

Rad-G™ Pulse Oximeter



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OPERATOR'S MANUAL

Not for Sale in the USA - For Export Only

These instructions provide the necessary information for proper operation of all models of the Rad-G™ Pulse Oximeter. There may be information provided in this manual that is not relevant to your device model. General knowledge of pulse oximetry and an understanding of the features and functions of the Rad-G™ Pulse Oximeter are prerequisites for its proper use. Do not operate Rad-G™ Pulse Oximeter without completely reading and understanding these instructions.

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

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

ABOUT THIS MANUAL

This manual explains how to set up and use Rad-G™ 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

Product Description

The Rad-G™ Pulse Oximeter is a noninvasive device intended to measure functional oxygen saturation of arterial hemoglobin (SpO₂), Pulse Rate (PR), Perfusion Index (Pi), and Pleth Respiration Rate (RRp).

The following key features are available for Rad-G:

- Masimo SET® technology performance.
- SpO₂ and pulse rate measuring in motion and low perfusion environments.
- Respiration rate determined by plethysmographic waveform (RRp).

INDICATIONS FOR USE

The Masimo Rad-G™ Pulse Oximeter and accessories are indicated for noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (PR), and/or respiratory rate (RR). The Masimo Rad-G™ Pulse Oximeter and accessories are indicated for use with 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, home, and mobile environments.

CONTRAINDICATIONS

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

SAFETY INFORMATION, WARNINGS, AND CAUTIONS

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

Safety Warnings and Cautions

- **WARNING:** Do not use Rad-G if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.
- **WARNING:** Do not adjust, repair, open, disassemble, or modify the Rad-G. Damage to the device may result in degraded performance and/or patient injury.
- **WARNING:** Do not start or operate the Rad-G unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.
- **WARNING:** Do not place the Rad-G or accessories in any position that might cause it to fall on the patient.
- **WARNING:** Only use Masimo authorized devices with Rad-G. Using unauthorized devices with Rad-G may result in damage to the device and/or patient injury.
- **WARNING:** All sensors and cables are designed for use with specific devices. Verify the compatibility of the device, cable, and sensor before use; otherwise degraded performance and/or patient injury can result.
- **WARNING:** Do not use the Rad-G in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide to avoid risk of explosion.
- **WARNING:** Do not use the Rad-G during magnetic resonance imaging (MRI) or in an MRI environment.
- **WARNING:** Rad-G may be used during defibrillation. However, to reduce the risk of electric shock, the operator should not touch the Rad-G during defibrillation.
- **WARNING:** To protect against electrical shock injury, follow the directions below:
 - Avoid placing the device on surfaces with visible liquid spills.
 - Do not soak or immerse the device in liquids.
 - Do not attempt to sterilize the device.
 - Use cleaning solutions only as instructed in this Operator's Manual.
 - Do not attempt to clean the Rad-G while monitoring patient.

- **WARNING:** To ensure safety, avoid placing anything on the device during operation.
- **WARNING:** As with all medical equipment, carefully route patient cables to reduce the possibility of patient entanglement or strangulation.
- **CAUTION:** Do not place the Rad-G where the controls can be changed by the patient.
- **CAUTION:** Do not place Rad-G where the AC power supply cannot be readily disconnected when used on AC power.
- **CAUTION:** 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.
- **Note:** The maximum skin surface temperature is measured to be less than 41°C (106°F) in a 35°C (95°F) environment. This was verified by measuring the skin interface temperature with Rad-G operating under reasonable worst-case conditions.

Performance Warnings and Cautions

- **WARNING:** The Screening Mode in the Rad-G is intended to help clinicians follow established screening protocols and is not intended to be used as a diagnostic or sole screening tool.
- **WARNING:** The Screening Mode screening result is not a definitive assessment of the patient's condition. The result should be evaluated in conjunction with the patient's clinical status and confirmed with additional diagnostic tests consistent with each hospital's policy.
- **WARNING:** During Screening, the SpO₂ trend line should be monitored for low saturation events.
- **WARNING:** Rad-G is intended for spot-checking only, no physiological alarms are provided.
- **WARNING:** Rad-G should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- **WARNING:** The Rad-G and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.
- **WARNING:** If any measurement seems questionable, first check the patient's vital signs by alternate means and then check Rad-G for proper functioning.
- **WARNING:** Rad-G should not be used as a replacement or substitute for ECG-based arrhythmia analysis.
- **WARNING:** Rad-G may be used during defibrillation. This may affect the accuracy or availability of the parameters and measurements.
- **WARNING:** Rad-G may be used during electrocautery. This may affect the accuracy or availability of the parameters and measurements.
- **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:** Do not use Rad-G on patients that have been injected with dyes or any substance containing dyes, the change in usual blood pigmentation may cause 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 SpO₂ values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- **WARNING:** SpO₂ is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- **WARNING:** Optical, pleth-based measurements (e.g. SpO₂ and RRP) can be affected by the following:
 - Improper sensor application or use of use of incorrect sensor.
 - Blood pressure cuff applied to the same arm as the sensor site.
 - Intravascular dyes such as indocyanine green or methylene blue.
 - Venous congestion.
 - Abnormal venous pulsations (e.g. tricuspid valve regurgitation, Trendelenburg position).
 - Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).
 - Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
 - Moisture, birthmarks, skin discoloration, nail aberration, deformed fingers, or foreign objects in the light path.
 - Elevated levels of bilirubin.
 - Physiological conditions that can significantly shift the oxygen dissociation curve.
 - A physiological condition that may effect vasomotor tone or changes in vasomotor tone.
- **WARNING:** Inaccurate SpO₂ readings may be caused by:
 - Elevated levels of COHb and/or MetHb.
 - Severe anemia.
 - Extremely low arterial perfusion.
 - Excessive induced motion.
 - Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (Quantitative defects such as Thalassemias).
- **WARNING:** Inaccurate RRP readings may be caused by:
 - Low arterial perfusion.
 - Motion induced artifact.
 - Severe anemia.
- **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 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 Directions for Use for the specified duration of patient monitoring time.
- **Note:** Physiological conditions that result in loss of pulsatile signal may result in no SpO₂ or RRP readings.
- **Note:** 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 Module.
- **Note:** A functional tester cannot be used to assess the accuracy of Rad-G.

Cleaning, Disinfecting, 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: 2007, Medical Device Directive 93/42/EEC. 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.

TECHNOLOGY OVERVIEW

The following chapter contains general descriptions about functional oxygen saturation (SpO₂) and Signal IQ used by Masimo products.

Functional Oxygen Saturation (SpO₂)

The Rad-G is calibrated to measure and display functional oxygen saturation (SpO₂): 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.

Signal IQ

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

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

DESCRIPTION

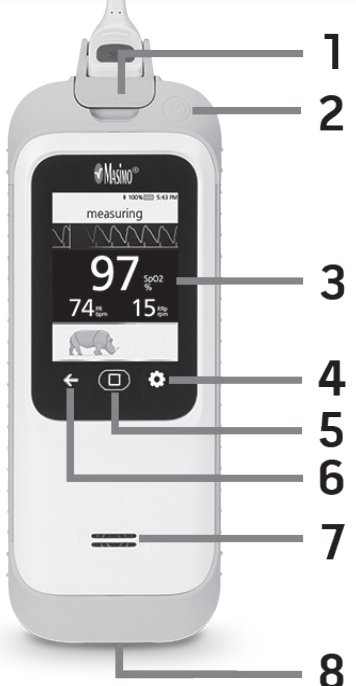
General System Description

The Rad-G system includes the following:

- Rad-G Device
- Rad-G Sensor
- AC/DC Power Supply

Note: Only use with GlobTek Model No. GTM41134-0606-1.0; Input Rating 100-240V~, 50-60Hz, 0.6A; Output 5V, 1.2A, 6W.

Features

Front View	
	1 Patient Sensor Connector: Allows connection to a patient sensor.
	2 Power Button: Power Rad-G On and Off. See Powering Rad-G ON and OFF section.
	3 Display and Touchscreen: Provides a user interface to view and change settings.
	4 Main Menu: Provides access to main menu settings. See Accessing Main Menu Options section.
	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.

SETTING UP

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** section.
2. Rad-G should not be operated outside the environmental conditions listed in the specifications section. See **Environmental** section.



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.

Note: After 5 minutes without activity, Rad-G powers OFF automatically.

To Power OFF Rad-G:

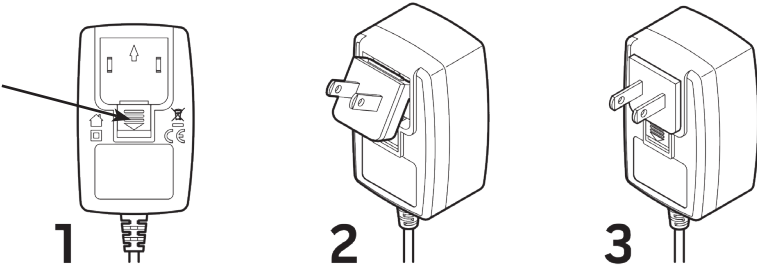
1. Press and hold the Power Button for more than two (2) seconds until one (1) audible tone sounds.
2. The Rad-G powers OFF.

Initial Battery Charging

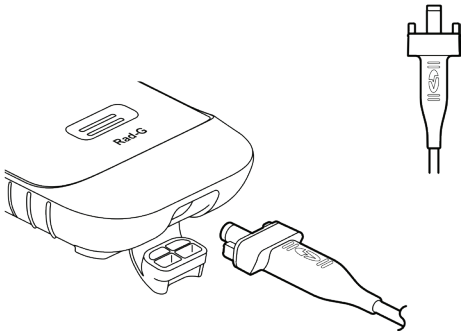
Before use, the Rad-G battery must be fully charged.
Note: The Rad-G must be ON during recharging if the battery is completely depleted.

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 below).
2. Insert the tip of the blade assembly into the power supply at a 30-60 degree angle (see image 2 below).
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 below). 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** section.
5. Plug the AC power supply into the Rad-G DC input connector. Verify the plug orientation is correct during connection (see the images below).



AC Power Indicator

When Rad-G is ON and connected to an AC power source, 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 connected to an AC power source and is fully charged.
	Battery is unplugged from AC power source; the Battery Charge Status Indicator icon provides a visual indication of the current battery charge condition.
	The battery charge reaches a low level: <ul style="list-style-type: none">• 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.

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.

Mode Selection

After the Rad-G is powered ON, select either Spot Check Mode or SpO₂/Respiration Rate Screening. The mode can be selected only at power ON. The mode can be changed only if the device is powered OFF and ON again.

MODE SELECTION	REF.	FEATURE	INFORMATION
	1	Music Enabled	Displays when music volume is set to Low, Medium, or High. See Accessing Main Menu Options to change the music volume settings.
	2	Voice Enabled	Displays when voice volume is set to Low, Medium, or High. See Accessing Main Menu Options to change the voice volume settings.
	3	Rad-G Battery Charge/AC Power Indicator	Displays battery charge status and percentage. See Initial Battery Charging section and AC Power Indicator section.
	4	Current Time	Displays the current time. See Accessing Main Menu Options section to change the time.
	5	Spot Check Mode	See Spot Check Mode section.
	6	SpO ₂ /Respiration Rate Screening Mode	See SpO₂/Respiration Rate Screening section.

Accessing Main Menu Options

- To access Main Menu options, touch the Main Menu button on the bottom-right corner of the touchscreen. See **Front View** section.
- To exit the Main Menu, touch the Home Button or the Backward Navigation button.

The Main Menu options are:

MAIN MENU OPTIONS	DISPLAY BUTTON	DESCRIPTION	DEFAULT	OPTIONS
Manual		Displays web address to obtain operator's manual: http://techdocs.masimo.com/	N/A	N/A
Sounds		Controls the Music and/or Voice volume.	High	Off, Low, Medium, or High
Brightness		Controls the brightness of the display screen.	100%	25%, 50%, 75%, or 100%
Date and Time		Set the current date and/or current time.	N/A	N/A
About		Shows the device's software version information as well as serial number. These details may be helpful during troubleshooting or when contacting Masimo for assistance.	N/A	N/A

Performing SpO₂/Respiration Rate Screening

To perform SpO₂/Respiration Rate Screening, the Rad-G must be powered ON with the battery charged and the sensor must be connected to the device (See *Directions for Use* for sensor).

- If the Rad-G is powered OFF, press the power button ON.
Note: If Rad-G is already ON and in *Spot Check Mode*, cycle the the power OFF and ON to change modes.
- Touch *SpO₂/Respiration Rate Screening* mode.
- Touch the *SpO₂/Respiration Rate Screening* home screen.
- Select the *age* of the patient.
- Touch *Next*.
- Place the sensor on the patient (See *Directions for Use* for sensor).
- Touch *Start* to begin the *SpO₂/Respiration Rate Screening*. Rad-G searches for a pulse and changes to a measuring screen. The screening result is either negative or positive. See the table below.
- Touch *Done* to complete the screening.

RESULT DISPLAYED	DESCRIPTION	RESULT DISPLAYED	DESCRIPTION
	The "screen negative" message has green font to indicate parameter measurements are within an ACCEPTABLE screening range (See SpO₂/Respiration Rate Screening Criteria). The numbers displayed are ranges, not measured results.		The "screen positive" message has red font to indicate parameter measurement(s) within an UNACCEPTABLE range (See SpO₂/Respiration Rate Screening Criteria). The numbers displayed are ranges, not measured results.

SpO2/Respiration Rate Screening Criteria*

PARAMETER	AGE GROUP	SCREEN POSITIVE	SCREEN NEGATIVE
SpO2	All	< 90%	≥ 90%
RRp	0 to 2 months	≥ 60	< 60
	2 to 12 months	≥ 50	< 50
	1 to 10 years	≥ 40	< 40
	> 10 years	≥ 40	< 40

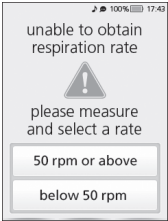


*SpO2/Respiration Rate Screening criteria results described are based on an established protocol by World Health Organization, Integrated Management of Childhood Illness.

Performing Spot Check

To perform Spot Check, the Rad-G must be powered ON with the battery charged and a sensor must be connected to the device (See Directions for Use for sensor).

1. If the Rad-G is powered OFF, press the power button ON.
Note: If Rad-G is already ON and in *SpO2/Respiration Rate Screening* mode, cycle the power OFF and ON to change modes.
2. Touch *Spot Check Mode*.
3. Touch the *Spot Check* screen.
4. Select the *age* of the patient.
5. Touch *Next*.
6. Place the sensor on the patient (See *Directions for Use* for sensor).
7. Touch *Start* to begin Spot Check measurement. Rad-G searches for a pulse and changes to a measuring screen. Rad-G will continue to measure parameters until the sensor is removed.
8. To view results, remove the sensor from the patient. Spot Check will stop and the “sensor off patient” message will be displayed with results.
9. To return to Spot Check screen: Place the sensor on the patient OR touch *Done* OR press the Home button.

SCREENING EXCEPTIONS

SCREENING EXCEPTION	MESSAGE	NEXT STEPS
unable to obtain respiration rate		<ul style="list-style-type: none">Manually count respiration rate.Respiration rate range must be selected to view the results screen.The range is determined by the age of the patient (see SpO2/Respiration Rate Screening Criteria).
motion detected		<ul style="list-style-type: none">The “motion detected” message will cycle to “hold still” message.The “motion detected” and “hold still” messages will repeat until the patient stops moving.
hold still		<ul style="list-style-type: none">The “hold still” message will repeat until the patient stops moving.

MESSAGES AND TROUBLESHOOTING

Messages

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

MESSAGE	POTENTIAL CAUSES	NEXT STEPS
Connect a Sensor	<ul style="list-style-type: none">Sensor not fully inserted into the device. May be an incorrect sensor, defective sensor or defective cable.Sensor latch is not fully closed.	<ul style="list-style-type: none">Disconnect and reconnect sensor.Close sensor latch.See <i>Directions for Use</i> for sensor.
Replace the Sensor	<ul style="list-style-type: none">Sensor is non-functional.Defective sensor or cable.	<ul style="list-style-type: none">Replace sensor.
Sensor Off Patient	<ul style="list-style-type: none">Sensor has been removed from patient during spot check monitoring.	<ul style="list-style-type: none">Place sensor on patient to continue spot check.

MESSAGE	POTENTIAL CAUSES	NEXT STEPS
Screening Stopped	<ul style="list-style-type: none"> • Sensor has been removed from patient during screening. 	<ul style="list-style-type: none"> • Place sensor on patient. • Repeat measurement or screening.
Low Battery Please Charge	<ul style="list-style-type: none"> • Battery charge is low. 	<ul style="list-style-type: none"> • Charge battery by powering the device with AC line power.
Battery Depleted Shutting Down	<ul style="list-style-type: none"> • Battery charge is completely depleted. 	<ul style="list-style-type: none"> • Charge battery by powering the device with AC line power.
Device Too Hot Shutting Down	<ul style="list-style-type: none"> • The operating temperature is too high. 	<ul style="list-style-type: none"> • See Environmental Section
Unable to Obtain Respiration Rate	<ul style="list-style-type: none"> • RRp is unable to be determined. 	<ul style="list-style-type: none"> • Manually count respiration rate. • Select a respiration rate range.
An Error Occurred Please Start Over	<ul style="list-style-type: none"> • Sensor is damaged or not functioning. • Improper sensor type or application. • Excessive motion. • Low perfusion. 	<ul style="list-style-type: none"> • Repeat screening • 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/cable. • Minimize or eliminate motion at the measurement site.

TROUBLESHOOTING MEASUREMENTS

The following section lists possible measurement symptoms, the potential cause, and next steps.

For additional information, see **Safety Warnings and Cautions** Section.

MESSAGE	POTENTIAL CAUSES	NEXT STEPS
Difficulty obtaining a reading or unexpected readings.	<ul style="list-style-type: none"> • Inappropriate sensor or sensor size • Improper sensor type or application. • Low perfusion. • Sensor displacement. • Excessive motion artifact. • Excessive ambient or strobing light. • Low battery/ not plugged into AC power supply. • Interference from line frequency-induced noise. 	<ul style="list-style-type: none"> • Allow time for parameter reading to stabilize. • Verify sensor type and size and re-apply sensor. See 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.
Dimly Lit Parameters	<ul style="list-style-type: none"> • Low signal quality. 	<ul style="list-style-type: none"> • Assess the patient. • Verify sensor type and size and re-apply sensor. See 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** section.

SYMPTOM	POTENTIAL CAUSES	NEXT STEPS
Device does not turn on or screen is blank.	<ul style="list-style-type: none"> • Depleted Battery. • Internal failure. • EMI (Electro Magnetic Interference). 	<ul style="list-style-type: none"> • Check AC Power connection. • Contact Masimo Service. (See Contacting Masimo section). • Turn Rad-G OFF and ON.
System failure or device is not working	<ul style="list-style-type: none"> • Internal failure. • EMI (Electro Magnetic Interference). • Device audible settings may be incorrect. 	<ul style="list-style-type: none"> • Turn Rad-G OFF and ON. • Contact Masimo service. (See Contacting Masimo section). • 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.
Speaker does not work	<ul style="list-style-type: none"> • Device audible settings may be incorrect. • Internal failure. 	<ul style="list-style-type: none"> • Turn Rad-G OFF and ON. • Check that Sounds have not been silenced. • Check Sounds volume settings. • Check that the device speaker is not being muffled. • Contact Masimo service. (See Contacting Masimo section).

SYMPTOM	POTENTIAL CAUSES	NEXT STEPS
Battery run time significantly reduced	<ul style="list-style-type: none">• Battery not fully charged.• Battery damaged.• Battery capacity effected.	<ul style="list-style-type: none">• Check battery charge level indicator.• Check battery is fully charged.• Contact Masimo service. (See Contacting Masimo section).
Battery not charging after plugged into AC power source	<ul style="list-style-type: none">• Battery is completely depleted.	<ul style="list-style-type: none">• Check the Rad-G is ON during recharging if the battery is completely depleted.• Contact Masimo service. (See Contacting Masimo section).

SPECIFICATIONS

Display Range

MEASUREMENT	DISPLAY RANGE
SpO ₂ (Functional Oxygen Saturation)	0% to 100%
PR (Pulse Rate)	0 BPM to 240 BPM
Pi (Perfusion Index)	0.00 to 20.0
RRp (Respiration Rate from the Pleth)	0 RPM to 90 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%

RESPIRATORY RATE (RRP) [5], [6], [7]	
Range of 4 to 90 RPM	1 RPM

* ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study.

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

Electrical

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

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) [9]
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.

Resolution

PARAMETER	RESOLUTION
SpO ₂ (Functional Oxygen Saturation)	1%
PR (Pulse Rate)	1 BPM
Pi (Perfusion Index)	0.01
RRp (Respiration Rate)	1 RPM

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

Battery

BATTERY	
Type	Lithium ion
Capacity	24 hours [8]
Charging Time	8 hours*

*Time to reach 80% capacity at 25°C ambient temperature.

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 60601-1-2:2007, Class B
EN/ISO 80601-2-61:2011, 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)
	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

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

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	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power lines	+/- 2 kV for power lines es	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	


































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
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	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. Recommended separation distance: $d = \left[\frac{3.5}{V_1} \right] \sqrt{P} \quad 150 \text{ kHz to } 80 \text{ MHz}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	20 V/m	
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 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 K Hz 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.			

RAD-G DEVICE SYMBOLS

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

SYMBOL	DEFINITION	SYMBOL	DEFINITION
 (blue background)	Follow instructions for use		Consult instructions for use
	The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual	 ETL CLASSIFIED C-UL US 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.
	Recyclable		Separate collection for electrical and electronic equipment (WEEE)
	Non-Sterile		Defibrillation-proof. Type BF applied part
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a 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 code
IC Model:	Industry Canada Identification		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		Catalogue number (model number)
	Storage temperature range		Masimo reference number
	Keep dry		Serial number
	Storage humidity limitation		Fragile, handle with care
	Atmospheric pressure limitation		Do not use if package is damaged
	AC current		DC current
	Stand-By		China Restriction of Hazardous Substances
 0123	Mark of conformity to European Medical Device Directive 93/42/EEC		Class II Equipment
	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eIFU is not available for CE mark countries.		

Patents: www.masimo.com/patents.htm

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Rad-G™ and X-Cal™ are trademarks of Masimo Corporation. All other trademarks and registered trademarks are property of their respective owners.

CITATIONS

- [1] The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70–100% SpO₂ against a laboratory CO-Oximeter and ECG monitor.
- [2] The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70–100% SpO₂ against a laboratory CO-Oximeter and ECG monitor.
- [3] The Rad-G has been validated for low perfusion accuracy in bench-top testing against a BioteK Index 2TM* simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70%–100%.
- [4] Masimo sensors have been validated for pulse rate accuracy for the range of 25–240 bpm in bench top testing against a Fluke BioteK Index 2 simulator.
- [5] The Masimo RRP™ (Respiration Rate from Pleth) spot-check technology used in Rad-G has been bench tested for respiration rate accuracy in the range of 4–90 rpm.
- [6] RRP has been validated on subjects 11 days to 6 years old, in the range of 22 to 86 rpm.
- [7] The Rad-G reusable finger clip sensor accommodates digits and measurement sites for populations ≥3kg. See the sensor DFU for more information. Sensor size on these patients is applicable based on the sensor.
- [8] 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: SpO₂ only operation and default value of Brightness set for a display.
- [9] If the batteries are to be stored for extended periods of time, it is recommended that they be stored between –20°C to +30°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.

SERVICE AND MAINTENANCE

Cleaning

Rad-G is a non-sterile and reusable device. The surface of the Rad-G should be cleaned when the device is visibly dirty, before and after each procedure, and/or according to hospital practice.

To surface clean, wipe down the outer surface of Rad-G using any of the following:

- A soft cloth dampened with a mild detergent and warm water solution
- Cidex Plus (3.4% glutaraldehyde)
- 10% bleach solution
- 70% isopropyl alcohol solution

Note: Do not allow liquids to enter the interior of the device.

Note: The performance of a device with a touchscreen will not be affected when using the recommended cleaning solutions.

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 section.

To charge the Rad-G battery, refer to Initial Battery Charging section.

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

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 the Troubleshooting section.

Touchscreen Function Test

1. Connect the Rad-G to AC power.
2. Perform the operations outlined in the Operation section.

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 the **Cleaning** section. Make sure the equipment is fully dry before packing. To return the device for service, refer to the **Return Procedure** section.

RETURN PROCEDURE

Clean contaminated/dirty equipment before returning, following instructions in the **Cleaning** section. 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** section.

CONTACTING MASIMO

USA, Canada, and Asia Pacific:	Europe:	All Other Locations:
Masimo Corporation	Masimo	Contact your local Masimo
52 Discovery	International Sàrl	representative.
Irvine, CA 92618, USA	Puits-Godet 10	
Tel.: 949-297-7000	2000 Neuchâtel-Switzerland	
Fax.: 949-297-7001	Tel.: +41 32 720 1111	
www.masimo.com	Fax: +41 32 724 1448	

LIMITED WARRANTY

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product (Rad-G™ 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.

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