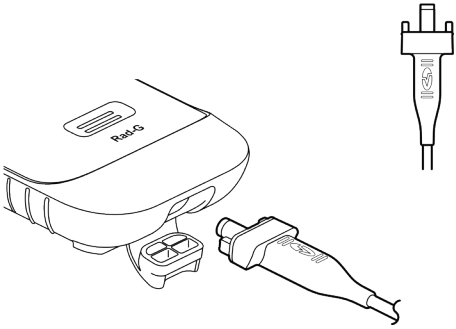
To charge Rad-G:

1. If an 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).
2. Insert the tip 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.
3. Push the blade assembly down until locked in place (see image 3). A clicking sound will be heard when locked in place.



4. Plug the AC power supply cord into an AC power source. See ***AC Power Indicator*** on page 26.
5. Plug the AC power supply into the DC input connector. 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:

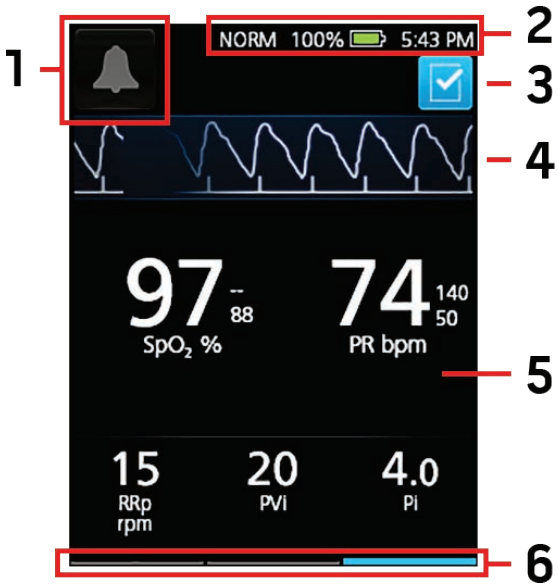
1. Press and hold the Power Button for more than two (2) seconds until one (1) audible tone sounds.
2. The Rad-G powers OFF.

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.

About the Main Screen

The *Main Screen* consists of different areas.

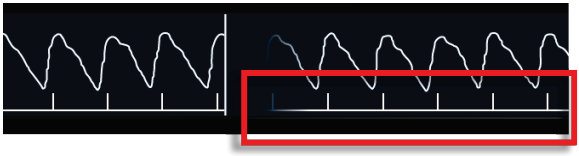


Item	Feature	Description
1	Alarm Acknowledgment	Displays active alarms and allows silencing of active alarms. See ***About Alarms*** on page 38.
2	Status Bar	Displays device status. See ***About the Status Bar*** on page 25.
3	Surgical Safety Checklist	Provides access to the checklist. See ***Surgical Safety Checklist*** on page 24.
4	Waveform	Displays pulse rate and signal confidence. See ***Signal IQ Indicators*** on page 24.

Item	Feature	Description
5	Parameter Display	Displays the parameter readings. See ***Parameter Settings*** on page 27.
6	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 20.

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 SpO_2 measurement displayed.



Surgical Safety Checklist

The *Surgical Safety Checklist* is accessed from the Main Screen. See ***About the Main Screen*** on page 23. The checklist can be enabled and disabled through the device settings. See ***Additional Settings*** on page 32. When disabled, the icon does not appear on the *Main Screen*.

Items displayed in the checklist include the following:

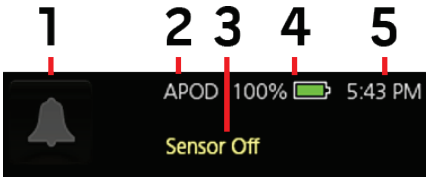
- Patient Identified
- Site Marked
- Procedure Verified
- Medication Check
- Allergy/Airway Check

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 39.
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 25.
3	Status Message	Messages related to Rad-G operation appear in this area. See ***Messages*** on page 40.
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 26.
5	Current Time	Displays the current time. Time can be set in the *Localization* screen, which contains settings related to local time and date. See ***Localization*** on page 34.

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 32. 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.
	The battery charge reaches a low level: • The Battery Charge Status Indicator icon will change color (Red). • A "Low Battery" message appears. Connect the battery to AC power to prevent the device from powering OFF and to charge the battery.

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 20.

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	• Set alarm limits for all parameters. • Additional settings for SpO_2, PVi, and Pi.	See ***Parameter Settings*** on page 27.
	Additional Settings	• Set sensitivity mode to Max, Norm, or APOD. • Enable/disable the surgery safety checklist.	See ***Additional Settings*** on page 32.
	Sounds	• Set alarm volume, pulse tone volume, and silence duration. • Enable/disable SmartTone.	See ***Sounds*** on page 33.
	Device Settings	• Set device to local date and time. • Set display brightness. • Enable/disable all mute. • Restore factory defaults.	See ***Device Settings*** on page 34.
	About	Shows the device's software version and serial number.	See ***About*** on page 36.

Parameter Settings

Follow the instructions below to access any of the available parameter setting screens. See ***Accessing Main Menu Options*** on page 26.

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 28.
   - See ***PR Settings*** on page 29.
   - See ***Respiration Rate (RRp) Settings*** on page 30.
   - See ***PVi Settings*** on page 30.
   - See ***Pi Settings*** on page 31.

SpO2 Settings

Allows access to any of the following options:

SpO2 Alarms on page 28

Additional Settings for SpO2 on page 28

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**

Options	Description	Factory Default Settings	User Configurable Settings
FastSat	See ***FastSat Overview*** on page 29.	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 29

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

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.

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

RRp Alarms on page 30.

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

PVi Settings

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

PVi Alarms on page 31

Additional Settings for PVi on page 31

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	40	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	5	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 all data points.	Long	Short or Long

Pi Settings

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

Pi Alarms on page 32

Additional Settings for Pi on page 32

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

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 ***Sensitivity Modes Overview*** on page 25.	APOD	MAX, APOD, NORM

Options	Description	Factory Default Settings	User Configurable Settings
Enable Checklist	Enable or disable the surgery safety checklist. See ***Surgical Safety Checklist*** on page 24.	Off	On or Off

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

* Requires user to have All Mute Enabled turned on in the *Access Control* menu. See ***Access Control*** on page 35.

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 34.

Brightness

See ***Brightness*** on page 35.

Access Control

See ***Access Control*** on page 35.

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 25.

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.

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
All Mute Enabled	Enables parameter Alarm Silence menu option. See ***Sounds*** on page 33.	Off	On or Off
Factory Defaults	Options are restored to factory values.	N/A	Press **Restore**.

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.

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

Chapter 5: Alarms and Messages

The following chapter contains information about alarms and messages. For more information, see ***Chapter 6: Troubleshooting*** on page 41.

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.

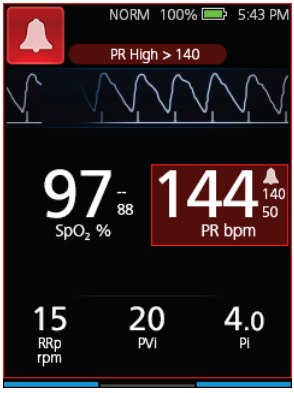
Priority	Alarm Sound
High	10-pulse burst
Medium	3-pulse burst

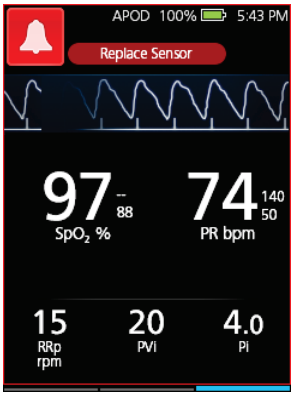
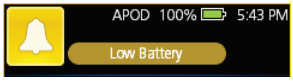
Visual Alarms

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

Main Screen

The following table describes visual alarm behaviors.

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
	**System Level:** The example shown here is a "Replace Sensor" alarm. 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).
	High Priority Alarm The example shown here is a Replace Sensor alarm. 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).
	**Medium Priority Alarm** The example shown here is a Low Battery alarm. 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).

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 33.

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

Icon Appearance	Description	Visual Alarms
	High Priority Alarm. There is currently at least one active alarm that has **not** been silenced.	Yes
	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
No Sensor *No Cable*	• Sensor or cable is not fully inserted into the device. • An incorrect sensor or cable, defective sensor or cable used. • Sensor latch is not fully closed.	• Disconnect and reconnect sensor or cable. • See *Directions for Use* for sensor. • Close sensor latch.
Replace the Sensor	• Sensor is non-functional. • Defective sensor or cable.	Replace sensor.
Sensor Off	Sensor has been removed from patient during monitoring.	Place sensor on patient.
Low Battery	Battery charge is low.	Charge battery by powering the device with AC line power.
System Fault Ox##.#	Internal component failure.	Contact Masimo service. See ***Contacting Masimo*** on page 59.

Chapter 6: 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 9.

Symptom	Potential Causes	Next Steps
Difficulty obtaining a reading or unexpected readings.	• 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.	• Allow time for parameter reading to stabilize. • Verify sensor type and size and re-apply sensor. See *Directions for Use* 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.

Symptom	Potential Causes	Next Steps
Dimly Lit Parameters	• Low signal quality.	• Assess the patient. • Verify sensor type and size and re-apply sensor. See *Directions for Use* 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.

Troubleshooting Rad-G

The following section lists possible Rad-G symptoms, potential causes, and next steps. For more information, see ***Messages*** on page 40.

Symptom	Potential Causes	Next Steps
Device does not turn on or screen is blank	• Depleted Battery. • Internal failure. • EMI (Electro Magnetic Interference).	• Check AC Power connection. • Turn Rad-G OFF and ON. • Contact Masimo service. See ***Contacting Masimo*** on page 59.
System failure or device is not working	• Internal failure. • EMI (Electro Magnetic Interference). • Device audible settings may be incorrect.	• 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 59.

Symptom	Potential Causes	Next Steps
Speaker does not work	• Device audible settings may be incorrect. • Internal failure.	• Turn Rad-G OFF and ON. • 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 59.
Battery run time significantly reduced	• Battery not fully charged. • Battery damaged. • Battery capacity reduced.	• Check battery charge level indicator. • Check battery is fully charged. • Contact Masimo service. See ***Contacting Masimo*** on page 59.
Battery not charging after plugged into AC power source	• Battery is damaged.	• Contact Masimo service. See ***Contacting Masimo*** on page 59.

Chapter 7: Specifications

The following chapter contains specifications for the Rad-G.

Display Range

Measurement	Display Range
SpO_2 (Functional Oxygen Saturation)	0% to 100%
PR (Pulse Rate)	25 bpm to 240 bpm
Pi (Perfusion Index)	0.00 to 20
PVi (Pleth Variability Index)	0 to 100
RRp (Respiration Rate from the Pleth)	4 rpm to 70 rpm

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%
Motion [2] (SpO_2 from 70% to 100%)	Adults, Pediatrics, Infants	3%
Low perfusion [3] (SpO_2 from 70% to 100%)	Adults, Pediatrics, Infants	2%
Pulse Rate (PR)		
Range	25 bpm to 240 bpm	
No motion	Adults, Pediatrics, Infants	3 bpm
Motion [4]	Adults, Pediatrics, Infants	5 bpm
Low Perfusion	Adults, Pediatrics, Infants	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

* 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 +/- A_{RMS} of the reference measurements in a controlled study.

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

Resolution

Parameter	Resolution
SpO_2 (Functional Oxygen Saturation)	1%
PR (Pulse Rate)	1 bpm
Pi (Perfusion Index)	0.01
RRp (Respiration Rate)	1 rpm

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 [6]

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	
While battery is charging*	0°C to 40°C (32°F to 104°F)
While battery is NOT charging	0°C to 50°C** (32°F to 122°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)

** Exceeding this temperature can cause charging to stop.*

*** Compliance with IEC 60601-1 surface temperature requirements evaluated at 40°C.*

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, Class B
EN/ISO 80601-2-61:2014, Clause 202.6.2.3, 20 V/m

Safety Standards Compliance
ANSI/AAMI ES 60601-1:2005
CAN/CSA C22.2 No. 60601-1
IEC 60601-1:2005
IEC 62366
IEC 60601-1-6
IEC 60601-1-11
EN/ISO 80601-2-61:2011

Equipment Classification per IEC 60601-1	
Type of Protection	Class II (AC power)

Equipment Classification per IEC 60601-1	
	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 Declarations - Electromagnetic Emissions

Guidance and Manufacturer's Declarations - 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.
RF Emissions CISPR 11	Class B	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.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration - 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	+6 kV contact +8 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.
	+/- 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.
	+/- 2 kV line(s) to earth	+/- 2 kV line(s) to earth	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	100% dip in mains voltage for 0.5 cycle	100% dip in mains voltage for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
	60% dip in mains voltage for 5 cycle	60% dip in mains voltage for 5 cycle	
	30% dip in mains voltage for 25 cycle	30% dip in mains voltage for 25 cycle	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
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 6 Vrms in ISM bands	3 Vrms 6 Vrms in ISM bands	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHZ to 2.7 GHz	20 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
			$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
necessary, such as re-orienting or relocating the ME Equipment. **(b)** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment			
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.018	0.035
0.1	0.37	0.057	0.11
1	1.17	0.18	0.35
10	3.7	0.57	1.1
100	11.7	1.8	3.5
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC	ETL CLASSIFIED C ETL LISTED US Intertek 3149433	ETL Intertek certification See ***Declarations on Page 1*** for certifications
	Recyclable		Separate collection for electrical and electronic equipment (WEEE)
NON STERILE	Non-Sterile		Defibrillation-proof. Type BF applied part
Rx ONLY	**Caution:** Federal law restricts this device to sale by or on the order of a licensed physician.		Caution
IP22	Protection from ingress of particulates > than 12.5 mm and protection against vertically falling water drops when enclosure is tilted at 15 degrees	LOT	Lot code
IC Model:	Industry Canada Identification	EC REP	Authorized representative in the European community
FC	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device
	Electrostatic		No parameter alarms

Symbol	Description	Symbol	Description
	Manufacturer	LATEX	Not made with natural rubber latex
	Date of manufacture YYYY-MM-DD	REF	Catalog number (model number)
	Storage temperature range	####	Masimo reference number
	Keep dry	SN	Serial number
	Storage humidity limitation		Fragile, handle with care
	Atmospheric pressure limitation		Do not use if package is damaged
	Stand-By		DC current
	AC current		China Restriction of Hazardous Substances
	Class II Equipment	10	The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual
MD	Medical Device	UDI	Unique Device Identifier
eIFU indicator	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note: eIFU is not available for CE mark 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% SpO_2 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% SpO_2 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 approximate run time at the lowest indicator brightness and pulse tone turned off using a fully charged battery. The minimum run time estimate is based on a fully charged battery and the following specific operating modes: SpO_2 only operation and default value of Brightness set for a display.

[7] If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20°C to +30°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 8: 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. Wipe the outer surfaces using a dampened soft cloth with one of the recommended cleaning solutions twice or until the surfaces are free of any visible residue.
3. Wipe twice or until the surfaces are free of any visible residue.
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
- Glutaraldehyde
- 10% bleach (5% - 5.25% sodium hypochlorite) to 90% water solution
- Quaternary ammonium chloride solutions
- 0.5% hydrogen peroxide

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 26.

To charge the Rad-G battery, refer to ***Initial Battery Charging*** on page 21.

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 41.

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 23.

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 33.
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 6: Troubleshooting*** on page 41.

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 59.

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 59 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™ Continuous Pulse Oximeter) 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.

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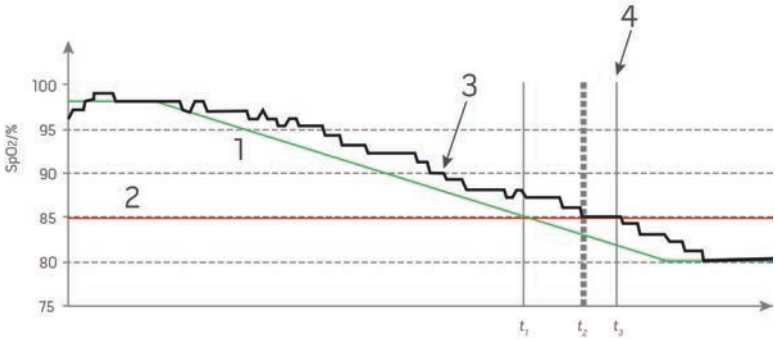
Appendix: Concepts of Alarm Response Delay

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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