Operator's Manual

Rad-67™ Pulse CO-Oximeter®

Spot-Check

Masimo

For Sale in the USA

These operating instructions provide the necessary information for proper operation of all models of the Rad-67. 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-67 are prerequisites for its proper use. Do not operate Rad-67 without completely reading and understanding these instructions.

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

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

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Wireless Radio
FCC ID: VKF-MWM1 Model Rad-67 IC: 7362A-MWM1 IC Model: MWM1

Masimo Corporation
52 Discovery
Irvine, CA 92618, USA
Tel.: 949-297-7000
Fax.: 949-297-7001
www.masimo.com

CE 0123

EU authorized representative for Masimo Corporation:

EC REP

MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

3149433

MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1:2005, CAN/CSA C22.2 No. 60601-1:2008, and applicable Particular (EN/ISO 80601-2-61:2011) and related Collateral (IEC 60601-1-8:2006) Standards for which the product has been found to comply by Intertek.

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

Contents

About This Manual

This manual explains how to set up and use Rad-67™ Pulse CO-Oximeter®. Important safety information relating to general use of Rad-67 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-67™ Pulse CO-Oximeter® is a non-invasive device intended to measure functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and perfusion index (Pi), along with optional non-invasive measurement of total hemoglobin (SpHb®).

The following key features are available for Rad-67:

- Masimo® SET® and rainbow® SET technology performance.
- SpO_2 and pulse rate measuring in motion and low perfusion environments.
- Spot-Check monitoring of total hemoglobin (SpHb).
- Wireless radio for transfer of parameter data.

Indications for Use

The Masimo Rad-67™ Pulse CO-Oximeter® and Accessories are intended for use in clinical and non-clinical settings.

The Masimo Rad-67™ Pulse CO-Oximeter® and Accessories are indicated for non-invasive spot-check monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) for adult and pediatric patients who are well or poorly perfused during both motion and no motion conditions.

The Masimo Rad-67™ Pulse CO-Oximeter® and Accessories are indicated for non-invasive spot-check monitoring of total hemoglobin concentration (SpHb) for adult patients.

Contraindications

The Rad-67 is not intended for use as an apnea monitor.

The Rad-67 is not intended to measure hemoglobin (SpHb) on pregnant women.

Safety Information, Warnings and Cautions

CAUTION: Rad-67 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-67 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-67. Damage to the device may result in degraded performance and/or patient injury.

WARNING: Do not start or operate the Rad-67 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-67 or accessories in any position that might cause it to fall on the patient.

WARNING: Only use Masimo authorized devices with Rad-67. Using unauthorized devices with Rad-67 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-67 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-67 during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: Rad-67 may be used during defibrillation. However, to reduce the risk of electric shock, the operator should not touch the Rad-67 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-67 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-67 where the controls can be changed by the patient.

CAUTION: Do not place Rad-67 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 port must be done using only authorized data cables.

Note: Disconnect the device from AC mains by unplugging the AC power supply from the Rad-67.

Note: Use and store the Rad-67 in accordance with specifications. See the Specifications section in this manual.

Performance Warnings and Cautions

WARNING: Rad-67 is intended for spot-check monitoring only, no physiological alarms are provided.

WARNING: Rad-67 should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: Do not utilize SpHb spot-check measurements as the sole basis for clinical decisions on blood transfusions. The SpHb spot-check accuracy range does not include values below 8 g/dL, which may be important for determining the need for transfusions.

WARNING: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check Rad-67 for proper functioning.

WARNING: SpHb is not intended for use in pediatrics, pregnant patients, and patients with renal disease.

WARNING: Variation in hemoglobin measurements may be profound and may be affected by sample type, body positioning, as well as other physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

WARNING: Rad-67 should not be used as a replacement or substitute for ECG-based arrhythmia analysis.

WARNING: Rad-67 may be used during defibrillation. This may affect the accuracy or availability of the parameters and measurements.

WARNING: Rad-67 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-67 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 SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

WARNING: Optical, pleth-based measurements (e.g. SpO_2 and SpHb) 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 effect vasomotor tone or changes in vasomotor tone.

WARNING: Inaccurate SpO_2 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 SpHb readings may be caused by:

- Low arterial perfusion.
- Motion induced artifact.
- Low arterial oxygen saturation levels.
- Elevated COHb and/or MetHb levels.
- Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (quantitative defects such as Thalassemias).
- Severe anemia.

CAUTION: If using Rad-67 during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.

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

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

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

CAUTION: When using a compatible sensor, ensure the gender has been entered correctly. Entering an incorrect gender may affect measurement performance of the device.

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-67.

CAUTION: Do not place the Rad-67 near electrical equipment that may affect the device, preventing it from working properly.

CAUTION: Failure to charge Rad-67 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: In order to establish and maintain Rad-67's minimum Quality of Service, the following network specifications should be met before and after installation:

- Wired Network Connection
  During Ping Test, passing result if:
  a. At least 98% of packets have latency ≤ 30 milliseconds, and
  b. No more than 2 % packets loss.
- Wireless Network Connection
  During Ping Test, passing result if:
  a. At least 98% of packets have latency ≤ 100 milliseconds,
  b. No more than 2 % packets loss, and
  c. Primary access point signal strength at least -67 dBm.

CAUTION: The wireless quality of services may be influenced by the presence of other devices that may create radio frequency interference (RFI). Some RFI devices to consider are as follows: electrocautery equipment, cellular telephones, wireless PC and tablets, pagers, RFID, MRI electrically powered wheelchair, etc. When used in the presence of potential RFI devices, consideration should be taken to maximize separation distances and to observe for any potential signs of interference such as loss of communication or reduced Wi-Fi signal strength.

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 SpO_2 or SpHb readings.

Note: Rad-67 is provided with a Wi-Fi signal indicator as an indication of Wi-Fi communication.

Note: Always charge Rad-67 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-67.

Note: When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the Rad-67 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-67, 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-67 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-67. Service of Rad-67 should be done by qualified personnel only.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the Rad-67 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-67, 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-67. These substances affect the device's materials and device failure can result.

CAUTION: Do not submerge the Rad-67 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-67 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: In accordance with international telecommunication requirements, the frequency band of 2.4 GHz and 5.15 to 5.25 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

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: Disposal of Product: 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 required country or regional requirements.

Note: Use Rad-67 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 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.

Note: 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.

Chapter 1: Technology Overview

The following chapter contains general descriptions about parameters, measurements, and the technology used by Masimo products.

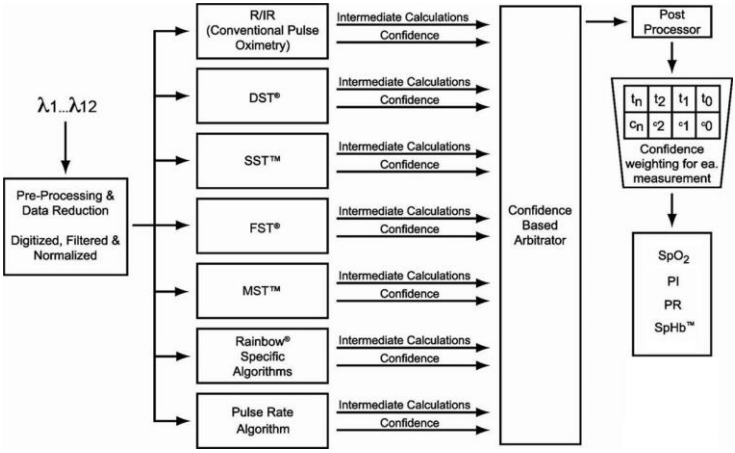
Signal Extraction Technology® (SET®)

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.

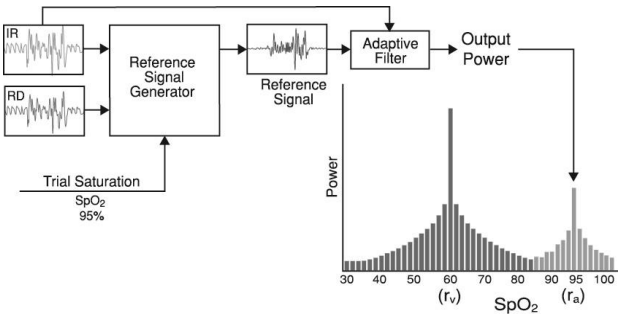
Masimo rainbow SET® Parallel Engines

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-67 is calibrated to measure and display functional oxygen saturation (SpO_2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.

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

General Description for Pulse Rate (PR)

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

General Description for Perfusion Index (Pi)

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

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.

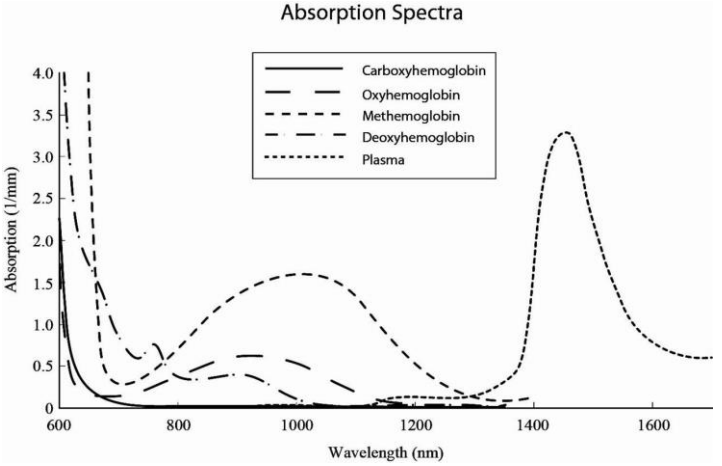
With motion, the plethysmographic waveform is often distorted and may be obscured by noise artifact. Shown as a vertical line, the SpO_2 SIQ coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Signal IQ identifies the timing that the algorithms 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. See ***About the Status Bar*** on page 34.

rainbow Pulse CO-Oximetry Technology®

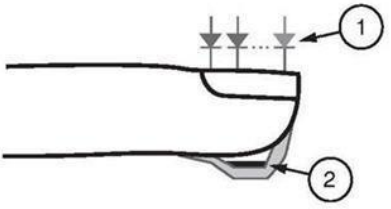
rainbow Pulse CO-Oximetry technology is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).
2. The amount of arterial blood in tissue changes with pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.



Rad-67 uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma.

Rad-67 utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to a diode (detector). Signal data is obtained by passing various visible and infrared lights (LEDs, 500 to 1400nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the Rad-67 for calculation.



1. Light Emitting Diodes (LEDs) (7 + wavelengths)
2. Detector

Once Rad-67 receives the signal from the sensor, it utilizes proprietary algorithms to calculate the patient's functional oxygen saturation (SpO_2 [%]), total hemoglobin concentration (SpHb [g/dL]) and pulse rate (PR). The SpHb measurements rely on a multi-wavelength calibration equation to quantify the percentage of carbon monoxide and methemoglobin and the concentration of total hemoglobin in arterial blood. Maximum skin-sensor interface temperature was tested to be less than 41° C (106° F) in a minimum ambient temperature of 35° C (95° F). The tests were conducted with sensors operating at reasonable worst case power.

Pulse CO-Oximetry vs. Drawn Whole Blood Measurements

When SpO_2 and SpHb measurements obtained from the Rad-67 (noninvasive) are compared to drawn whole blood (invasive) measurements by blood gas and/or laboratory CO-Oximetry methods, caution should be taken when evaluating and interpreting the results.

The blood gas and/or laboratory CO-Oximetry measurements may differ from the SpO_2 and SpHb measurements of the Rad-67. Any comparisons should be simultaneous, meaning the measurement on the device should be noted at the exact time that blood is drawn.

In the case of SpO_2, different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen (pO_2) and saturation, such as: pH,temperature, the partial pressure of carbon dioxide (pCO_2), 2,3-DPG, and fetal hemoglobin.

In the case of SpHb, variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. As with most hemoglobin tests, a laboratory blood sample should be analyzed prior to clinical decision making.

High levels of bilirubin may cause erroneous SpO_2 and SpHb readings. As blood samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation (SaO_2), levels of carboxyhemoglobin (COHb), and MetHb of the patient are stable and not changing over the period of time that the blood gas sample is taken. Subsequently, blood gas and laboratory CO-Oximetry measurements of SpO_2 and SpHb may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn whole blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

Measurements with Low Signal IQ should not be compared to laboratory measurements.

General Description for Total Hemoglobin (SpHb)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of total hemoglobin (SpHb) in arterial blood. It relies on the same principles of pulse oximetry to make its SpHb measurement.

Successful Monitoring for SpHb

A stable SpHb reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. See ***Safety Information, Warnings and Cautions*** on page 11 and ***Troubleshooting Measurements*** on page 67.

General Description for Total Arterial Oxygen Content (CaO2)

Oxygen (O_2) is carried in the blood in two forms, either dissolved in plasma or combined with hemoglobin. The amount of oxygen in the arterial blood is termed the oxygen content

(CaO_2) and is measured in units of ml O_2/dL blood. One gram of hemoglobin (Hb) can carry 1.34 ml of oxygen, whereas 100 ml of blood plasma may carry approximately 0.3 ml of oxygen*. The oxygen content is determined mathematically as:

$$CaO_2 = 1.34\ (ml\ O_2/g) \times Hb\ (g/dL) \times HbO_2 + PaO_2\ (mmHg) \times 0.003\ (ml\ O_2/dL/mmHg)$$

Where HbO_2 is the fractional arterial oxygen saturation and PaO_2 is the partial pressure of arterial oxygen.

For typical PaO_2 values, the second part of the above equation is approximately 0.3 ml O_2/dL based on PaO_2 being approximately 100 mmHg. Furthermore, for typical carboxyhemoglobin and methemoglobin levels, the functional saturation (SpO_2) as measured by a pulse oximeter is given by:

$$SpO_2 = 1.02 \times HbO_2$$

**Martin, Laurence. All You Really Need to Know to Interpret Arterial Blood Gases, Second Edition. New York: Lippincott Williams & Wilkins, 1999.*

SpHb Measurements During Patient Motion

The Rad-67 displays measurements of SpHb during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be reliable during excessive motion. In this case, the measurement value for SpHb displays as dashes (---) and a message (*Low SpHb SIQ*) displays to alert the clinician that the device does not have confidence in the value due to poor signal quality caused by excessive motion or other signal interference.

Chapter 2: Description

This chapter contains the description of the Rad-67 physical features.

General System Description

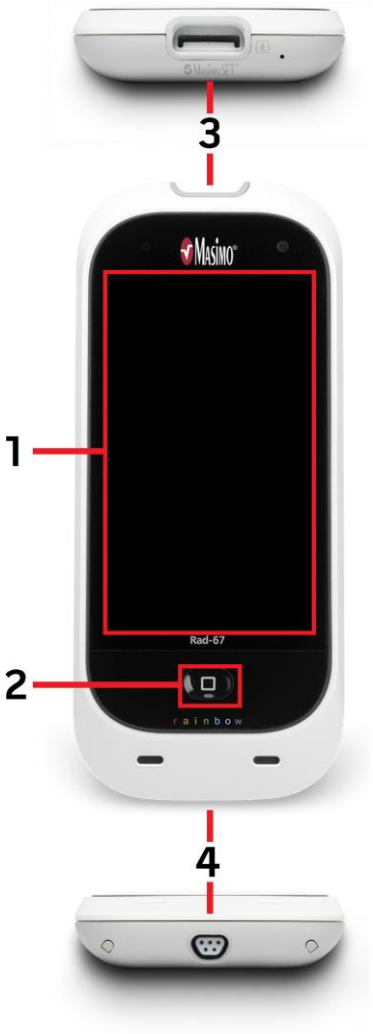
The Rad-67 system includes the following:

- Rad-67 Device
- Rad-67 AC Power Supply
- Patient Cable
- Sensor

For a complete list of compatible sensors and cables, visit http://www.masimo.com.

Features

Front, Top, and Bottom Views



1. Display and Touchscreen

Provides a user interface to view and change settings.

2. Home Button

Provides a multipurpose user interface that allows for navigation to the home screen as well as turning the device on and off.

3. Patient Cable Port

Provides a connection to a patient cable.

4. Masimo Proprietary Port

Provides a connection to:

- AC power supply for battery charging.
- Provides data transfer and upgrade ability using a Masimo proprietary cable.

Note: Always connect the Rad-67 to the mains power for continuous operation and/or battery recharging.

Note: Unplug the Masimo Proprietary cable to disconnect the AC power supply.

Chapter 3: Setting Up

This chapter contains information about setting up Rad-67 before use.

Unpacking and Inspection

To unpack and inspect the Rad-67:

1. Remove the Rad-67 from the shipping carton and examine it for signs of shipping damage.
2. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.
3. If anything is missing or damaged, contact the Masimo Technical Service Department. See ***Return Procedure*** on page 95.

Preparation for Use

Prior to setting up the Rad-67 for spot-check monitoring, perform the following steps:

1. Confirm that you have all system components:
   - Rad-67 Device
   - Rad-67 AC Power Supply
   - Patient Cable
   - Sensor
2. Read the ***Safety Information, Warnings and Cautions*** on page 11.
3. Setup the Rad-67 according to the directions provided in this Operator's Manual.

Guidelines for Setting Up

When setting up Rad-67, follow these guidelines:

1. Charge Rad-67's battery fully before use. See ***Initial Battery Charging*** on page 27.
2. Rad-67 should not be used outside the environmental conditions listed in the specifications section. See ***Environmental*** on page 79.

Initial Battery Charging

Before use, the Rad-67 battery must be charged completely.

To charge Rad-67

1. Plug the Rad-67 AC Power Supply into the device. Make sure it is securely plugged in.
2. Plug the Rad-67 AC Power Supply into an AC power source.
3. Verify that the battery is charging:

- When Rad-67 is ON and charging, the AC Power Indicator lightning bolt icon appears on the screen.

- When Rad-67 is OFF and charging, the Home button will illuminate Orange.

4. When the battery is fully charged and Rad-67 is ON, the AC Power Indicator changes to a plug icon.

Touch the AC Power Indicator icon to view battery charge details. See ***Rad-67 Battery*** on page 52. For additional information, see ***Battery Operation and Maintenance*** on page 94.

Powering the Rad-67 ON and OFF

To turn ON the Rad-67

1. Press and hold the Home Button for more than two (2) seconds, until two (2) audible tones sound.

2. The Home Button will illuminate Green and the Rad-67 will power on.
3. Once the device in ON and a cable is connected, the spot-check operation begins. See ***Chapter 5: Spot-Check*** on page 57 for complete information about performing a spot-check.

Note: When powering on Rad-67 after the battery is completely discharged, the device will prompt to enter current time and date.

To turn OFF the Rad-67

1. Press and hold the Home Button for more than 2 seconds, until two (2) audible tones sound.
2. The Home Button will flash Orange.
3. The Rad-67 will power down and turn off.

Chapter 4: Operation

The information in this chapter assumes that Rad-67 is set up and ready for use. This chapter provides necessary information for proper operation of the device. Do not operate Rad-67 without completely reading and understanding these instructions.

Using the Touchscreen and Home Button

1. Main Screen

To access settings and other screens, touch a value or icon on the Display View. See ***About the Main Screen*** on page 33.

2. Home / Power button

To return to the *Main Screen*, press the Home button.

The Home button is also used to power the device ON and OFF. See ***Powering the Rad-67 ON and OFF*** on page 28.

The Home Button changes color depending on the on the charge status when the device is off.

Using the Touchscreen Interface

Using the gestures described below, the user is able to customize the viewing experience, including displaying the highest priority parameters and measurements. Feature navigation availability is dependent on which medical devices are connected to Rad-67.

Action	Illustration	Example	Description
Touch			Touch and release. Action performed once finger is released.
Touch and Hold			Touch and hold. Action performed once hold duration is reached. A notification is displayed.
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.
Drag and Drop		See ***Understanding Windows*** on page 37.	Touch, hold, drag an object to desired position, and drop it by releasing.

Below is a list of all the different types of controls available on Rad-67 and the various ways to interact with each type of control.

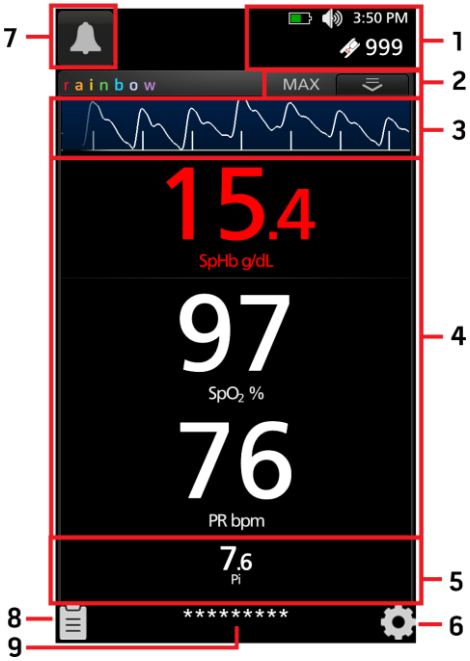
Control	Applicable Actions	Description
Toggle	Touch and slide knob	• Switches between toggle states
	Touch and slide left or right of toggle	• Quickly moves knob left or right
Labeled Toggle	Touch and slide knob	• Switches between toggle states

Control	Applicable Actions	Description
	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)
Icon Menu	Touch tile	• Opens menu specified by tile
	Swipe left or right (anywhere)	• Scrolls icons left or right

Control	Applicable Actions	Description
	Touch bottom indicator icon	• Quickly centers tile corresponding to indicator icon
Window	Touch parameter or measurement	• Opens parameter or measurement menu
	Touch and hold	• Enables parameter and measurement drag and drop
Well	Touch parameter or measurement	• Opens parameter or measurement menu
	Touch and hold	• Enables parameter and measurement drag and drop
Alert Silence icon	Touch	• Silences all audible alerts
Other Status Bar icons	Touch	• Opens relevant menu
Back Arrow	Touch	• Exits menu, abandons any changes

About the Main Screen

The *Main Screen* consists of different areas.



Ref.	Feature	Information
1	Status Bar	See ***About the Status Bar*** on page 34.
2	Action Menu	See ***About the Action Menu*** on page 36.
3	Waveform View	See ***Signal IQ Indicators*** on page 44.
4	Parameter Display	See ***Understanding Windows*** on page 37.
5	Well	See ***Understanding Windows*** on page 37.
6	Main Menu	See ***Accessing Main Menu Options*** on page 38.
7	Alert Acknowledgment	See ***About Alerts*** on page 63.

Ref.	Feature	Information
8	Sessions List	See ***Sessions List*** on page 45.
9	Label	See ***Chapter 5: Spot-Check*** on page 57.

About the Status Bar

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

Ref.	Feature	Description
1	Alert Acknowledgment	Displays status and acknowledge all active alerts. See ***Acknowledging Alerts*** on page 64.
2	Bluetooth	Provides access to the *Bluetooth* screen. If this icon is visible, then Bluetooth connectivity has been enabled. See ***Bluetooth*** on page 51.
3	Wi-Fi	Provides access to the *Wi-Fi* screen. If this icon is visible, then Wi-Fi connectivity has been enabled. The icon itself also indicates the strength of the wireless signal. See ***Wi-Fi*** on page 49.
4	Rad-67 Battery Charge/AC Power Indicator	Displays charging status. Provides access to the *Battery* screen. The example shows that Rad-67 is running on battery power. See ***AC Power Indicator*** on page 35and ***Battery Charge Status Indicator*** on page 35.
5	Sounds	Provides access to the *Sounds* screen to adjust alert and pulse tone volume. This icon does **not** indicate the actual volume level of the alarm and pulse tone. See ***Sounds*** on page 47.

Ref.	Feature	Description
6	Current Time	Displays the current time and provides access to the *Localization* screen, which contains settings related to local time, language, and geography. See ***Localization*** on page 48.
7	Remaining Spot-Checks	Displays the number of spot-checks remaining for the connected sensor.*

* Remaining spot-checks are applicable to the connected sensor. See ***Spot-Check Settings*** on page 44.

AC Power Indicator

Whenever Rad-67 is connected to an AC power source and ON, the AC Power Indicator icon will appear on the display as follows:

Icon	Status
	Battery is currently charging
	Battery is fully charged

Touch the AC Power Indicator icon to view battery charge details. See ***Rad-67 Battery*** on page 52.

Battery Charge Status Indicator

When unplugged from AC power, the Battery Charge Status Indicator icon provides a visual indication of the current battery charge condition.

When the battery charge reaches a low level:

- The Battery Charge Status Indicator icon will change color (Red).
- A "Low Battery" message appears and a medium priority alert tone will sound with a Yellow border on the display.

Connect the Rad-67 to AC power to prevent the device from powering off and to charge the battery. When connected to power, the AC Power Indicator icon will be displayed.

Touch the Battery Charge Status Indicator icon to view battery details. See ***Rad-67 Battery*** on page 52.

Low Power Mode

To conserve the Rad-67 battery, the device automatically dims the display after approximately 10 seconds, and turns the display off after another 10 seconds, when the following criteria are met:

- The device is not currently performing a spot-check measurement on a patient.
  AND
- There is no user interaction with the device display.

Touch the display to return it to its full brightness.

About the Action Menu

To expand the *Action Menu*, select the arrow in the upper right corner of the window.

The Action Menu allows quick access to the following settings directly from the *Main Screen*:

- **Sensitivity** - Selecting this option cycles through the available sensitivity modes: APOD, NORM and MAX. See ***Sensitivity Modes Overview*** on page 36.

Note: After approximately 10 seconds without interaction, the *Action Menu* will retract.

Sensitivity Modes Overview

Three sensitivity levels enable a clinician to tailor the response of Rad-67 to the needs of the particular patient situation. Sensitivity Modes are accessed through the *Action Menu*. See ***About the Action Menu*** on page 36.

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.

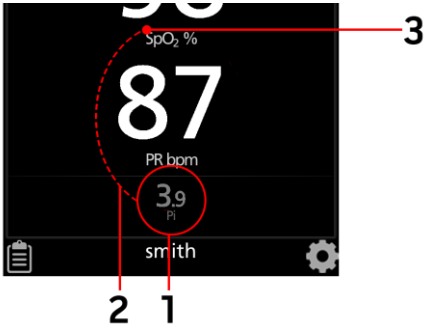
Understanding Windows

The following information describes how to customize the information viewed on the *Main Screen*.

Customizing Windows

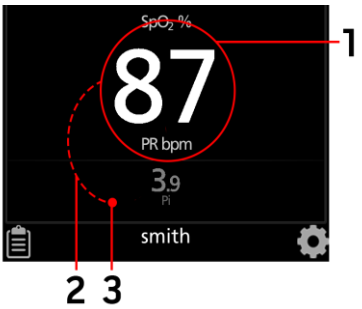
Windows can be customized by expanding and minimizing parameters and measurements. When a parameter is minimized, it is only displayed in the Well with its Numeric Value and Parameter Label. When a parameter is expanded, it will be shown in the Parameter display.

To expand a parameter or measurement



Order	Instruction
Step 1	Touch and hold the Numeric Value until it dims.
Step 2	Drag the Numeric Value over the Parameter Display.
Step 3	Release the Numeric Value.

To minimize a parameter or measurement



Order	Instruction
Step 1	Touch and hold the Numeric Value until it shrinks.
Step 2	Drag the Numeric Value to the Well.
Step 3	Release the Numeric Value.

Accessing Main Menu Options

To access the Main Menu options, press the Main Menu icon at the bottom right corner of the touchscreen:

The Main Menu options are:

Parameter Settings

See ***Parameter Settings*** on page 40.

Additional Settings

See ***Additional Settings*** on page 43.

Spot-Check Settings

See ***Spot-Check Settings*** on page 44.

Sessions

See ***Spot-Check Sessions*** on page 44.

Sounds

See ***Sounds*** on page 47.

Device Settings

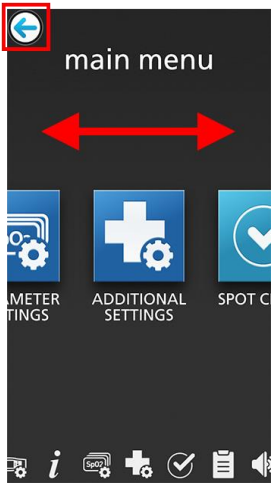
See ***Device Settings*** on page 47.

About

See ***About*** on page 54.

Navigating the Main Menu

Once the Main Menu screen is displayed, users can access additional screens, information and settings. Swipe the screen left or right to pan through the menu icons. Touch the arrow icon to return to the *Main Screen*.



Icons at the bottom edge of the displayed menu screen correspond to the settings. Touch an icon to jump to the setting on the displayed menu screen.

Display Timeout

When viewing any of the menu screens, and no user interaction occurs within one (1) minute, the display times out and returns to the *Main Screen*.

Navigating Through Menus

When configuring settings, all changes must be confirmed by selecting *OK*. To cancel the changes, select *Cancel*.

Any screen requiring selection of option(s) will time out after one (1) minute of inactivity and return to the *Display View*.

To navigate to the previous screen, press the arrow in the top left corner of the touchscreen.

To return to the *Main Screen*, press the Home Button at any time.

Parameter Settings

The following is an example of the Rad-67 *Parameter Settings* screen.

To access any of the available parameter setting screens:

1. From the *Parameter Settings* screen, to access the desired parameter, swipe the on-screen icons left or right.
2. Touch the icon of the desired parameter.

- See ***SpO2 Settings*** on page 41.
- See ***PR Settings*** on page 42.
- See ***SpHb Settings*** on page 42.
- See ***Pi Settings*** on page 42.

SpO2 Settings

Allows access to any of the following options:

Additional Settings for SpO2 on page 41

About Parameter Information on page 43

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 41.	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-67 is set to FastSat *On*, the averaging algorithm evaluates all saturation values, providing an averaged saturation value that is a better representation of the patient's current oxygenation status. With FastSat set to On, the averaging time is dependent on the input signal.

PR Settings

From the *PR Settings* screen, the following option is available:

About Parameter Information on page 43

SpHb Settings

From the *SpHb Settings* screen, the following options are available:

Additional Settings for SpHb on page 42

About Parameter Information on page 43

Additional Settings for SpHb

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.	Medium	Short, Medium, or Long
Arterial/Venous Mode	Provides an arterial or venous value that displays on the main screen.	Arterial	Arterial or Venous
Unit of Measure	Displays total hemoglobin (SpHb) as g/dL (grams per deciliter), g/L (grams per liter), or mmol/L (millimoles per liter). Unit of Measure cannot be changed during spot-check.	g/dL	mmol/L, g/dL, or g/L
Precision	Allows the user to set the precision of the displayed SpHb value. **Note:** When unit is g/L, Precision is always 1 (whole numbers)	0.1	0.1, 0.5, or 1.0

Pi Settings

From the *Pi Settings* screen, the following options are available:

Additional Settings for Pi on page 43

About Parameter Information on page 43

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

About Parameter Information

Additional information about each parameter is available.

To access additional information about parameters:

1. From the *Parameter Settings* screen, touch the **About** icon. The following is an example for SpO_2.

2. An *About* screen appears for the selected parameter and displays information about the parameter.

Additional Settings

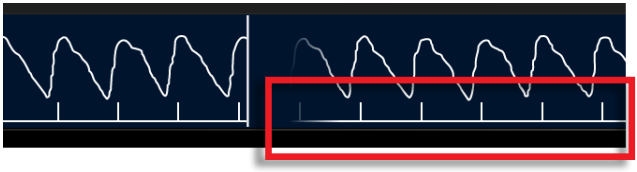
Use the *Additional Settings* screen to configure the following:

Options	Description	Factory Default Settings	User Configurable Settings
Sensitivity Mode	Change Sensitivity Mode. See ***Sensitivity Modes Overview*** on page 36.	MAX	MAX, APOD, NORM

Options	Description	Factory Default Settings	User Configurable Settings
SmartTone	Enable or disable the SmartTone. See ***Sounds*** on page 47.	Off	On, Off

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.



Spot-Check Settings

Use the *Spot-Check Settings* screen to configure the following:

Option	Description	Factory Default Settings	User Configurable Settings
Require Label	Require or not require a label when performing a spot-check	On	Off or On

Spot-Check Sessions

Sessions allows the ability to review or clear previous spot-check sessions.

Sessions List

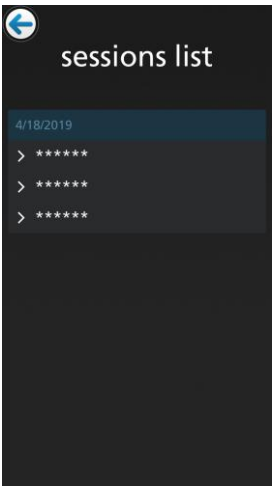
Previous spot-check sessions are accessed two ways:

- Through the *Sessions List* menu  .
- By touching the *Sessions List* icon  located at the bottom of the Rad-67 screen.

Note: When SpHb is not selected to be included in the spot-check, the SpHb value displays "0". See ***Spot-Check Settings*** on page 44.

Spot-check sessions are organized by date. Under each date are the spot-check labels entered before the spot-check.

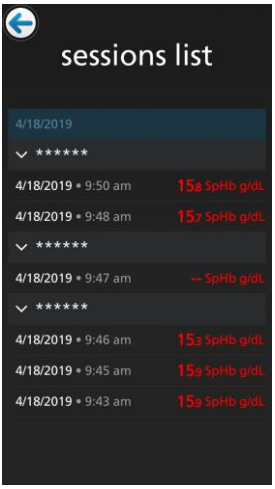
Spots-checks that do not require a label (or are performed using the skip feature) are listed by date and time of the spot-check. See ***Spot-Check Settings*** on page 44 to change spot-check label preferences.



Touch the desired spot-check label to view the date and time of the spot-check session as well as the SpHb reading.

Note: If multiple spot-check sessions are performed using the same label, all sessions are listed under that label.

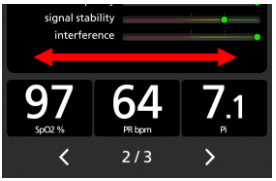
Touch the spot-check date and time to view the results screen for the spot-check session. See ***Spot-Check Results*** on page 61.



The results screen for the spot-check session displays.

To close the results screen, touch the back arrow.

When multiple sessions are available for the same patient, swipe the screen left or right to view each session result.



Touching any of the SpHb criteria gauges displays an informational window for that specific item.

The window can be closed by touching the **OK** button or closes automatically after one minute.

Signal Stability is shown in the example.

Sessions Settings

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

Option	Description	Factory Default Settings	User Configurable Settings
Clear Sessions	Clears all previous spot-check sessions from Rad-67.	NA	Press **Clear**

Sounds

Use the *Sounds* screen to control the volume of sounds on Rad-67. Users can also access the *Sounds* screen by pressing the *Sounds* icon on the Status Bar. See ***About the Status Bar*** on page 34.

Option	Description	Factory Default Setting	Configurable Settings
Alert Volume	Sets the alert volume level.	Highest volume	Slide towards the left to decrease volume and to silence.
Pulse Tone Volume	Sets the pulse tone volume level.	Highest volume	Slide towards the left to decrease volume and to silence.
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-67. The Device Settings options are:

Localization

See ***Localization*** on page 48.

Wi-Fi

See ***Wi-Fi*** on page 49.

Rad-67 Battery

See ***Rad-67 Battery*** on page 52.

Brightness

See ***Brightness*** on page 52.

Access Control

See ***Access Control*** on page 53.

Localization

Use the *Localization* screen to view the current date and time and configure settings related to local time, language and geography. The user can also access the *Localization* screen by pressing the current time on the Status Bar. See ***About the Status Bar*** on page 34.

Option	Description	Factory Default Settings	User Configurable Settings
Language	Select the language display for Rad-67.	English	Choose from available languages.
Date Format	Set the display format for current date.	mm/dd/yy	mm/dd/yy or dd/mm/yy
Time Format	Set the display format for current time.	12 hour	12 or 24 hour
Line Frequency	Set to match regional power line frequency.	60 Hz	50 Hz or 60 Hz
Date	Set the current date.	N/A	month, date, and year
Time	Set the current time.	N/A	hour and minutes AM or PM

Wi-Fi

The Wi-Fi radio allows for networked communication of Rad-67 data and alerts over an IEEE 802.11 a/b/g wireless network.

Use the *Wi-Fi* screen to enable or disable Wi-Fi connectivity or connect to a wireless network. When Rad-67 is connected to a Wi-Fi network, the Wi-Fi icon on the Status Bar indicates the strength of the connection. The user can also access the Wi-Fi screen by pressing the Wi-Fi icon on the Status Bar. See ***About the Status Bar*** on page 34.

Option	Description	Factory Default Setting	User Configurable Settings
Wi-Fi	Enables or disables Wi-Fi connectivity.	Off	On or Off
Selected Network	Displays the currently connected wireless network.	NA	See ***Selected Network*** on page 49.
Status	Displays currently connected wireless network status.	NA	See ***Status*** on page 50.
Change Network	Allows device to be connected to a different wireless network.	NA	See ***Change Network*** on page 50.

Selected Network

The *Selected Network* field displays the SSID of the currently connected wireless network.

Touching the info icon  displays information about the current network.

Forget Network

The Selected network info screen also allows the user to *Forget* the network if the currently connected wireless network is no longer needed. Scroll to the bottom of the screen and press/select the **Forget** button.

CAUTION: There are no prompts to confirm the *Forget* network request. Once selected, the network is disconnected and removed from Rad-67.

Status

The *Status* field displays the connection status of the wireless network. Touching the edit icon  allows the currently connected wireless network settings to be modified. A different network can also be connected to directly if desired (when the SSID, network security type and password are known) by entering the information directly. This may be helpful if the desired network is hidden and not shown during a network scan.

Note: When a different network is connected, the current network settings are not saved.

Option*	Description	Factory Default Setting	User Configurable Settings
Network Name	SSID for the wireless network.	NA	Alphanumeric
Security	Allows the wireless network security to be set.	WPA2	WPA, WPA2, WPA Enterprise, or WPA2 Enterprise
Password	Password for the wireless network.	NA	Alphanumeric
Save	Saves any changes to the fields.	NA	Press/select to save.

* Not all options listed may be displayed on the device. Available options depend on the security settings of the wireless network.

Change Network

The *Change Network* screen allows manual setup of a network (similar to Status) or ability to scan for a network that is not hidden.

Note: When a different network is connected, the currently connected wireless network settings are not saved.

Manual Setup

Press/select the *Manual Setup* option to display the *Manual Setup* screen.

Option	Description	Factory Default Setting	User Configurable Settings
Network Name	SSID for the wireless network.	NA	Alphanumeric

Option	Description	Factory Default Setting	User Configurable Settings
Security	Allows the network security to be set.	WPA2	WPA, WPA2, WPA Enterprise, or WPA2 Enterprise
Username*	Username for the network.	NA	Alphanumeric
Password**	Password for the network.	NA	Alphanumeric
Save	Saves any changes to the fields.	NA	Press/select to save.

* Displays when WPA Enterprise or WPA2 Enterprise is selected for security.

** Displays when any of the security options are selected.

Network Scan

To scan for and connect to an available wireless network, perform the following:

1. Press/select the search icon  next to *Manual Setup* to display the *Select a Network* screen. A network search is automatically performed and a list of available wireless networks displays.
2. Select a wireless network from the list of available networks.
3. Depending on the security settings of the network, enter the username and/or the password for the desired wireless network.

   Note: The security settings are automatically configured.
4. Press/select the Save button to save the settings and connect to the wireless network.

Bluetooth

Use the *Bluetooth* screen to enable or disable Bluetooth connectivity. When Bluetooth connectivity is enabled, the Bluetooth icon will appear in the Status Bar. The user can also access the Bluetooth screen by pressing the *Bluetooth* icon on the Status Bar. See ***About the Status Bar*** on page 34.

Option	Description	Factory Default Setting	User Configurable Settings
Bluetooth	Enables or disables Bluetooth connectivity.	Off	On or Off
Additional fields in the *Bluetooth* screen display read-only settings about the Bluetooth connection that cannot be configured by the user.			

Your Masimo sales representative can provide necessary information regarding an initial Bluetooth connection.

Rad-67 Battery

Use the Battery screen to view the specific percentage of charge remaining in Rad-67's battery. The user can also access the Battery screen by pressing the Battery icon on the Status Bar. See ***About the Status Bar*** on page 34.

Option	Description
State of Charge	Provides a read-only display of battery level remaining.
Battery Diagnostics	Allows trained personnel to access battery diagnostic information (password protected).

Brightness

Use the *Brightness* screen to adjust the brightness of Rad-67's display.

Option	Description	Factory Default Settings	User Configurable Settings
Auto Brightness	Allows automatic adjustment of display brightness based on the ambient light level.	Off	On or Off

Option	Description	Factory Default Settings	User Configurable Settings
Brightness	Adjust the brightness level of the display manually.	4	1 (dimmest), 2, 3, 4 (brightest)

Access Control

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

To enter Access Control

1. Press the  key.

2. When the screen displays, enter the following: **6 2 7 4**
   Asterisks (****) will be displayed.
   To undo an entry, press *Backspace*.
3. Press *Enter* to access the password-protected screen.

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

Option	Description	Factory Default Setting	User Configurable Settings
USB Port Baudrate	Sets the USB port communication speed.	921600	9600, 19200, 38400, 57600, 115200, 230400, or 921600
Factory Defaults	Options are restored to factory values.	N/A	Press **Restore**.

About

For information about individual parameters, see ***About Parameter Information*** on page 43.

Use the *About* screen to view the serial number as well as Rad-67 software and hardware version information. These details may be helpful during troubleshooting.

Option *	Description
Serial Number	Displays the serial number for the device.
MCU	Displays the version number of the device board software.
Processor	Displays the version number of the system level software.
MX Board	Displays the version number of the technology level software.

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

Screenshot Capture

The user is able to take screenshots of Rad-67 displays and download them as .png files onto a USB drive. To download screenshots, a Rad-67 Data Transfer Download Cable is required.

To ensure quick downloads, the number of screenshots that can be stored in Rad-67 is limited to 20; once the limit is reached, every new screenshot taken will replace the oldest screenshot taken.

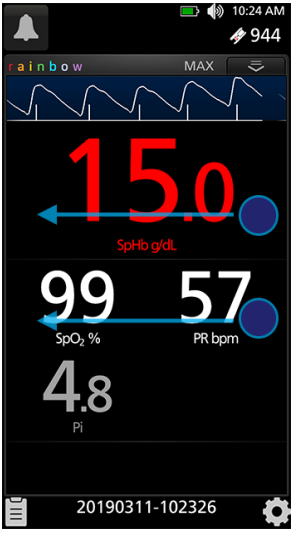
Note: Download the images onto a USB drive to avoid loss of the screenshots.

Note: The USB drive must be formatted to FAT or FAT32 system file to enable the download of the screenshots. There must also be a folder titled "screen_shot" at the root level on the USB drive as Rad-67 looks for this folder to download the screenshots to.

Capturing Screenshots

To take a screenshot, swipe across the Rad-67 screen from right to left using 2 or more fingers simultaneously.

- A confirmation flash will appear on the entire screen and a status message will be displayed briefly at the top of the Rad-67 screen.
- The status message indicates the filename of the screenshot taken.
- Patient ID, age and gender are not captured in the screenshot feature and are displayed as asterisk *****.



Downloading Screenshots

To download the screenshots:

1. Remove any sensors connected to the patient to stop monitoring, and acknowledge any alarms triggered on Rad-67.
2. Connect the Rad-67 Data Transfer Download Cable to the Masimo Proprietary port of Rad-67. See ***Front, Top, and Bottom Views*** on page 26.

   Note: Before connecting the USB drive in the next step, there must be a folder titled "screen_shot" in the USB drive with a FAT or FAT32 system file to enable the download of the screenshots.
3. Plug the USB drive into the USB end of the cable, and the screenshots will automatically download. A status message displays briefly at the top of the Rad-67 screen to indicate the start of the download.
4. A confirmation status message displays briefly at the top of the Rad-67 screen when the file transfer is complete.
5. Unplug the USB drive from the cable and the Data Transfer Download Cable from the Rad-67.

To import the screenshots from the USB drive onto a computer, plug the USB drive into the computers USB port, then open the folder titled "screen_shot" (from the USB drive) on the computer to access the .png files.

Chapter 5: Spot-Check

The Rad-67 begins the spot-check procedure under the following conditions:

- The Rad-67 is powered ON.
- A previous spot-check is completed and reviewed.

If at any time during a spot-check a sensor and cable are not connected, a message displays to connect a cable to the Rad-67.

If a sensor is not connected to the cable or non-spot-check sensor (and the cable is connected to the device), a message displays to connect a sensor to the cable.

Performing a Spot-Check

Once a spot-check SpHb sensor is connected, the screen instructs the user to enter the following patient information:

- Label
- Age
- Gender

Note: This step can be skipped by selecting skip in the lower left corner of the screen. When ***skip*** is selected, results are tagged by date and time. See ***Sessions List*** on page 45.

When *Label* is selected, a keyboard appears to enter the desired identification.

Note: If *Require Label* is off in *Spot-Check Settings*, the label field does not display. See ***Spot-Check Settings*** on page 44. An age and gender selection must still be made to continue with the spot-check session (unless skip is selected).

Note: If label, age and gender selections are visible (and skip is not selected), all are required to continue with the spot-check session. If gender is not visible, label and age are required to continue with the spot-check session.

After entering a label and/or selecting an age and gender, touch *Start* to begin the spot-check session.

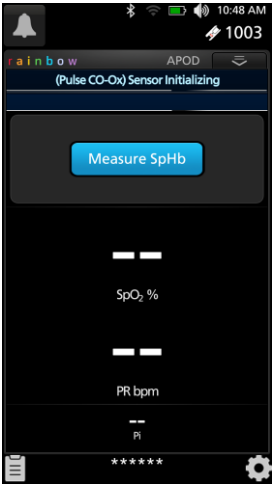
Place the sensor on the patient's digit. Refer to the Directions for Use for the specific sensor for proper site selection and application.

After the sensor is placed, the Rad-67 looks for a pulse. Once a pulse is detected, the spot-check begins.

Note: If the sensor is already on a digit and a pulse is detected, this step is skipped and the spot-check begins.

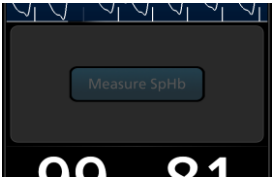
The spot-check requires user input if SpHb is to be included and measured. Select the **Measure SpHb** button to include SpHb in the spot-check.

After the sensor initializes, a pleth is displayed and spot-check measurement begins to display available values.



Note: In the following situations, the ability to include SpHb is not available and the **Measure SpHb** button is grayed out.

- When ***skip*** is selected instead of entering a patient label (when required), age and gender.
- When the entered patient age is 17 or less. SpHb measurement can only be performed on patients 18 years of age or older.



If during the spot-check, low signal stability is detected, Rad-67 instructs the user to keep the measurement site stable.

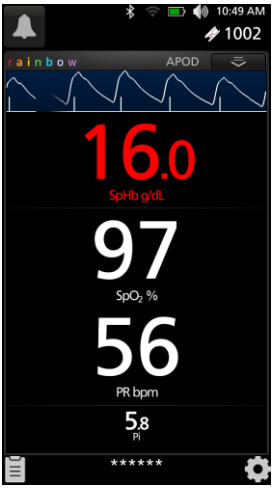
If a low perfusion condition occurs, Rad-67 instructs the user to select a new location to place the sensor.

Complete the Spot-Check

After a spot-check is performed, the values display.

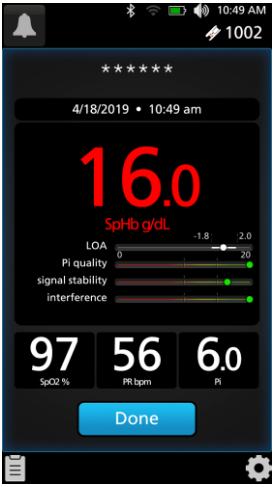
Note: The spot-check measurement displays for five (5) minutes or until the sensor is removed, whichever occurs first.

To complete the spot-check session, remove the sensor from the patient and the spot-check results screen displays. See ***Spot-Check Results*** on page 61.

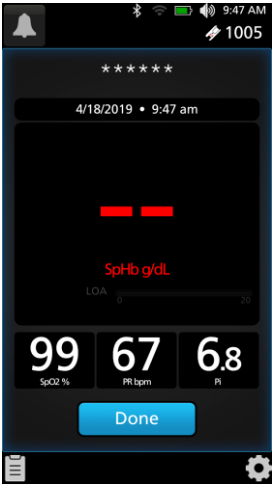


Spot-Check Results

When the sensor is removed from the patient, or after the five (5) minute measurement period (whichever occurs first), the screen displays spot-check measurement information with SpHb as the most prominent value.



When SpHb is not included in the spot-check, the SpHb value displays as dashes "--".



Touch the **Done** button to complete the spot-check session.

Spot-check sessions are stored on the device for review at a later time. See ***Sessions List*** on page 45.

Limits of Agreement (LoA) Gauge

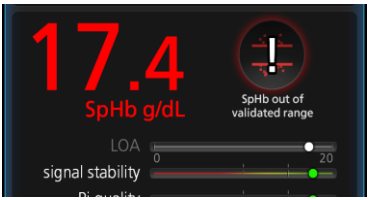
Rad-67 provides an LoA gauge with white bars to indicate the upper and lower 95% limits of agreement for the displayed SpHb measurement. In the gauge, the dot indicates where the SpHb measurement falls across the display range. LoA is an interval that provides an estimate of accuracy. 95% of the time, the difference between the SpHb value and a gold-standard reference analyzer lie within this range.

In the example shown, SpHb displayed is within the accuracy range and the LoA gauge is displayed.

This example shows when the SpHb measurement is outside of the accuracy range (see ***SpHb Accuracy Data*** on page 77).

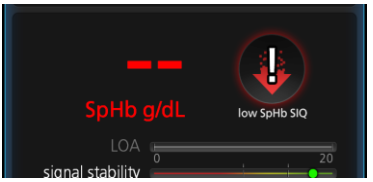
The *SpHb out of validated range* message displays. The LoA gauge is disabled.

See ***Troubleshooting Measurements*** on page 67.



If low SIQ is encountered while attempting to read SpHb, SpHb is displayed as dashes "--", the LoA gauge is disabled and *low SpHb SIQ* displays.

See ***Troubleshooting Measurements*** on page 67.



Chapter 6: Alerts and Messages

The following chapter contains information about alerts and messages.

For more information, see ***Chapter 7: Troubleshooting*** on page 67.

About Alerts

The *Alert Acknowledgment* icon is an indicator as well as a functional button. It always indicates the presence of alerts, and it can be used to acknowledge alerts.

Icon Appearance	Description	Visual Alerts
	There are currently no active alerts, and no alerts have been acknowledged. **Note:** If an alert has been acknowledged, this icon also appears.	No
	There is currently at least one active alert that has **not** been acknowledged.	Yes

Alert Interface

Alert Source/Example	Explanation
	The example shown here is a "Low Battery" alert. Note that the border of the entire Rad-67 display is illuminated, and the explanation of the alert is shown in the Status Bar (Low Battery).

Acknowledging Alerts

Alerts are conveyed visibly.

To acknowledge alerts:

1. Touch the *Alert Acknowledgment* icon  .
2. Visual alerts are suspended.
3. Explanation of the alert remains in the Status Bar.

Messages

The following section lists common Rad-67 messages, potential causes, and next steps.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Replace Cable *or* *Please replace cable*	• Incompatible cable • Unrecognized cable • Defective cable • Cable life expired	• Replace the patient cable.
(Pulse CO-Ox) Cable Near Expiration	• Cable life near expiration	• Replace the patient cable.
(Pulse CO-Ox) Replace Sensor *or* *Please replace sensor*	• Incompatible sensor • Unrecognized sensor • Defective sensor • Sensor life expired	• Replace the sensor.
(Pulse CO-Ox) Sensor Initializing	• Device is initializing the sensor.	• Allow time for parameter reading to stabilize.
(Pulse CO-Ox) Pulse Search	• Device is searching for pulse.	• Allow time for parameter reading to stabilize.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Interference Detected	• High intensity light (pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight) or other monitor displays. • Incorrect monitor line frequency setting (Hz).	• Place a Masimo Optical Light Shield over the sensor. • Adjust the Line Frequency to the correct Hz setting. See ***Device Settings*** on page 47.
Low Perfusion	• Signal strength is too weak.	• Select different sensor site that is better perfused. See ***Troubleshooting Measurements*** on page 67.
Low Signal Stability	• Motion during SpHb measurement.	• Keep measurement site stable. See ***Troubleshooting Measurements*** on page 67.
Demo Mode	• Device is in demo mode setting.	• Disable demo mode prior to patient spot-check measurements.
SpO_2 Only Mode	• Occurs during an unsuccessful SpHb sensor initialization/pulse search routine or during measurement.	• See the Directions for Use provided with your sensor. • Use a Masimo light shield to cover the sensor and adjust the sensor. • Ensure proper sensor application. • Replace sensor.
Low SpHb SIQ	• Indicates low signal quality of SpHb measurement. • The SpHb reading is outside of the accuracy range.	• Ensure proper sensor application. • Replace the sensor. • See ***Chapter 8: Specifications*** on page 75.

Message	Potential Causes	Next Steps
SpHb out of validated range	• Measured SpHb value is outside of the validated accuracy range.	• Verify sensor type and size and re-apply sensor. See Directions for Use for sensor. • Check and see if blood flow to the 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. • Submit blood sample for laboratory CO-Oximetry test for comparison. • Check patient conditions indicated to affect SpHb accuracy.
"- -" (Dashes shown as parameter value)	• Unable to provide a parameter value.	• Allow time for parameter reading to stabilize. • Check patient's vital condition. • Ensure proper sensor application. • Replace the sensor.
Low Battery	• Battery charge is low.	• Connect device to the AC power supply to charge the battery.
Speaker Failure	• Device requires service.	• Contact Masimo Tech Support. See ***Chapter 9: Service and Maintenance*** on page 93.

Chapter 7: Troubleshooting

Troubleshooting Measurements

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

For additional information, see ***Safety Information, Warnings and Cautions*** on page 11.

Symptom	Potential Causes	Next Steps
Low SIQ message displayed (Low signal quality)	• Sensor is damaged or not functioning. • Improper sensor type or application. • Excessive motion. • Low perfusion.	• 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. • Set to Maximum Sensitivity. See ***Sensitivity Modes Overview*** on page 36.

Symptom	Potential Causes	Next Steps
Difficulty obtaining a reading	• Inappropriate sensor or sensor size. • Improper sensor type or application. • Low perfusion. • Excessive motion artifact. • Excessive ambient or strobing light. • 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 measurement site. • Verify and set 50 or 60Hz menu setting. See ***Localization*** on page 48.
Parameter readings displayed as dashes "- -"	• Parameter may not have stabilized. • Improper sensor type or application. • Low SIQ Value	• 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 proper sensor and sensor size for the patient.

Symptom	Potential Causes	Next Steps
SpHb Measurement Ability Unavailable	• Entered patient age is 17 or younger. • Skip was selected instead of entering a patient label (when required), age and gender. • Sensor does not have ability to measure SpHb.	• SpHb is not measured on patients 17 years old and younger. • Ensure a patient label (when required), age and gender are entered when performing a spot-check. • Ensure proper sensor application. • Replace the sensor.
Spot Check Results do not display SpHb (SpHb displays as "--")	• **Measure SpHb** button was not selected during spot-check. • Entered patient age is 17 or younger. • Low SIQ Value	• Ensure **Measure SpHb** button is selected during spot-check. • SpHb is not measured on patients 17 years old and younger. • 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.
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 measurement site. • Set to MAX Sensitivity. See ***Sensitivity Modes Overview*** on page 36.

Symptom	Potential Causes	Next Steps
SpHb reading is dim and "Low SpHb SIQ" message displays	• Improper sensor application. • Excessive motion. • Low perfusion.	• Verify and re-apply sensor. See Directions for Use for sensor. • Check and see if blood flow to the 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. • Submit blood sample for laboratory CO-Oximetry test for comparison. • Check patient conditions indicated to affect SpHb accuracy.
Unexpected Parameter Readings	• Low SIQ or Pi values. • Inappropriate sensor size or sensor measurement location. • Excessive motion.	• Reposition sensor to site with strong SIQ and Pi. Average readings taken from three different sites to improve accuracy. • Submit blood sample for laboratory CO-Oximetry test for comparison. • Verify proper sensor for patient size. • Verify proper sensor site. See *Directions for Use* for sensor. • Minimize or eliminate motion at the monitoring site.
Unable to export SpHb data	• Poor connection to network. • Incorrect network configuration. • Cable is not fully seated in device. • Baud rate does not match between device and data download application. See settings.	• See ***Troubleshooting Rad-67*** on page 71. • Verify proper network configuration. • Verify proper connection between cable and device. • Verify baud rate settings. See ***Access Control*** on page 53.

Troubleshooting Rad-67

The following section lists possible Rad-67 symptoms, potential causes, and next steps.

For more information, see ***Chapter 6: Alerts and Messages*** on page 63.

Symptom	Potential Causes	Next Steps
Device does not turn on	• Depleted Battery. • Internal failure.	• Check AC power supply. • Contact Masimo Service. See ***Contacting Masimo*** on page 95.
System failure technical alarm active	• Internal failure.	• Turn Rad-67 Off and On. See ***Powering the Rad-67 ON and OFF*** on page 28. • Contact Masimo service. See ***Contacting Masimo*** on page 95.
Speaker does not work	• Device audible settings may be incorrect. • Internal failure.	• Turn Rad-67 Off and On. See ***Powering the Rad-67 ON and OFF*** on page 28. • Check that *Alerts* and *Sounds* have not been silenced. • Check that *Alerts* and *Sounds* volumes settings. • Check that the device speaker is not being muffled. • Contact Masimo service. See ***Contacting Masimo*** on page 95.
Device screen is dim	• The device is in low power mode to conserve power. • The brightness display is not correct.	• Touch the screen to return the display to full brightness. • Adjust the brightness setting. See ***Brightness*** on page 52.

Symptom	Potential Causes	Next Steps
Device screen is blank	• The device is in low power mode to conserve power. • The device is Off. • The brightness display is not correct. • Battery may be depleted. • Internal failure.	• Touch the screen to turn the display On. • Turn Rad-67 Off and On. See ***Powering the Rad-67 ON and OFF*** on page 28. • Adjust the brightness setting. See ***Brightness*** on page 52. • Check AC power connection and recharge. • Contact Masimo service. See ***Contacting Masimo*** on page 95.
Touchscreen/Buttons do not respond when pressed	• EMI (Electro Magnetic Interference). • Internal failure.	• Turn Rad-67 Off and On. See ***Powering the Rad-67 ON and OFF*** on page 28. • Relocate the device from other devices that may cause electromagnetic interference. • Contact Masimo service. See ***Contacting Masimo*** on page 95.
Battery run time significantly reduced	• Battery not fully charged. • Battery damaged. • Battery capacity effected.	• Check battery charge level indicator. • Check battery is fully charged. • Contact Masimo service. See ***Contacting Masimo*** on page 95.
Device does not detect that patient cable is connected	• Cable connector not properly connected to the device. • Damaged connector. • Damaged cable. • Cable expired. • Internal failure.	• Remove and reconnect cable. • Ensure the connector is fully connected to the device. • Replace cable. • Contact Masimo service. See ***Contacting Masimo*** on page 95.

Symptom	Potential Causes	Next Steps
Device does not detect that the sensor is connected	• Sensor not properly connected to device. • Improper placement of sensor. • Damaged sensor. • Internal failure.	• Remove and reconnect sensor. • Ensure the connector is fully connected to the device. • Reapply sensor to the patient. Refer to sensor *Directions For Use*. • Replace sensor. • Turn Rad-67 Off and On. See ***Powering the Rad-67 ON and OFF*** on page 28. • Contact Masimo service. See ***Contacting Masimo*** on page 95.
Device does not communicate to other external devices through wireless connection	• External device is not compatible. • Wi-Fi is not turned on and/or not correctly configured. • Location does not have wireless availability. • Connected network is not available. • Internal failure.	• Check external device compatibility. • Check that the wireless feature is on and correctly configured. See ***Wi-Fi*** on page 49. • Check wireless availability for location. • Check network settings and availability. • Contact Masimo service. See ***Contacting Masimo*** on page 95.

Chapter 8: Specifications

The following chapter contains specifications for the Rad-67.

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
SpHb (Hemoglobin)*	0.0 g/dL to 25.0 g/dL 0 g/L to 250 g/L 0.0 mmol/L to 15.5 mmol/L

* See ***Chapter 7: Troubleshooting*** on page 67 for assistance when measurement ranges are outside of the accuracy range.

Accuracy (ARMS*)

Oxygen Saturation (SpO_2)		
No Motion [1] (SpO_2 from 70% to 100%)	Adults, Pediatrics, Infants	2%
Motion [2] (SpO_2 from 70% to 100%)	Adults, Pediatrics, Infants	3%
Low perfusion [3] (SpO_2 from 70% to 100%)	Adults, Pediatrics, Infants	2%
Pulse Rate (PR)		
Range	25 to 240 bpm	
No motion	Adults, Pediatrics, Infants	3 bpm
Motion [4]	Adults, Pediatrics, Infants	5 bpm
Low Perfusion	Adults, Pediatrics, Infants	3 bpm

Total Hemoglobin (SpHb) [5]	
Range of 8 g/dL to 17 g/dL	Adults**
Upper 95% LoA	2.07
Lower 95% LoA	-1.82

* 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.

** For SpHb measurements, an Adult is defined as a person 18 years of age or older.

Note: A functional tester cannot be used to assess the accuracy of Rad-67.

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 rainbow 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 (rainbow DCI-mini) Sensors	
SpO_2 Accuracy Range (%)	A_{RMS} (%)
70-80	1.9
80-90	1.7
90-100	1.2
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.

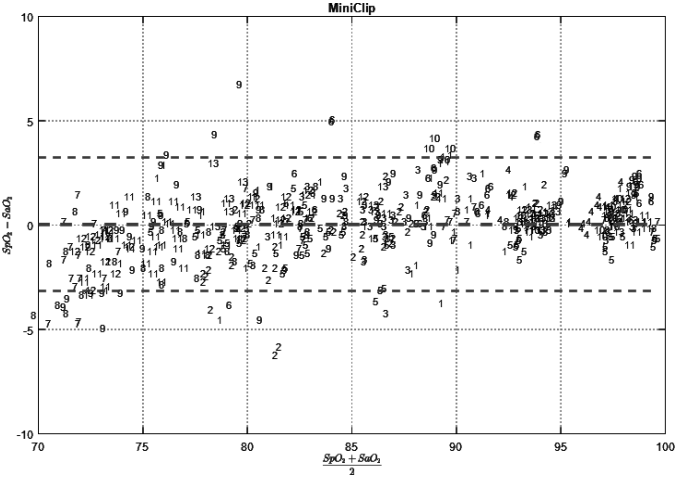


Figure 1: Reusable (rainbow DCI-mini) Sensors (ARMS 70-100%)

SpHb Accuracy Data

The data in this section describes the accuracy of SpHb measurements with Rad-67. Accuracy testing for SpHb was performed on adult subjects.

The following table provides the 95% Limits of Agreement (LOA) based upon the clinical validation of the SpHb performance. The 95% LOA was determined by the comparison of SpHb measurements against the tHb values determined by a HiCN reference method over the specification range of 8-17 g/dL. The lower 95% limit of agreement is the mean difference minus 1.96 standard deviation and the upper 95% limit of agreement is the mean difference plus 1.96 standard deviation.

Group	Bias	Precision	Samples	Upper LOA*	Lower LOA*
Overall	0.1	1.0	660	2.07	-1.82

** See Bland and Altman. Agreement between methods of measurement with multiple observations per individual. Journal of Biopharmaceutical Statistics (2007) vol. 17 pp. 571-582.*

The below Bland-Altman plot represents the correlation of the (SpHb - HiCN tHb) versus (SpHb + HiCN tHb)/2 with an upper 95% and lower 95% limits of agreement.

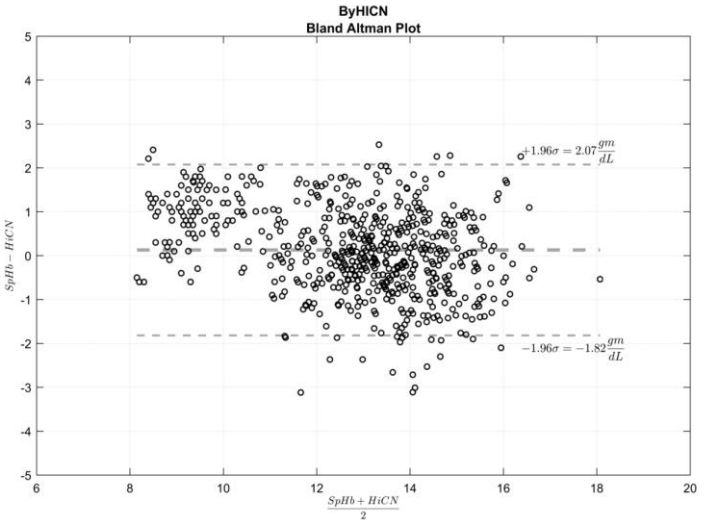


Figure 2: Bland-Altman plot of SpHb vs. HiCN tHb

Resolution

Parameter	Resolution
SpO_2	1%
PR	1 BPM
SpHb	0.1 g/dL 0.1 mmol/L 1 g/L

Electrical

AC Power Requirements	
AC Power (Power Supply) requirements	100-240Vac, 50/60Hz, 0.5A
Power consumption	< 15W

Battery	
Type	Lithium ion
Capacity	6 hours [6]
Charging Time	6 hours [7]

Environmental

Environmental Conditions	
Operating Temperature	0°C to 35°C (32°F to 95°F)
Storage/Transport Temperature	-20°C to 60°C [8] (-4°F to 140°F)
Operating Humidity	10% to 95%, non-condensing
Storage/Transport Humidity	10% to 95%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1,060 mbar (540 hPa to 1060 hPa)

Physical Characteristics

Physical Characteristics	
Dimensions	19.4 cm x 8.2 cm x 2.4 cm (7.6" x 3.2" x 0.9")

Physical Characteristics	
Weight	0.37 kg. (0.81 lbs.)

Display Indicators

Item	Description
Display Update Rate	1 Second
Type	Backlit Active Matrix TFT LCD
Pixels	720 dots x 1280 dots

Compliance

EMC Compliance
IEC 60601-1-2:2007, Class B

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

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

Equipment Classification per IEC 60601-1	
Degree of Protection against Electrical Shock	Defibrillation proof BF-Applied Part
Protection against harm from solid and liquid ingress	IP24 (Protection from ingress of particulates > than 12 mm and water spray from any direction.)
Mode of Operation	Continuous operation

Output Interface

Masimo Proprietary Port

Wireless Specifications

Communication (Wi-Fi)	
Type	WLAN Radio: IEEE 802.11 a/b/g
Channels	802.11a: • USA: 36, 40, 44, 48, 52, 56, 60, 64, 100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140, 149, 153, 157, 161, and 165 802.11b: • USA, Canada and Taiwan: 1 to 11 • Most European Countries: 1 to 13 • Japan: 1 to 14 802.11g: • USA and Canada: 1 to 11 • Most European Countries: 1 to 13
Max Peak Output Power	WLAN 17 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory

Communication (Wi-Fi)	
Modulation Types	OFDM, BPSK, CCK
Modulation Signals	Analog and Digital
Available Data Rates	802.11a - 6, 9, 12, 18, 24, 36, 48, 54 Mbps. 802.11b - 1, 2, 5.5, 11 Mbps. 802.11g - 6, 9, 12, 18, 24, 36, 48, 54 Mbps.

Security and Authentication	
Encryption	64/128-bit WEP, Dynamic WEP, WPA-TKIP, WPA2-AES
Authentication	Open System, Shared Key, Pre-Shared Key (PSK), 802.1X: LEAP, PEAP< TTLS, TLS, EAP-FAST

Radio Compliance	
USA	FCC Title 47, Part 15 FCC ID: VFK MWM1 Model - RAD-67
Canada	IC:7362A-MWM1 IC Model: MWM1 RSS-210
Europe	EN 301 489-1 EN 301 489-17 R & TTE Directive
Japan	TELEC

Guidance and Manufacturer's Declaration-Electromagnetic Emissions

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

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+6 kV contact	+6 kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	+8 kV air	+8 kV air	
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power lines	+/- 2 kV for power lines	Mains power quality should be that of a typical commercial or hospital environment.
	+/- 1 kV for input/ output lines	+/- 1 kV for input/ output lines	
Surge IEC 61000-4-5	+/-1 kV line(s) to line(s)	+/-1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
	+/- 2 kV line(s) to earth	+/- 2 kV line(s) to earth	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	100% dip in mains voltage for 0.5 cycle	100% dip in mains voltage for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
	60% dip in mains voltage for 5 cycle	60% dip in mains voltage for 5 cycle	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
	30% dip in mains voltage for 25 cycle	30% dip in mains voltage for 25 cycle	
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.
			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
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHZ to 2.5 GHz	20 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
			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, should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
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

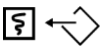
Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment			
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic 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 = 1.17*Sqrt (P)	80 MHz to 800 MHz d = 0.18*Sqrt (P)	800 MHz to 2.5GHz d = 0.35*Sqrt (P)
0.01	0.12	0.018	0.035
0.1	0.37	0.057	0.11
1	1.17	0.18	0.35
10	3.7	0.57	1.1
100	11.7	1.8	3.5
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC		ETL Intertek certification See ***Declarations on Page 1*** for certifications
IP24	Protection from ingress of particulates > than 12 mm and water spray from any direction.		Class II Equipment
	Non-Sterile		Defibrillation-proof. Type BF applied part
	Separate collection for electrical and electronic equipment (WEEE)		Recyclable
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician	EC REP	Authorized representative in the European community
	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device
	Non-ionizing electromagnetic radiation	IC Model:	Industry Canada Identification
	Warning, electricity		Biohazardous Waste

Symbol	Description	Symbol	Description
	Electrostatic		Not for continuous monitoring (No alarm for SpO_2)
	No parameter alarms		Product contains no PVC (polyvinyl chloride) material
	Caution		Not made with natural rubber latex
	Manufacturer		Catalog number (model number)
	Date of manufacture YYYY-MM-DD		Masimo reference number
	Storage temperature range		Serial number
	Keep dry		Fragile, handle with care
	Storage humidity limitation		Do not use if package is damaged
	Atmospheric pressure limitation		Equipotential Ground Terminal
	AC current		SatShare Interface
	Fuse		Wireless Symbol level
	Stand-By		Wireless features can be used in member states with the restriction of indoor use in France -Class 2 wireless device

Symbol	Description	Symbol	Description
	RS-232 Interface		Iris Connection
	Analog Out Interface		Ethernet
	USB port		Nurse Call Interface
	Less than		Greater than
	China Restriction of Hazardous Substances		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual
	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 rainbow SET technology with Masimo sensors has 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 rainbow SET technology with Masimo sensors has 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 touching 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-67 has been validated for low perfusion accuracy in bench-top testing against a Biotek Index 2™ 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 rainbow SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator.

[5] SpHb accuracy has been validated on healthy and unhealthy adult male and female volunteers and on patients with light to dark skin pigmentation in the range of 8 g/dL to 17 g/dL SpHb against tHb reference blood measurements determined by HiCN methods. The SpHb accuracy has not been validated with motion or low perfusion.

[6] This represents approximate run time using a fully charged battery with all connectivity options turned off and brightness level set to level 3.

[7] This represents approximate recharge time at operating temperature of 25°C.

[8] 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

The Rad-67 is a reusable device. The device is supplied and is intended to be used non-sterile.

WARNING: To avoid electric shock, always turn off the Rad-67 and physically disconnect the AC power and all patient connections before cleaning.

CAUTION: To avoid permanent damage to the Rad-67, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

To surface clean the Rad-67:

- Wipe the outer surfaces using a dampened soft cloth with one of the recommended cleaning solutions twice or until the surfaces are free of any visible residue.

Note: Pay particular attention to cracks, crevices, and hard to reach areas of the device.

- Repeat the above cleaning step using a fresh wipe.
- Allow the Rad-67 to dry thoroughly before using again.

CAUTION: To avoid permanent damage to the Rad-67, do not use excessive amounts of liquids to clean the device.

The surfaces of the Rad-67 may be cleaned with the following solution(s):

- ≤ 70% Isopropyl Alcohol
- Cidex Plus (3.4% glutaraldehyde)
- 10% (1:10) chlorine bleach to water solution
- Quaternary ammonium chloride solution wipe

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-67 following repairs or during routine maintenance, follow the procedure outlined in this chapter. If the Rad-67 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-67 to AC power and fully charge the battery.
- Disconnect any patient cables or pulse oximetry probes from the front of the Rad-67.

Power-On Self-Test

To conduct a Power-On Self-Test

1. Power on the device by pressing the home button.
2. Upon powering on, the device should emit a tone and the Masimo logo should display.

Note: If the Rad-67 does not pass the Power-On Self-Test, a system failure technical alarm will be activated. See ***Chapter 7: Troubleshooting*** on page 67.

Touchscreen Function Test

To conduct a Touchscreen Function Test

1. Connect the Rad-67 to AC power.
2. Perform the gestures outlined in ***Using the Touchscreen Interface*** on page 30.

Maintenance

Battery Operation and Maintenance

The Rad-67 includes a lithium ion rechargeable battery.

Before using the Rad-67 without the AC power connected, check the battery status indicator and ensure that the battery is fully charged. See ***Battery Charge Status Indicator*** on page 35.

To charge the Rad-67 battery, refer to ***Initial Battery Charging*** on page 27.

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

Run Time for Rad-67

The following table outlines the estimated minimum run time of the battery in the Rad-67.

- The time estimates are based on a fully charged battery.
- Time estimates are also based on specific operating modes.

For optimal battery run time, configure the device to automatically adjust the brightness. See ***Brightness*** on page 52.

Configuration	Operating Mode	Minimum run time (Est.)
Rad-67	• Not connected to AC power • All connectivity options turned off • Brightness level set to level 3	6 hours

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*** on page 93. Make sure the equipment is fully dry before packing.

To return the device for service, refer to ***Return Procedure*** on page 95.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in ***Cleaning*** on page 93. 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-67. 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-67 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-67 has been decontaminated for bloodborne pathogens.
- Return the Rad-67 to the shipping address listed in ***Contacting Masimo*** on page 95 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-67™ Pulse CO-Oximeter®) and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months and any batteries for six (6) months from the original date the Product was obtained by the end-user purchaser.

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

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

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

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

Limitation of Warranty

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

Sales & End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the

parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Restrictions

1. Copyright Restrictions: The Software and the accompanying written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged, or included with other software, or the written materials is expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of this Agreement. Nothing in this License provides any rights beyond those provided by 17 U.S.C. §117.
2. Use Restrictions: Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other device. Purchaser may not disclose, publish, translate, release, distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Software or the written materials.
3. Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Masimo's prior written consent; except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.
4. U.S. Government Rights: If Purchaser is acquiring Software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the Software and documentation are deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the Software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this Agreement.

Index

G

I

L

M

N

O

P

R

S

T

U

W

www.masimo.com

300362/LAB-10262A-0419