Operators Manual

Rad-G® Spot-Check

For Sale in the USA

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 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: 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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ETL CLASSIFIED
Intertek
3149433

MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY 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.html

Contents

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 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 functional saturation of arterial oxygen hemoglobin (SpO_2) and pulse rate (PR), Pleth Variability Index (PVi), and Respiration Rate determined by plethysmographic waveform (RRp).

Indications for Use

The Rad-G® and Accessories are intended for the noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO_2), Pulse Rate (PR), and Pleth Respiration Rate (RRp).

The Rad-G® and Accessories are indicated for noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO_2) 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 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 performing a spot-check.

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: 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: Rad-G is not intended to be used for continuous monitoring. Physiological alarms are not provided.

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: 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 performing spot-checks, 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 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, 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 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: 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: 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: 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 spot-checking 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 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: A functional tester can only provide an indication of the contribution to the total error from the monitor which is different from the independently demonstrated accuracy of the calibration curve for the monitor and sensor combination

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.

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.

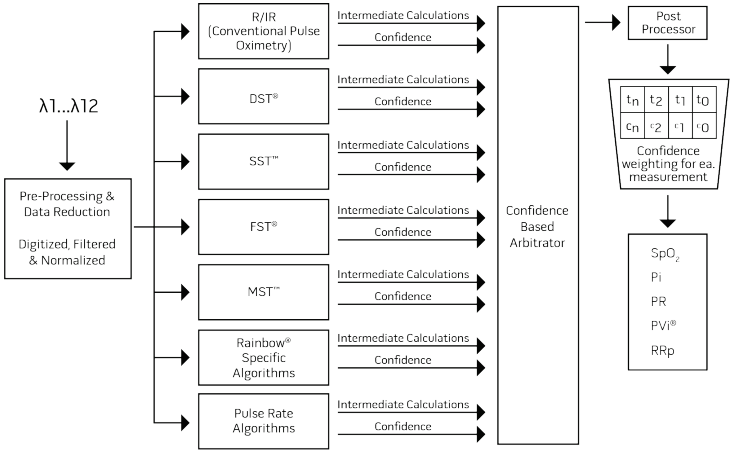
Signal Extraction Technology® (SET®)

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.

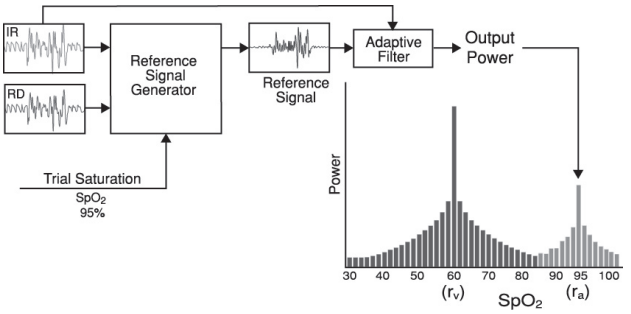
Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.



Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (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 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)

1. *Cannesson M., Desebbe O., Rosamel P., Delannoy B., Robin J., Bastien O., Lehot J.J. Pleth Variability Index to Monitor the Respiratory Variations in the Pulse Oximeter Plethysmographic Waveform Amplitude and Predict Fluid Responsiveness in the Operating Theatre. Br J Anaesth. 2008 Aug;101(2):200-6.*
2. *Forget P, Lois F, de Kock M. Goal-Directed Fluid Management Based on the Pulse Oximeter-Derived Pleth Variability Index Reduces Lactate Levels and Improves Fluid Management. Anesth Analg. 2010 Oct;111(4):910-4.*
3. *Zimmermann M., Feibicke T., Keyl C., Prasser C., Moritz S., Graf B.M., Wiesenack C. Accuracy of Stroke Volume Variation Compared with Pleth Variability Index to Predict Fluid Responsiveness in Mechanically Ventilated Patients Undergoing Major Surgery. Eur J Anaesthesiol. 2010 Jun;27(6):555-61.*
4. *Desebbe O, Boucau C, Farhat F, Bastien O, Lehot JJ, Cannesson M. Anesth Analg. The Ability of Pleth Variability Index to Predict the Hemodynamic Effects of Positive End-Expiratory Pressure in Mechanically Ventilated Patients under General Anesthesia. 2010 Mar 1;110(3):792-8.*
5. *Tsuchiya M., Yamada T., Asada A. Pleth Variability Index Predicts Hypotension During Anesthesia Induction. Acta Anesthesiol Scand. 2010 May;54(5):596-602.*
6. *Loupec T., Nanadoumgar H., Frasca D., Petitpas F., Laksiri L., Baudouin D., Debaene B., Dahyot-Fizelier C., Mimoz O. Pleth Variability Index Predicts Fluid Responsiveness in Critically Ill Patients. Crit Care Med. 2011 Feb;39(2):294-9.*
7. *Fu Q., Mi W.D., Zhang H. Stroke Volume Variation and Pleth Variability Index to Predict Fluid Responsiveness during Resection of Primary Retroperitoneal Tumors in Hans Chinese. Biosci Trends. 2012 Feb;6(1):38-43.*
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10. *Feissel M., Kalakhy R., Banwarth P., Badie J., Pavon A., Faller J.P., Quenot JP. Plethysmographic Variation Index Predicts Fluid Responsiveness in Ventilated Patients in the Early Phase of Septic Shock in the Emergency Department: A Pilot Study. J Crit Care. 2013 Oct;28(5):634-9.*
11. *Yu Y., Dong J., Xu Z., Shen H., Zheng J. Pleth Variability Index-Directed Fluid Management in Abdominal Surgery under Combined General and Epidural Anesthesia. J Clin Monit Comput. 2014 Feb 21.*
12. *Desgranges F.P., Desebbe O., Ghazouani A., Gilbert K., Keller G., Chiari P., Robin J.,Bastien O., Lehot J.J., Cannesson M. Br. J. Anaesth 2011 Sep;107(3):329-35.*
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

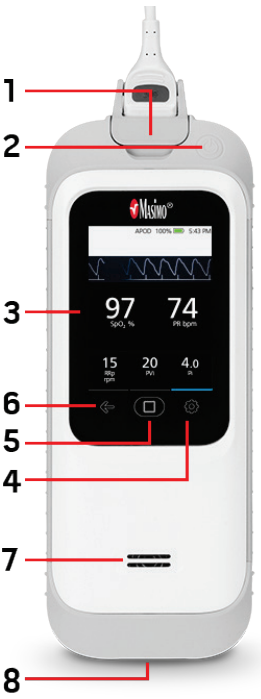
The Rad-G system includes the following:

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

* 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: 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. See ***Using the Touchscreen and Home Button*** on page 25.

4. Main Menu Button: Provides access to main menu settings. See ***Accessing Main Menu Options*** on page 29.

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

6. Backward Navigation Button: 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.

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

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.

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 on 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 61.

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
   - Rad-G Sensor and/or Patient Cable
   - Power Supply Cable and Charger Plug Adapter
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 even during charging. See ***Environmental*** on page 51.
3. Set the date and time on the device as instructed on the startup screen. See ***Localization*** on page 33.

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.

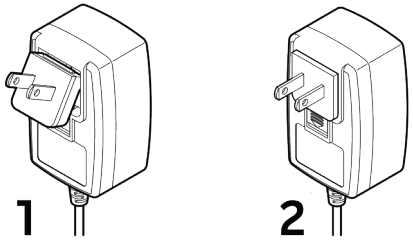
To charge Rad-G:

1. Before charging, make sure the plug configuration is appropriate.

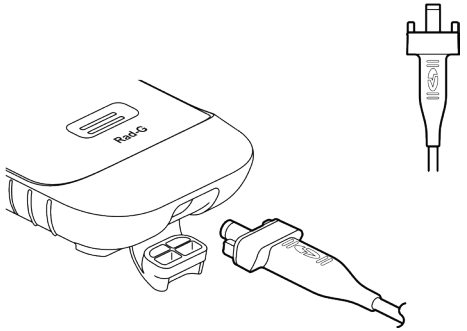
   a) Attach the correct plug insert by tipping of the blade assembly into the power supply at a 30-60 degree angle (see image **1**).

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

b) Push the blade assembly down until locked in place (see image **2**). A clicking sound will be heard when locked in place.



2. Plug the charger (AC power supply) into a socket (AC power source). See AC Power Indicator.
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 release the power button on Rad-G.

2. An audible tone sounds and the Rad-G turns ON.

To Power OFF Rad-G:

1. Press the power button.
2. The *Confirm Power Off* screen displays and one (1) audible tone sounds.
3. Touch the **Power Off** button on the screen to turn off the device. Alternatively, press **Cancel** to continue using the device.

Automatic Power OFF

Rad-G turns off automatically after a duration of inactivity (no active monitoring). This is done by the *Auto Power Off* Setting to save battery life. The duration for *Auto Power Off* is set to 1 minute by default. This feature cannot be disabled. See ***Access Control*** on page 34 for *Auto Power Off* settings.

Note: The duration of *Auto Power Off* is calculated after the *Measurement Timeout*. For example, if both *Auto Power Off* and *Measurement Timeout* is set as 1 minute each, the auto power off will be longer than 1 minute of the *Measurement Timeout*, if there is inactivity. See ***Additional Settings*** on page 32 for *Measurement Timeout* settings.

Force Shut Down

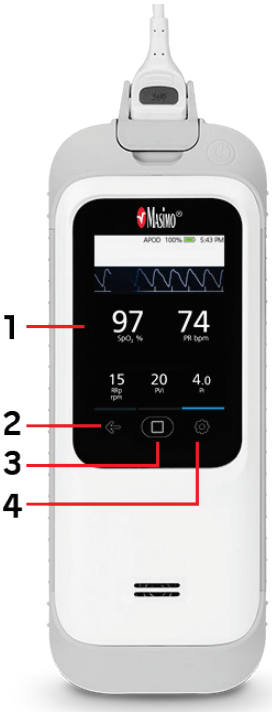
When the user presses and holds the physical power button on the device for longer than 3 seconds, the *Force Shut Down* screen displays.

- If the user continues to press and hold the power button, audible tones sound and the device shuts down after a few seconds.
- If the user releases the power button, this cancels the force shut down and Rad-G returns to the *Confirm Power Off* screen.

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 27.

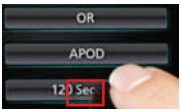
2. Backward Navigation: Navigate backwards or exit a *Main Menu* item.

3. Home Button: While viewing another screen, to return to the *Main Screen*, press the Home button.

4. Main Menu: Access to the main menu settings. See ***Accessing Main Menu Options*** on page 29.

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.

Action	Illustration	Example	Description
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.

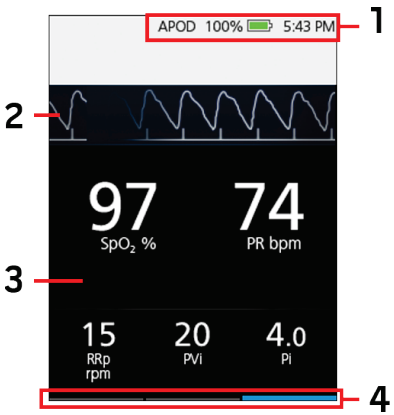
Below is a list of all the different types of controls available on Rad-G and the various ways to interact with each type of control.

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	• When closed, expands spinner • When 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
	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	• 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)

Control	Applicable Actions	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

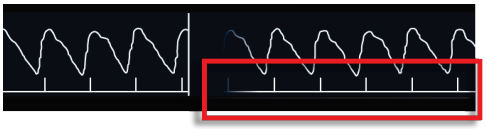
The *Main Screen* consists of different areas.



Item	Feature	Description
1	Status Bar	Displays device status. See ***About the Status Bar*** on page 28.
2	Waveform	Displays pleth waveform and signal confidence. See ***Signal IQ Indicators*** on page 28. **Note:** The pleth waveform is normalized.
3	Parameter Display	Displays the parameter readings. See ***Parameter Settings*** on page 30.
4	Available Function Bar	Displays the functions (back, home or main menu) that can be accessed while viewing the current screen. See ***Front View*** on page 19.

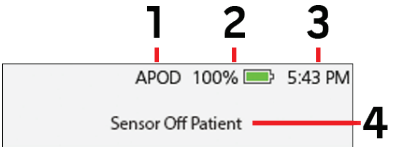
Signal IQ Indicators

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.



About the Status Bar

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



Item	Feature	Description
1	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 28.
2	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.
3	Current Time	Displays the current time. Time must be set along with the date when the setting option appears on starting the device. Time can be changed in the *Localization* screen, under Settings. See ***Localization*** on page 33.
4	Status Message	Messages related to Rad-G operation appear in this area. See ***Rad-G Messages*** on page 39.

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

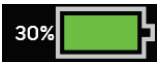
pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.

- **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:

Note: To conserve battery use, Rad-G powers OFF automatically after 1 minute without activity. See ***Automatic Power OFF*** on page 23.

Icon	Status
	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 currently charging. • 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 19.

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**	Additional settings for SpO_2, PVi, and Pi.	See ***Parameter Settings*** on page 30.

Display Icon	Main Menu Option	Description	Information
	**Additional Settings**	• Set sensitivity mode to Max, Norm, or APOD. • Set Measurement Timeout.	See ***Additional Settings*** on page 32.
	**Sounds**	• Set pulse tone volume. • Enable/disable SmartTone.	See ***Sounds*** on page 32.
	**Device Settings**	• Set device to local date and time. • Set display brightness. • Set Auto Power Off. • Restore factory defaults.	See ***Device Settings*** on page 33.
	**About**	Shows the device's software version and serial number.	See ***About*** on page 34.
	**Trend Settings**	Allows trend information to be cleared.	See ***Trend Settings*** on page 35.

Parameter Settings

Follow the instructions below to access any of the available parameter setting screens. See ***Accessing Main Menu Options*** on page 29.

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 30.
   - See ***PVi Settings*** on page 31.
   - See ***Pi Settings*** on page 31.

Note: Parameter settings for PR and RRp and not available.

SpO2 Settings

From the *SpO_2 Settings* screen, allows access to the following option:

Additional Settings* for SpO2 on page 30.

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 31.	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.

PVi Settings

From the *PVi Settings* screen, allows access to the following option:

Additional Settings for PVi on page 31

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, allows access to the following screen:

Additional Settings for Pi on page 32

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 28.	APOD	MAX, APOD, NORM
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

Sounds

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

Option	Description	Factory Default Settings	User Configurable Settings
Pulse Tone Volume	Sets the pulse tone volume level.	High	High, Medium, Low or Off
SmartTone	Allows the audible pulse to continue to beep when the pleth graph shows signs of motion.	Off	On or Off

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 33.

Brightness

See ***Brightness*** on page 34.

Access Control

See ***Access Control*** on page 34.

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 28.

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
Language	Select the language display for Rad-G.	English	English French (Français), German (Deutsch), Italian (Italiano), Spanish (Español), or Japanese (日本語),

* When changes are made, trend memory is erased.

** 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
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**.

* This setting is affected by the **Measurement Timeout** settings. See ***Automatic Power OFF*** on page 23.

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 and build 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.

Trend Settings

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.

Note: Stored data can only be viewed and transferred using Masimo Trace and a data download cable to a computer.

Chapter 5: Performing a Spot-Check

Overview

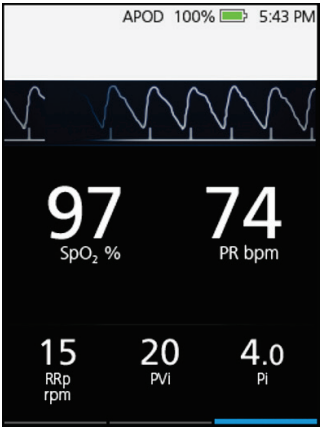
Spot-check allows spot-checking of parameters.

Spot-Checking

Place 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 waveform displays and the measurement begins as the Rad-G obtains values.

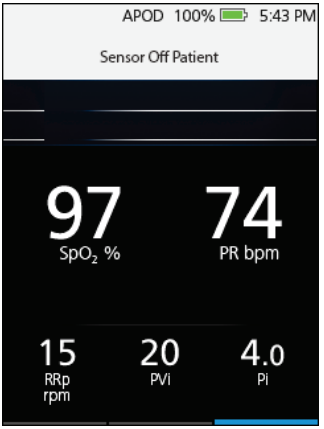
To complete the spot-checking, remove the sensor from the patient and final parameter values will display. See ***Spot-Check Values*** on page 37.



Spot-Check Values

By default, 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 32.



Chapter 6: Messages

The following chapter contains information about messages that appear on Rad-G. For more information, see ***Chapter 7: Troubleshooting*** on page 41.

Rad-G Messages

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

Message	Potential Causes	Next Steps
Pulse Search	Device is searching for pulse.	If device fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.
Connect Sensor	• 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. • If problem still persists, contact Customer Service. See ***Contacting Masimo*** on page 61.
Replace the Sensor	• Sensor is non-functional. • Defective sensor or cable.	Replace sensor.
Sensor Off Patient	Sensor not on patient.	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 61.

Chapter 7: 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 spot-check site. • Connect AC power supply.
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 spot-check site.

Troubleshooting Rad-G

The following section lists possible Rad-G symptoms, potential causes, and next steps. For more information, see ***Messages*** on page 39.

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 61.
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 muffled. • Contact Masimo service. See ***Contacting Masimo*** on page 61.
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 muffled. • Contact Masimo service. See ***Contacting Masimo*** on page 61.
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 61.
Battery not charging after plugged into AC power source	Battery is damaged.	Contact Masimo service. See ***Contacting Masimo*** on page 61.

Chapter 8: 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

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

* 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.

Note: A functional tester can only provide an indication of the contribution to the total error from the monitor which is different from the independently demonstrated accuracy of the calibration curve for the monitor and sensor combination.

SpO2 Performance Specifications

Accuracy testing for SpO_2 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.

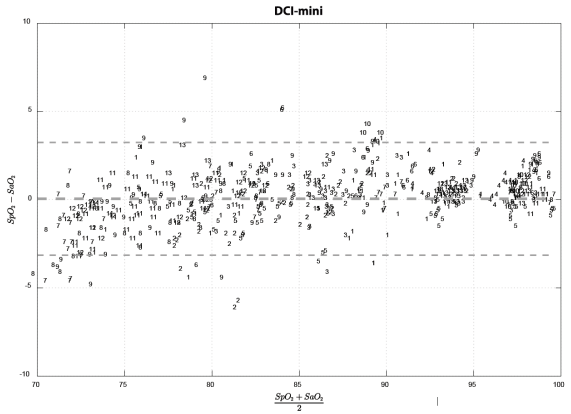


Figure 1: Reusable DCI-mini Sensors (ARMS 70-100%)

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.

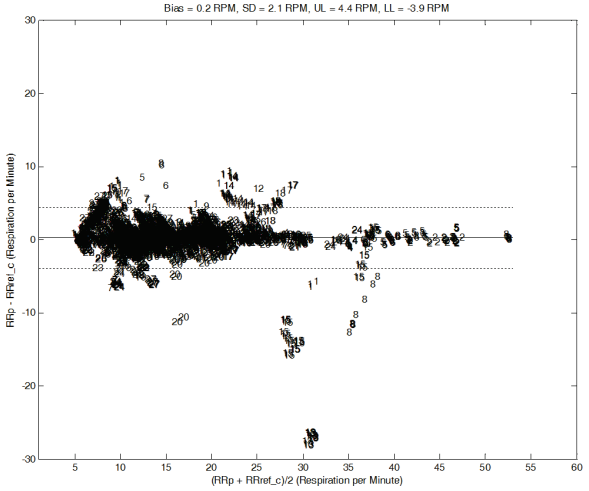


Figure 1: Subject by Subject Bland-Altman plot of RRp with respect to RRref_c

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.

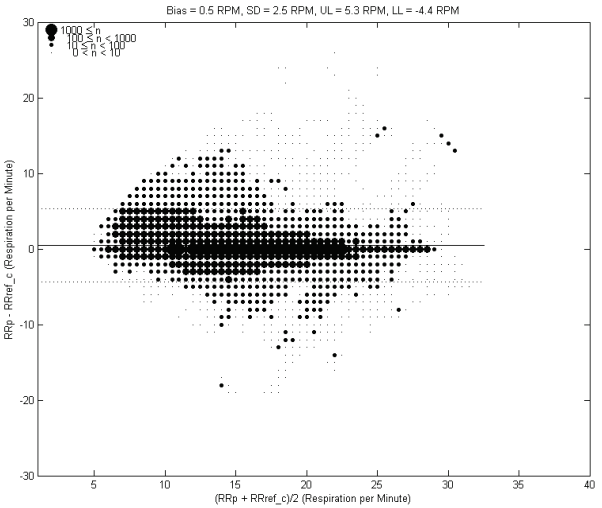


Figure 2: Bland-Altman plot of RRp with respect to RRref_c

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.

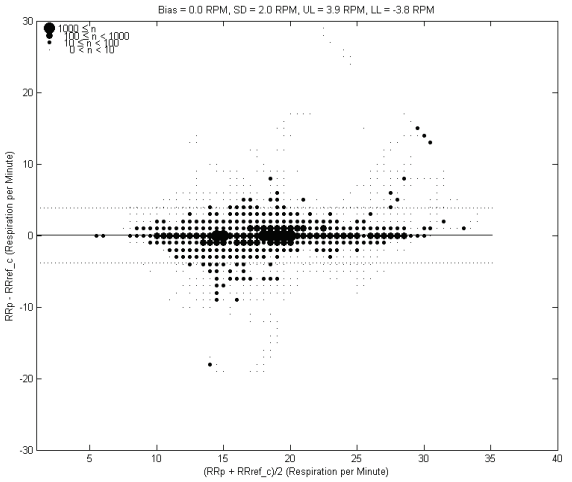


Figure 3: Bland-Altman plot of RRp with respect to RRref_c

Medical Conditions

Adult Medical Conditions

Medical Conditions from Clinical Study of Hospitalized Adult Patients

	N
Autoimmune	
Psoriasis	1
Cardiovascular	
Atrial Septal Defect	1
Coronary Disease	1
Hypertension	22
Congenital	
Arthrogyposis Multiplex Congenita	1

	N
Musculoskeletal and Connective Tissue (Cont.)	
End stage arthritis and osteonecrosis, bilateral hips	1
Fasciotomy wounds of right foot and tibia.	1
Idiopathic scoliosis and kyphoscoliosis	1
Left Femur Fracture, surgical treated with intramedullary Rod	1
Left Femur tumor	1
Left Hip Pathological fracture	1
Lower limb length difference (discrepancy)	1

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Endocrine/Metabolic	
Diabetes	2
Hyperlipidemia	8
Hypomagnesemia	1
Hypothyroidism	2
Morbid Obesity	6
Gastrointestinal	
Acid Reflux	1
Appendicitis	5
Chronic Constipation	1
Constipation	1
Crohn's Disease	1
Emesis	1
GERD	4
Hiatal Hernia	1
Jaundice	1
Reflux Disease	1
Genitourinary	
Bladder Cancer	1
Breast Cancer/Breast Cancer History	2
Cervical Cancer	1
Endometrial Cancer	1
Fibroid Uterus	1
Rectocele	1
Urinary tract infection	1
Hematology	
Acute Blood Loss Anemia	1
Anemia	4
Blood Clotting Disorder/Unspecified	1
Nonunion of left long finger metacarpal fracture	1
Osteoarthritis	4
Right fourth metatarsal fracture	1
Right lower leg and foot compartment syndrome	1
Scar contracture left hand	1
Traumatic amputation of left thumb with complication	1
NA	
None Reported	9
Neoplasm	
Hodgkin's lymphoma	1
Lipoma	1
Malignant Tumor	1
Nephrology	
Hydronephrosis	1
Neurological	
Peripheral Neuropathy	1
Autism Spectrum Disorder	1
Bilateral Hand Tremors	1
Head injury	1
Infantile cerebral palsy, unspecified	1
Neuropathy	1
Restless Leg Syndrome	1
Neurological/Orthopedic	
Scoliosis, Distal Femoral epiphyseal arrest	1
Obstetrics and Gynecology	
Left ovarian Endodermal sinus tumor	1
Pregnancy	1
Premature Birth (27 weeks)	1
Ophthalmology	

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Chronic Thrombocytopenia	1
Hereditary Spherocytosis	1
Leukocytosis	1
Sickle Cell Disease	1
Hepatobiliary	
Cholecystitis	1
Cholecystitis with Choledocholithiasis	1
Cholelithiasis	5
Chronic Cholecystitis	1
Gall Stones	2
Liver Cyst	1
Infections	
Cellulitis	1
Muscular	
Ventral Hernia	2
Musculoskeletal	
Umbilical Hernia	1
Musculoskeletal and Connective Tissue	
Bilateral tibial fracture.	1
Closed Fracture of Left Shaft of Femur	1
Closed fracture of neck of left femur	1
Complete traumatic metarpophalangeal amputation of left index finger	1
Congenital deformity of hip (joint)	1
Contracture, Achilles tendon	1
Crushing injury of left wrist, hand, and finger (following MVC)	1
Degenerative arthritis of hip	1
Degenerative Joint Disease	1
Dupuytren's Contracture (Right Hand)	1

Glaucoma	2
Opthalmology	
Glaucoma	1
Other	
Lethargy	1
Subdural Hematoma	1
Pain	
Acute post-operative pain	1
Psychiatric	
ADHD (Attention Deficit Hyperactivity Disorder)	1
Anxiety	1
Psychiatric/Developmental	
Learning Disability and Slight Anxiety	1
Renal	
Kidney Disease	2
Kidney Failure	1
Kidney Stones	1
Respiratory	
Asthma	7
Pneumonia	2
Risk of Sleep Apnea	3
Sleep Apnea	13
Urology	
Enuresis	1
Vascular	
Hemangioma - Lower lip	1
Raynaud Phenomenon	1

Pediatric Medical Conditions

Medical Conditions from Clinical Study of Hospitalized Pediatric Patients

	N
Congenital	
Arthrogryposis Multiplex Congenita	1
Congenital/Neurological	
Cerebral Palsy	1
Congenital/Orthopedic	
Genu Valgum and Leg length Discrepancy (Surgically treated)	1
Endocrine/Metabolic	
Hypothyroidism-Congenital	1
Gastrointestinal	
Appendicitis	8
Chronic Constipation	1
Constipation	1
GERD	2
Jaundice	1
General	
Unintentional weight loss	1
Genitourinary	
Urinary tract infection	1
Hematology	
Anemia	1
Hereditary Spherocytosis	1
Hypogammaglobinemia, Thrombocytopenia	1
Hepatobiliary	
Cholecystitis with Choledocholithiasis	1
Cholelithiasis	2
Musculoskeletal and Connective Tissue	

	N
Musculoskeletal and Connective Tissue (Cont.)	
Radius and ulna distal fracture, left sequela	1
Right fourth metatarsal fracture	1
Right Leg Pain	1
Right lower leg and foot compartment syndrome	1
Scar contracture left hand	1
Traumatic amputation of left thumb with complication	1
Musculoskeletal and Connective Tissue/neoplasm	
Rt. Leg Mass (Tumor), Sarcoma Rt. Femur)	1
Nephrology	
Hydronephrosis	1
Neurological	
Autism Spectrum Disorder	1
Congenital Hydrocephalus p/s Shunt	1
Head injury	1
Infantile cerebral palsy, unspecified	1
Sensorineural hearing loss, Bilateral	1
Stage IV neuroblastoma S/P, resection Chemotherapy with Stem Cell Transplant	1
Neurological/Orthopedic	
Scoliosis (Spine disorder)	1
Scoliosis, Distal Femoral epiphyseal arrest	1
Obstetrics and Gynecology	
Left ovarian Endodermal sinus tumor	1
Premature Birth (27 weeks)	1
Opthalmology	
Glaucoma	1

Bilateral tibial fracture.	1
Closed Fracture of Left Shaft of Femur	1
Closed fracture of neck of left femur	1
Complete traumatic metarpophalangeal amputation of left index finger	1
congenital deformity of hip (joint)	1
Congenital dislocation of one hip with subluxation of other hip	1
Contracture, Achilles tendon	1
Crushing injury of left wrist, hand, and finger (following MVC)	1
Dislocation of hip (bilateral)	1
Fasciotomy wounds of right foot and tibia.	1
Femur fracture, open (right femoral shaft)	1
Hip dysplasia	1
Idiopathic scoliosis and kyphoscoliosis	1
Left Femur Fracture, surgical treated with intramedullary Rod	1
Lower limb length difference (discrepancy)	1
Malunion, fracture	1
Nonunion of left long finger metacarpal fracture	1
Other congenital deformity of hip	1

Otolar	
Hearing Impaired	1
Pain	
Acute post-operative pain	1
Peritoneal/Retroperitoneal	
Peritonitis	1
Psychiatric	
ADHD (attention deficit hyperactivity disorder)	1
Anxiety	1
Psychiatric/Developmental	
Learning Disability and Slight Anxiety	1
Respiratory	
Asthma	6
Pulmonary Nodule	1
Urology	
Enuresis	1
Vascular	
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 [6]
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 (Width) x 19.8 cm (Height) x 2.5 cm (Depth) 2.9 inches (Width) x 7.8 inches (Height) x 1.0” inches (Depth)
Weight	0.27 kg. (0.59 lbs.)
Color Display	6 cm (2.4") diagonally
Service Life	10 Years

Historical Data Storage*

Historical Data Storage*	
Data Storage	96 hours

*Stored data may be viewed and transferred using Masimo Trace and a data download cable to a computer.

Display Indicators

Item	Description
Display Update Rate	1 second
Type	TFT LCD

Item	Description
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 60601-1-11
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 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 Declarations - Electromagnetic Immunity

Guidance and Manufacturer's Declarations - 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.
	+/- 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.

Guidance and Manufacturer's Declarations - Electromagnetic Immunity			
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
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 a/n	Pulse modulation (b) 217 Hz	0.2	0.3	9
5500						
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.

Recommended Separation Distances

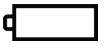
Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment			
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic 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
IP22	Protection from ingress of particulates > than 12.5 mm and protection against vertically falling water drops when enclosure is tilted at 15 degrees		ETL Intertek certification See ***Declarations on Page 1*** for certifications

Symbol	Description	Symbol	Description
	Recyclable		Separate collection for electrical and electronic equipment (WEEE)
	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
UDI	Unique Device Identifier	LOT	Lot code
IC Model:	Industry Canada Identification	EC REP	Authorized representative in the European community
	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device
	Electrostatic		No parameter alarms
	Manufacturer		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

Symbol	Description	Symbol	Description
	Class II Equipment		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual
	Medical Device		Battery
	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% 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 typical run time at the default display brightness, indoor lighting conditions, and no audio.

[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 9: 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.

NOTE: Rad-G is a reusable device and may be used on multiple patients, as per the instructions in this manual.

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 Rad-G AC Power Indicator.

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 25.

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 32.
2. Increase and decrease the Pulse Tone Volume level. The speaker should respond and sound in relationship to the adjustment.
   - If the speaker does not sound, see ***Chapter 7: 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 61.

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 61 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

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