Operator's Manual

Rad-97™ Pulse CO-Oximeter®

Masimo

For Sale in the USA

These operating instructions provide the necessary information for proper operation of all models of the Rad-97. 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-97 are prerequisites for its proper use. Do not operate Rad-97 without completely reading and understanding these instructions.

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

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

Wireless Radio
FCC ID:VKF-MWM1 Model–Rad-97 IC:7362A- MWM1 IC Model: MWM1

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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 (IEC60601-1-8:2006) 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-97™ Pulse CO-Oximeter®. Important safety information relating to general use of Rad-97 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-97™ Pulse CO-Oximeter® is a non-invasive device that measures functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI®) along with optional non-invasive measurements of total hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet®), and Acoustic Respiration Rate (RRa®).

The following key features are available for the Rad-97:

- Masimo SET® and rainbow® SET technology performance.
- SpO_2 and pulse rate monitoring in motion and low perfusion environments.
- Continuous and non-invasive monitoring of carboxyhemoglobin (SpCO), methemoglobin (SpMet), and total hemoglobin (SpHb).
- Respiration rate determined by an acoustic (RRa) waveform.
- Wireless radio for transfer of parameter data.

Indications for Use

The Masimo Rad-97™ Pulse CO-Oximeter® and accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rad-97™ Pulse CO-Oximeter® and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments.

Contraindications

The Rad-97 is not intended for use as an apnea monitor.

Safety Information, Warnings and Cautions

CAUTION: Rad-97 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-97 if it appears or is suspected to be damaged. Damage to the device enclosure can result in exposed electrical circuits that may cause patient harm.

WARNING: Do not adjust, repair, open, disassemble, or modify the Rad-97. Damage to the device may result in degraded performance and/or patient injury.

WARNING: Do not start or operate the Rad-97 unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.

WARNING: Only use Masimo authorized devices with Rad-97. Using unauthorized devices with Rad-97 may result in damage to the device.

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-97 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-97 during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: Rad-97 may be used during defibrillation. However, to reduce the risk of electric shock, the operator should not touch the Rad-97 during defibrillation.

WARNING: To protect against Electric Shock Hazard, 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-97 while monitoring patient.

WARNING: To ensure safety, avoid placing anything on the instrument 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-97 where the controls can be changed by the patient.

CAUTION: Do not place Rad-97 where the appliance inlet or the AC power plug cannot be readily disconnected.

CAUTION: Use a grounded outlet for proper equipment grounding. A hospital-grade outlet is required.

CAUTION: To avoid risk of electrical shock, this equipment must only be connected to a supply mains with a protective earth connection. Do not under any circumstances remove the grounding conductor from the power plug.

CAUTION: Only use the AC power cable provided by Masimo. Using a different AC power cable could cause damage to Rad-97. Check the power cord and plug to ensure that it is intact and undamaged.

CAUTION: To ensure patient electrical isolation, all external device connections to the Data Output/Nurse Call connectors must be IEC 60950-1, IEC 60601-1, or UL1069 compliant.

Note: If there is any doubt about the integrity of the protective earth conductor arrangement, operate the Rad-97 on internal battery power until the AC power supply protective conductor is fully functional.

Note: Disconnect the device from AC mains by removing the AC power cord connector from the appliance inlet.

Note: Use and store the Rad-97 in accordance with specifications. See the Specifications section in this manual.

Performance Warnings and Cautions

WARNING: Rad-97 should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check Rad-97 for proper functioning.

WARNING: Do not use Rad-97 as an apnea monitor. Rad-97 does not have alarms to alert you when you are not breathing properly.

WARNING: Rad-97 should not be used as a replacement or substitute for ECG-based arrhythmia analysis.

WARNING: Rad-97 may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: Rad-97 may be used during electrocautery. This may affect the accuracy or availability of the parameters and measurements.

WARNING: Wireless communication of alarms to a secondary monitoring station should not be relied upon as a primary alarm.

WARNING: Avoid placing Rad-97 against a surface that may cause the alarm to be muffled. This may result in the inability to detect the audible alarms.

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-97 on patients that have been injected with dyes or any substance containing dyes, the change usual blood pigmentation may cause no or incorrect readings.

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

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

WARNING: No or inaccurate SpO_2 readings may be caused by:

- Improper sensor application.
- Blood pressure cuff applied to the same arm as the sensor site.
- Arterial catheter
- Elevated levels of COHb and/or MetHb. Note: High levels of COHb or MetHb may occur with a seemingly normal SpO_2.
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous congestion.
- Excessive venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg position).
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.

- Moisture, birthmarks, skin discoloration, or foreign objects in the light path.
- Elevated levels of bilirubin.
- Severe anemia.
- Very low arterial perfusion.
- Hypocapnic or Hypercapnic conditions.
- Excessive motion.
- Vasospastic disease such as Raynaud's.
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Peripheral vascular disease.
- EMI radiation interference.

WARNING: Inaccurate SpHb and SpOC readings may be caused by:

- Improper sensor application.
- Blood pressure cuff applied to the same arm as the sensor site
- Intravascular dyes, such as indocyanine green or methylene blue.
- Excessive venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg position).
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Elevated PaO_2 levels.
- Elevated levels of bilirubin.
- Low arterial perfusion.
- Motion artifact.
- Low arterial oxygen saturation levels.
- Elevated COHb and/or MetHb levels.
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Vasospastic disease such as Raynaud's.
- Peripheral vascular disease.
- Liver disease.
- EMI radiation interference.

WARNING: Inaccurate SpCO and SpMet readings may be caused by:

- Improper sensor application.
- Intravascular dyes such as indocyanine green or methylene blue.
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.

- Elevated PaO_2 levels.
- Elevated methemoglobin levels.
- Abnormal hemoglobin levels.
- Low arterial perfusion.
- Low arterial oxygen saturation levels including altitude induced hypoxemia.
- Elevated total bilirubin levels.
- Motion artifact.
- Vasospastic disease such as Raynaud's.
- Peripheral vascular disease.
- Liver disease.
- EMI radiation interference.

WARNING: SpCO readings may not be provided if there are Low arterial oxygen saturation levels or elevated methemoglobin levels.

WARNING: Inaccurate respiration rate measurements may be caused by:

- Improper sensor application.
- Low arterial perfusion.
- Motion artifact.
- Low arterial oxygen saturation.
- Excessive ambient or environmental noise.
- Improper sensor placement.

CAUTION: SpHb readings may be inaccurate for patients with conditions that may cause edema at the measurement site (eg. kidney disease, pregnancy, etc.).

CAUTION: Do not place the Rad-97 on electrical equipment that may affect the instrument, preventing it from working properly.

CAUTION: Failure to charge Rad-97 promptly after a Low Battery alarm may result in the instrument shutting down.

CAUTION: If using Rad-97 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 instrument might read zero for the duration of the active irradiation period.

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

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

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

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

CAUTION: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to Rad-97.

CAUTION: In order to establish and maintain Rad-97'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: To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time Rad-97 is used.

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

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

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

Note: The wireless communication status between Rad-97 and Patient SafetyNet is displayed by Patient SafetyNet.

Note: Rad-97 is provided with a Wi-Fi signal indicator as an indication of Wi-Fi communication.

Note: Rad-97's alarm capabilities have been designed to be independent of the Wi-Fi communication feature in order to preserve Rad-97's primary alarms.

Note: Always charge Rad-97 when it is not in use to ensure that the Rad-97 Battery Module 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-97.

Note: When monitoring acoustic respiration, Masimo recommends minimally monitoring both oxygenation (SpO_2) and respiration (RRa).

Note: When using Rad-97 in the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the sensor becomes dislodged from the patient in this setting, false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.

Cleaning and Service Warnings and Cautions

WARNING: Do not attempt to remanufacture, recondition or recycle the Rad-97 as these processes may damage the electrical components, potentially leading to patient harm.

WARNING: To avoid electric shock, always turn off the Rad-97 and physically disconnect the AC power and all patient connections before cleaning.

WARNING: To avoid electric shock, do not attempt to replace or remove the Battery from the Rad-97. Service of Rad-97 should be done by qualified personnel only.

WARNING: Do not incinerate the Rad-97 Battery. The battery should be properly disposed according to local laws and regulations.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the Rad-97 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-97, 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-97. These substances affect the device's materials and instrument failure can result.

CAUTION: Do not submerge the Rad-97 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-97 in any liquid solution.

CAUTION: Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

Compliance Warnings and Cautions

WARNING: Changes or modifications not expressly approved by the party responsible for compliance 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.

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

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

Note: Use Rad-97 in accordance with the Environmental Specifications section in the Operator's Manual.

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

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

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

Note: This equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 60601-1-2: 2007, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

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

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

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

Chapter 1: Technology Overview

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

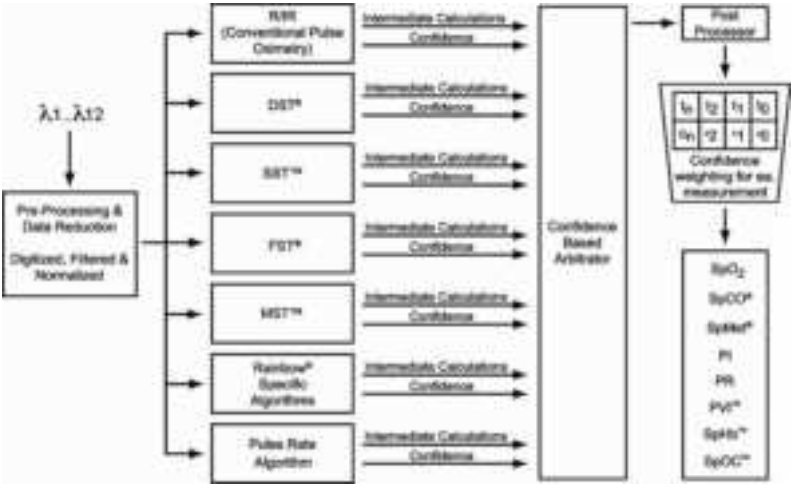
Signal Extraction Technology® (SET®)

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.

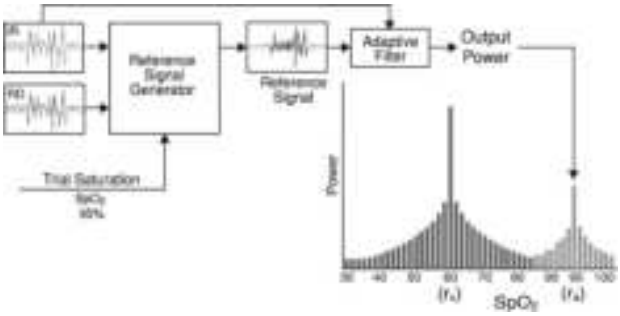
Masimo rainbow SET® Parallel Engines

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 mode 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-97 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 non-invasive measure of peripheral perfusion that can be continuously and non-invasively obtained from a pulse oximeter.

General Description for Pleth Variability Index (PVI)

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

Pleth Variability Index (PVI) may show changes that reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.

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

Citations for Pleth Variability Index (PVI)

1. *Cannesson M., Desebbe O., Rosamel P., Delannoy B., Robin J., Bastien O., Lehot J.J. Pleth Variability Index to Monitor the Respiratory Variations in the Pulse Oximeter Plethysmographic Waveform Amplitude and Predict Fluid Responsiveness in the Operating Theatre. Br J Anaesth. 2008 Aug; 101(2):200-6.*
2. *Forget P, Lois F, de Kock M. Goal-Directed Fluid Management Based on the Pulse Oximeter-Derived Pleth Variability Index Reduces Lactate Levels and Improves Fluid Management. Anesth Analg. 2010 Oct; 111(4):910-4.*
3. *Zimmermann M., Feibicke T., Keyl C., Prasser C., Moritz S., Graf B.M., Wiesenack C. Accuracy of Stroke Volume Variation Compared with Pleth Variability Index to Predict Fluid Responsiveness in Mechanically Ventilated Patients Undergoing Major Surgery. Eur J Anaesthesiol. 2010 Jun; 27(6):555-61.*
4. *Desebbe O, Boucau C, Farhat F, Bastien O, Lehot JJ, Cannesson M. Anesth Analg. The Ability of Pleth Variability Index to Predict the Hemodynamic Effects of*

Positive End-Expiratory Pressure in Mechanically Ventilated Patients under General Anesthesia. 2010 Mar 1; 110(3):792-8.

5. *Tsuchiya M., Yamada T., Asada A. Pleth Variability Index Predicts Hypotension During Anesthesia Induction. Acta Anesthesiol Scand. 2010 May; 54(5):596-602.*
6. *Loupec T., Nanadoumgar H., Frasca D., Petitpas F., Laksiri L., Baudouin D., Debaene B., Dahyot-Fizelier C., Mimoz O. Pleth Variability Index Predicts Fluid Responsiveness in Critically Ill Patients. Crit Care Med. 2011 Feb; 39(2):294-9.*
7. *Fu Q., Mi W.D., Zhang H. Stroke Volume Variation and Pleth Variability Index to Predict Fluid Responsiveness during Resection of Primary Retroperitoneal Tumors in Hans Chinese. Biosci Trends. 2012 Feb; 6(1):38-43.*
8. *Haas S., Trepte C., Hinteregger M., Fahje R., Sill B., Herich L., Reuter D.A. J. Prediction of Volume Responsiveness using Pleth Variability Index in Patients Undergoing Cardiac Surgery after Cardiopulmonary Bypass. Anesth. 2012 Oct; 26(5):696-701.*
9. *Byon H.J., Lim C.W., Lee J.H., Park Y. H., Kim H.S., Kim C.S., Kim J.T. Br. J. Prediction of fluid Responsiveness in Mechanically Ventilated Children Undergoing Neurosurgery. Anaesth 2013 Apr; 110(4):586-91.*
10. *Feissel M., Kalakhy R., Banwarth P., Badie J., Pavon A., Faller J.P., Quenot JP. Plethysmographic Variation Index Predicts Fluid Responsiveness in Ventilated Patients in the Early Phase of Septic Shock in the Emergency Department: A Pilot Study. J Crit Care. 2013 Oct; 28(5):634-9.*
11. *Yu Y., Dong J., Xu Z., Shen H., Zheng J. Pleth Variability Index-Directed Fluid Management in Abdominal Surgery under Combined General and Epidural Anesthesia. J Clin Monit Comput. 2014 Feb 21.*
12. *Desgranges F.P., Desebbe O., Ghazouani A., Gilbert K., Keller G., Chiari P., Robin J.,Bastien O., Lehot J.J., Cannesson M. Br. J. Anaesth 2011 Sep; 107(3):329-35.*
13. *Cannesson M. Arterial pressure variation and goal-directed fluid therapy. J Cardiothorac Vasc Anesth. 2010 Jun; 24(3):487-97.*
14. *Takeyama M, Matsunaga A, Kakihana Y, Masuda M, Kuniyoshi T, Kanmura Y. Impact of Skin Incision on the Pleth Variability Index. J Clin Monit Comput 2011 Aug; 25(4):215-21.*

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.

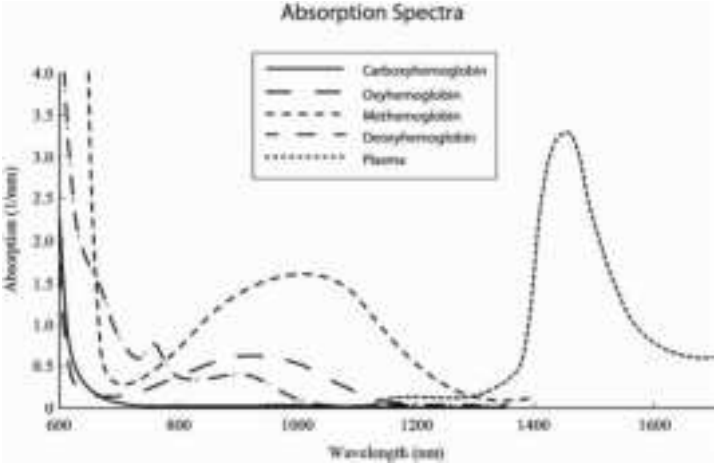
With motion, the plethysmographic waveform is often distorted and may be obscured by noise artifact. Shown as a vertical line, the SpO_2 SIQ coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Signal IQ identifies the timing that the algorithms 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 48.

rainbow Pulse CO-Oximetry Technology®

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

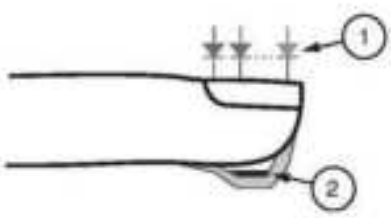
1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).
2. The 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.



The Rad-97 uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma.

The Rad-97 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-97 for calculation.



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

Once the Rad-97 receives the signal from the sensor, it utilizes proprietary algorithms to calculate the patient's functional oxygen saturation (SpO_2 [%]), blood levels of carboxyhemoglobin saturation (SpCO [%]), methemoglobin saturation (SpMet [%]), total hemoglobin concentration (SpHb [g/dL]) and pulse rate (PR). The SpCO, SpMet and 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, SpCO, SpMet, and SpHb measurements obtained from the Rad-97 (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, SpCO, SpMet, SpHb, and SpOC measurements of the Rad-97. 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 SpCO, different results are also expected if the level of methemoglobin (MetHb) in the blood gas sample is abnormal (greater than 2% for MetHb).

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, SpMet, SpCO, 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, SpCO, SpMet, SpHb, and SpOC 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 non-invasive 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 105.

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:

$$SpO_2 = 1.02 \times HbO_2$$

When calculating oxygen content (SpOC), the Rad-97 will use $SpfO_2$™ if available instead of SpO_2. $SpfO_2$ is the measured fractional arterial oxygen saturation.

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

General Description for SpOC

The above approximations result in the following reduced equation for oxygen content via the Pulse CO-Oximeter:

$$SpOC\ (ml/dL^*) = 1.31\ (ml\ O_2/g) \times SpHb\ (g/dL) \times SpO_2 + 0.3\ (ml\ O_2/dL)$$

*When ml O_2/g Hb is multiplied by g/dL of SpHb, the gram unit in the denominator of ml/g cancels the gram unit in the numerator of g/dL resulting in ml/dL (ml of oxygen in one dL of blood) as the unit of measure for SpOC. See ***Safety Information, Warnings and Cautions*** on page 11.

General Description for Carboxyhemoglobin (SpCO)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of carboxyhemoglobin saturation (SpCO) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpCO measurement.

The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry device or through a device patient cable.

The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data as percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

Successful Monitoring for SpCO

A stable SpCO reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site). Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

General Description for Methemoglobin (SpMet)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of methemoglobin saturation (SpMet) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpMet measurement.

The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry device or through a patient cable.

The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data as percentage value for the SpMet.

Successful Monitoring for SpMet

A stable SpMet reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (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.

SpCO, SpMet, and SpHb Measurements During Patient Motion

The Rad-97 displays measurements of SpCO, SpMet, and 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 SpCO, SpMet, or SpHb displays as dashes (---) and a message (*Low SpCO SIQ*, *Low SpMet SIQ*, or *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.

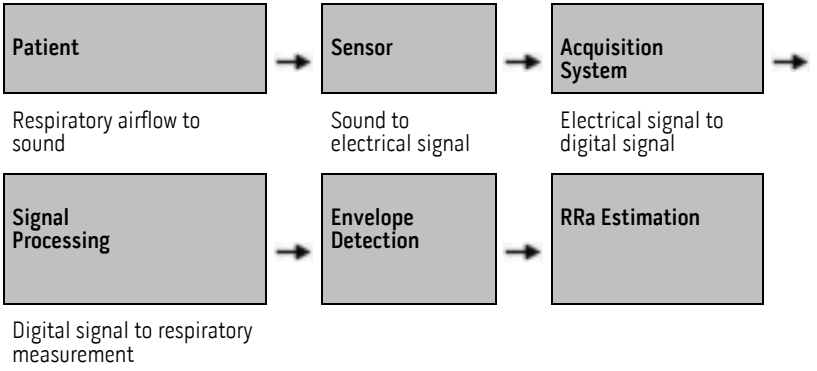
rainbow Acoustic Monitoring™ (RAM™)

rainbow Acoustic Monitoring (RAM) continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Sensor, which is applied on the patient's neck, translates airflow sounds generated in the upper airway to an electrical signal that can be processed to produce a respiration rate, measured as breaths per minute.

Respiratory sounds include sounds related to respiration such as breath sounds (during inspiration and expiration), adventitious sounds, cough sounds, snoring sounds, sneezing sounds, and sounds from the respiratory muscles [1].

These respiratory sounds often have different characteristics depending on the location of recording [2] and they originate in the large airways where air velocity and air turbulence induce vibration in the airway wall. These vibrations are transmitted, for example, through the lung tissue, thoracic wall and trachea to the surface where they may be heard with the aid of a stethoscope, a microphone or more sophisticated devices.rainbow Acoustic Monitoring Architecture

The following figure illustrates how a respiratory sound produced by a patient can be turned into a numerical measurement that corresponds to a respiratory parameter.



Patient

The generation of respiratory sounds is primarily related to turbulent respiratory airflow in upper airways. Sound pressure waves within the airway gas and airway wall motion contribute to the vibrations that reach the body surface and are recorded as respiratory sounds.

Although the spectral shape of respiratory sounds varies widely from person to person, it is often reproducible within the same person, likely reflecting the strong influence of individual airway anatomy [2-6].

Sensor

The sensor captures respiratory sounds (and other biological sounds) much like a microphone does. When subjected to a mechanical strain, (e.g., surface vibrations generated during breathing), the sensor becomes electrically polarized.

The degree of polarization is proportional to the applied strain. The output of the sensor is an electric signal that includes a sound signal that is modulated by inspiratory and expiratory phases of the respiratory cycle.

Acquisition System

The acquisition system converts the electric signal provided by the sensor into a digital signal. This format allows the signal to be processed by a computing device.

Signal Processing

The digital signal produced by the acquisition system is converted into a measurement that corresponds to the respiratory parameter of interest. As shown in the previous figure, this can be performed by, for example, determining the digital signal envelope or outline which in turn may be utilized to determine the respiratory rate. In this way, a real-time, continuous breath rate parameter can be obtained and displayed on a monitor which, in many cases, may be real-time and continuous.

The respiratory cycle envelope signal processing principle is similar to methods that sample airway gasses and subsequently determine a respiratory rate.

Citations

[1] A.R.A. Sovijärvi, F. Dalmasso, J. Vanderschool, L.P. Malmberg, G. Righini, S.A.T. Stoneman. Definition of terms for applications of respiratory sounds. Eur Respir Rev 2000; 10:77, 597-610.

[2] Z. Moussavi. Fundamentals of respiratory sounds analysis. Synthesis lectures on biomedical engineering #8. Morgan & Claypool Publishers, 2006.

[3] Olsen, et al. Mechanisms of lung sound generation. Semin Respir Med 1985; 6: 171-179.

[4] Pastercamp H, Kraman SS, Wodicka GR. Respiratory sounds – Advances beyond the stethoscope. Am J Respir Crit Care Med 1977; 156: 974-987.

[5] Gavriely N, Cugell DW. Airflow effects on amplitude and spectral content of normal breath sounds. J Appl Physiol 1996; 80: 5-13.

[6] Gavrieli N, Palti Y, Alroy G. Spectral characteristics of normal breath sounds. J Appl Physiol 1981; 50: 307-314.

Chapter 2: Description

This chapter contains the description of the Rad-97 physical features.

General System Description

The Rad-97 system includes the following:

- Rad-97 Device
- AC Power Cord
- Patient Cable
- Sensor

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

Features

Front View

1. Display and Touchscreen

Provides a user interface to view and change settings.

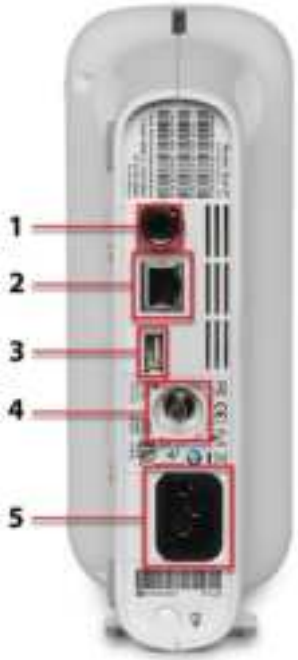
2. Home Button

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 Connector

Provides a connection to a patient cable or sensor.

Back View



1. Nurse Call Connector

Provides connection with a Nurse Call system.

Caution: To ensure patient electrical isolation, all external device connections to the Analog Output/Nurse Call connectors must be IEC 60950-1, IEC 60601-1, or UL 1069 compliant.

See ***Nurse Call Connection*** on page 39.

2. Ethernet

Provides a network connection to Rad-97 using an RJ-45 cable.

3. USB

Provides USB 2.0 connectivity.

4. Equipotential Ground Connector

Provides optional functional earthing for Rad-97 to eliminate potential differences between the earth connections for Rad-97 and another medical device. The use of the Equipotential Ground Connector should be in accordance with IEC 60601-1.

5. Power Entry Module

Provides connection to an AC power cord.

Note: Always connect the Rad-97 to the mains power for continuous operation and/ or battery recharging.

Note: Use the power cord as the means to disconnect the device from AC power.

Side and Top Views

1. Speaker

The speaker provides audio alarms. Care should be taken not to cover the speaker.

2. Swivel Foot

Provides stability to support the Rad-97 when placed on a surface in a vertical position.

3. Foot Pads

Provides physical support to the Rad-97 when placed on a surface in a horizontal position.

4. System Status Light

Provides an indication of alarm status. See ***About the System Status Light*** on page 55.

Chapter 3: Setting Up

This chapter contains information about setting up Rad-97 before use.

Unpacking and Inspection

To unpack and inspect the Rad-97:

1. Remove the Rad-97 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 133.

Preparation for Use

Prior to setting up the Rad-97 for monitoring, perform the following steps:

1. Confirm that you have all system components:
   - Rad-97 Device
   - AC Power Cord
   - Patient Cable
   - Sensor
2. Read the ***Safety Information, Warnings and Cautions*** on page 11.
3. Setup the Rad-97 according to the directions provided in this Operator's Manual.

Guidelines for Setting Up

When setting up Rad-97, follow these guidelines:

1. Place on a stable, hard, flat, dry surface near the patient.

   Caution: Do not place the Rad-97 where the controls can be changed by the patient.

   Note: If placed in a vertical position, rotate the swivel foot at the base of the device as shown in ***Side and Top Views*** on page 35 for stability.
2. Maintain a minimum of three (3) centimeters (approximately one [1] inch) of free space around Rad-97.
3. Ensure that the Speaker is not covered to avoid a muffled alarm sound.
4. Charge Rad-97's battery fully before use. See ***Initial Battery Charging*** on page 39.
5. Rad-97 should not be operated outside the environmental conditions listed in the specifications section. See ***Environmental*** on page 116.

Powering the Rad-97 ON and OFF

To turn ON the Rad-97

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

2. The Home Button will illuminate Green and the Rad-97 will power on.

To turn OFF the Rad-97

When turning off the Rad-97, the device remembers the last settings if the Power on Profile is set to *Previous Profile*. See ***Access Control*** on page 81.

1. Press and hold the Home Button for more than 8 seconds, until two (2) audible tones sound.
2. The Home Button will flash Orange.
3. The Rad-97 will power down and turn off.

Initial Battery Charging

Before use, the Rad-97 battery must be charged completely.

To charge the Rad-97

1. Plug the AC power cord into the power entry module. Make sure it is securely plugged in.
2. Plug the AC power cord into an AC power source.
3. Verify that the battery is charging:
   - When the Rad-97 is ON and charging, the AC Power Indicator lightning bolt icon will appear on the screen. See ***AC Power Indicator*** on page 50.
   - When the Rad-97 is OFF and charging, the Home button will illuminate Orange.
4. When the battery is fully charged:
   - When the Rad-97 is ON and fully charged, the AC Power Indicator will change to a plug icon. See ***AC Power Indicator*** on page 50.

Touch the AC Power Indicator icon to view battery charge details. See ***Rad-97 Battery*** on page 79. For additional information, see ***Battery Operation and Maintenance*** on page 130.

Nurse Call Connection

To connect to a Nurse Call System

1. Identify the Nurse Call connection end (1/4 inch round male connector) of the cable.
2. Insert the Nurse Call cable connector securely into the compatible port (1/4 inch round female connector) on the rear of the Rad-97. See ***Back View*** on page 35.
3. Depending on the connection type of the Nurse Call System, it may be necessary to orient the other end of the Nurse Call connection cable to fit correctly into the system connection.
4. It may be necessary to configure the settings of the Nurse Call output. See ***Device Output*** on page 83 for additional information.

Chapter 4: Operation

The information in this chapter assumes that Rad-97 is set up and ready for use. This chapter provides necessary information for proper operation of the device. Do not operate Rad-97 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 45.

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-97 ON and OFF*** on page 38.

The Home Button changes color depending on the selected profile. See ***Profiles Overview*** on page 87.

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-97.

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.
Pinch			Touch, move, and release via two touch points. Moving touch points apart zooms in, and moving them together zooms out.
Drag and Drop		See ***Understanding Windows*** on page 52.	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-97 and the various ways to interact with each type of control.

Control	Applicable Actions	Description
Toggle	Touch and slide knob	• Switches between toggle states
	Touch and slide left or right of toggle	• Quickly moves knob left or right
Labeled Toggle	Touch and slide knob	• Switches between toggle states
	Touch and slide left or right of toggle	• Quickly moves knob left or right
	Touch label	• Quickly moves knob left or right
Spinner	Touch center (focused) tile	• When closed, expands spinner • When open, collapses spinner
	Swipe up or down	• When open, scrolls through spinner tiles
	Touch unfocused tile	• When open, scrolls tile into center (focused) position
	Touch anywhere outside spinner	• When open, collapses spinner
Slider	Touch and slide knob	• Moves knob
	Press anywhere along slider path	• Quickly moves knob to tap position
Slider Spinner	Touch and slide knob	• Moves knob
	Touch anywhere along slider path	• Quickly moves knob to tap position
	Touch center (focused) tile	• When closed, expands spinner • When open, collapses spinner
	Swipe up/down	• When open, scrolls through spinner tiles
	Touch unfocused tile	• When open, scrolls tile into center (focused) position

Control	Applicable Actions	Description
	Touch anywhere outside spinner	• When open, collapses spinner
Button	Touch	• Performs action (as defined by the button description)
Icon Menu	Touch tile	• Opens menu specified by tile
	Swipe left or right (anywhere)	• Scrolls icons left or right
	Touch bottom indicator icon	• Quickly centers tile corresponding to indicator icon
Window	Touch parameter or measurement	• When no parameter or measurement alarm is present, opens parameter or measurement menu • When parameter or measurement alarm is present, silences parameter or measurement alarm
	Touch and hold	• Enables parameter and measurement drag and drop
Well	Touch parameter or measurement	• When no parameter or measurement alarm is present, opens parameter or measurement menu • When parameter or measurement alarm is present, silences parameter or measurement alarm
	Touch and hold	• Enables parameter and measurement drag and drop
Live Waveform	Swipe down	• Separates pleth and acoustic waveforms
	Swipe up	• Combines pleth and acoustic waveforms
Trend Line	Pinch in	• Zooms out
	Pinch out	• Zooms in
	Pan	• Changes time range

Control	Applicable Actions	Description
	Touch y-axis	• Opens parameter or measurement trend menu
Trend Zoom	Touch '+'	• Increases time range
	Touch '-'	• Decreases time range
	Touch time label	• Resets time range to default
Alarm Silence icon	Touch	• Silences all alarms
Audio Pause icon	Touch	• Enables Audio Pause
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:

Status Bar - See ***About the Status Bar*** on page 48.

Action Menu - See ***About the Action Menu*** on page 51.

Waveform View - See ***Waveform Settings*** on page 71.

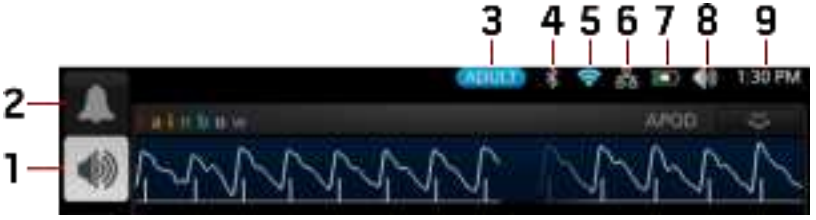
Parameter Display - See ***Understanding Windows*** on page 52.

Well - The Well displays selected parameters in a smaller size and is located along the bottom of the screen. See ***Understanding Windows*** on page 52.

Main Menu - See ***Accessing Main Menu Options*** on page 56.

About the Status Bar

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



Ref.	Feature	Description
1	Audio Pause	Suspends all audible alarms and displays remaining Audio Pause Duration time on Rad-97 when activated during an alarm event. Visual alarms are not impacted and will still display. See ***Audio Pause*** on page 73.
2	Alarm Silence	Displays alarm status and mutes all active audible alarms for Rad-97. See ***Silencing the Alarms*** on page 94.

Ref.	Feature	Description
3	Profiles	Provides access to the *Profiles* screen. The example shown illustrates that Profiles is currently set to Adult, for an adult patient. See ***Chapter 5: Profiles*** on page 87.
4	Bluetooth	Provides access to the *Bluetooth* screen. If this icon is visible, then Bluetooth connectivity has been enabled. See ***Bluetooth*** on page 78.
5	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 77.
6	Ethernet	Provides access to the *Ethernet* screen. If this icon is visible, then Ethernet connectivity has been enabled. See ***Ethernet*** on page 78.
7	Rad-97 Battery Charge/AC Power Indicator	Displays charging status for Rad-97. Provides access to the *Battery* screen. The example shows that AC power is connected and the battery is currently charging. See ***AC Power Indicator*** on page 50 and ***Battery Charge Status Indicator*** on page 50.
8	Sounds	Provides access to the *Sounds* screen to adjust alarm and pulse tone volume. This icon does **not** indicate the actual volume level of the alarm and pulse tone. See ***Sounds*** on page 73.
9	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 76.

AC Power Indicator

Whenever Rad-97 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-97 Battery*** on page 79.

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 alarm tone will sound with a Red border on the display. The system status light will flash Yellow.

Connect the battery 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-97 Battery*** on page 79.

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 51.
- **Trend View** - Displays values in Trend View. See ***Customizing Trend View*** on page 53.
- **Numeric View** - Displays values in a standard grid view.

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-97 to the needs of the particular patient situation. Sensitivity Modes are accessed through the Action Menu. See ***About the Action Menu*** on page 51.

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 where 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 general wards. 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 in both Trend View and Numeric View. 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 as either a Trend or Grid View. See ***Customizing Trend View*** on page 53.

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 any Trend Display.
Step 3	Release the Numeric Value.

Minimizing 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.

Customizing Trend View

There are different ways to view trend information. The following is an example of trend information for SpO_2, PR and SpHb as they appear within the *Main Screen* with the device in the horizontal position:

In Trend View, a parameter or measurement is displayed as a graph of its values over time.

The following diagram and table describe key features of a parameter's trend display in Trend View.

Ref.	Feature	Description
1	Value Range	Indicates current range of the displayed parameter or measurement. Press to access the Trend Menu from which the minimum and maximum values in the range can be modified.
2	Trend Graph	Displays parameter and measurement over a period of time. Zoom in and out of a Trend Graph by pinching out and in.
3	Numeric Value	Indicates current reading of the parameter or measurement.
4	Alarm Limits	Indicate high and low alarm limits for the parameter or measurement, if applicable.
5	Parameter or Measurement Label	Indicates the name of the parameter or measurement.

Data can be added to or removed from Trend View in the same manner as described in Customizing Windows. Data can be manipulated using the touchscreen as follows:

1. Swipe the trend view display left or right to scroll the trend view data forward or backward in time.
2. Tap the trend view in a specific spot to view the values at that location.
3. Touch the box in the lower right corner of the screen to change the amount of trend view data displayed on the screen. Select from 0:10h (10 minutes) to 24:00h (24 hours).

About the System Status Light

The System Status Light provides visual indications of alarms and system messages. The light will illuminate in different colors depending on the state of the device.

To locate the System Status Light, see ***Side and Top Views*** on page 35.

Light Status	Alarm Priority	Indication
None	None	System is off
Green	None	System is monitoring on patient, no alarms.
Yellow	Low	There is an active low priority. Examples: • No cable is connected. • Cable connected with no sensor connected to cable. • Sensor is off patient and has been acknowledged.
Flashing Yellow	Medium	There is an active medium priority alarm.
Flashing Red	High	There is an active high priority alarm.

Accessing Main Menu Options

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

The Main Menu options are:

Parameter Settings

See ***Parameter Settings*** on page 58.

Additional Settings

See ***Additional Settings*** on page 70.

Profiles

See ***Chapter 5: Profiles*** on page 87.

Sounds

See ***Sounds*** on page 73.

Device Settings

See ***Device Settings*** on page 75.

About

See ***About*** on page 84.

3D Alarms

See ***3D Alarms*** on page 95.

Trends

See ***Trends*** on page 85.

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 the 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.

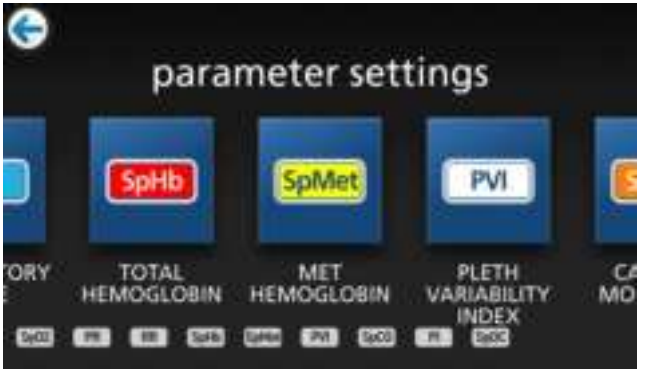
Any screen requiring selection of option(s) will time out after one (1) minute of inactivity and return to the Display View.

To navigate to the previous screen, press the arrow  at 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 *Parameter Settings* screen. Only parameters that have been loaded onto the system will be visible.



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. For details, see any of the following sections:

- See ***SpO2 Settings*** on page 59
- See ***PR Settings*** on page 61
- See ***Respiration Rate (RR) Settings*** on page 62
- See ***SpHb Settings*** on page 64
- See ***SpMet Settings*** on page 65
- See ***PVI Settings*** on page 66
- See ***SpCO Settings*** on page 67
- See ***PI Settings*** on page 68
- See ***SpOC Settings*** on page 70

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 SpHb.

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

SpO2 Settings

Access any of the following options:

SpO2 Alarms on page 60

Additional Settings for SpO2 on page 60

Trends on page 85

About Parameter Information on page 59

About Desat Index on page 96

SpO2 Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	Configurable Options
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	2% to 99% in steps of 1%, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	88%	1% to 98% in steps of 1%
Rapid Desat	Sets the Rapid Desat limit threshold to the selected amount below the Low Alarm Limit. When SpO_2 value falls below rapid desat limit the audio and visual alarm are immediately triggered without respect to the alarm delay.	NA	-10%	Off, -5%, or -10%
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	NA	15 seconds	0, 5, 10, or 15 seconds
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 sec, 1 or 2 minutes

Additional Settings for SpO2

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

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

Options	Description	Factory Default Settings	User Configurable Settings
FastSat	See ***FastSat Overview*** on page 61.	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-97 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 Setting*s screen, change any of the following options:

PR Alarms on page 61

Trends on page 85

About Parameter Information on page 59

PR Alarms

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

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

Options	Description	Alarm Priority	Factory Default Settings	Options
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 sec, 1, 2 or 5 minutes

Respiration Rate (RR) Settings

The Rad-97 can determine Respiration Rate (RR) by the acoustic signal (RRa).

From the RR Settings screen, change any of the following options:

RRa Alarms on page 63

Additional Settings for RRa on page 63

Trends on page 85

About Parameter Information on page 59

RRa Settings

RRa is active when the following conditions are all met:

- RRa is installed on the Rad-97.
- A dual rainbow cable is connected.
- An acoustic sensor is connected.

When using an acoustic sensor, Respiration Rate (RR) is determined by the acoustic (RRa) signal. See ***rainbow Acoustic Monitoring™ (RAM™)*** on page 29. When the respiratory rate is determined by the acoustic signal, the *Main Screen* labels respiratory rate as *RRa*, as shown below.

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

RRa Alarms on page 63

Additional Settings for RRa on page 63

About Parameter Information on page 59

RRa Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	Configurable Options
High Limit	High Limit is the upper threshold that triggers an alarm.	High	30 breaths per minute	6 to 69 breaths per minute in steps of 1 breaths per minute, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	6 breaths per minute	5 to 68 breaths per minute in steps of 1 breaths per minute
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2 or 5 minutes
Respiratory Pause	The duration of time that triggers an alarm if no breaths are detected.	NA	30 seconds	20, 25, 30, 35, 40, or 15 seconds
Alarm Delay	When a High or Low alarm condition occurs, this feature delays the audible part of an alarm.	NA	30 seconds	0, 10, 15, 30, or 60 seconds

Additional Settings for RRa

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.	Slow	Trending, No Averaging, Fast, Medium, or Slow
Freshness	The duration of time that, during interference, the system displays the last valid reading.	5 minutes	0, 1, 5, 10 or 15 minutes

SpHb Settings

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

SpHb Alarms on page 64

Additional Settings for SpHb on page 65

Trends on page 85

About Parameter Information on page 59

SpHb Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	High	17.0 g/dL (170 g/L) (11.0 mmol/L)	2.0 g/dL to 24.5 g/dL in steps of 0.1 g/dL, or Off (20 g/L to 245 g/L in steps of 1 g/L, or Off) (2.0 mmol/L to 15.0 mmol/L in steps of 0.1 mmol/L, or Off) When SpHb Precision is set to 1.0, values are rounded down. When set to Off, alarm is disabled.
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	7.0 g/dL (70 g/L) (4.0 mmol/L)	1.0 g/dL to 23.5 g/dL in steps of 0.1 g/dL, or Off (10 g/L to 235 g/L in steps of 1 g/L, or Off) (1.0 mmol/L to 14.5 mmol/L, in steps of 0.1 mmol/L, or Off) When SpHb Precision is set to 1.0, values are rounded down. When set to Off, alarm is disabled.

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2 or 5 minutes

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
Calibration	Provides an arterial or venous value that displays on the main screen.	Arterial	Arterial or Venous
Precision (units of g/dL and mmol/L)	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 (whole numbers)
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 active monitoring.	g/dL	g/dL, g/L, or mmol/L,

*Changing Unit of Measure will delete all prior trend data for all parameters.

SpMet Settings

From the *SpMet Settings* screen, access the following screens:

SpMet Alarms on page 66

Trends on page 85

About Parameter Information on page 59.

SpMet Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Alarm Limit is the upper threshold that triggers an alarm.	High	3.0	1% to 2% in steps of 0.1%, or 2.5% to 99.5% in steps of 0.5%, or Off
Low Limit	Low Alarm Limit is the lower threshold that triggers an alarm.	Medium	Off	Off, 0.1% to 2.0% in steps of 0.1%, or 2.5% to 99% in steps of 0.5%
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2 or 5 minutes

PVI Settings

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

PVI Alarms on page 66

Additional Settings for PVI on page 67

Trends on page 85

About Parameter Information on page 59

PVI Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	40	2 to 99, in steps of 1, or Off When set to Off, alarms are disabled.

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	5	1 to 98 in steps of 1, or Off When set to Off, alarms are disabled.
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2, 5 or 10 minutes

Additional Settings for PVI

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

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

SpCO Settings

From the *SpCO Setting*s screen, access the following screens:

SpCO Alarms on page 68

Trends on page 85

About Parameter Information on page 59

SpCO Alarms

From the *SpCO Settings* screen, access the following screens:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	High	10	2% to 98%, in steps of 1%, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	Off, 1% to 97%, in steps of 1% When set to Off, alarm is disabled
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2 or 5 minutes

PI Settings

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

PI Alarms on page 69

Additional Settings for PI on page 69

Trends on page 85

About Parameter Information on page 59

PI Delta on page 98

PI Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	Off or Step size: 0.04 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 19 in steps of 1
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	0.3	Step size: 0.03 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 18 in steps of 1, or Off
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2 or 5 minutes

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

SpOC Settings

From the *SpOC Settings* screen, access the following screens:

SpOC Alarms on page 70

Trends on page 85

About Parameter Information on page 59

SpOC Alarms

From the *SpOC Alarms* screen, access the following screens:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	25	2 ml/dl to 34 ml/dl in steps of 1 ml/dl, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	10	Off, or 1 ml/dl to 33 ml/dl in steps of 1 ml/dl
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, 2 or 5 minutes

Additional Settings

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

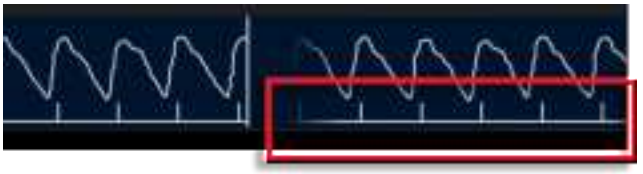
Option	Description	Configurable Settings
Sensitivity Mode	Change Sensitivity Mode. See ***Sensitivity Modes Overview*** on page 51.	MAX, APOD, NORM
Waveform Mode	Change the Waveform View. See ***Waveform Settings*** on page 71.	Acoustic, Pleth + Sig IQ, Pleth + Sig IQ + Acoustic, PVI Pleth + Sig IQ, PVI Pleth + Sig IQ + Acoustic
SmartTone	Enable or disable the SmartTone. See ***Sounds*** on page 73.	On, Off
SpO_2 low % limit	Set the SpO_2 low limit alarm. See ***SpO2 Settings*** on page 59.	Off, 1% to 98%

Waveform Settings

The following section contains information about waveforms viewable on the *Main Screen*. The following are examples of some of the views available.

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.



Acoustic Waveform View

Shows the parameter values at the top of the screen. The RRa waveform is located above the parameter values. Acoustic Respiratory Rate (RRa) must be available for this feature to be shown. This view contains RRa waveform only.

Pleth + Sig IQ + Acoustic View

Shows the parameter values on the top of the screen. The waveform is located above the parameter values. This view contains the Pleth waveform, signal quality indicators, and acoustic waveform.

Sounds

Use the *Sounds* screen to control the volume of sounds and duration of audio pause on Rad-97. Users can also access the *Sounds* screen by pressing the *Sounds* icon on the Status Bar. See ***About the Status Bar*** on page 48.

Option	Description	Factory Default Setting	Configurable Settings
Alarm Volume	Sets the alarm 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.
Audio Pause Duration	Sets the length of time that the audible alarm remains silenced, when Audio Pause is enabled. See ***Audio Pause*** on page 73.	2 minutes	1, 2, or 3 minutes, Permanent*, Permanent with Reminder*. If *Permanent* is selected, there will be no audible alarms, but visual alarms will still display. If *Permanent with Reminder* is selected, a tone will sound every three (3) minutes as a reminder that *Permanent* is active.
Smart Tone	Allows the audible pulse to continue to beep when the pleth graph shows signs of motion.	Off	On or Off

*Requires user to have All Mute Enabled turned on in the Access Control menu. See ***Access Control*** on page 81.

Audio Pause

Audio Pause temporarily suspends all audible alarms on Rad-97. When it is active, visual alarms are not impacted and will still display. The Audio Pause icon is located on the left side of the Status Bar; do not confuse it with the Sounds icon on the right side of the Status Bar. See ***About the Status Bar*** on page 48.

By default, Audio Pause is deactivated, and the icon appears in as follows:

Audio Pause inactive

To activate Audio Pause, press the icon. It will turn red and the remaining Audio Pause Duration time counts down next to the icon. The default duration for Audio Pause is 120 seconds. In the example below, Audio Pause is activated, and there are 15 seconds left until Audio Pause is inactive again.

Audio Pause active. 15 seconds remain until Audio Pause is inactive.

To configure Audio Pause, see ***Sounds*** on page 73.

Note: When Audio Pause is activated, powering off and then powering on Rad-97 will return Audio Pause to its default inactive state.

Device Settings

The *Device Settings* menu allows the user to view and customize settings for Rad-97. The Device Settings options are:

Localization

See ***Localization*** on page 76.

Screen Orientation

See ***Screen Orientation*** on page 76.

Ethernet

See ***Ethernet*** on page 78.

Wi-Fi

See ***Wi-Fi*** on page 77.

Bluetooth

See ***Bluetooth*** on page 78.

Rad-97 Battery

See ***Rad-97 Battery*** on page 79.

Brightness

See ***Brightness*** on page 80.

Access Control

See ***Access Control*** on page 81.

Device Output

See ***Device Output*** on page 83.

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 48.

Option	Description	Factory Default Setting	Configurable Settings
Language	Selects the language display for Rad-97.	English	Choose from available languages.
Date Format	Sets the display format for current date.	mm/dd/yy	mm/dd/yy or dd/mm/yy
Time Format	Sets the display format for current time.	12 hour	12 or 24 hour
Line Frequency	Sets to match regional power line frequency.	60 Hz	50 Hz or 60 Hz
Date	Sets the current date.	N/A	N/A
Time	Sets the current time.	N/A	N/A

Screen Orientation

Use *Screen Orientation* to set screen preferences.

From the *Screen Orientation* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Auto Orientation	Allows the device to automatically adjust screen content depending on device orientation.	On	Off or On
Orientation	When Auto Orientation is Off, allows the user to manually set screen orientation.	Portrait (with device in vertical position) Landscape (with device in horizontal position)	Portrait, Inverted Portrait, Landscape, or Inverted Landscape

Wi-Fi

The Wi-Fi radio allows for networked communication of data and alarm signals between Rad-97 and a secondary patient monitoring station, Masimo's Patient SafetyNet, over an IEEE 802.11 a/b/g wireless network. The wireless data transmission is an optional network data transmission to the wired network data transmission, using Rad-97's integrated Ethernet Port.

Rad-97 uses only configured MAC addresses to establish wireless communications, to prevent unauthorized connections to other wireless devices. As risk mitigation, in the event of the loss of wireless communication, Rad-97 alarm capabilities are designed to be independent of Wi-Fi communication in order to ensure alarms are received.

Use the *Wi-Fi* screen to enable or disable Wi-Fi connectivity. When Rad-97 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 48.

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

Your Masimo sales representative can provide necessary information regarding an initial Wi-Fi connection.

Ethernet

Use the *Ethernet* screen to enable or disable Ethernet connectivity. When Ethernet connectivity is enabled, the Ethernet icon will appear in the Status Bar. The user can also access the Ethernet screen by pressing the Ethernet icon on the Status Bar. See ***About the Status Bar*** on page 48.

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

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 48.

Option	Description	Factory Default Setting	Configurable Settings
Bluetooth	Enables or disables Bluetooth connectivity.	Off	On or Off
Presence Monitoring	Used in conjunction with MyView on Masimo Patient Safety Net (see the Masimo Patient SafetyNet Operator's Manual)	Off	On or Off

Note: Presence Monitoring must be disabled in order for Rad-97 to function. For more information on how to configure the Masimo MyView Presence Tag, see the Masimo Patient SafetyNet Operator's Manual.

Rad-97 Battery

Use the *Battery* screen to view the specific percentage of charge remaining in Rad-97'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 48.

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

Brightness

Use the *Brightness* screen to adjust the brightness of Rad-97's display.

Option	Description	Factory Default Setting	Configurable Settings
Auto Brightness	Allows automatic adjustment of Rad-97's display brightness based on the ambient light level.	Off	On or Off

Option	Description	Factory Default Setting	Configurable Settings
Brightness	Adjust the brightness level of Rad-97 display by sliding the button (4 is brightest).	4	1, 2, 3, 4

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	Configurable Settings
Power on Profile	Sets the profile used when the device is powered on. See ***Chapter 5: Profiles*** on page 87.	Previous Profile	Adult, Pediatric, Neonatal, or Previous Profile
All Mute Enabled	Enables parameter Alarm Silence menu option. See ***Sounds*** on page 73.	Off	On or Off

Option	Description	Factory Default Setting	Configurable Settings
Lock Alarm Volume	Sets the lowest alarm volume level.	Off	3, 4, or Off
Screen Lock	Allows the user to lock the touchscreen to prevent accidental changes.	Off	On or Off
USB Port Baudrate	Sets the USB port communication speed.	921600	9600, 19200, 38400, 57600, 115200, 230400, or 921600
Data Collection Enabled	Enables or disables physical data collection mode.	Off	On or Off
Save as Adult*	Saves current profile parameter as the Adult Profile.	N/A	Press **Save** to update the profile.
Save as Pediatric*	Saves current profile parameter as the Pediatric Profile.	N/A	Press **Save** to update the profile.
Save as Neo*	Saves current profile parameter as the Neonatal Profile.	N/A	Press **Save** to update the profile.
Factory Defaults	Options are restored to factory values.	N/A	Press **Restore**.

* See ***Replacing Factory Default Settings for Adult, Pediatric and Neonatal Profiles*** on page 90.

Device Output

The *Device Output* screen allows the user to configure additional data output options. A Nurse Call can be triggered based on alarm, low Signal IQ events, or both. In addition, Nurse Call Polarity can be inverted to accommodate local Nurse Call station requirements.

Option	Description	Factory Default Setting	Configurable Settings
Nurse Call Trigger	Controls the source of monitoring which sets off the trigger.	Alarms	Alarms, Signal IQ and Alarms, or Signal IQ
Nurse Call Polarity	Controls the mechanism of action for triggering to occur. Should be changed to accommodate institutional Nurse Call settings.	Normal	Normal or Inverted
USB Port	Controls the communication protocol used to transmit parameter data to a 3rd party device or an EMR system.	IAP	None, ASCII 1, IAP, or IntelliBridge
IntelliBridge Module	Identifies the type of IntelliBridge Module connected to the USB Port. **Note:** USB Port selection must be Intellibridge for option to be effective.	EC-10/B	EC-10/B or A

Note: The Nurse Call feature is disabled when Audio Pause is enabled and Nurse Call Trigger is set to *Alarms*. For more information about Audio Pause, see ***Audio Pause*** on page 73.

About

For information about individual parameters, see ***About Parameter Information*** on page 59.

Use the *About* screen to view the serial number as well as Rad-97 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.

Trends

Trend settings are available for each parameter to change the Y-axis maximum and Y-axis minimum. The maximum and minimum possible values are different depending on the selected parameter. See ***Customizing Trend View*** on page 53 for additional information.

Trend Settings

Use the *Trend Settings* screen to configure Trend Views on the *Main Screen* and trend data storage on Rad-97.

Option	Description	Factory Default Setting	Configurable Settings
Default Duration	Sets the time duration displayed in trend lines.	2 hours	15, 30, or 45 minutes 1, 2, 4, 8, 12, or 24 hours
Clear Trends	Deletes all stored trend data.	N/A	Press **Clear** to delete all stored trend data.

Chapter 5: Profiles

The following chapter contains information about profiles and profile settings.

Profiles Overview

Rad-97 contains a *Profiles* screen which lets the user customize settings for different patient populations:

- **Adult**
  Adult profile is the factory default profile. Displays in the Status bar as *ADULT* and the color of the Profile button turns Blue.
- **Pediatric**
  Displays in the Status bar as *PEDIATRIC* and the color of the Profile button turns Green.
- **Neonatal**
  Displays in the Status bar as *NEO* and the color of the Profile button turns Pink.

If the Profile setting is changed to *NEO*, Rad-97 will remain in the previously selected Profile setting even after the device is powered off and on again.

Note: If no changes are made to the profile settings, Rad-97 automatically resets to the default *Adult* profile after the device is powered off and on again.

The active profile displays in the Status Bar. In the following example, the *Adult* profile is active.

To restore all Rad-97 settings to factory default settings, see ***Access Control*** on page 81.

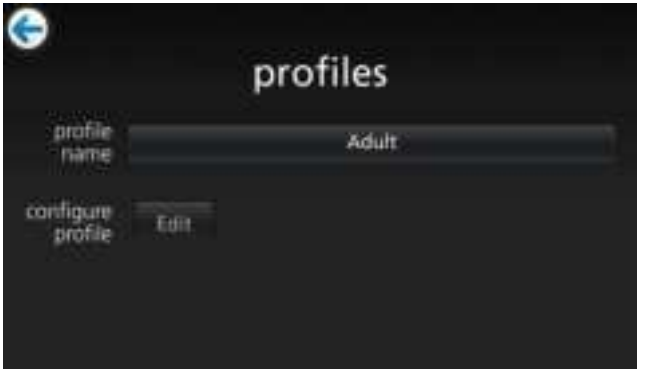
Changing Profiles

Changing Profiles is done through the *Profiles Settings* screen. There are different ways to access the *Profiles Settings* screen.

- Touch the *Profiles* shortcut in the Status Bar, as shown below.

- Select *Profiles* from the Main Menu as shown below.

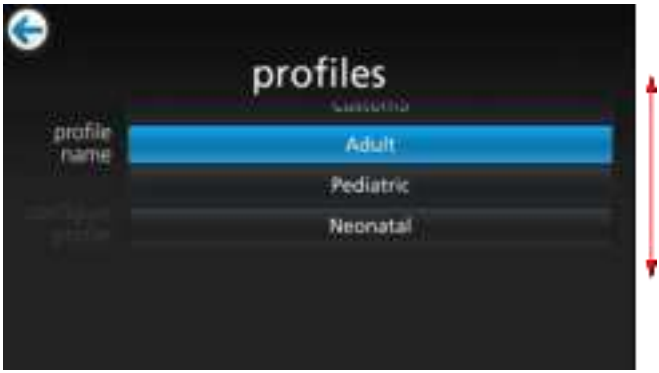
Once the *Profiles* screen displays you can switch to a different profile or choose a different patient category (Adult, Pediatric, Neonate) for the selected profile.



To switch to a different profile:

From the *Profiles* screen, touch the *Profile Name* field.

1. Select the desired profile by scrolling up or down.



2. When finished, touch **OK**. To confirm selection, check the Status Bar.
   The Home Button color will change as follows, depending on the profile selected:
   - Adult = Blue
   - Pediatric = Green
   - Neonatal = Purple
   - If the profile is displayed with an asterisk*, Home button illumination is turned Off.

To choose a different category for the selected patient profile:

From the *Profiles* screen, touch the *Configure Profile* Edit button.

1. Select the desired patient category by scrolling up or down.
2. When finished, touch **OK**. To confirm selection, check the Status Bar.
3. If a non-matching category is selected, the profile will be displayed with an asterisk* and the profile name on the status bar will not be highlighted with a color.

Profiles Settings

The Rad-97 can be configured for various patient types through the Profiles option located under the main menu options. See ***Accessing Main Menu Options*** on page 56.

Use the *Profiles Settings* screen to select patient type.

Option	Description	Factory Default Setting	Configurable Settings
Profile Name	Identifies the profile currently active on Rad-97.	Adult	Adult, Pediatric, Neonatal, Custom
Patient Category *	Identifies the patient category type.	Adult	Adult, Pediatric, Neonatal

* Select *Edit* to access the Patient Category options screen.

In addition to the three (3) standard profiles (Adult, Pediatric, Neonatal), up to five (5) custom profiles can be created as well.

Replacing Factory Default Settings for Adult, Pediatric and Neonatal Profiles

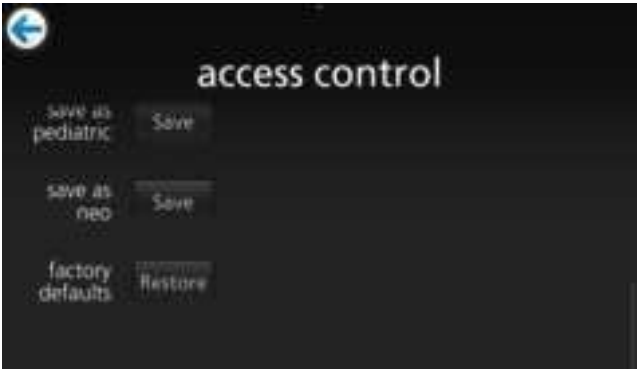
The default *Adult, Pediatric* and *Neonatal* profile settings can be modified to suit user preferences and the modified profiles saved as the default settings. This allows Rad-97 to remember customized settings for adult, pediatric and neonatal patients when the default *Adult, Pediatric* and *Neonatal* profiles are selected, even after the device is powered down and restarted. When customized settings for *Adult, Pediatric* and *Neonatal* profiles are saved

in place of the factory default settings, the *Profile* button still changes to the same Blue, Green or Pink color, respectively. See ***Profiles Overview*** on page 87.

The user can also load preferred profile settings into the Rad-97 using a separate tool.

To change the factory default settings for *Adult*, *Pediatric* or *Neonatal* profile settings

1. Change Rad-97 settings to the desired configuration.
2. Navigate to the *Access Control* screen. See ***Access Control*** on page 81.
3. Touch **Save** to save the change to the default profile.



4. Touch **Ok** to confirm the change.
5. Alternatively, the user can restore all *Profile* settings to factory default values by touching **Restore** and then **Ok**.
6. Confirm the changes by powering off and powering on Rad-97; the modified profile settings should remain intact.

Chapter 6: Alarms and Messages

The following chapter contains information about alarms and messages.

For more information, see ***Chapter 7: Troubleshooting*** on page 105.

About Alarms

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

Silence Duration configurations vary across different parameters and measurements. For more information about Silence Duration, refer to ***Parameter Settings*** on page 58.

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

Silencing the Alarms

Alarms are conveyed in several ways: audibly, visibly, or both ways simultaneously.

To silence or dismiss alarms:

- Touch **Silence** in the highlighted area of the Status Bar or the *Alarm Silence* button.
- If the alarm is for a specific parameter, touch the alarming parameter. Parameters are highlighted when in an alarm state.
- Audible alarms that are temporarily suspended by pressing the *Alarm Silence* button can be unsuspended by pressing the *Alarm Silence* button again.

The following is an example of a visual alarm:

The following is an example of a typical medium priority alarm due to parameter limit violation.

To silence audible alarms

Touch the **Alarm Silence** icon or the highlighted value one time to silence the audible alarm.

The audible alarm is silenced for the Silence Duration. A countdown timer will display as shown below.

The length of time for parameter limit audible alarm remains silenced can be changed using the Silence Duration feature located in the *Alarms* menu for each parameter.

3D Alarms

3D Alarms, accessible from the Main Menu, include the following:

Desat Index on page 97

About Desat Index on page 96

PI Delta on page 98

About PI Delta on page 97

About Desat Index

The 3D Desat Index Alarm allows a clinician to request audible and visual alarms if a patient experiences a specified number of desaturations beyond a defined level from the patient's baseline saturation over a specific period of time.

Traditional high and low SpO_2 alarm limits alert clinicians to saturation levels that exceed user-selected thresholds. These thresholds are typically established to detect significant changes from patients' baseline saturation levels. However, in select patient populations, substantial desaturation events that remain above a typical low alarm limit threshold may be preceded by a cycle of smaller transient desaturations over a limited period of time. The ability to alert clinicians when a cycle of smaller transient desaturations occur may provide an earlier indication of a potential significant decline in patient status, allowing for more focused monitoring and/or a change in treatment.

To address the select patient populations in which detecting a cycle of transient desaturations may be helpful, set a 3D Desat Index Alarm.

To set a 3D Desat Index Alarm see ***Desat Index*** on page 97.

Desat Index

From the *Desat Index* menu screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Delta	The change in saturation from the patient's baseline measurement.	4%	2% to 10%, in steps of 1%.
Time	The period of time in which saturation events that exceed the delta will be monitored.	1 hour	1 to 4 hours, in steps of 1 hour.
Number of Events	The number of desaturations exceeding the delta which will activate audible and visual alarms.	Off	Off, 1 to 24 desaturations in steps of 1.

About PI Delta

The Perfusion Index (PI) Delta Alarm allows a clinician to request audible and visual alarms if perfusion at the monitored site decreases by a specified level (delta) over a specific period of time.

Perfusion Index gives an indication of the level of perfusion at the monitored site. Rad-97 measures perfusion at the monitored SpO_2 site by comparing the pulsatile signal to the non-pulsatile signal, and expressing that ratio as a percentage. PI has been clinically proven to be useful as a predictor of the level of illness in neonates and adults. It has also been shown that PI may change dramatically in response to sympathetic changes caused by inhalational agents and pain stimulation.* If PI decreases over time, there may be underlying physiological reasons that may need to be addressed.

PI Delta audibly and visually alerts the user to important changes in a patient's perfusion, as compared to the patient's baseline PI rate. The baseline is set by Rad-97 once the user has enabled the alarm and represents 30 seconds of currently averaged PI. To set a PI Delta alarm, see ***PI Delta*** on page 98. The feature includes a user-selectable PI Delta Alarm. This allows the clinician to request an audible and visual alarm if perfusion at the monitored site decreases by a specified level (delta) over a specified window of time. Three of the variables are selectable by the user within established ranges as noted in PI Delta Alarms.

**De Felice C, Latini G, Vacca P, Kopotic RJ. The pulse oximeter perfusion index as a predictor for high illness severity in neonates. Eur J Pediatr. 2002; 161:561-562.*

PI Delta

From the *PI Delta* menu screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Set Baseline	Sets the Perfusion Index (PI) value to be used as the baseline.	Off	On or Off
Percent Change	The change in PI from the baseline that, if maintained for the Timeout length, will trigger audible and visual alarms.	50%	10% to 99%, in steps of 1%
Timeout	The length of time over which the percent change in PI is monitored.	None	1, 5, 30 minutes, 1, 4, 8, 12, 24, 36, 48 hours, or None

Messages

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

Message	**Potential Causes**	**Next Steps**
(Pulse CO-Ox) Replace Cable or *(RAM) Replace Cable*	• The patient cable is non-functional or the patient monitoring time of the cable has expired.	• Replace the patient cable.
(Pulse CO-Ox) Cable Near Expiration or *(RAM) Cable Near Expiration*	• Patient cable has less than 10% of patient monitoring time remaining.	• Replace with new patient cable.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) No Cable Connected or *(RAM) No Cable Connected*	• Cable not attached or not fully inserted into the connector.	• Disconnect and reconnect cable into connector.
(Pulse CO-Ox) Incompatible Cable	• Not a proper cable.	• Replace with a proper cable.
(Pulse CO-Ox) Replace Sensor or *(RAM) Replace Sensor*	• Reusable sensor has used all its available patient monitoring time • Sensor is non-functional • Defective sensor.	• Replace sensor.
(Pulse CO-Ox) Sensor Near Expiration or *(RAM) Sensor Near Expiration*	• Reusable sensor has less than 10% patient monitoring time remaining.	• Replace with new reusable sensor.
(Pulse CO-Ox) Adhesive Near Expiration or *(RAM) Adhesive Near Expiration*	• Disposable sensor has less than 10% patient monitoring time remaining.	• Replace with new disposable sensor.
(Pulse CO-Ox) Incompatible Sensor or *(RAM) Incompatible Sensor*	• Not a proper Masimo sensor. • Sensor is attached to a device without an appropriate parameter installed.	• Replace with a proper Masimo sensor. • Use a compatible sensor. Contact your local Masimo Representative to learn more about optional parameter upgrades.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Incompatible Adhesive Sensor or *(RAM) Incompatible Adhesive Sensor*	• Not a proper Masimo sensor. • Sensor is attached to a device without an appropriate parameter installed.	• Replace with a proper Masimo sensor. • Use a compatible sensor. Contact your local Masimo Representative to learn more about optional parameter upgrades.
(Pulse CO-Ox) No Sensor Connected or *(RAM) No Sensor Connected*	• Sensor not fully inserted into the connector. May be an incorrect sensor or a defective sensor or cable. • Device is searching for patient's pulse. • Sensor is disconnected from patient cable. Sensor connected upside down into patient cable.	• Disconnect and reconnect sensor. See the instructions for use provided with the sensor. • Disconnect and reconnect the sensor into the Patient Cable connector. • Check to see if the sensor LED is flashing. Disconnect and reconnect the sensor. If the LED fails to operate, replace the sensor.
(Pulse CO-Ox) Sensor Initializing	• Device is checking the sensor for proper function and performance.	• If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.
(Pulse CO-Ox) Sensor Off Patient or *(RAM) Sensor Off Patient*	• Sensor off patient. • Sensor not connected to patient properly. Sensor is damaged.	• Disconnect and reconnect sensor. • Reattach sensor. • Properly reapply the sensor to the patient and reconnect the sensor to the device or patient cable. If the sensor is damaged, replace the sensor.
(RAM) RAM Check Sensor	• RAM unable to collect data through RAM Sensor.	• Ensure proper sensor application. Check that no object is pulling on the sensor cable, which may cause the sensor to peel off.

Message	Potential Causes	Next Steps
(RAM) Sensor Initializing	• Device is checking the sensor for proper function and performance.	• If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.
(Pulse CO-Ox) Replace Adhesive Sensor or *(RAM) Replace Adhesive Sensor*	• When a single-patient-use sensor is used, the adhesive portion of the sensor is non-functional, or the life of the adhesive portion of the sensor has expired.	• Replace the adhesive portion of the sensor.
(Pulse CO-Ox) No Adhesive Sensor Connected or *(RAM) No Adhesive Sensor Connected*	• When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.	• Ensure the adhesive portion is firmly connected to the sensor.
(Pulse CO-Ox) Low Perfusion Index	• Signal strength is too weak.	• Move sensor to better perfused site. See ***Troubleshooting Measurements*** on page 105.
(Pulse CO-Ox) Low Signal IQ	• Indicates low signal confidence in the value displayed due to poor signal strength.	• Ensure proper sensor application. Move sensor to a better perfused site. See ***Signal IQ Indicators*** on page 72.
(Pulse CO-Ox) Pulse Search	• Device is searching for pulse.	• If device fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Interference Detected or *(RAM) 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 75.
(Pulse CO-Ox) SpO_2 Only Mode	• Occurs during an unsuccessful sensor initialization/pulse search routine or during monitoring.	• See the directions for use provided with your sensor. Use a Masimo light shield to cover the sensor and adjust the sensor.
Low SpCO SIQ	• Indicates low signal confidence in the SpCO measurement displayed.	• Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. See ***Successful Monitoring for SpCO*** on page 28.
Low SpMet SIQ	• Indicates low signal quality of SpMet measurement.	• Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. See ***Successful Monitoring for SpMet*** on page 29.
Low SpHb SIQ	• Indicates low signal quality of SpHb measurement.	• Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. See ***Successful Monitoring for SpHb*** on page 27.
"- -" (Dashes shown as parameter value)	• Unable to provide a parameter value.	• Check patient's vital condition.
Low Battery	• Battery charge is low.	• Charge battery by powering the device with AC line power.
Speaker Failure	• Device requires service.	• Contact Masimo Tech Support. See ***Chapter 9: Service and Maintenance*** on page 129.

Message	Potential Causes	Next Steps
RTC Battery Low	• Device requires service.	• Contact Masimo Tech Support. See ***Chapter 9: Service and Maintenance*** on page 129.

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. • Minimize or eliminate motion at the monitoring site. • Set to Maximum Sensitivity. See ***Sensitivity Modes Overview*** on page 51.
Difficulty obtaining a reading.	• Inappropriate sensor or sensor size. • Improper sensor type or application. • Low Perfusion. • Excessive Motion Artifact. • Excessive ambient or strobing light. • Low battery/ not plugged into AC power supply. • Interference from line frequency-induced noise.	• Allow time for parameter reading to stabilize. • Verify sensor type and size and re-apply sensor. See *Directions for Use* for Sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Verify the device and sensor are configured with the parameter. • Verify proper sensor and sensor size for the patient. • Shield the sensor from excessive or strobing light. • Minimize or eliminate motion at the monitoring site. • Connect AC power supply. • Verify and set 50 or 60Hz menu setting. See ***Localization*** on page 76.

Symptom	Potential Causes	Next Steps
Parameter readings displayed as dashes.	• Parameter may not have stabilized. • Device may not be configured with the parameter. • Sensor is not compatible with the parameter.	• 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.
Dimly Lit Parameters	• Low Signal Quality	• Assess the patient. • Verify sensor type and size and re-apply sensor. See *Directions for Use* for Sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Minimize or eliminate motion at the monitoring site. • Set to MAX Sensitivity. See ***Sensitivity Modes Overview*** on page 51.
Parameter Values Do Not Correlate With Clinical Assessment or Arterial Blood Gas Measurements	• Low perfusion • Sensor displacement	• Check for error messages. See ***Chapter 6: Alarms and Messages*** on page 93. • Check placement of sensor or if it is too tight. Reapply sensor or select a new site. Set to MAX sensitivity and confirm that the sensor is securely placed on the patient. See *Directions for Use* for Sensor.

Symptom	Potential Causes	Next Steps
Unexpected Parameter Readings	• Low SIQ or PI values • Inappropriate sensor size or sensor measurement location	• 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.

Troubleshooting Rad-97

The following section lists possible Rad-97 symptoms, potential causes, and next steps.

For more information, see ***Chapter 6: Alarms and Messages*** on page 93.

Symptom	Potential Causes	Next Steps
Device does not turn on	• Depleted Battery. • Internal failure.	• Check AC Power connection. • Contact Masimo Service. See ***Contacting Masimo*** on page 133.
System failure technical alarm active	• Internal failure.	• Turn Rad-97 Off and On. • Contact Masimo service. See ***Contacting Masimo*** on page 133.
Speaker does not work	• Device audible settings may be incorrect. • Internal failure.	• Turn Rad-97 Off and On. • Check that *Alarms* and *Sounds* have not been silenced. • Check that *Alarms* and *Sounds* volumes settings. • Check the device is not in *All Mute*. • Check that the device speaker is not being muffled. • Contact Masimo service. See ***Contacting Masimo*** on page 133.
Device screen is blank	• The device is Off. • The brightness display is not correct. • Battery may be depleted • Internal failure.	• Turn Rad-97 Off and On. • Adjust the brightness setting. See ***Brightness*** on page 80. • Check AC power connection. • Contact Masimo service. See ***Contacting Masimo*** on page 133.

Symptom	Potential Causes	Next Steps
Touchscreen/Buttons do not respond when pressed	• EMI (Electro Magnetic Interference) • Internal failure.	• Check device AC power is properly grounded. • Relocate the device from other devices that may cause electromagnetic interference. • Contact Masimo service. See ***Contacting Masimo*** on page 133.
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 133.
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 133.
Device does not detect that the sensor is connected	• Sensor not properly connected to device. • Improper placement of sensor. • Damaged sensor. • Sensor expired. • 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-97 Off and On. • Contact Masimo service. See ***Contacting Masimo*** on page 133.

Symptom	Potential Causes	Next Steps
Nurse Call does not work	• Nurse call connector not properly connected to the device. • Nurse call port not configured correctly. • Nurse call system not available. • Internal failure.	• Check Nurse call connector is fully connected to the device. • Check Nurse call port configuration. See ***Device Output*** *on page 83*. • Check Nurse call system availability. • Contact Masimo service. See ***Contacting Masimo*** on page 133.
Device does not communicate to other external devices through wired connection	• External device is not compatible. • Device port settings are not configured correctly. • Communication cable is not properly connected. • Connected network is not available. • Internal failure.	• Check external device compatibility. • Check device data port settings. See ***Device Output*** *on page 83*. • Check communication cable connection. • Check connected network settings and availability. • Contact Masimo service. See ***Contacting Masimo*** on page 133.
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 77. • Check wireless availability for location. • Check network settings and availability. • Contact Masimo service. See ***Contacting Masimo*** on page 133.

Chapter 8: Specifications

The following chapter contains specifications for the Rad-97.

Measurement Range

Measurement	Display Range
SpO_2 (Functional Oxygen Saturation)	0% to 100%
PR (Pulse Rate)	25 bpm to 240 bpm
PI (Perfusion Index)	0.02% to 20%
PVI (Pleth Variability Index)	0% to 100%
RRa (Respiration Rate)	4 breaths per minute to 70 breaths per minute
SpHb (Hemoglobin)	0 g/dL to 25.0 g/dL 0 g/L to 250 g/L (0 mmol/L to 15.52 mmol/L)
SpCO (Carboxyhemoglobin)	0% to 99%
SpMet (Methemoglobin)	0% to 99.9%
SpOC (Oxygen Content)	0 ml of O_2/dL to 35 ml of O_2/dL of blood

Accuracy (ARMS)*

Oxygen Saturation (SpO_2)		
No Motion [1] (SpO_2 from 60% to 80%)	Adults, Pediatrics, Infants	3%
No Motion [2] (SpO_2 from 70% to 100%)	Adults, Pediatrics, Infants	2%
	Neonates	3%

Motion [3] (SpO_2 from 70% to 100%)	All patient populations	3%
Low perfusion [4] (SpO_2 from 70% to 100%)	All patient populations	2%
Pulse Rate (PR)		
Range	25 to 240 bpm	
No motion	All patient populations	3 bpm
Motion [5]	All patient populations	5 bpm
Low Perfusion	All patient populations	3 bpm
Carboxyhemoglobin Level (SpCO) [1]		
Range of 1% to 40%	Adults, Pediatrics, Infants	3%
Methemoglobin Level (SpMet) [1]		
Range 1% to 15%	All patient populations	1%
Total Hemoglobin SpHb [6]		
Range of 8 g/dL to 17 g/dL	Adults, Pediatrics	1 g/dL
Respiratory Rate (RRa) [9]		
Range of 4 to 70 bpm	Adults, Pediatrics	1 bpm

* The A_{RMS} Accuracy is calculated based upon measurement values that are statistically distributed; approximately 68% of the measured values fell within +/- the ARMS value when compared to the reference device in a controlled study.

Resolution

Parameter	Resolution
SpO_2	1%
SpCO	1%
SpMet	0.1%
SpHb	0.1 g/dL
SpOC	1.0 ml/dL
Pulse Rate	1 beat per minute
Respiration Rate	1 breath per minute

Electrical

AC Power Requirements	
AC Power requirements	100 to 240 VAC, 47 to 63 Hz
Power consumption	60 VA
Fuses	UL, Metric (5x20mm), rated min. 250 VAC, 1 Amp, Time Delay, min.1500A breaking capacity

Battery	
Type	Lithium ion
Capacity	7 hours [7]
Charging Time	3 hours

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 90%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1,060 mbar (540 hPa to 1060 hPa)
Operating Altitude	5000 m to -382 m (16,404 ft to -1253 ft)

Physical Characteristics

Physical Characteristics	
Dimensions	22.9 cm x 10.2 cm x 16.5 cm (9" x 4" x 6.5")
Weight	< 1.36 kg. (3.0 lbs.)

Alarms

Alarm Priority	Alarm Status Color	Audio Alarm Description
High Priority	Flashing red	571 Hz tone, 10-pulse burst, pulse spacing: 0.25s, 0.25s, 0.50s, 0.25s, repeat time:10s

Alarm Priority	Alarm Status Color	Audio Alarm Description
Medium Priority	Flashing yellow	550 Hz tone, 3-pulse burst, pulse spacing: 0.375s, 0.375s, repeat time: 7s
Low Priority	Solid yellow	No audible alarms

Alarm Characteristic	Description
Alarm Volume*	High Priority: 75 dB (min) Medium Priority: 70 dB (min)

* When volume is set to the highest level.

Display Indicators

Item	Description
Trend Memory	Max of 96 hours at 2-second resolution
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
EN/ISO 80601-2-61:2011, Clause 202.6.2.3, 20 V/m

Safety Standards Compliance
ANSI/AAMI ES 60601-1:2005
UL 60601-1
CAN/CSA C22.2 No. 60601-1
CAN/CSA C22.2 No. 601-1
IEC 60601-1:2005
IEC 60601-1:1988 +A1:1991 +A2:1995
EN/ISO 9919
EN/ISO 80601-2-61:2011

Equipment Classification per IEC 60601-1	
Type of Protection	Class I (AC power)
	Internally powered (Battery power)
Degree of Protection of Electrical Shock	Defibrillation proof BF-Applied Part
Protection against harm from liquid ingress	IP21, Protection from ingress of particulates > than 12.5 mm and ingress from vertically dripping liquids.

Equipment Classification per IEC 60601-1	
Mode of Operation	Continuous operation

Output Interface

USB 2.0, Type-A Connector
Nurse Call connector

Wireless Specifications

Communication (Wi-Fi)	
Type	WLAN Radio: IEEE 802.11 a/b/g
Frequency	802.11a: 5180-5240 MHz, 5745-5825 MHz 802.11b/g: 2412-2462 MHz
Max Peak Output Power	WLAN 17 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
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.

Communication (Bluetooth)	
Type	Bluetooth
Frequency	2402-2480 MHz
Max Peak Output Power	Bluetooth 1.3 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	DH5
Modulation Signals	Analog and Digital
Available Data Rates	Bluetooth 1 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 ID: VKF-MWM1 Model - RAD-97
Canada	IC:7362A-MWM1 IC Model: MWM1 RSS-210

Radio Compliance	
Europe	EN 300 328 EN 301 893 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 +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power lines +/- 1 kV for input/ output lines	+/- 2 kV for power lines +/- 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/-1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Voltage dips, short interruptions and voltage variations on power supply input lines	100% dip in mains voltage for 0.5 cycle 60% dip in mains voltage for 5 cycle 30% dip in mains voltage for 25 cycle	100% dip in mains voltage for 0.5 cycle 60% dip in mains voltage for 5 cycle 30% dip in mains voltage for 25 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 3 V/m 80 MHZ to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 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 range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
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 are found on the Rad-97, or packaging and are defined below.

Symbols	Definition	Symbols	Definition
	Follow Instructions for use		Separate collection for electrical and electronic equipment (WEEE)
	Manufacturer		Atmospheric pressure limitation
	Date of Manufacture YYYY-MM-DD		Storage temperature range
	Non-ionizing electromagnetic radiation		Storage humidity limitation
IP21	Protection from ingress of particulates > than 12.5 mm and against vertically falling water drops		Keep Dry
Rx ONLY	**Caution:** Federal law restricts this device to sale by or on the order of a licensed physician.		Fragile, handle with care
	ETL Intertek certification Conforms to ANSI/AAMI ES 60601-1:2005 and certified to CAN/CSA STD C22.2 No. 60601-1:2008		Equipotential Ground Terminal

FC	Federal Communications Commission (FCC) licensing		USB port
IC Model:	Industry Canada identification		AC current
CE 0123	Mark of Conformity to European medical device directive 93/42/EEC		Nurse Call Interface
EC REP	Authorized representative in the European community		Defibrillation Proof Type BF
	Wireless features can be used in member states with the restriction of indoor use in France -Class 2 wireless device		Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note: eIFU is not available for CE mark countries.**

Citations

[1] SpO_2, SpCO, and SpMet accuracy was determined by testing on healthy adult volunteers in the range 60% to 100% SpO_2, 0% to 40% SpCO, and 0% to 15% SpMet against a laboratory CO-Oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7 days to 135 days old and weighing between 0.5 kg and 4.25 kg. Seventy-nine (79) data samples were collected over a range of 70% to 100% SaO_2 and 0.5% to 2.5% HbMet with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet. Contact Masimo for testing specifications.

[2] 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.

[3] 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.

[4] The Rad-97 has been validated for low perfusion accuracy in bench-top testing against a Biotek Index 2TM simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70%-100%.*

[5] 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.

[6] SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8 g/dL to 17 g/dL SpHb against a Coulter Counter. The SpHb accuracy has not been validated with motion or low perfusion.

[7] This represents approximate run time at the lowest indicator brightness and pulse tone turned off using a fully charged battery.

[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.

[9] Respiration rate accuracy for the Masimo Acoustic Respiration Sensor and Instrument has been validated for the range of 4 to 70 Respirations per minute in bench top testing. Clinical validation for up to 30 Respiration per minute was also performed with the Masimo Acoustic Respiration Sensor and Instrument.

**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-97 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-97 and physically disconnect the AC power and all patient connections before cleaning.

CAUTION: To avoid permanent damage to the Rad-97, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

To surface clean the Rad-97:

- 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-97 to dry thoroughly before using again.

CAUTION: To avoid permanent damage to the Rad-97, do not use excessive amounts of liquids to clean the device.

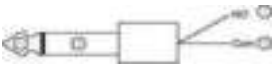
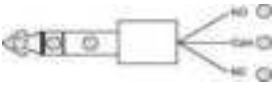
The surfaces of the Rad-97 may be cleaned with the following solution(s):

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

Nurse Call Setting Connections

For maximum flexibility, either normally open or normally closed signals are available. During an alarm condition or a low Signal IQ event, depending on the configuration of the device output, the normally open pin will be connected to the common pin and the normally closed pin will be disconnected. In addition, the Nurse Call Polarity can be inverted to accommodate various nurse call station requirements.

Only qualified personnel should connect one of these two signals to a hospital's Nurse Call system.

Cable Description	Nurse Call Event	**Menu Setting**
	2 contacts normally opened	Nurse Call Polarity Normal
	2 contacts normally closed	Nurse Call Polarity Inverse
	1 and 2 contacts normally opened 2 and 3 contacts normally closed	Nurse Call Polarity Normal
	1 and 2 contacts normally closed 2 and 3 contacts normally opened	Nurse Call Polarity Inverse
	1 and 2 contacts normally closed 2 and 3 contacts normally opened	Nurse Call Polarity Inverse

Battery Operation and Maintenance

The Rad-97 includes a lithium ion rechargeable battery.

Before using the Rad-97 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 50.

To charge the Rad-97 battery, refer to ***Initial Battery Charging*** on page 39.

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

Run Time for Rad-97

The following table outlines the estimated minimum run time of the battery in the Rad-97.

- 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 80.

Configuration	Operating Mode	Minimum run time (Est.)
Rad-97	• Not connected to AC power • Wireless connected • Bluetooth connected • Brightness level set to maximum	2 hours

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-97 following repairs or during routine maintenance, follow the procedure outlined in this chapter. If the Rad-97 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-97 to AC power and fully charge the battery.
- Disconnect any patient cables or pulse oximetry probes from the front of the Rad-97.
- Disconnect nurse call, ethernet or USB cable from the rear of the Rad-97.

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-97 does not pass the Power-On Self-Test, a system failure technical alarm will be activated. See ***Chapter 7: Troubleshooting*** on page 105.

Touchscreen Function Test

To conduct a Touchscreen Function Test

1. Connect the Rad-97 to AC power.
2. Perform the gestures outlined in Using the Touchscreen Interface.

Alarm Limit Test

Alarm Limit Test

1. Connect a sensor to the Rad-97. Place the sensor on a finger to obtain an SpO_2 value.
2. Change the High SpO_2 Alarm parameter to a value two points below the currently selected value. See ***SpO2 Alarms*** on page 60.
3. Verify that the newly set parameter is shown on the *Display* screen.
4. Return the parameter to its original setting.
5. Repeat steps 1 to 3 for all active parameters.
6. Reset the alarm limits again to the original settings.

Testing with the optional Masimo SET Tester

To conduct a test with the optional Masimo SET® Tester

1. Turn off and then turn on the Rad-97.
2. Use the Patient Cable connector on the Rad-97 to connect the Masimo SET® Tester to the Rad-97.
3. See the directions for use that were provided with the Masimo SET® Tester.

Nurse Call Test

To conduct a Nurse Call test

1. Disconnect any patient cables, sensors, or accessories from the Rad-97.
2. Turn the Rad-97 Off and On again.
3. Ensure that there are no audible alarms or audible alarms that are not paused.
4. Verify the Nurse Call polarity is set to normal. See ***Device Output*** on page 83.
5. Connect one end of a Nurse Call interconnection cable with 1/4" round connector on each end to the nurse call port of the Rad-97. See ***Back View*** on page 35.
6. Connect the common lead of a digital multi-meter to the pin 12 of the Nurse Call (Common) connector on the Rad-97. Connect the positive lead of the digital multi-meter to pin 6 of the Nurse Call (Normally Open) connector and measure that the resistance is greater than 1 MW (open circuit).
7. Trigger an alarm on the monitor (for example, by disconnecting a sensor after it was measuring data). Verify that the resistance is less than 35 ohms.

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 129. Make sure the equipment is fully dry before packing.

To return the device for service, refer to ***Return Procedure*** on page 133.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in ***Cleaning*** on page 129. 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-97. 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-97 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-97 has been decontaminated for bloodborne pathogens.
- Return the Rad-97 to the shipping address listed in ***Contacting Masimo*** on page 133 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-97™ 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.

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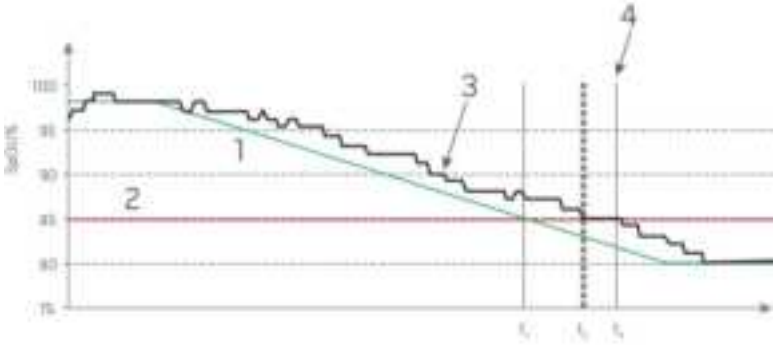
Appendix: Concepts of Alarm Response Delay

Concepts of Alarm Response Delay

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



Reference	Definition
1	SaO_2
2	Alarm Limit
3	Displayed SpO_2
4	Alarm Signal Generation
SpO_2	Saturation
t	Time

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

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

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

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

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