Operator's Manual

Radical-7® Pulse CO-Oximeter®

Masimo

For Sale in the USA

These operating instructions provide the necessary information for proper operation of all models of the Radical-7. 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 Radical-7 are prerequisites for its proper use. Do not operate Radical-7 without completely reading and understanding these instructions. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

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.

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

Wireless Radio:
Contains: FCC ID: VFK-RAD7A or VFK-RAD7B | FCC Model: Radical-7 | IC ID: 7362A-RAD7A or 7362A-RAD7B | IC Model: VFK-RAD7A or VFK-RAD7B

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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/A1, CAN/CSA C22.2 No. 60601-1:2014, and applicable Particular (EN/ISO 80601-2-61:2011) and related Collateral (IEC 60601-1-8:2006/AMD1:2012) 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 Radical-7® Pulse CO-Oximeter®. Important safety information relating to general use of Radical-7 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

The Radical-7 is a noninvasive monitor that measures arterial oxygen saturation (SpO_2), pulse rate (PR), and perfusion index (Pi), along with optional measurements of hemoglobin (SpHb), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet), Pleth Variability Index (PVi®), Acoustic Respiration Rate (RRa®), and Pleth Respiration Rate (RRp).

The Radical-7 can be used as either a Handheld or a Standalone monitor. The Radical-7 features a touchscreen that continuously displays numeric values for all parameters.

The Radical-7 provides graphical displays for plethysmographic waveform, respiratory waveform, Signal Identification and Quality Indicator (Signal IQ).

The Radical-7 can also be used to interface with a multi-parameter patient monitor to send Masimo SET pulse oximetry information to that monitor for display.

The Radical-7 has an embedded 802.11 wireless radio that can be used for connectivity.

Key Features

The following features are available for the Radical-7. Some features are optional:

- Masimo SET® technology is clinically proven to satisfy all sensitivity and specificity requirements for pulse oximetry.
- Masimo rainbow® technology uses 7+ wavelengths of light to continuously and noninvasively measure carboxyhemoglobin (SpCO), methemoglobin (SpMet), and total hemoglobin (SpHb), as well as providing a more reliable probe-off detection.
- Total oxygen content (SpOC) provides a calculated measurement of the amount of oxygen in arterial blood, which may provide useful information about oxygen both dissolved in plasma and combined with hemoglobin.
- Perfusion Index (Pi) with trending capability indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion.
- 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 is unknown at this time and requires further clinical studies. Technical factors that may affect PVi include probe malposition and patient motion.]
- Respiration rate can be determined by the acoustic (RRa) or plethysmographic waveform (RRp).
- Signal IQ waveform for signal identification and quality indication during excessive motion and low signal to noise situations.
- FastSat tracks rapid changes in arterial O_2.
- Variable pitch provides tonal variance for every 1% change in saturation.
- SatShare interface allows transfer of SpO_2 and pulse rate to an existing multi-parameter monitor and allows for the reading of SpCO, SpMet, SpHb, and SpOC on adjacent Radical-7 monitor.

- Automatic screen rotation provides upright display for vertical or horizontal monitor positioning.
- Multi-gesture touchscreen interface.
- Detachable portable Handheld for patient transport.
- Remote alarm interface.
- Ability to display data on a secondary display.

Indications for Use

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) of 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, mobile, and home environments.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radical-7 and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from photoplethysmogram (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

Contraindications

Radical-7 is not intended for use as an apnea monitor.

Safety Information, Warnings and Cautions

CAUTION: Radical-7 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. Refer to Operator's Manuals of Root, Patient SafetyNet and Kite for additional safety information, warnings, and cautions.

Safety Warnings and Cautions

WARNING: Do not use the Radical-7 if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.

WARNING: Do not adjust, repair, open, disassemble, or modify the Radical-7. Damage to the device may result in degraded performance and/or patient injury.

WARNING: Do not start or operate Radical-7 unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.

WARNING: Do not place the Radical-7 or accessories in any position that might cause it to fall on the patient.

WARNING: Only use Masimo authorized devices with Radical-7. Using unauthorized devices with Radical-7 may result in damage to the device and/or patient injury.

WARNING: All sensors and cables are designed for use with specific devices. Verify the compatibility of the device, cable, and sensor before use; otherwise degraded performance and/or patient injury can result.

WARNING: Do not use the Radical-7 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 Radical-7 during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: Radical-7 may be used during defibrillation. However, to reduce the risk of electric shock, the operator should not touch the Radical-7 during defibrillation.

WARNING: When positioned on a flat surface, the device should be secured with a mounting system recommended by Masimo.

WARNING: To reduce the risk of explosion, only replace battery with Masimo supplied parts.

WARNING: To protect against injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this Operator's Manual.
- Do not attempt to clean Radical-7 while monitoring patient.

WARNING: To protect from electric shock, always remove the sensor and completely disconnect Radical-7 before bathing the patient.

WARNING: To ensure safety, avoid placing anything on the device during operation.

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

CAUTION: Do not place the Radical-7 where the controls can be changed by the patient.

CAUTION: Electric shock hazard: Do not open the Radical-7 cover except to replace the battery or batteries.

CAUTION: To ensure patient electrical isolation, only dock to Masimo devices that have been designed for Radical-7.

CAUTION: Do not place Radical-7 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 Radical Docking Station. 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 Radical-7 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: Do not monitor more than a single patient at a time on Radical-7.

Note: Use and store the Radical-7 in accordance with specifications. See the Specifications chapter in this manual.

Kite

WARNING: Do not adjust, repair, open, disassemble, or physically modify the Kite host device. Injury to personnel or equipment damage could occur. Return the Kite host device for servicing.

Performance Warnings and Cautions

WARNING: Radical-7 should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: The Radical-7 and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

WARNING: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check Radical-7 for proper functioning.

WARNING: Variation in hemoglobin measurements may be profound and may be affected by sample type, body positioning, as well as other physiological conditions. As with most hemoglobin data, Radical-7 trend data should be scrutinized in light of a specific patient condition. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional data.

WARNING: Do not use Radical-7 as an apnea monitor. Radical-7 does not have alarms to alert you when you are not breathing properly.

WARNING: Radical-7 should not be used used as a replacement or substitute for ECG-based arrhythmia analysis.

WARNING: Radical-7 may be used during defibrillation; however, the display may require up to 15 seconds to return to normal operation.

WARNING: Radical-7 may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: Radical-7 may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: Avoid placing Radical-7 against a surface that may cause the alarm to be muffled. This may result in the inability to detect the audible alarms.

WARNING: Radical-7 may not fully charge in a high ambient temperature environment.

WARNING: Do not place containers with liquids on or near Radical-7. Liquids spilled on Radical-7 may cause it to perform inaccurately or fail.

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 Radical-7 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: Display parameter may not be accurate when a low SIQ message is provided. Clinicians should consider additional information to supplement values to completely understand the patient's condition.

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

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

WARNING: Optical, pleth-based measurements (e.g. SpO_2, SpHb, SpOC, SpMet, SpCO, and RRp) can be affected by the following:

- Improper sensor application or use of use of incorrect sensor.
- Blood pressure cuff applied to the same arm as the sensor site.
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous congestion.

- Abnormal venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg position).
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Moisture, birthmarks, skin discoloration, nail aberration, deformed fingers, or foreign objects in the light path.
- Elevated levels of bilirubin.
- Physiological conditions that can significantly shift the oxygen disassociation curve.
- A physiological condition that may effect vasomotor tone or changes in vasomotor tone.
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.

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:

- Intravascular dyes, such as indocyanine green or methylene blue.

- Excessive venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg position).
- 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 RRa measurements may be caused by:

- Improper sensor application or use of incorrect sensor.
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).

- Motion artifact.
- Excessive ambient or environmental noise.

WARNING: Inaccurate RRp measurements may be caused by:

- Low arterial perfusion.
- Motion induced artifact.
- Severe anemia.
- Arrhythmia

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

WARNING: A functional tester cannot be used to assess the accuracy of the Radical-7.

CAUTION: The RRp value may be inaccurate under conditions where the pulse rate is less than two times the respiration rate. The following conditions may include, but it's not limited to: patients with high respiration rate and low heart rate, or patients with specific medical conditions such as sick sinus syndrome, bradycardia due to any primary cardiac conditions as well as secondary condition from beta blockers, digoxin etc.

CAUTION: Respiration rate provides an indicator of central ventilatory drive and not a direct indication that air is moving through the upper airway.

CAUTION: If using Radical-7 during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.

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

CAUTION: The device must be configured to match your local power line frequency to allow for the cancelation of noise introduced by fluorescent lights and other sources.

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: For home use, ensure that the Radical-7 alarm can be heard from other rooms in the house, especially when noisy appliances such as vacuum cleaners, dishwashers, clothes dryers, televisions, or radios are operating.

CAUTION: When Silence Duration is set to All Mute or All Mute with Reminder on Radical-7, there will be no audible alarms on Radical-7 or Patient SafetyNet; however, there will be visual alarms displayed on Radical-7 and Patient SafetyNet view.

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 Radical-7.

CAUTION: Do not place the Radical-7 on electrical equipment that may affect the device, preventing it from working properly.

CAUTION: Failure to charge Radical-7 promptly after a Low Battery alarm may result in the device shutting down.

CAUTION: To minimize electromagnetic interference, only use a SatShare cable that has a ferrite bead installed.

CAUTION: During SatShare operation, alarms may be muted on the Radical-7. Use the multi-parameter monitor for audible alarms during SatShare operation.

CAUTION: Ensure Radical Docking Station is connected to AC power source when charging Radical-7.

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

CAUTION: In order to establish and maintain Radical-7'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 the Radical-7 is used.

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: If the Radical-7 stops communicating with Root, parameters and measurements will not show on the Root display; however, this will not affect Radical-7's ability to monitor the patient.

Note: It is recommended that Radical-7 battery is fully charged prior to use.

Note: Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.

Note: Additional information specific to the Masimo sensors compatible with Radical-7, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).

Note: Physiological conditions that result in loss of pulsatile signal may result in no PaO_2, SpHb, SpOC, SpCO, SpMet, and RRp readings.

Note: Radical-7 is provided with a Wi-Fi signal indicator as an indication of Wi-Fi communication.

Note: Radical-7's alarm capabilities have been designed to be independent of the Wi-Fi communication feature in order to preserve Radical-7's primary alarms.

Note: Always charge Radical-7 when it is not in use to ensure that the Radical-7 battery remains fully charged.

Note: All batteries lose capacity with age, thus the amount of run time at Low Battery will vary depending upon the age of the Battery Module.

Note: The 3D Desat Index™ alarm is intended as an adjunct alarm rather than in place of the Low SpO_2 alarm.

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

Note: When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the Radical-7 is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.

Note: SatShare signals are ideal simulated waveforms corresponding to the calculated saturation and pulse rate values and do contain all of the information contained in physiological waveforms. The multi-parameter patient monitor decodes these signals into saturation and pulse rate values.

Kite

WARNING: Kite does not generate or manage alarms. The connected device's alarms, used in conjunction with clinical signs and symptoms, are the primary sources for determining that an alarm condition exists.

CAUTION: Kite is not a primary display. Medical decisions should be made using data from the primary display of a device in conjunction with clinical signs and symptoms.

CAUTION: Kite is intended to operate across the facility's network. Unanticipated failure or alteration of network components (including but not limited to: disconnection or malfunctioning of a networking device/switch/router/ethernet cable) may result in loss of connectivity of Kite to other hospital systems. Altering or making changes to the hospital network should be done with proper knowledge.

Patient SafetyNet

Note: The wireless communication status between Radical-7 and Patient SafetyNet is displayed by Patient SafetyNet.

Cleaning and Service Warnings and Cautions

WARNING: Do not attempt to remanufacture, recondition or recycle the Radical-7 as these processes may damage the electrical components, potentially leading to patient harm.

WARNING: To avoid electric shock, always turn off the Radical-7 and physically disconnect the AC power and all patient connections before cleaning.

WARNING: Electrical Shock Hazard: The battery should be installed and/or removed from the Radical-7 by qualified personnel only.

WARNING: Do not incinerate the Radical-7 Battery. The battery should be properly disposed according to local laws and regulations.

WARNING: Fire Hazard: To protect against fire hazard, on docking station replace only with fuses of same type, current rating, and voltage rating.

WARNING: Electrical Shock Hazard: The Docking Station battery if provided should be installed and/or removed from the Docking Station only by qualified personnel.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the Radical-7 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 Radical-7, 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 Radical-7. These substances affect the device's materials and device failure can result.

CAUTION: Do not submerge Radical-7 in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage Radical-7.

CAUTION: To prevent damage, do not soak or immerse Radical-7 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: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

WARNING: In accordance with international telecommunication requirements, the frequency band of 2.4 GHz and 5.15 to 5.25 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

CAUTION: Dispose of used batteries according to required country or regional instructions.

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

CAUTION: External device connections to the SatShare port must be IEC-60601-1 compliant.

Note: Cleared Use Only: The device and related accessories have obtained CE Mark for noninvasive patient monitoring and may not be used for any processes, procedures, experiments or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the instructions for use or labeling.

Note: Use Radical-7 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.

Note: This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Note: Users are advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5.25-5.35 GHz and 5.65-5.85 GHz and that these radars could cause interference and/or damage to LE-LAN devices.

Note: In accordance with FCC requirements, radio accessories on Radical-7 cannot be attached directly to the patient using any accessory containing metal components.

Note: Change or modifications that are not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Chapter 1: Technology Overview

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

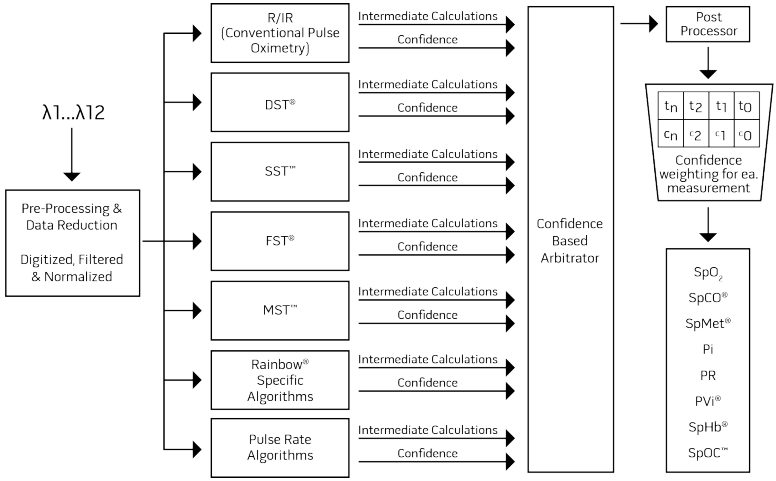
Signal Extraction Technology® (SET®)

Masimo Signal Extraction Technology's signal processing differs from that of conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise).

Masimo SET® pulse oximetry utilizes parallel engines and adaptive filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET® signal processing algorithm, Discrete Saturation Transform® (DST®), in parallel with Fast Saturation Transform (FST®), reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

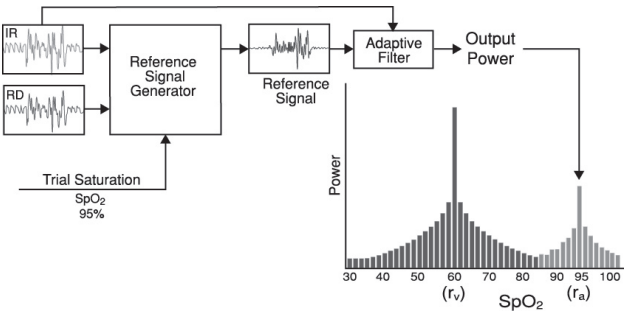
Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.



Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (SpO2)

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
2. The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Successful Monitoring for SpO2, PR and Pi

Stability of the SpO_2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each.

The stability of the readings over time is affected by the averaging time being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer averaging times delay the response of the oximeter and reduce the measured variations of SpO_2 and pulse rate.

Functional Oxygen Saturation (SpO2)

The Radical-7 is calibrated to measure and display functional oxygen saturation (SpO_2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.

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

General Description for Pulse Rate (PR)

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

General Description for Perfusion Index (Pi)

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

General Description for Pleth Variability Index (PVi)

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

PVi may show changes that reflect physiological factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.

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

Citations for Pleth Variability Index (PVi)

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.*

General Description for Respiration Rate (RRp)

Respiration rate can be determined by the plethysmographic waveform (RRp). This method measures respirations per minute (rpm) based on cyclic variation in photoplethysmogram (i.e. pleth or PPG) to establish a respiration rate measurement.

Signal IQ

The Signal IQ provides an indicator of the assessment of the confidence in the displayed SpO_2 value. The SpO_2 SIQ can also be used to identify the occurrence of a patient's pulse.

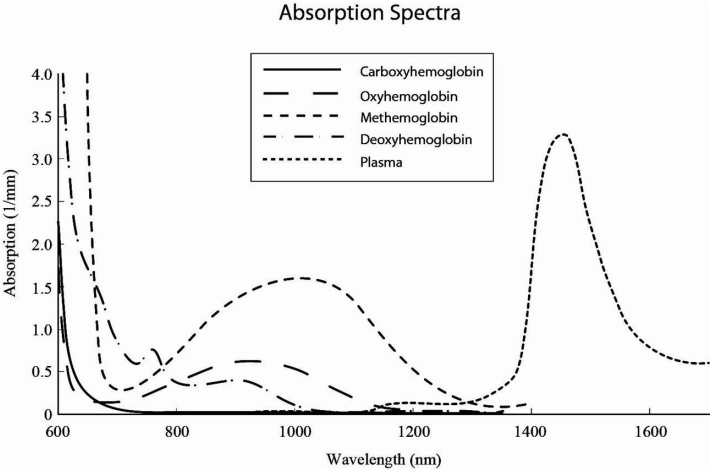
With motion, the plethysmographic waveform is often distorted and may be obscured by noise artifact. Shown as a vertical line, the SpO_2 SIQ coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Signal IQ identifies the timing that the algorithms have determined for the arterial pulsation. The pulse tone (when enabled) coincides with the vertical line of the SpO_2 SIQ.

The height of the vertical line of the SpO_2 SIQ provides an assessment of the confidence in the measurement displayed. A high vertical bar indicates higher confidence in the measurement. A small vertical bar indicates lower confidence in the displayed measurement. When the Signal IQ is very low, this suggests that the accuracy of the displayed measurement may be compromised. See ***About the Status Bar*** on page 54.

rainbow Pulse CO-Oximetry Technology

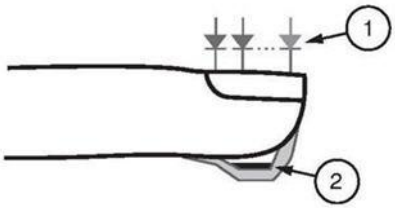
rainbow Pulse CO-Oximetry technology is governed by the following principles:

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 Radical-7 uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma.

The Radical-7 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 Radical-7 for calculation.



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

Once Radical-7 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 Radical-7 (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 Radical-7. 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 noninvasive method of measuring the levels of total hemoglobin (SpHb) in arterial blood. It relies on the same principles of pulse oximetry to make its SpHb measurement.

Successful Monitoring for SpHb

A stable SpHb reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the

measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. See ***Safety Information, Warnings and Cautions*** on page 11 and ***Troubleshooting Measurements*** on page 113.

General Description for Total Arterial Oxygen Content (CaO2)

Oxygen (O_2) is carried in the blood in two forms, either dissolved in plasma or combined with hemoglobin. The amount of oxygen in the arterial blood is termed the oxygen content (CaO_2) and is measured in units of ml O_2/dL blood. One gram of hemoglobin (Hb) can carry 1.34 ml of oxygen, whereas 100 ml of blood plasma may carry approximately 0.3 ml of oxygen*. The oxygen content is determined mathematically as:

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

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

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

$$SpO_2 = 1.02 \times HbO_2$$

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

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 Radical-7 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™)

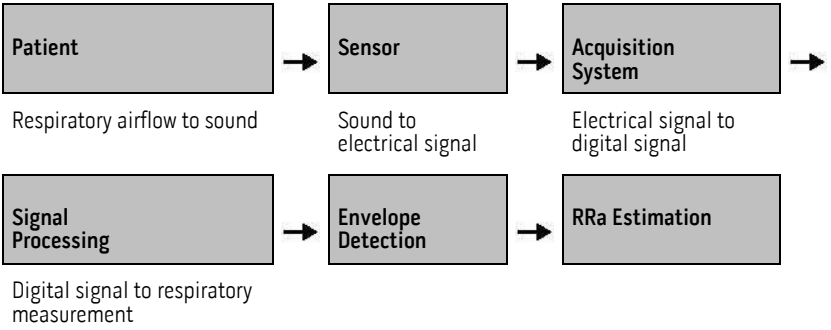
rainbow Acoustic Monitoring (RAM) continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Sensor, which is applied on the patient's neck, translates airflow sounds generated in the upper airway to an electrical signal that can be processed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

The following chapter contains the Radical-7 descriptions, including descriptions of the Handheld monitor, the Standalone monitor (Docking Station), and the optional SatShare monitor interface.

General System Description

The Radical-7 system includes the following:

1. Device
2. Patient Cable
3. Sensor

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

Functionality of the Radical-7

The Radical-7 provides the functionality of three devices in one:

Handheld Pulse Oximeter

The Handheld contains the majority of the device features. All measurements and device status data are displayed on the touchscreen. All user input is performed through the touchscreen and control buttons. The sensor cable connector is located on the Handheld.

RDS Docking Station

The Handheld snaps into the Docking Station to provide a fully featured Standalone Monitor. The Docking Station connects to AC power for standalone operation or charging of the Handheld. An optional Docking Station battery is available. The Standalone features a Nurse Call interface, analog output, and serial output.

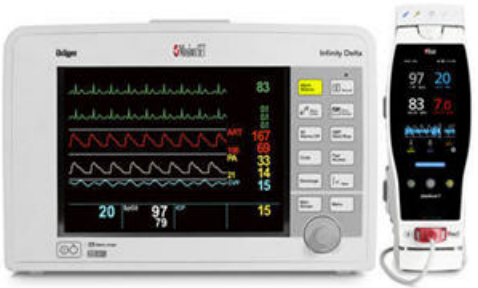
Root

The Handheld snaps into Root. Root charges the Handheld and displays Handheld parameters.

For complete information, see the Operator's Manual for Root.

Monitor Interface

Utilizing a SatShare cable, the standalone Radical-7 also interfaces with the SpO_2 input of a validated multi-parameter patient monitor, instantly upgrading the conventional pulse oximetry to Masimo SET® pulse oximetry.



The SatShare cable attaches to the back of the Radical Docking Station.

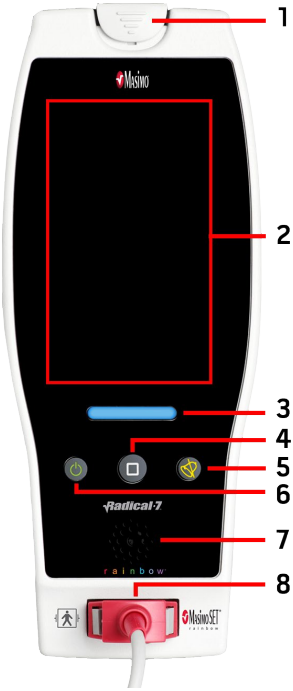
SatShare cables are available to interface with most multi-parameter patient monitors.

Handheld

All user input and displays are controlled by this component. The patient cable connects into the connector on the Handheld device. The Handheld is battery powered and can be used either as a transport monitor or as a Handheld Pulse CO-Oximeter for spot checks.

Handheld Front View

The following figure numbers and corresponding table describe the hardware features of the Radical-7.



1. Handheld Release button
Press downwards to remove Radical-7 from the docking station or Root.

2. Touchscreen Display
Provides a user interface to view and change settings.

3. Profile button
Provides instant access to the Profile Screen. See ***Chapter 5: Profiles*** on page 99.

4. Home button
Provides instant access to the *Main Screen*.

5. Alarm Silence Button
Temporarily silences alarms. See ***Silencing the Alarms*** on page 104.

6. Power button
Turns Radical-7 on or off or places in standby mode.

7. Speaker
Provides audio alarms and feedback.

8. Patient Cable Connector
Provides a connection to a patient cable or sensor.

CAUTION: Refer to the Directions for Use for each type of sensor before applying it to patients.

Handheld Back View

The Handheld back panel features the connection to the Docking Station, an accessory mount for the pole clamp accessory, and access to the Handheld battery pack.

1. Connector
The Handheld interfaces with the Docking Station through this connector.

2. Pole Clamp
The optional Pole Clamp accessory attaches to this holder. See the Directions for Use of the Pole Clamp accessory for attachment instructions.

3. Battery Compartment
The Handheld is powered by a lithium-ion battery located in this compartment. For battery care and replacement, see ***Battery Operation and Maintenance*** on page 149.

Docking Station

When the Handheld is placed into a Docking Station, the two components become a full-featured Standalone system. In this manual, when the Handheld and an RDS Docking Station are connected, they are referred to as *Standalone*. The Standalone acts as a battery charger for the Handheld and has AC power connection capabilities. If the AC power from the wall outlet is temporarily interrupted, then the battery in the Handheld allows for continuous operation. The Standalone can also interface with serial devices, Nurse Call or analog output devices, and multi-parameter patient monitors through a SatShare cable.

There are four (4) models of compatible Docking Stations available: RDS-1, RDS-1B, RDS-2, and RDS-3. RDS-1 and RDS-3 are optionally available with SafetyNet capability.

There are two (2) models of Root available: Root and Root with noninvasive blood pressure and temperature (NIBPT). All Root devices are available with SafetyNet capability.

The following table lists which features are available for each type of dock.

Docking Station Physical Features	RDS-1	RDS-1B	RDS-2	RDS-3	Root	Root NIBPT
AC Power Input	■	■	■	■	■	■
SatShare Interface	■	■				
Serial RS-232 Interface	■	■		■		
Nurse Call/Analog Output Interface	■	■		■	■	■
12-hour extended battery		■				
Automatic Display Rotation Support (Gravity Detector)	■	■		■		
Docking Station Battery Charging Indicator	■	■		■	■	■
Handheld Battery Charging Indicator	■	■	■	■	■	■
Visual (Red) Alarm Indicator	■	■		■		
AC Power Indicator	■	■	■	■	■	■
Docking Indicator	■	■		■		

To determine the RDS Docking Station being used with Radical-7, RDS-1 and RDS-1a have a SatShare Interface connector on the rear, RDS-2 and RDS-3 does not. See ***Docking Station Back Panel*** on page 39.

Docking Station Front View

1. Handheld Battery Charging indicator - The Handheld Battery Charging Indicator is illuminated when the Handheld battery is connected and charging. The indicator blinks just prior to charging. The Charging Indicator does not illuminate when the battery is fully charged or when the battery is not present.

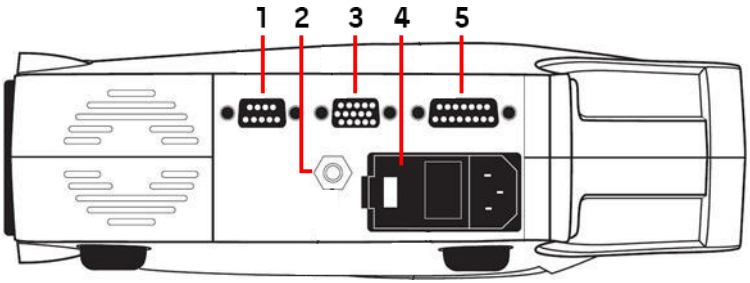
2. Visual Alarm Indicator - The Visual Alarm Indicator is illuminated when an alarm condition is active and the Alarm Status Indicator is shown on the screen of the Handheld.

3. AC Power Indicator - The AC Power Indicator is illuminated when the Radical-7 Docking Station is plugged into AC line power.

4. Docking Indicator - The Docking Indicator is illuminated when the Handheld device is turned on and is properly interfaced to a Docking Station.

Note: When the Docking Station is first turned on, all indicator LEDs initially turn on and off.

Docking Station Back Panel



1. Serial Output connector - Provides connection with a serial device, including a serial printer, a monitoring system, or PC to the Radical-7. The data is provided in standard RS-232C format. All external device connections to the Serial Output connector must be IEC-60950 compliant.

2. Equipotential Ground connector - Provides optional functional earthing for Radical-7 to eliminate potential differences between the earth connections for Radical-7 and another medical device. The use of the Equipotential Ground Connector should be in accordance with IEC 60601-1.

3. Analog Output/Nurse Call connector - Provides connection to interface with an analog output device, such as a chart recorder or Nurse Call system. All external device connections to the Analog Output/Nurse Call connector must be IEC-60950 compliant.

See ***Serial Interface Specifications*** on page 135.

4. Power Entry module - Contains the input connector for AC power and two fuses. The AC input provides power to the system from the AC line.

Note: Always connect the Docking Station 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. To disconnect the device from AC power, first disconnect the power cord from the power outlet, rather than from the device.

5. SatShare Cable connector (RDS-1 only) - Used to connect a SatShare cable to the SpO_2 input connector of a validated multi-parameter patient monitor. All external device connections to the SatShare Cable Connector must be IEC-60601-1-1 compliant. SatShare cables are available to interface with most major multi-parameter patient monitors. Check the label on the SatShare cable and the SatShare Directions for Use to ensure that the correct cable is used for each type of patient monitor.

Visit ***www.masimo.com*** for the latest SatShare cables and validated devices.

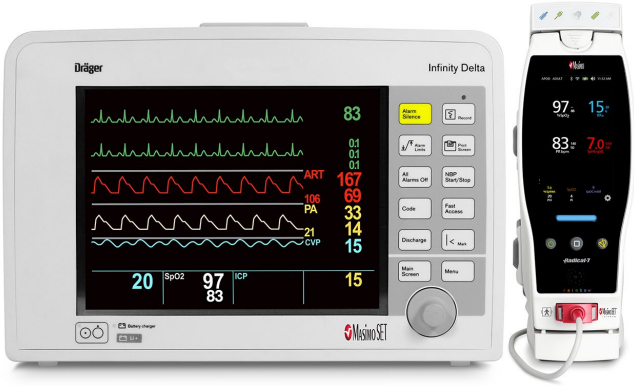
Root

When the Radical-7 Handheld is placed (docked) into Root and Root is powered on, Root displays the Radical-7 parameters. Root acts as a battery charger for the Handheld.

For complete information about using Radical-7 with Root, refer to the Operator's Manual for Root.

Monitor Interface With SatShare

The Radical-7 has a unique SatShare interface that links to most existing validated multi-parameter patient monitors through a SatShare cable that connects to the rear of the Docking Station.



- Upgrades any approved and validated monitor to Masimo SET® performance by using the calculated SpO_2 and pulse rate determined by Radical-7 to simulate an ideal plethysmograph waveform, which is sent to the validated multi-parameter patient monitor.
- Connects into the SpO_2 patient cable or SpO_2 input connector of the multi-parameter patient monitor.

See ***SatShare Setup and Use*** on page 45.

Chapter 3: Setup

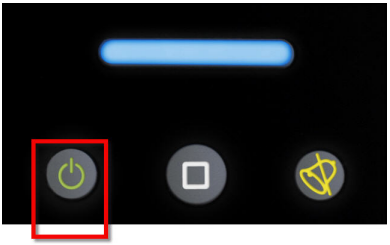
The following chapter contains information about setting up the Radical-7 with the Docking Station before use. For information on setting up Root, refer to the Operator's Manual for Root.

Unpacking and Inspection

To unpack and inspect the device

1. Remove the device 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 Technical Service Department. See ***Return Procedure*** on page 154.

Powering Radical-7 On, Standby, and Power Off



Use the *Power Button* to Power On, put the Radical-7 in Standby Mode, or completely Power Off.

State	Description
Power On	Press and release the *Power Button*. A single audible tone sounds, the Power, Home and Alarm Silence buttons illuminate and the device powers up.
Standby Mode	Press and hold the *Power Button* for three (3) seconds until a single audible tone sounds, then release the button. Standby Mode conserves power while enabling a quicker startup sequence. To take the Radical-7 out of Standby Mode, press the *Power Button*.
Power Off	Press and hold the *Power Button* for eight (8) seconds, until two (2) audible tones sound. The *Power Button* will flash on and off and the display will indicate the device is powering off. Power Off completely shuts down Radical-7 and results in a longer startup sequence.

Initial Battery Charging

To charge the Handheld and Docking Station:

1. Snap the Radical-7 into the Docking Station.
2. Plug in the AC power cord to the Docking Station power entry module. Make sure it is securely plugged in.
3. Plug the AC power cord into an AC power source.
4. Verify that the Handheld batteries are charging.
   - The Battery Charging indicator on the Docking Station flashes prior to charging and remains illuminated while the batteries are charging. See ***Docking Station Front View*** on page 38 and ***AC Power Indicator*** on page 55.

To charge the Handheld using Root:

1. Snap the Radical-7 into Root. Make sure Root is securely plugged into an AC power source.
2. Verify that the Radical-7 batteries are charging.
   - When properly connected, the Radical-7 Charging Indicator light will illuminate. A Radical-7 Battery icon will also appear in the Root Status Bar. Refer to the Operator's Manual for Root for Charging Indicator Light and Status Bar icon information.

Docking Station Setup

1. Place the Docking Station on a stable, hard, flat surface near the patient. Always place the Docking Station on a dry surface.
2. Maintain a minimum of 3 cm (1 inch) free space around the Docking Station and make sure that the Radical-7 speaker (in Standalone configuration) will not be covered when docked.
3. Snap the Radical-7 into the Docking Station.
4. If the Radical-7 is not yet turned on, press the power button on the Radical-7 to power it on.
5. When properly connected, the Radical-7 Charging Indicator light will illuminate on the Docking Station.

   CAUTION: Do not place the Radical-7 where the controls can be changed by the patient.

Docking Station Power Requirements

Refer to the Radical Docking Station Directions for Use for additional information and specifications.

- Always use a hospital-grade, AC power cable to connect the Docking Station to an AC power source.
- Do not connect the Docking Station to an AC outlet that is controlled by a switch because the power to the Docking Station may be inadvertently switched off.
- Verify the AC power voltage and line frequency before use.

- Verify that the power source can provide an adequate power rating as indicated on the rear panel of the Docking Station.
- The Radical-7 is designed to operate on 100 to 240V AC, 47-63 Hz.
- The Radical-7 is rated at 55 VA max.
- Connect a hospital-grade power cable (IEC-320 connector type at the device) to the Power Entry module on the Docking Station.
- Connect the power cable to an AC power source.
- Ensure that the device is adequately powered by verifying that the AC power indicator on the Docking Station is illuminated.
- See ***Safety Information, Warnings and Cautions*** on page 11.

Root Setup

Refer to the Operator's Manual for Root for complete setup instructions.

1. Place Root on a stable, hard, flat surface near the patient. Always place Root on a dry surface.
2. Turn on Root.
3. Snap the Radical-7 into Root.
4. If the Radical-7 is not yet turned on, press the power button on the Radical-7 to power it on.
5. When properly connected, the Root display will show active measurements and parameters from Radical-7.

CAUTION: Do not place the Radical-7 where the controls can be changed by the patient.

SatShare Setup and Use

Parameter values from the Radical-7 can be displayed on a validated multi-parameter monitor through the SatShare feature. The SatShare feature provides an ideal, simulated plethysmographic waveform that corresponds to the parameter values determined by the Radical-7. This waveform may be used to display these values on multi-parameter monitors through the multi-parameter oximetry sensor or input connector.

It is recommended that the Radical-7 be positioned near the multi-parameter monitor, with the Radical-7 screen displaying the plethysmographic waveform and the parameter values. Refer to the instructions for use provided with the multi-parameter monitor. See ***Compliance*** on page 133.

To set up for use with SatShare interface:

1. Select the SatShare cable that is appropriate for the multi-parameter monitor. For the latest list of available SatShare cables and validated devices, see ***www.masimo.com***.
2. Connect the labeled end of the SatShare cable to the SatShare Cable connector on the Docking Station. See ***Docking Station Back Panel*** on page 39. For a secure connection, tighten the cable connector screws.
3. Connect the other end of the SatShare cable to one of the following:
    - Sensor connector of the multi-parameter monitor cable

- Directly to the multi-parameter monitor

4. Verify that the multi-parameter monitor recognizes the SatShare cable.
5. As appropriate, configure alarm limits on the multi-parameter monitor.
6. Set the averaging time for the multi-parameter monitor to its lowest setting (or fastest response). The ideal waveform for the Radical-7 requires additional averaging by the monitor. If the averaging time of the multi-parameter monitor is not changed, the time to display physiological changes in saturation on the monitor is increased with SatShare. However, the delay can be minimized by reducing the averaging time on the multi-parameter monitor.

   While in SatShare mode, if there are any significant discrepancies between the readings from Radical-7 and those on the monitor displaying the values obtained from SatShare, the values reported by the Radical-7 are considered the correct values.

   It is possible to use the Standalone with SatShare while the Docking Station is not connected to AC power. However, in this configuration, battery run time is reduced. See ***Battery Operation and Maintenance*** on page 149.
7. On the Radical-7, turn on the *SatShare Numbers* option. See ***Device Output*** on page 94.
8. If displaying the simulated waveform is not desirable, it is recommended to turn off the plethysmographic waveform display of the multi-parameter patient monitor. See ***Serial Interface Specifications*** on page 135.

Philips, Agilent, or HP VueLink Setup

To set up for use with VueLink compatible monitors (Philips, Agilent, or HP):

1. On the Radical-7, on the *Device Output* screen, for the *Serial* option, select **HP VueLink**.
2. Connect one end of the VueLink cable to the Serial Output connector on the Docking Station.
3. Connect the other end of the VueLink cable to the VueLink module and insert the module into the VueLink compatible monitor rack.

   - The SpO_2 and pulse rate values appear on the VueLink compatible monitor.
4. In order for the plethysmographic waveform to be displayed on the VueLink compatible monitor, and for the VueLink monitor to convey alarm conditions measured by the Radical-7, the VueLink compatible monitor must be properly configured.
5. See the instructions for use provided with the VueLink compatible monitor and the VueLink module. See ***Compliance*** on page 133 and ***Serial Interface Specifications*** on page 135.

SpaceLabs Flexport Setup

To set up for use with SpaceLabs Flexport

1. On the Radical-7, on the *Device Output* screen, for the *Serial* option, select **SpaceLabs Flexport**.
2. Connect one end of the Spacelabs Flexport cable to the Serial Output connector on the Docking Station.

3. Connect the other end of the Spacelabs Flexport cable to the Spacelabs Universal Flexport connector.

   The SpO_2 and pulse rate values appear on the Spacelabs screen.
4. In order for the plethysmographic waveform to be displayed on the Spacelabs screen, and for the Spacelabs monitor to convey alarm conditions measured by the Radical-7, the Spacelabs monitor must be properly configured.
5. See the instructions for use provided with the Spacelabs monitor. See ***Compliance*** on page 133 and ***Serial Interface Specifications*** on page 135.

Chapter 4: Operation

The following chapter contains information about using the Radical-7. The Radical-7 Handheld, Docking Station, and Standalone should not be operated outside the environmental conditions listed in the specifications section ***Environmental*** on page 131.

Using the Touchscreen and Buttons

1. Main Screen

To access other screens, touch a value on the Main Screen. See ***About the Main Screen*** on page 53.

2. Profiles button

To the access the *Profiles* screen, press the Profiles button. See ***Chapter 5: Profiles*** on page 99.

3. Alarm Silence button

To temporarily silence audible alarms, press the Alarm Silence button. See ***Silencing the Alarms*** on page 104.

4. Home button

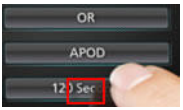
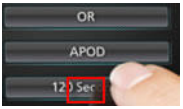
To return to the *Main Screen* from any screen, press the Home button.

5. Power button

Turns On, Off, and places the Radical-7 in Standby Mode. See ***Powering Radical-7 On, Standby, and Power Off*** on page 43.

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 Radical-7.

Action	Illustration	Example	Description
Press/select			Press/select and release. Action performed once finger is released.
Press/select and Hold			Press/select and hold. Action performed once hold duration is reached. A notification is displayed.
Swipe (Press/select and Move)			Press/select, move (left, right, up or down), and release. Moves an object across the display.
Flick			Press/select and quickly swipe (left, right, up or down), and release.
Pinch			Press/select, 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 57.	Press/select, 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 Radical-7 and the various ways to interact with each type of control.

Control	Applicable Actions	Description
Toggle	Slide knob	• Switches between toggle states

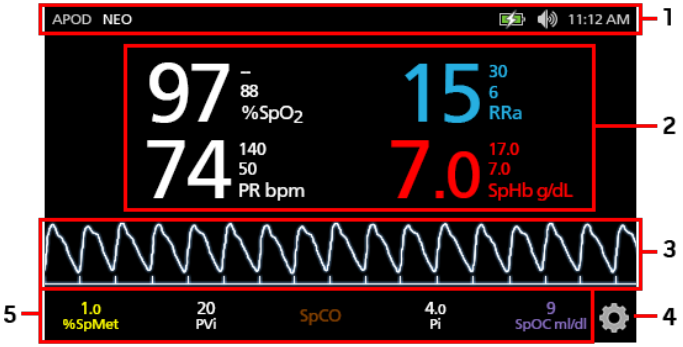
Control	Applicable Actions	Description
	Press left or right of toggle	• Quickly moves knob left or right
Labeled Toggle	Slide knob	• Switches between toggle states
	Press left or right of toggle	• Quickly moves knob left or right
	Press label	• Quickly moves knob left or right
Spinner	Press center (focused) tile	• When closed, expands spinner • When open, collapses spinner
	Swipe up or down	• When open, scrolls through spinner tiles
	Press unfocused tile	• When open, scrolls tile into center (focused) position
	Press anywhere outside spinner	• When open, collapses spinner
Slider	Slide knob	• Moves knob
	Press anywhere along slider path	• Quickly moves knob to tap position
Slider Spinner	Slide knob	• Moves knob
	Press anywhere along slider path	• Quickly moves knob to tap position
	Press center (focused) tile	• When closed, expands spinner • When open, collapses spinner
	Swipe up/down	• When open, scrolls through spinner tiles
	Press unfocused tile	• When open, scrolls tile into center (focused) position
	Press anywhere outside spinner	• When open, collapses spinner
Button	Press	• Performs action (as defined by the button description)
Icon Menu	Press tile	• Opens menu specified by tile

Control	Applicable Actions	Description
	Swipe left or right (anywhere)	• Scrolls icons left or right
	Press bottom indicator icon	• Quickly centers tile corresponding to indicator icon
Window	Press 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
	Press and hold	• Enables parameter and measurement drag and drop
Well	Press 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
	Press 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
	Press y-axis	• Opens parameter or measurement trend menu
Trend Zoom	Press '+'	• Increases time range
	Press '-'	• Decreases time range
	Press time label	• Resets time range to default

Control	Applicable Actions	Description
Alarm Silence icon	Press	• Silences all alarms
Audio Pause icon	Press	• Enables Audio Pause
Other Status Bar icons	Press	• Opens relevant menu
Back Arrow	Press	• Exits menu, abandons any changes

About the Main Screen

The *Main Screen* consists of different areas:



Ref.	Feature	Information
1	Status Bar	See ***About the Status Bar*** on page 54.
2	Parameter Display	See ***Understanding Windows*** on page 57.
3	Waveform View	See ***Waveform Views*** on page 57.
4	Main Menu	See ***Accessing Main Menu Options*** on page 67.
5	Well	See ***Understanding Windows*** on page 57.

About the Status Bar

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

Ref.	Feature	Description
1	Sensitivity Modes	Selecting this cycles through the available sensitivity modes, APOD, NORM and MAX. See ***Sensitivity Modes Overview*** on page 56.
2	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 99.
3	Wi-Fi	Provides access to the *Wi-Fi* screen. If this icon is visible, then Wi-Fi connectivity has been enabled. The icon itself also indicates the strength of the wireless signal. See ***Wi-Fi*** on page 89.
4	Bluetooth	Provides access to the *Bluetooth* screen. If this icon is visible, then Bluetooth connectivity has been enabled. See ***Bluetooth*** on page 89.
5	Radical-7 Battery Charge/AC Power Indicator	Displays charging status for Radical-7. 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 55 and ***Battery Charge Status Indicator*** on page 55.
6	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 86.

Ref.	Feature	Description
7	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 88.

AC Power Indicator

Whenever Radical-7 is ON and docked to Root or a Docking Station that is connected to AC power:

- **Docked to Docking Station -** The AC Power Indicator icon will appear on the Radical-7 display.
- **Docked to Root -** The AC Power Indicator icon will appear on the Root display.

When the AC Power Indicator icon is visible, the battery is currently charging. When the AC Power Indicator icon is completely Green, the battery is fully charged.

Touch the AC Power Indicator icon to view battery charge details. See ***Radical-7 Battery*** on page 90.

Battery Charge Status Indicator

When undocked from Root or the Docking Station, (disconnected from AC power), the Battery Charge Status Indicator icon provides a visual indication of the current battery charge condition. This icon above indicates the battery is fully charged (docked or undocked).

Note: When docked to Root, the indicator displays on the Root screen.

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.

Dock Radical-7 to the Docking Station or Root to charge the battery and prevent the device from powering off. When connected to power, the AC Power Indicator icon is displayed.

Touch the Battery Charge Status Indicator icon on Radical-7 or Root to view Radical-7 battery details. See ***Radical-7 Battery*** on page 90.

Sensitivity Modes Overview

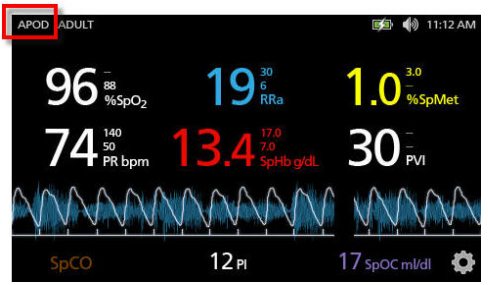
Three sensitivity levels enable a clinician to tailor the response of the Radical-7 to the needs of the particular patient situation. Access the menu by touching on the indicator in the upper left corner of the *Main Screen*. The sensitivity levels are as follows:

- **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 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 interpret and 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.

Changing Sensitivity Modes

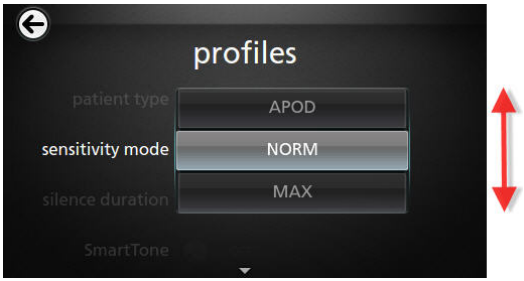
There are two ways to access the *Profiles* screen to change the sensitivity modes.

- Touch the text at the top left corner of the *Main Screen* as shown, to access the *Profiles* screen.



- From the *Main Menu*, touch the *Profiles* icon to access the *Profiles* screen. See ***Accessing Main Menu Options*** on page 67.

From the *Profiles* screen, select the desired mode by scrolling up or down. Then select **OK**.



Note: The device will revert to APOD mode after a power cycle. See ***Changing Profiles*** on page 99.

Using Screen Lock

When enabled, the *Screen Lock* feature may prevent unintentional interaction with the touchscreen. To enable or disable Screen Lock, see ***Access Control*** on page 91.

Using the Screen Lock feature

1. When turned on, any interaction with the touchscreen triggers the Screen Lock feature.
2. To bypass *Screen Lock* when it appears, press and hold the *Lock* icon until it unlocks.

Understanding Windows

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

Waveform Views

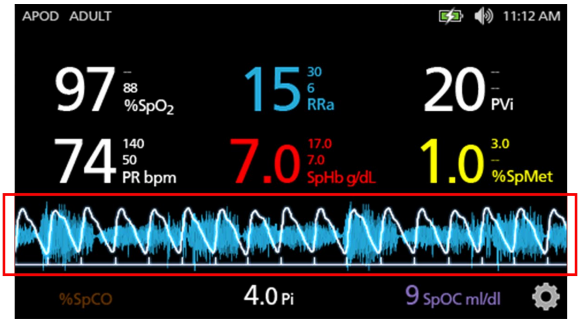
The following section contain information about the waveforms available in the *Trend Field* on the *Main Screen*.

Select Waveform

The *Trend Field* allows users to access various waveform views.

To access waveform views on the Display View screen

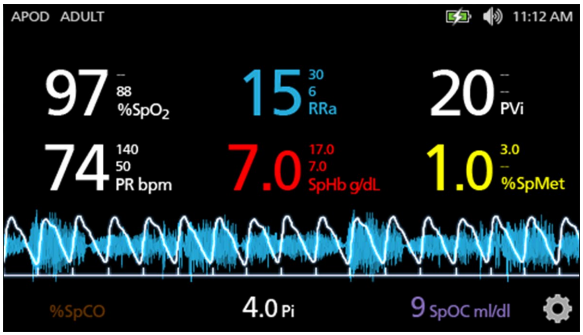
1. Press/select the **Trend Field**, as shown below.



2. The following screen appears.

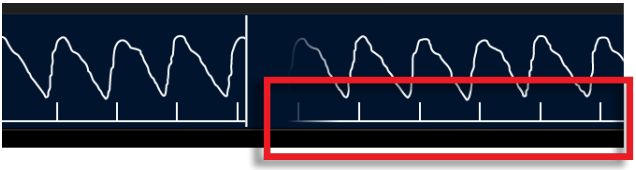
3. Swipe up or swipe down the available waveforms. Available waveforms include:
   - Pleth + Sig IQ
   - Pleth + Sig IQ + Acoustic
   - PVI Pleth + Sig IQ
   - PVI Pleth + Sig IQ + Acoustic
   - Acoustic
   - Any available parameter (SpO_2, Pi, PR, etc...)
4. Press/select the desired waveform option.

5. The *Trend Field* displays the specific waveform option that was selected.



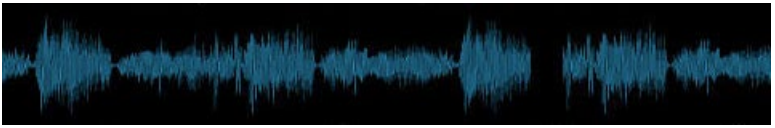
Signal IQ Indicators

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.



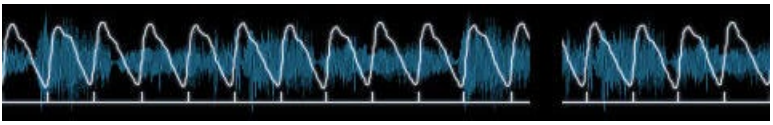
Acoustic Waveform View

The RRa waveform is located below the parameter values and above the *Well*. Acoustic Respiratory Rate (RRa) must be available for this feature to be shown. This view contains RRa waveform only.

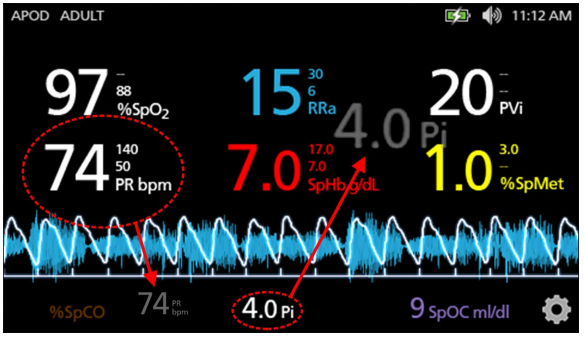


Pleth + Sig IQ + Acoustic View

The Pleth + Sig IQ + Acoustic waveform is located below the parameter values and above the *Well*. This view contains the Pleth waveform, signal quality indicators, and acoustic waveform (if RRa is available).



Customizing Windows



To change the size of parameter values on the Main Screen:

1. Press/select and hold any one of the parameters in the *Well* (Pi in this example). The well contains any parameters not displayed in the larger area above.
2. When the parameter value dims, shakes, and grows in size, drag and drop that parameter in the larger parameters above the waveform. See ***Trend Field*** on page 60.
3. The parameter value appears on the screen in a larger font. The device automatically configures the screen for optimal display of the parameter values.
4. To remove parameter values from the larger display, press and hold the larger parameter value (PR in this example), then drag and drop the parameter value to the *Well*.

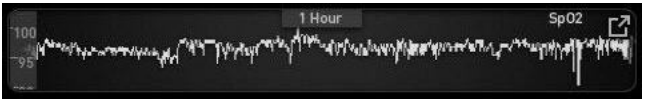
Customizing Trend Views

Trend Field

The *Trend Field* allows users to access various customizable views.

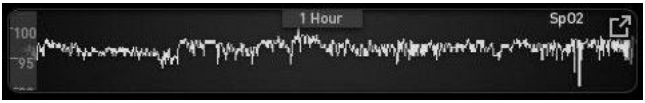
To access trend, waveform, or customize the views on the Display View screen

1. Touch the **Trend Field** (waveform) and swipe up or swipe down for the parameter trend options. See ***Select Waveform*** on page 58.
2. Select the desired parameter.
3. The *Trend Field* displays trend data specific to the parameter that was selected.



About Trend Views

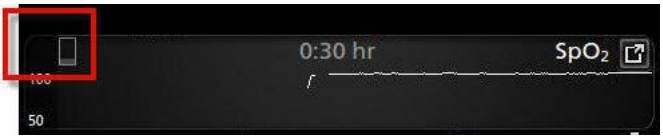
There are different ways to view trend information. The following is an example of trend information for SpO_2 as it appears within the *Display View* screen.



The following is an example of trend information for SpO_2 as it appears in the *Full Trend* screen.

Pulse Bar

The *Pulse Bar* is a visual indicator that conveys the detection of pulse and the Signal IQ (SIQ) displayed on each individual pulsation. The height of the bars provides an assessment of the confidence in the measurement displayed. See ***Signal IQ Indicators*** on page 59.

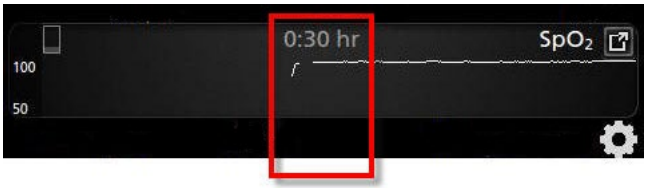


Changing the Time Interval of Trend Data

Users can change the time interval of trend data. The time options that can be selected are 10 minutes, 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, or 24 hours.

To change the time interval of trend data

1. From the *Display View*, in the *Trend Field*, or from the *Full Trend* screen, touch the *Time Interval* icon.

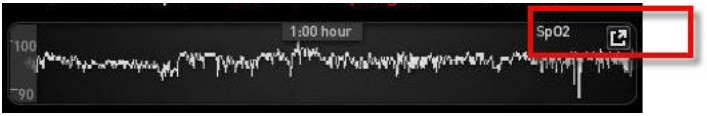


2. Scroll up or down to select a time interval.

Changing Between Trend Views

To toggle between Display View and Full Trend

1. From the *Display View*, in the *Trend Field*, touch the icon as shown below.

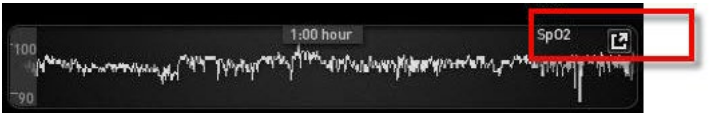


2. From the *Full Trend screen*, touch the icon as shown below.

Parameter Quick Trend View

This view displays the quick trend of the selected parameter over an adjustable period of time. The default is 1 hour. Enlarge the quick trend to the full trend view by touching the expand icon of the waveform display.

With a pinch gesture, using two fingers, the user can zoom in and out of the quick trend data within the *Trend Field*.



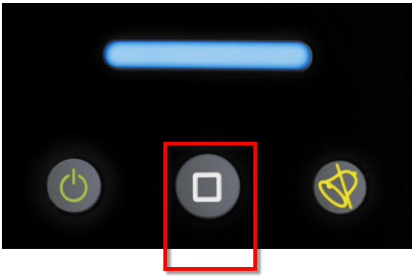
Manipulating View of Trend Data

On the *Full Trend* screen, with a pinch gesture, using two fingers, the user can zoom in and out of the trend time scale.

The user can add parameters to the *Trend* view by dragging and dropping parameters from the *Small Parameter* view. To add a parameter to the *Trend* view, press and hold any of the parameters inside the *Small Parameter* view, as shown below. When the parameter dims, shakes, and grows in size, drag and drop the parameter into the *Trend* view. See ***Customizing Windows*** on page 60.

To view past patient trend data, swipe the trend display to the left or to the right.

To exit a *Trend* view, press the **Home** button.

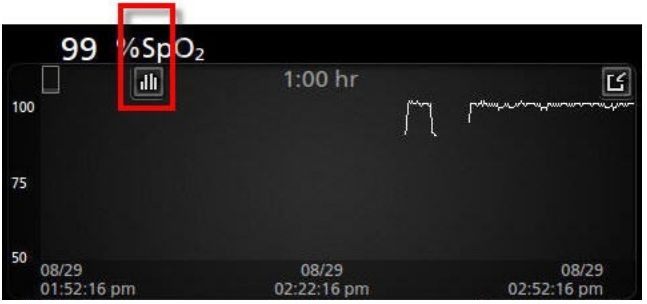


Using the Histogram Feature

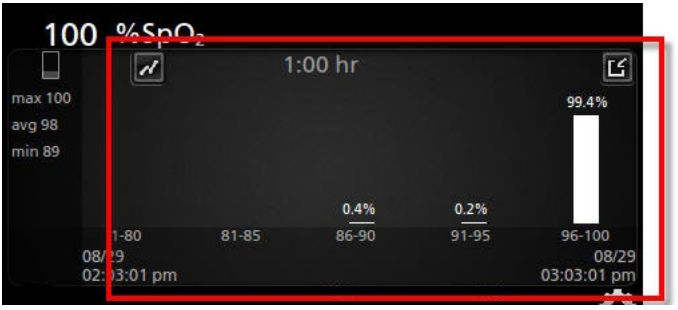
Users can view trend data using the Histogram feature. When turned on, the Histogram feature displays trend data as a histogram.

To turn on the Histogram feature

1. Navigate to a *Full Trend* screen. See ***Changing Between Trend Views*** on page 62.
2. The Histogram icon appears along the top of the *Trend Field*, as shown in the following example for SpO_2.

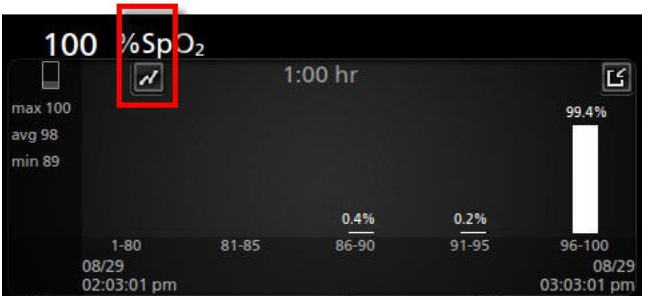


3. Touch the *Histogram* icon.
4. Trend data displays as a histogram.



To turn off the Histogram feature

- Touch the *Trends* icon, as shown.



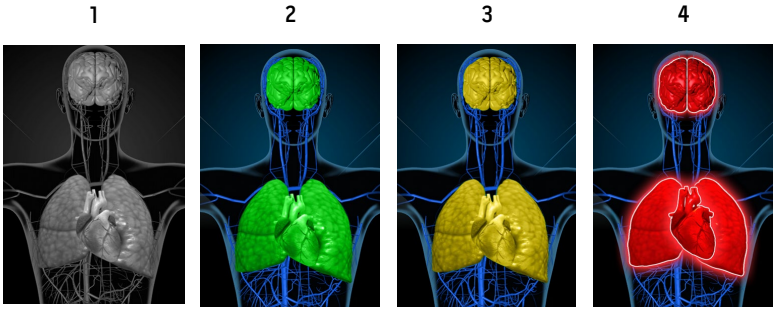
Visualization

When the Radical-7 is docked to Root, the Radical-7 provides a supplemental visualization of the alarm status for the connected Masimo medical technologies.

Note: The visualization may not be visible on Radical-7 depending on the layout settings in Root. Refer to the Operator's Manual for Root for layout setting information.

Visualizer Color Description Table

Colors are used to represent the status of monitoring and alarm conditions.



Ref	Color	Description
1	Gray	• Disconnected PoC device • No monitoring
2	Green	• Successful connection to PoC device • Monitoring: normal range
3	Yellow	• Successful connection to PoC device • Monitoring: Statuses, notifications, modifiers, notification devices not assigned to patient, or patient has not been successfully admitted to the Masimo System
4	Red	• Successful connection to PoC device • Monitoring: alarm range

Parameter Visualization Table

Monitoring and alarm status for various parameters and/or measurements are visualized using the following areas/organs on the screen:

Parameter or Measurement	Area Displayed on Visualization Screen
SpO_2	Lung
PR	Heart
Pi	N/A
PVi	Vascular
SpHb	Vascular
SpMet	Vascular
SpCO	Lung
RRa	Lung
SpOC	N/A
PSi*	Brain
rSO_2**	Brain

* For use with SedLine Sedation Monitor, when connected to Root.

** For use with O3 Regional Oximeter, when connected to Root.

Accessing Main Menu Options

To access Main Menu options, press the Main Menu icon in the bottom Right corner of the touchscreen:

The Main Menu options are:

Parameter Settings

See ***Parameter Settings*** on page 69.

Profiles

See ***Chapter 5: Profiles*** on page 99.

Sounds

See ***Sounds*** on page 86.

Device Settings

See ***Device Settings*** on page 86.

About

See ***About*** on page 95.

3D Alarms

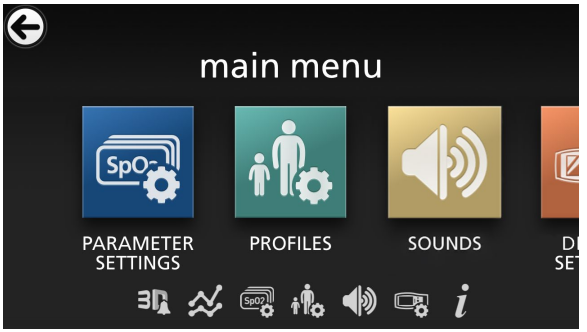
See ***3D Alarms*** on page 105.

Trends

See ***Trends*** on page 95.

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

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

Navigating Through Menus

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

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

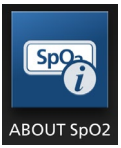
To return to the Main Screen, press the Home Button at any time.

About Parameter Information

Additional information about each parameter is available.

To access additional information about parameters:

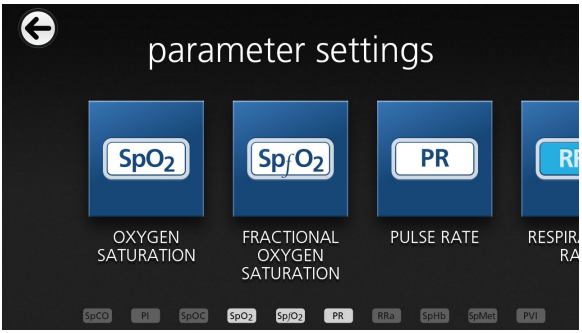
1. From the *Parameter Settings* screen, touch the **About** icon. The following is an example for SpO_2.



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

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, flick 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 71.
- See ***PR Settings*** on page 73.
- See ***Pi Settings*** on page 74.
- See ***PVi Settings*** on page 75.
- See ***Respiration Rate (RR) Settings*** on page 77.
- See ***SpHb Settings*** on page 80.
- See ***SpOC Settings*** on page 83.
- See ***SpMet Settings*** on page 84.

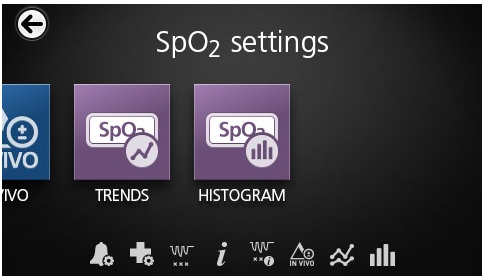
- See ***SpCO Settings*** on page 85.

Histogram Settings

Users can change the ranges of bins in the histogram view for each individual parameter displayed.

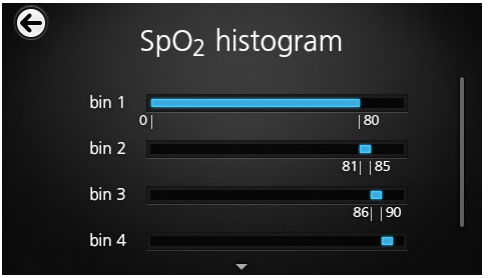
To access the histogram settings for any of the available parameters:

1. From the *Main Menu* screen, touch the *Parameter Settings* icon.
2. From any *Parameter Settings* screen, touch the *Histogram* icon (SpO_2 shown in this example).

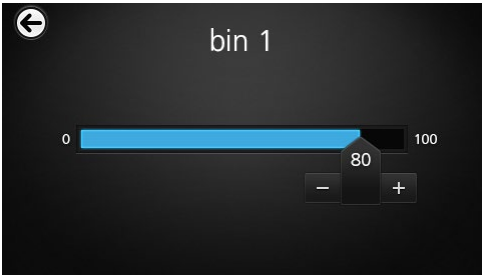


To change the histogram settings for any of the available parameters:

1. Touch any *bin* to change the range values.



2. Touch and drag the markers to adjust the range values.



Note: If one of the Bin settings is changed, all other Bin settings are effected. For example, if Bin 2 is changed to a span of 4 to 32, Bin 1 changes to a span of 0 to 3, and Bin 3 changes to a span of 33 to 60.

3. When finished, touch the back arrow and select **OK.**

SpO2 Settings

Access any of the following options:

SpO2 Alarms on page 71.

Additional Settings for SpO2 on page 72.

Desat Index on page 106.

About Parameter Information on page 68.

About Desat Index on page 105.

Trends on page 95.

SpO2 Histogram on page 72.

SpO2 Alarms

From the SpO_2 *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

Additional Settings for SpO2

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

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time*	The length of time over which the system calculates the average of all data points.	8 seconds	2-4, 4-6, 8, 10, 12, 14, or 16 seconds**
FastSat	See ***FastSat Overview*** on page 72.	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 Radical-7 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.

SpO2 Histogram

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

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0-80	0 to 96 in steps of 1
Bin 2		81-85	1 to 97 in steps of 1
Bin 3		86-90	2 to 98 in steps of 1
Bin 4		91-95	3 to 99 in steps of 1
Bin 5		96-100	4 to 100 in steps of 1

* See ***Histogram Settings*** on page 70 for additional information.

PR Settings

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

PR Alarms on page 73.

About Parameter Information on page 68.

Trends on page 95.

PR Histogram on page 73.

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 to 235 bpm, in steps of 5 bpm
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	50 bpm	30 to 230 bpm, in steps of 5 bpm

PR Histogram

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

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0-50	0 to 246 in steps of 1
Bin 2		51-100	1 to 247 in steps of 1
Bin 3		101-150	2 to 248 in steps of 1
Bin 4		151-200	3 to 249 in steps of 1
Bin 5		201-250	4 to 250 in steps of 1

* See ***Histogram Settings*** on page 70 for additional information.

Pi Settings

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

Pi Alarms on page 74.

Additional Settings for Pi on page 74.

About Parameter Information on page 68.

Pi Delta on page 107.

Trends on page 95.

Pi Histogram on page 75.

Pi Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	0.04 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 19 in steps of 1, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	0.3	Off, or 0.03 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 18 in steps of 1

Additional Settings for Pi

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

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

Pi Histogram

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

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0.0-4.0	0.0 to 19.6 in steps of 0.01
Bin 2		4.1-8.0	0.1 to 19.7 in steps of 0.01
Bin 3		8.1-12.0	0.2 to 19.8 in steps of 0.01
Bin 4		12.1-16.0	0.3 to 19.9 in steps of 0.01
Bin 5		16.1-20.0	0.4 to 20.0 in steps of 0.01

* See ***Histogram Settings*** on page 70 for additional information.

PVi Settings

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

PVi Alarms on page 75.

Additional Settings for PVi on page 76.

About Parameter Information on page 68.

Trends on page 95.

PVi Histogram on page 76.

PVi Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	2 to 99, in steps of 1, or Off When set to Off, 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	Off	Off or 1 to 98 in steps of 1 When set to Off, alarms are disabled.

Additional Settings for PVi

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

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

PVi Histogram

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

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0-20	0 to 96 in steps of 1
Bin 2		21-40	1 to 97 in steps of 1
Bin 3		41-60	2 to 98 in steps of 1
Bin 4		61-80	3 to 99 in steps of 1
Bin 5		81-100	4 to 100 in steps of 1

* See ***Histogram Settings*** on page 70 for additional information.

Respiration Rate (RR) Settings

Radical-7 can determine Respiration Rate (RR) either by the acoustic signal (RRa) or by the plethysmographic waveform (RRp).

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

RRa Alarms on page 78.

RRp Alarms on page 79.

Additional Settings for RRa on page 78.

Additional Settings for RRp on page 80.

About Parameter Information on page 68.

Trends on page 95.

RR Histogram on page 80.

RRa Settings

When using an acoustic sensor, respiration rate (RR) is determined by the acoustic (RRa) signal. See ***rainbow Acoustic Monitoring™ (RAM™)*** on page 30. When the respiratory rate is determined by the acoustic signal, the *Main Screen* conveys respiratory rate as *RRa*, as shown below.

The Radical-7 can monitor RRa or RRp but not both simultaneously.

RRa is active under the following conditions:

- RRa is installed on the Radical-7.
- Dual rainbow cable is connected.
- Acoustic sensor is connected.

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

RRa Alarms on page 78.

Additional Settings for RRa on page 78.

About Parameter Information on page 68.

Trends on page 95.

RR Histogram on page 80.

RRa Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	High	30 breaths per minute	6 to 119 breaths per minute in steps of 1 breaths per minute, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	6 breaths per minute	Off, or 5 to 118 breaths per minute in steps of 1 breaths per minute
Respiratory Pause	The duration of time that triggers an alarm if no breaths are detected.	NA	30 seconds	15, 20, 25, 30, 35, or 40 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	Slow, Medium, Fast, Trending, or No Averaging
Freshness	The duration of time that, during interference, the system displays the last valid reading.	5 minutes	0, 1, 5, 10, or 15 minutes

RRp Settings

When using a pulse oximetry or pulse CO-Oximetry sensor with Radical-7, respiration rate can be determined by the plethysmographic waveform (RRp). This method measures respirations per minute (rpm) based on cyclic variation in photoplethysmogram (i.e. pleth or PPG) to

establish a respiration rate measurement. When using a pulse oximetry or pulse CO-Oximetry sensor, RRp alarms and RRp settings are active and the *Main Screen* labels respiratory rate as *RRp*, as shown below.

Note that Radical-7 can monitor RRa or RRp but not both simultaneously.

RRp is active when the following conditions have all been met:

- RRp is installed on the Radical-7.
- No dual rainbow cable is connected.
- A pulse oximetry or pulse CO-Oximetry sensor is connected.
- The optical sensor must support RRp.

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

RRp Alarms on page 79.

Additional Settings for RRp on page 80.

About Parameter Information on page 68.

Trends on page 95.

RR Histogram on page 80.

RRp Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	High	30 breaths per minute	6 to 119 breaths per minute in steps of 1 breaths per minute, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	6 breaths per minute	Off, or 5 to 118 breaths per minute in steps of 1 breaths per minute
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 RRp

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

RR Histogram

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

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0-14	0 to 116 in steps of 1
Bin 2		15-28	1 to 117 in steps of 1
Bin 3		29-42	2 to 118 in steps of 1
Bin 4		43-56	3 to 119 in steps of 1
Bin 5		57-120	4 to 120 in steps of 1

* See ***Histogram Settings*** on page 70 for additional information.

SpHb Settings

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

SpHb Alarms on page 81.

Additional Settings for SpHb on page 82.

About Parameter Information on page 68.

Trends on page 95.

SpHb Histogram on page 82.

SpHb Alarms

From the SpHb *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 11.0 mmol/L 170 g/L	2.0 to 24.5 g/dL in steps of 0.1 g/dL, or Off 2.0 to 15.0 mmol/L in steps of 0.1 mmol/L, or Off 20 to 245 g/L in steps of 1 g/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 4.0 mmol/L 70 g/L	Off, or 1.0 to 23.5 g/dL in steps of 0.1 g/dL Off, or 1.0 to 14.5 mmol/L, in steps of 0.1 mmol/L Off, or 10 to 235 g/L in steps of 1 g/L When SpHb Precision is set to 1.0, values are rounded down. When set to Off, alarm is disabled.

Additional Settings for SpHb

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

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time	The length of time over which the system calculates the average of all data points.	Medium	Short, Medium, or Long
Arterial/Venous Mode	Provides an arterial or venous value that displays on the main screen.	Arterial	Arterial or Venous
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
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 can not 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.

SpHb Histogram

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

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0.0-7.0	0.0 to 24.6 in steps of 0.01
Bin 2		7.1-9.0	0.1 to 24.7 in steps of 0.1
Bin 3		9.1-11.0	0.2 to 24.8 in steps of 0.1
Bin 4		11.1-14.0	0.3 to 24.9 in steps of 0.1
Bin 5		14.1-25.0	0.4 to 25.0 in steps of 0.1

* See ***Histogram Settings*** on page 70 for additional information.

SpOC Settings

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

SpOC Alarms on page 83.

About Parameter Information on page 68.

Trends on page 95.

SpOC Histogram on page 83.

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 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 to 33 ml/dl in steps of 1 ml/dl

SpOC Histogram

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

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0.0-10.0	0.0 to 31.0 in steps of 1
Bin 2		11.0-13.0	1.0 to 32.0 in steps of 1
Bin 3		14.0-15.0	2.0 to 33.0 in steps of 1
Bin 4		16.0-20.0	3.0 to 34.0 in steps of 1
Bin 5		21.0-35.0	4.0 to 35.0 in steps of 1

* See ***Histogram Settings*** on page 70 for additional information.

SpMet Settings

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

SpMet Alarms on page 84.

About Parameter Information on page 68.

Trends on page 95.

SpMet Histogram on page 84.

SpMet Alarms

From the SpMet *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	3.0%	1.0 to 2.0% in steps of 0.1% 2.5 to 99.5% in steps of 0.5%, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	Off, or 1.0 to 2.0% in steps of 0.1% 2.5 to 99.0%, in steps of 0.5%

SpMet Histogram

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

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0.0-3.0	0.00 to 98.0 in steps of 0.1
Bin 2		3.1-6.0	0.01 to 98.5 in steps of 0.01
Bin 3		6.1-9.0	0.02 to 99.0 in steps of 0.01
Bin 4		9.1-12.0	0.03 to 99.5 in steps of 0.01
Bin 5		12.1-100.0	0.04 to 100.0 in steps of 0.01

* See ***Histogram Settings*** on page 70 for additional information.

SpCO Settings

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

SpCO Alarms on page 85.

About Parameter Information on page 68.

Trends on page 95.

SpCO Histogram on page 85.

SpCO Alarms

From the SpCO *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	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, or 1 to 97%, in steps of 1% When set to Off, alarm is disabled

SpCO Histogram

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

Options	Description	Factory Default Settings	User Configurable Settings*
Bin 1	Define the range of parameter values to be displayed under respective Bins in histogram view.	0-8	0 to 96 in steps of 1
Bin 2		9-16	1 to 97 in steps of 1
Bin 3		17-24	2 to 98 in steps of 1
Bin 4		25-32	3 to 99 in steps of 1
Bin 5		33-100	4 to 100 in steps of 1

* See ***Histogram Settings*** on page 70 for additional information.

Sounds

Use the *Sounds* screen to control the volume of sounds and duration of audio pause on Radical-7. Users can also access the *Sounds* screen by pressing the *Sounds* icon on the Status Bar. See ***About the Status Bar*** on page 54.

Option	Description	Factory Default Setting	Configurable Settings
Alarm Volume	Sets the alarm volume level.	4	1 (lowest) to 4 (highest) in steps of 1.
Pulse Tone Volume	Sets the pulse tone volume level.	3	0 (silent) to 4 (highest) in steps of 1.
Audio Pause Duration	Sets the length of time that the audible alarm remains silenced.	2 minutes	1, 2, or 3 minutes, all mute*, or all mute with reminder*
Smart Tone	Allows the audible pulse to continue to beep when the pleth graph shows signs of motion.	Off	On or Off

* If All Mute is selected, there are no audible alarms, but visual alarms still display. If All Mute with Reminder is selected, a tone sounds every three (3) minutes as a reminder that All Mute is active. Requires user to have *All Mute Enabled* turned On in the *Access Control* menu. See ***Access Control*** on page 91.

Device Settings

The *Device Settings* menu allows the user to view and customize settings for Radical-7. The Device Settings options are:

Screen Orientation

See ***Screen Orientation*** on page 87.

Localization

See ***Localization*** on page 88.

Wi-Fi

See ***Wi-Fi*** on page 89.

Bluetooth

See ***Bluetooth*** on page 89.

Radical-7 Battery

See ***Radical-7 Battery*** on page 90.

Brightness

See ***Brightness*** on page 91.

Sounds

See ***Sounds*** on page 86.

Access Control

See ***Access Control*** on page 91.

Device Output

See ***Device Output*** on page 94.

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, Portrait Inverted, Landscape, or Landscape Inverted

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 54.

Option	Description	Factory Default Setting	Configurable Settings
Current Date	Displays the current date set on the device	NA	NA
Current Time	Displays the current time set on the device	NA	NA
Language	Selects the language display for Radical-7.	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

Option	Description	Factory Default Setting	Configurable Settings
Time	Sets the current time.	N/A	N/A

Wi-Fi

The Wi-Fi radio allows for networked communication of data and alarm signals between Radical-7 and a secondary patient monitoring station, Masimo Patient SafetyNet, over an IEEE 802.11 a/b/g wireless network.

Radical-7 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, Radical-7 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 Radical-7 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 54.

Option	Description	Factory Default Settings	User 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.

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 54.

Option	Description	Factory Default Setting	Configurable Settings
Bluetooth	Enables or disables Bluetooth connectivity.	Off	On or Off
MAC Address	When Bluetooth is On, the MAC address for the device is displayed	NA	NA

Radical-7 Battery

Use the Battery screen to view the specific percentage of charge remaining in Radical-7'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 54.

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 Radical-7's display.

Option	Description	Factory Default Settings	User Configurable Settings
Auto Brightness	Allows automatic adjustment of display brightness based on the ambient light level.	Off	On or Off
Brightness	Adjust the brightness level of the display manually.	4	1 (dimmest), 2, 3, 4 (brightest)

Access Control

Access Control contains configurable options and settings that require a password.

Using the Password screen

1. On the Password screen, enter the following numbers: 6 2 7 4
   No numbers will be displayed, only asterisks (****).
2. To undo numbers, press/select *Backspace*.

3. To confirm, press/select *Enter*.

From the *Access Control* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Power On Profile	Allows user to select a specific Profile to be loaded the next time that the unit is powered on. This Profile can be one of the presets (ie. Adult, Pediatric, Neo), a customized Profile, or the last configuration used before the unit is powered off.	Previous Profile	Previous Profile, Adult, Pediatric, Neonatal, Custom, Profile 1, Profile 2, Profile 3, Profile 4, Profile 5, Profile 6, Profile 7, Profile 8
All Mute Enabled	All patient alarm conditions are silenced. Only system alarms will be indicated by an audible alarm.	Off	Off or On If On, *All Mute* and *All Mute with Reminder* become available settings from the *Silence Duration* option on the *Sounds* screen. See ***Sounds*** on page 86.
Lock Alarm Volume	When set to 3 or 4, 3 or 4 shows dimly lit in the *Alarm Volume* section of the *Alarms Menu* screen and cannot be changed.	Off	3, 4, or Off
SpO_2 Low % Limit	Threshold at which SpO_2 Low Alarm Limit cannot be reduced.	Off	Off, or 1% to 98% in steps of 1%
Sensor off Alarm Delay	This feature delays the audible part of the Sensor off alarm.	0 seconds	0, 5, 10, 15, 30, or 60 seconds
Lock Layout	Prevents the user from making changes to the parameter layout.	Off	On or Off

Options	Description	Factory Default Settings	User Configurable Settings
Screen Lock	Prevents unintentional interaction with the touchscreen.	Off	On or Off
Legacy Mode	Changes the display from color to monochrome.	Color	Mono or Color
Data Collection Enabled	Facilitates data collection for Masimo personnel use only.	Off	On or Off
Nurse Call Trigger*	The nurse call output will be activated based on the alarm events. The nurse call with be activated based on Low Signal or Alarm and Low Signal IQ events.	Alarms	Alarms, Low SIQ, or Alarms + SIQ
Nurse Call Polarity*	Sets the polarity of the nurse call connector on the rear of the docking station. Can be inverted to accommodate various nurse call station requirements.	Normal	Normal or Inverted
Save as Adult	Saves pre-configured profiles for adult patients.	N/A	Press **Save** to load all device configuration settings to adult profile.
Save as pediatric	Saves pre-configured profiles for pediatric patients	NA	Press **Save** to load all device configuration settings to pediatric profile.
Save as Neo	Saves pre-configured profiles for neonatal patients	N/A	Press **Save** to load all device configuration settings to neonatal profile.
Factory Defaults**	Options are restored to factory values.	N/A	Press **Restore** to return to factory default values.

* Displays only when docked in a docking station in stand alone configuration.

** **Disabled** if currently monitoring or a cable is connected to the device. Disconnect sensor and/or cable from Radical-7 to perform reset.

Device Output

The *Device Output* screen allows the user to configure additional data output options.

Options	Description	Factory Default Settings	User Configurable Settings
Serial*, **	Output to serial devices from the Serial Output connector is RS-232 based. See ***Docking Station Back Panel*** on page 39.	IAP	ASCII 1, ASCII 2L, IAP, IntelliBridge, HP Vuelink, or SpaceLabs Flexport
		ASCII 2L	ASCII 2L or HP VueLink***
Analog 1	An interface with various analog recording devices and/or strip chart recorders through connector located on Docking Station. Depending on the configuration, the following parameters are output continuously on the Analog 1 and Analog 2.	SpO_2 0-100%	Pulse Rate, Pleth, SIQ, 0V Output, 1V Output, SpO_2 0% to 100%, or SpO_2 50% to 100%
Analog 2		Pulse Rate	
Interface Alarm	This activates the transmission of SpO_2 and PR alarms to interfaced devices when SatShare is in use.	Off	On or Off
SatShare Diagnostics*, ****	Facilitates diagnostics of SatShare for Masimo Personnel use only.	Disabled	Enabled or Disabled (requires password to enable)
Docking Station Baud Rate*, ***	Sets the Baud Rate to serial devices.	9600	9600, 19200, 28800, 38400, or 57600

* Settings vary by docking station. To determine the docking station being used, see ***Docking Station*** on page 37.

** Output protocols that are not supported by the connected docking station are not shown as selectable options.

*** When ASCII 2L or HP VueLink are the only available options, Baud Rate is not adjustable.

**** Cannot be enabled on RDS-3.

About

For information about parameters, see ***About Parameter Information*** on page 68.

Use the *About* screen to view the serial number as well as Radical-7 software and hardware version information. These details may be helpful during troubleshooting.

Options*	Description
Serial Number	Displays the serial number of the Handheld.
MCU	Displays the version number of the device board software.
MX Board	Displays the version number of the technology level software.
Processor **	Displays the version number of the system level software.
Docking Station **	If docked, displays the current software version of the Docking Station (RDS). Information in this field can help determine the docking station. See ***Docking Station*** on page 37.

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

** These values do not display when docked to Root.

Trends

Trend settings allow the user to configure the Y-axis maximum and Y-axis minimum for each parameter. The maximum and minimum possible values differ depending on the selected parameter. See ***Customizing Trend Views*** on page 60 for additional information.

Trend Settings

Use the *Trend Settings* screen to configure Trend Views on the *Main Screen* and trend data storage on Radical-7.

Option	Description	Factory Default Setting	User Configurable Settings
Default Duration	Sets the time duration displayed in trend lines.	2 hours	15, 30, 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.
View Trends	Displays trend data for that parameter.	N/A	Press **View** to view trend data for that parameter.
SpO_2	Y-axis Max	100	5 to 100 in steps of 5
	Y-axis Min	50	0 to 95 in steps of 5
PR	Y-axis Max	200	30 to 240 in steps of 5
	Y-axis Min	25	25 to 235 in steps of 5
Pi	Y-axis Max	20.0	1.0 to 20.0 in increments of 1.0
	Y-axis Min	0.0	0.0 to 19.0 in increments of 1.0
PVi	Y-axis Max	30	1 to 100 in steps of 1
	Y-axis Min	0	0 to 99 in steps of 1
RRa	Y-axis Max	35	1 to 120 in steps of 1
	Y-axis Min	0	0 to 119 in steps of 1
RRp	Y-axis Max	35	1 to 120 in steps of 1
	Y-axis Min	0	0 to 119 in steps of 1
SpHb g/dL	Y-axis Max	20.0 g/dL	0.1 to 25.0 g/dL in increments of 0.1
	Y-axis Min	5.0 g/dL	0.0 to 24.9 g/dL in increments of 0.1

Option	Description	Factory Default Setting	User Configurable Settings
SpHb mmol/L	Y-axis Max	12.4 mmol/L	0.1 to 15.5 mmol/L in increments of 0.1
	Y-axis Min	3.1 mmol/L	0.0 to 15.4 mmol/L in increments of 0.1
SpHb g/L	Y-axis Max	200	1 to 250 g/L in increments of 1
	Y-axis Min	50	0 to 249 g/L in increments of 1
SpOC	Y-axis Max	20	1 to 35 in increments of 1
	Y-axis Min	0	0 to 34 in increments of 1
SpMet	Y-axis Max	15.0	1.0 to 100.0 in increments of 0.5
	Y-axis Min	0.0	0.0 to 99.5 in increments of 0.5
SpCO	Y-axis Max	40	1 to 100 in increments of 1
	Y-axis Min	0	0 to 99 in increments of 1

Chapter 5: Profiles

The Radical-7 can be configured for various patient types.

Profiles Overview

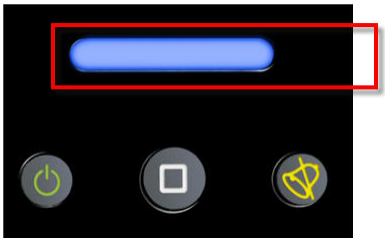
The Radical-7 contains a *Profiles* screen, which lets the user customize different settings for different patient populations:

- **Adult -** 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.
- **Custom -** Displays in the Status bar as *CUSTOM* and the Profile button is not illuminated and appears gray. Up to 8 custom alarm profiles can be created.

  Note: The three pre-determined alarm profiles cannot be removed.

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

The Radical-7 conveys the active profile by changing the color of the *Profiles* button. In the following example, the *Adult* profile is active (Blue).



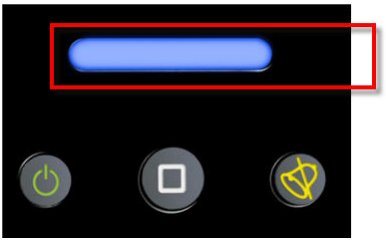
Changing Profiles

Adult is the factory default profile. Changing Profiles is done in the *Profiles* screen. If the Profile is changed from *Adult* to any other profile, after a power cycle, the Radical-7 remembers the selected Profile and does not default back to the *Adult* profile.

There are different ways to access the *Profiles* screen.

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

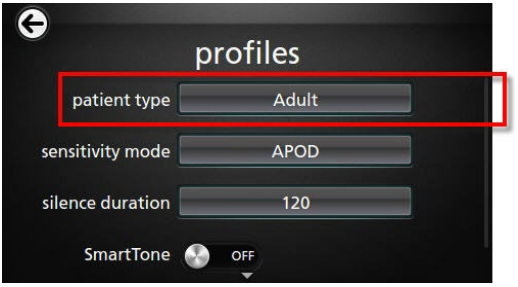
- Press the *Profile* button, as shown below.



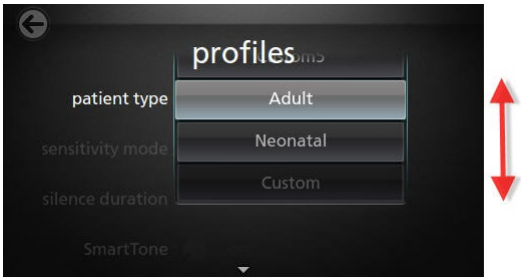
- Alternatively, from the *Main Menu* screen, touch the *Profiles* icon.

Change Patient Type

1. From the Profile screen, touch the *Patient Type* field.



2. Select the desired *Patient Type* by scrolling up or down.



3. When finished, touch **OK**. To confirm selection, check the *Status Bar*.

Profiles Settings

The Radical-7 can be configured for various patient types through the Profiles option located under the main menu options. See ***Accessing Main Menu Options*** on page 67.

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

Options	Description	Factory Default Settings	User Configurable Settings
Patient Type	Defines the patient population for which the device will operate.	Adult*	Adult, Pediatric, Neonatal, or Custom Profile 1 to 8.
Sensitivity Modes	Defines the sensitivity level for which the device will operate. See ***Sensitivity Modes Overview*** on page 56.	APOD	NORM, MAX, or APOD
Silence Duration	The amount of time for which the audible part of an alarm will be silenced. See ***Silencing the Alarms*** on page 104.	2 min	1 min, 2 min, or 3 min
Smart Tone	Allows the audible pulse to continue to beep when the pleth graph shows signs of motion.	Off	On or Off

* The default profile becomes the last set profile when the device is powered off and back on again.

Replacing Factory Default Settings for Adult and Neo Profiles

The *Adult*, *Pediatric* and *Neonatal* profiles can be modified to meet specific requirements and then they can replace the factory default settings for those profiles. As such, after a power cycle, the Radical-7 remembers the preferred settings for *Adult*, *Pediatric* and *Neonatal* profiles instead of the factory default settings. When preferred settings for *Adult*, *Pediatric* and *Neonatal* are saved in place of the factory default settings, the *Profile* button changes to the same blue, green or pink color respectively. See ***Profiles Overview*** on page 99.

A user can also load preferred profile configurations into the Radical-7 using a separate tool.

Change Default Profile Settings:

1. Change the Radical-7 *Adult*, *Pediatric* or *Neonatal* profile settings to the desired configuration.
2. Navigate to the *Access Control* screen. See ***Access Control*** on page 91.
3. Scroll down the *Access Control* screen and select *Save* next to *Adult*, *Pediatric* or *Neo,* then *OK*.
4. Confirm the changes by powering off and on the Radical-7 and verify the modified settings remain intact.

Restore Factory Default Profile Settings:

1. Navigate to the *Access Control* screen.
2. Scroll down the *Access Control* screen and select *Restore* next to *Factory Defaults,* then *OK*.

Chapter 6: Alarms and Messages

The following chapter contains information about alarms and messages.

For more information, see ***Chapter 7: Troubleshooting*** on page 113.

About Alarms

The Radical-7 visually and audibly indicates alarm conditions that the system detects. Audible alarms may be silenced, without affecting the operation of visual alarms. See ***Safety Information, Warnings and Cautions*** on page 11.

There are three priorities for alarms:

- High
- Medium
- Low

Alarm Delay

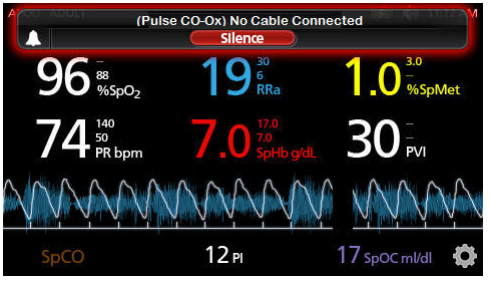
When an alarm condition is met, this feature delays the audible part of an alarm.

Alarms Interface

Alarms can have different priority levels and come from different sources. The following tables describe alarm behaviors on Radical-7 in more detail.

Note: When Radical-7 is docked to Root, the alarms may be displayed and interacted with directly through the Root display. Refer to the Operator's Manual for Root for complete information.

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

Alarm Source/Example	Explanation
	**Parameter Level** This example is a SpO_2 alarm (SpO_2 Low) as the reading exceeds the lower alarm limit. **Note:** The SpO_2 parameter is illuminated red, and the Silence option is shown at the top of the screen.
	**System Level** This example is a "No Cable Connected" alarm. **Note:** The Silence option is shown at the top of the screen and the explanation of the alarm is displayed (No Cable Connected).

Silencing the Alarms

To silence or dismiss alarms:

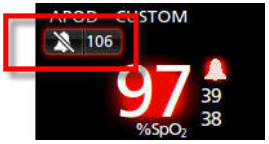
- Touch **Silence** (the highlighted area of the *Status Bar*).

Audible alarms can be temporarily suspended by pressing the *Alarm Silence* button. When alarms are in the *suspend state*, pressing the *Alarm Silence* button again cancels the alarm suspend.

To silence audible alarms:

1. When an audible alarm is active, push **Alarm Silence** one time.

2. The audible alarm is silenced for up to 120 seconds and a countdown timer displays.



3. The length of time for which an audible alarm remains silenced (suspended) can be changed using the Silence Duration feature located on the *Sounds* screen. See ***Sounds*** on page 86.

3D Alarms

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

Desat Index on page 106

About Desat Index on page 105

Pi Delta on page 107

About Pi Delta on page 106

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 106.

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. Radical-7 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 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 Radical-7 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 107. 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	None or 1, 5, 30 minutes, 1, 4, 8, 12, 24, 36, 48 hours

Radical-7 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 life 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 active monitoring life remaining.	• Replace with new patient cable.
(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.

Message	Potential Causes	Next Steps
(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 monitoring time, sensor is non-functional, or defective sensor.	• Replace sensor.
(Pulse CO-Ox) Sensor Near Expiration or *(RAM) Sensor Near Expiration*	• Reusable sensor has less than 10% active monitoring life remaining.	• Replace with new reusable sensor.
(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) 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.
(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.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Adhesive Near Expiration or *(RAM) Adhesive Near Expiration*	• Disposable sensor has less than 10% active monitoring life remaining.	• Replace with new disposable 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) 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) 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.
(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.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Low Perfusion Index	• Signal strength is too weak.	• Move sensor to better perfused site. See ***Troubleshooting Measurements*** on page 113.
(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 59.
(*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.
(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 86.
(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 30.
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 30.

Message	Potential Causes	Next Steps
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 28.
"- -" (Dashes shown as parameter value - Invalid parameter alarm)	• Unable to provide a parameter value.	• Check patient's vital condition.
Low Battery	• Battery charge is low.	• Charge battery by placing the Handheld into the Docking Station and powering the device with AC line power. Replace battery if necessary.
Speaker Failure	• Device requires service.	• Contact Masimo Tech Support. See ***Chapter 9: Service and Maintenance*** on page 149.
RTC Battery Low	• Device requires service.	• Contact Masimo Tech Support. See ***Chapter 9: Service and Maintenance*** on page 149.

Chapter 7: Troubleshooting

The following chapter contains information about troubleshooting the Radical-7 system.

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 56.

Symptom	Potential Causes	Next Steps
Difficulty obtaining a reading.	• Inappropriate sensor or sensor size. • Improper sensor type or application. • Low Perfusion. • Excessive Motion Artifact. • Excessive ambient or strobing light. • 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. • Insert Handheld into Docking Station, verify Docking Station AC power cord is plugged in and Docking Station power indicator light is illuminated. • Verify and set 50 or 60Hz menu setting. See ***Localization*** on page 88.
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.

Symptom	Potential Causes	Next Steps
Dimly Lit Parameters	• Low Signal Quality	• Assess the patient. • Verify sensor type and size and re-apply sensor. See *Directions for Use* for Sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Minimize or eliminate motion at the monitoring site. • Set to MAX Sensitivity. See ***Sensitivity Modes Overview*** on page 56.
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 103. • 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.
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.
Unexpected High SpCO Reading	• Possible elevated methemoglobin level.	• Submit blood sample for laboratory CO-Oximetry test. See ***Appendix: Concepts of Alarm Response Delay*** on page 157.

Troubleshooting the Radical-7

The following section lists possible Radical-7 symptoms, potential causes, and next steps.

For more information, see ***Chapter 6: Alarms and Messages*** on page 103.

Symptom	Potential Causes	Next Steps
Device does not turn on	• Depleted Battery. • One or both fuses are blown. • Internal failure.	• Charge the battery. • Check and replace the fuses. See ***Replacing the Fuses*** on page 151. • Contact Masimo Service. See ***Contacting Masimo*** on page 154.
System failure technical alarm active (continuous speaker tone)	• Internal failure.	• To silence an alarm, press the *Alarm Silence* button. If alarm continues to sound, turn off the Radical-7. If necessary, remove Handheld battery. • Contact Masimo service. See ***Contacting Masimo*** on page 154.
Speaker does not work	• Device audible settings may be incorrect. • Internal failure.	• Turn Radical-7 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 154.
Device screen is blank	• The device is Off. • The brightness display is not correct. • Battery may be depleted. • Internal failure.	• Turn Radical-7 Off and On. • Adjust the brightness setting. See ***Brightness*** on page 91. • Charge the battery. • Contact Masimo service. See ***Contacting Masimo*** on page 154.

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 154.
Battery run time significantly reduced	• Battery not fully charged. • Battery damaged. • Battery capacity effected.	• Check battery charge level indicator. • Check battery is fully charged. • Replace battery. See ***Replacing the Batteries*** on page 150. • Contact Masimo service. See ***Contacting Masimo*** on page 154.
Battery does not charge	• AC power cable disconnected. • Battery damaged. • Internal failure.	• Connect AC power cable to docking station. • Replace battery. See ***Replacing the Batteries*** on page 150. • Contact Masimo service. See ***Contacting Masimo*** on page 154.
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 154.
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 Radical-7 Off and On. • Contact Masimo service. See ***Contacting Masimo*** on page 154.

Symptom	Potential Causes	Next Steps
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 94.* • Check communication cable connection. • Check connected network settings and availability. • Contact Masimo service. See ***Contacting Masimo*** on page 154.
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 89. • Check wireless availability for location. • Check network settings and availability. • Contact Masimo service. See ***Contacting Masimo*** on page 154.
Indicators on Docking Station Continuously Flash	• Incompatible version of software on Handheld and Docking Station.	• Upgrade to current software versions. • Match Handheld to Docking Station with compatible software versions.

Chapter 8: Specifications

The following chapter contains specifications for the Radical-7 Handheld, compatible Docking Stations, and the Standalone system.

Display Range

Measurement	Display Range
SpO_2 (Functional Oxygen Saturation)	0% to 100%
PR (Pulse Rate)	0 bpm to 240 bpm
Pi (Perfusion Index)	0.00 to 20
PVi (Pleth Variability Index)	0 to 100
RRa (Respiration Rate)	0 RPM to 120 RPM
SpHb (Hemoglobin)	0.0 g/dL to 25.0 g/dL 0.0 mmol/L to 15.5 mmol/L 0 g/L to 250 g/L
SpCO (Carboxyhemoglobin)	0% to 99%
SpMet (Methemoglobin)	0.0% to 99.9%
SpOC (Oxygen Content)	0 ml/dl to 35 ml/dl
RRp (Respiration Rate)	0 RPM to 120 RPM

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) [7]		
Range of 4 rpm to 70 rpm	Adults, Pediatrics	1 rpm
Range of 4 rpm to 120 rpm	Infants, Neonates	1 rpm
Respiratory Rate (RRp) [8]		
Range	4 rpm to 70 rpm	
No Motion	Adults, Pediatrics (>2 years of age)	3 rpm A_{RMS}* ±1 rpm mean error

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

Note: A functional tester cannot be used to assess the accuracy of Radical-7.

Resolution

Parameter	Resolution
SpO_2	1%
PR	1 BPM
RRa	1 RPM
SpHb	0.1 g/dL
	0.1 mmol/L
	1 g/L
SpCO	1%
SpMet	0.1%
SpOC	1.0 ml/dL
RRp	1 RPM

RRp Performance Specifications

The below Bland Altman plots represent the correlation of RRp and the reference respiration rate in healthy adult subjects with upper 95% and lower 95% limits of agreement.

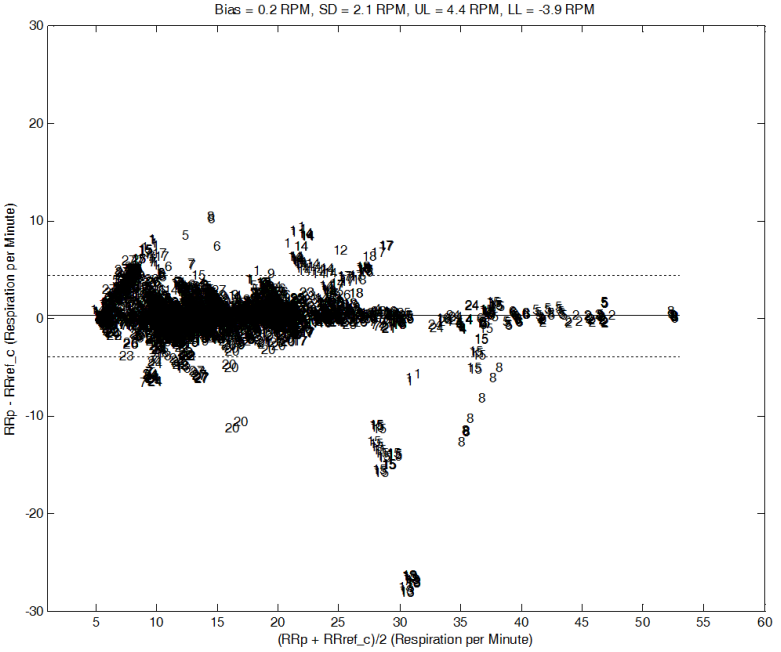


Figure 1: Subject by Subject Bland-Altman plot of RRp with respect to RRref_c

The below Bland Altman plots represent the correlation of RRp and the reference respiration rate in hospitalized adult subjects with upper 95% and lower 95% limits of agreement.

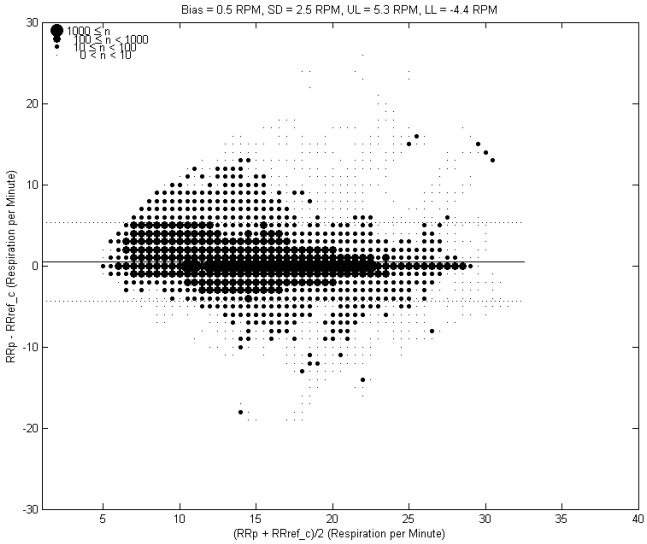


Figure 2: Bland-Altman plot of RRp with respect to RRref_c

The below Bland Altman plots represent the correlation of RRp and the reference respiration rate in hospitalized pediatric subjects with upper 95% and lower 95% limits of agreement.

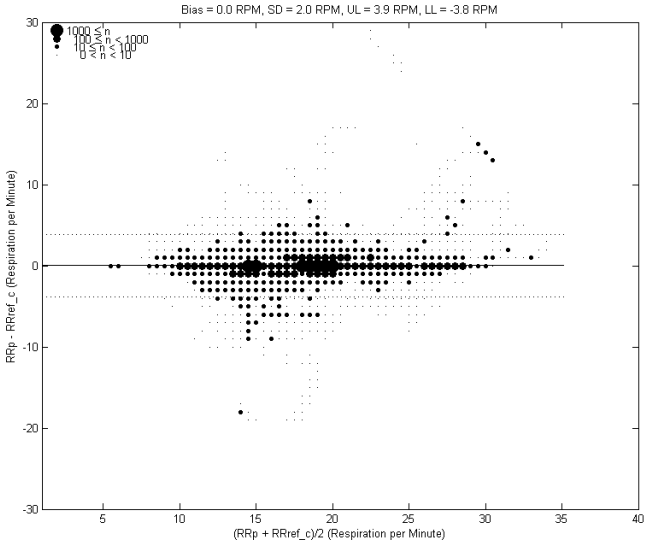


Figure 3: Bland-Altman plot of RRp with respect to RRref_c

Medical Conditions

Adult Medical Conditions

Medical Conditions from Clinical Study of Hospitalized Adult Patients

	N
Autoimmune	
Psoriasis	1
Cardiovascular	
Musculoskeletal and Connective Tissue (Cont.)	
End stage arthritis and osteonecrosis, bitateral hips	1
Fasciotomy wounds of right foot and tibia.	1

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Atrial Septal Defect	1
Coronary Disease	1
Hypertension	22
Congenital	
Arthrogyposis Multiplex Congenita	1
Endocrine/Metabolic	
Diabetes	2
Hyperlipidemia	8
Hypomagnesemia	1
Hypothyroidism	2
Morbid Obesity	6
Gastrointestinal	
Acid Reflux	1
Appendicitis	5
Chronic Constipation	1
Constipation	1
Crohns Disease	1
Emesis	1
GERD	4

Idiopathic scoliosis and kyphoscoliosis	1
Left Femur Fracture, surgical treated with intramedullary Rod	1
Left Femur tumor	1
Left Hip Pathological fracture	1
Lower limb length difference (discrepancy)	1
Nonunion of left long finger metacarpal fracture	1
Osteoarthritis	4
Right fourth metatarsal fracture	1
Right lower leg and foot compartment syndrome	1
Scar contracture left hand	1
Traumatic amputation of left thumb with complication	1
NA	
None Reported	9
Neoplasm	
Hodgkin's lymphoma	1
Lipoma	1
Malignant Tumor	1
Nephrology	
Hydronephrosis	1

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Hiatal Hernia	1
Jaundice	1
Reflux Disease	1
Genitourinary	
Bladder Cancer	1
Breast Cancer/Breast Cancer History	2
Cervical Cancer	1
Endometrial Cancer	1
Fibroid Uterus	1
Rectocele	1
Urinary tract infection	1
Hematology	
Acute Blood Loss Anemia	1
Anemia	4
Blood Clotting Disorder/Unspecified	1
Chronic Thrombacytopenia	1
Hereditary Spherocytosis	1
Leukocytosis	1
Sickle Cell Disease	1
Hepatobiliary	

Neurological	
Peripheral Neuropathy	1
Autism Spectrum Disorder	1
Bilateral Hand Tremors	1
Head injury	1
Infantile cerebral palsy, unspecified	1
Neuropathy	1
Restless Leg Syndrome	1
Neurological/Orthopedic	
Scoliosis, Distal Femoral epiphyseal arrest	1
Obstetrics and Gynecology	
Left ovarian Endodermal sinus tumor	1
Pregnancy	1
Premature Birth (27 weeks)	1
Ophthalmology	
Glaucoma	2
Opthamology	
Glaucoma	1
Other	
Lethargy	1

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Cholecystitis	1
Cholecystitis with Choledocholithiasis	1
Cholelithiasis	5
Chronic Cholecystitis	1
Gall Stones	2
Liver Cyst	1
Infections	
Cellulitis	1
Muscular	
Ventral Hernia	2
Musculoskeletal	
Umbilical Hernia	1
Musculoskeletal and Connective Tissue	
Bilateral tibial fracture.	1
Closed Fracture of Left Shaft of Femur	1
Closed fracture of neck of left femur	1
Complete traumatic metarpophalangeal amputation of left index finger	1
Congenital deformity of hip (joint)	1
Contracture, Achilles tendon	1

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

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Crushing injury of left wrist, hand, and finger (following MVC)	1
Degenerative arthritis of hip	1
Degenerative Joint Disease	1
Dupuytrens Contracture (Right Hand)	1

Vascular	
Hemangioma - Lower lip	1
Raynaud Phenomenon	1

Pediatric Medical Conditions

Medical Conditions from Clinical Study of Hospitalized Pediatric Patients

	N
Congenital	
Arthrogyposis Multiplex Congenita	1
Congenital/Neurological	
Cerebral Palsy	1
Congential/Orthopedic	
Genu Valgam, and Leg length Discrepancy (Surgically treated)	1
Endocrine/Metabolic	
Hypothyroidism-Congenital	1
Gastrointestinal	
Appendicitis	8

	N
Musculoskeletal and Connective Tissue (Cont.)	
Radius and ulna distal fracture, left sequela	1
Right fourth metatarsal fracture	1
Right Leg Pain	1
Right lower leg and foot compartment syndrome	1
Scar contracture left hand	1
Traumatic amputation of left thumb with complication	1
Musculoskeletal and Connective Tissue/neoplasm	
Rt. Leg Mass (Tumor), Sarcoma Rt. Femur)	1
Nephrology	

Chronic Constipation	1
Constipation	1
GERD	2
Jaundice	1
General	
Unintentional weight loss	1
Genitourinary	
Urinary tract infection	1
Hematology	
Anemia	1
Hereditary Spherocytosis	1
Hypogammaglobinemia, Thromboctopenia	1
Hepatobiliary	
Cholecystitis with Choledocholithiasis	1
Cholelithiasis	2
Musculoskeletal and Connective Tissue	
Bilateral tibial fracture.	1
Closed Fracture of Left Shaft of Femur	1
Closed fracture of neck of left femur	1
Complete traumatic metarpophalangeal amputation of left index finger	1

Hydronephrosis	1
Neurological	
Autism Spectrum Disorder	1
Congenital Hydrocephalus p/s Shunt	1
Head injury	1
Infantile cerebral palsy, unspecified	1
Sensorineural hearing loss, Bilateral	1
Stage IV neuroblastoma S/P, resection Chemotherapy with Stem Cell Transplant	1
Neurological/Orthopedic	
Scoliosis (Spine disorder)	1
Scoliosis, Distal Femoral epiphyseal arrest	1
Obstetrics and Gynecology	
Left ovarian Endodermal sinus tumor	1
Premature Birth (27 weeks)	1
Opthamology	
Glaucoma	1
Otolar	
Hearing Impaired	1
Pain	
Acute post-operative pain	1

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

Peritoneal/Retroperitoneal	
Peritonitis	1
Psychiatric	
ADHD (attention deficit hyperactivity disorder)	1
Anxiety	1
Psychiatric/Developmental	
Learning Disability and Slight Anxiety	1
Respiratory	
Asthma	6
Pulmonary Nodule	1
Urology	
Enuresis	1
Vascular	
Hemangioma - Lower lip	1

Electrical

Radical-7 Battery	
Type	Lithium ion
Capacity	4 hours [9]
Charge Time	6 hours*

* When docked to Docking Station or Root.

Docking Station	
AC Power requirements	100 to 240 VAC, 47 to 63 Hz
Power consumption	55 VA
Fuses	UL Listed, Metric (5x20mm), rated 250 VAC, 2 Amp, Time Delay, 1500A breaking capacity

Environmental

Environmental Conditions	
Operating Temperature	0°C to 50°C (32°F to 122°F)
Storage/Transport Temperature	-40°C to 70°C [10] (-40°F to 158°F)
Operating Humidity	10% to 95%, non-condensing
Storage/Transport Humidity	10% to 95%, non-condensing
Operating Atmospheric Pressure	500 mbar to 1,060 mbar (540 hPa to 1060 hPa)

Physical Characteristics

Dimensions	
Handheld	8.8" x 3.5" x 1.7" (22.3 cm x 8.9 cm x 4.3 cm)
Standalone Configuration*	10.5" x 3.5" x 7.7" (26.7 cm x 8.9 cm x 19.5 cm)

Weight	
Handheld	1.3 lbs. (0.59 kg)
Docking Station (RDS-1, RDS-3)	2.5 lbs. (1.14 kg)
Standalone Configuration*	3.8 lbs. (1.73 kg)

* Handheld Docked to RDS-1 or RDS-3 Docking Stations.

Trending

Sensitivity	NORM, MAX, and APOD [11]

Maximum of 96 hours trending at 2-second resolution.

Alarms

Technical Alarm Type	Alarm Status Color	Description
High Priority	Flashing red	571 Hz tone, 5-pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time:10s
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: 70 dB (minimum) Medium Priority: 70 dB (minimum)
Sensitivity	NORM, MAX, APOD [12]

* 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	480 dots x 272 dots
Dot Pitch	0.25 mm

Compliance

EMC Compliance
IEC 60601-1-2:2007
IEC 60601-1-2:2014

Safety Standards Compliance
IEC 60601-1:2005/AMD1:2012
IEC 62304:2006/AMD1:2015
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-8:2006/AMD1:2012
EN/ISO 80601-2-61:2011
EN 60601-1:2006/AMD1:2013
ANSI/AAMI ES60601-1:2005/A1:2012
CAN/CSA C22.2 No. 60601-1:2014

Equipment Classification per IEC 60601-1	
Type of Protection	Internally powered (on battery power)
Degree of Protection of Electrical Shock	Defibrillation proof BF-Applied Part
Protection against harm from liquid ingress	IPX1 Protection against liquid drops falling vertically.
Mode of Operation	Continuous

Cable Compliance	
Cable	**Length**
Analog Cable	2 m (6.6 ft)
Satshare Cable	2.13 m (7 ft)
Serial Cable	2 m (6.6 ft)
Equipotential Ground Cable	3.75 m (12.3 ft)
AC Power Cable	2 m (6.6 ft)
Patient Cable	See Masimo website for details. (www.Masimo.com)

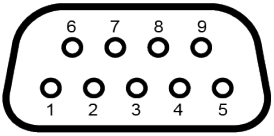
Output Interface

Docking Station
Serial RS-232 (RDS-1, RDS-1B, RDS-3)*
Nurse Call/Analog Output (RDS-1, RDS-1B, RDS-3)
SatShare (RDS-1, RDS-1B). See ***Serial Interface Specifications*** on page 135.

* For available communication protocol options, see ***Device Output*** on page 94.

Serial Interface Specifications

The digital interface for serial communication is based on the standard RS-232 protocol. See ***Handheld Back View*** on page 36. The Radical-7 by default always outputs ASCII 1 text data through the serial port, unless the user selects a different output mode. The Radical-7 serial interface is only available when the Radical-7 Handheld is properly attached to the Docking Station.



Note: RDS-2 does NOT have a Serial RS-232 Interface.

The pin-outs for the RS-232 connector are shown in the following table:

Pin	Signal name
1	No Connection
2	Receive data – RS-232 ±9 V (±5 Vmin)
3	Transmit data – RS-232 ±9 V (±5 Vmin)
4	No Connection
5	Signal Ground Reference for COM signals
6	No Connection
7	No Connection
8	No Connection
9	No Connection

Serial Interface Setup

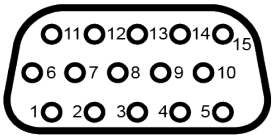
To interface with the Radical-7 and receive serial text data, connect a serial interface cable with a ferrite bead installed to the serial output connector located on the back of the Radical-7 Docking Station. See ***Handheld Back View*** on page 36. Once serial communication is established, packets of data are communicated at 1 second intervals. See ***Device Settings*** on page 86.

To interface with the Docking Station serial port, set the following communication parameters on the interfacing serial device:

Parameter	Setting
Baud Rate	9600 baud bi-directional
Number of bits per character	8
Parity	None
Bits	1 start, 1 stop
Handshaking	None
Connector type	Female DB-9

Analog Output and Nurse Call Specifications

Analog Out and Nurse Call are accessible on the same female high-density DB-15 connector. See ***Handheld Back View*** on page 36. Analog Output and Nurse Call interface are only available when the Handheld is attached to the Docking Station. Only use an Analog and Nurse Call cable that has a ferrite bead installed.



Note: RDS-2 does NOT have an Analog Output and Nurse Call Interface.

The following table shows the pin out of the Analog Output and Nurse Call.

Pin	Signal Name	Pin	Signal Name	Pin	Signal Name
1	+5V (60mA max.)	6	Nurse Call (Normally Open)	11	Ground
2	Ground	7	Nurse Call (Normally Closed)	12	Nurse Call - Common
3	Ground	8	Ground	13	Ground
4	Ground	9	Analog 1	14	Ground
5	Ground	10	Ground	15	Analog 2

Analog Output

The Radical-7 can interface with various analog recording devices or strip chart recorders through its Analog Output connector located on the back of the Docking Station. The output

signals vary from approximately 0 to 1 volt in a linear fashion. The actual analog output voltage generated may not exactly range between 0.0V to 1.0V. A variance of ± 40 mV is acceptable.

Calibration

For device calibration purposes, the analog output signals can be set to either 0 Volts or 1 Volt. Calibrate the analog recording system to those levels before use.

Nurse Call

The Nurse Call feature is available when the Radical-7 is operating as a standalone. Nurse Call is based on the relay closing or opening depending on alarm, Low Signal IQ events, or both. For maximum flexibility, either normally open (pin 6) or normally closed (pin 7) signals are available. Only qualified personnel should connect one of these two signals and common (pin 12) to a hospital's Nurse Call system. During an alarm condition or a Low Signal IQ event, depending on the configuration, the normally open pin will be connected to the common pin and the normally closed will be disconnected. The Nurse Call polarity can be inverted to accommodate various Nurse Call station requirements.

Parameter	Specification
Max voltage	100V DC or AC peak
Max Current	100mA

Wireless Specifications

Communication (Wi-Fi)	
Type	WLAN Radio: IEEE 802.11 a/b/g
Frequency	2.4 GHz - 802.11b/g/n: 2412-2472 MHz 5.0 GHz - 802.11a/n: 5150-5250 MHz, 5250-5350 MHz, 5470-5725 MHz, 5725-5825 MHz
Max Peak Output Power	18 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	OFDM, BPSK, CCK
Modulation Signals	Analog and Digital

Communication (Wi-Fi)	
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. 802.11n - MCS 0-7 HT20/HT40

Communication (Bluetooth)	
Type	Bluetooth
Frequency	2402-2480 MHz
Max Peak Output Power	<12 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	1, 2, 3 Mbps

Communication (WiFi and Bluetooth)	
Duty Cycle	6% (maximum) *(Note: The software sends 120 bytes at 62.5 Hz for 7,500 bytes per second, or 60 Kbps. Worst duty cycle will be at the minimum transmission bit rate of 1.1 Mbps. Therefore, the calculated duty cycle is 0.06 Mbps / 1.1 Mbps, which results in a duty cycle of approximately 6%.)*

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: , EAP-PEAP, EAP-TLS

Radio Compliance	
USA	FCC ID: VKF-RAD7A or VKF-RAD7B FCC Model: Radical-7 FCC Title 47, Part 15
Canada*	IC ID: 7362A-RAD7A or 7362A-RAD7B IC Model: VKF-RAD7A or VKF-RAD7B RSS-247
Europe	EU Radio Equipment Directive (RED 2014/53/EU) EN 300 328:V2.1.1 EN 301 893:V2.1.1 EN 301 489-1:V2.2.0 EN 301 489-17 V3.1.1 EN 62311
Japan	TELEC Article 2-1-19 Article 2-1-19-3 Article 2-1-19-3-2
Korea	KN 301 489-1 V2.2.0 KN 301 489-17 V3.1.1

* The Per RSS-Gen, Section 8.4 This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

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	

Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communication Equipment

Test Frequency (MHz)	**Band (a) (MHz)**	**Service (a)**	**Modulation (b)**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-395	TETRA 400	Pulse modulation **(b)** 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM (c) +/- 5 kHz deviation 1 kHz sine	2	0,3	28

Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
710	704-787	LTE Band 13, 17	Pulse modulation (**b**) 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation (**b**) 18 Hz	2	0,3	28
870						
930						
1 720	1 700-1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3. 4. 35: UMTS	Pulse modulation (**b**) 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400-2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation (**b**) 217 Hz	2	0,3	28
5 240	5 100-5 800	WLAN 802.11 a/n	Pulse modulation (**b**) 217 Hz	0,2	0,3	9
5 500						
5 785						

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

(**a**) For some services, only the uplink frequencies are included.
(**b**) The carrier shall be modulated use a 50% duty cycle square wave signal.
(**c**) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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		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		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% dip in mains voltage for 0.5 cycle 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.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Recommended separation distance**
Conducted RF IEC 61000-4-6	3Vrms	3V	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	20 V/m 80 MHz to 2.5 GHz	20 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment. **(b)** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment

The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 K Hz to 80 MHz d = 1.17*Sqrt (P)	80 MHz to 800 MHz d = 0.18*Sqrt (P)	800 MHz to 2.5GHz d = 0.35*Sqrt (P)
0.01	0.12	0.018	0.035
0.1	0.37	0.057	0.11
1	1.17	0.18	0.35
10	3.7	0.57	1.1
100	11.7	1.8	3.5

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC	 3149433	ANSI/AAMI ES60601-1 Certification
IPX1	Protection against vertically falling water drops	 T2A 250V	Fuse replacement - Only replace with time-delay fuses specified in this Instructions for Use.
 NON STERILE	Non-Sterile		Defibrillation-proof. Type BF applied part
	Separate collection for electrical and electronic equipment (WEEE)		Recyclable
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician	EC REP	Authorized representative in the European community
FC	Federal Communications Commission (FCC) Licensing	FCC ID:	Identifies unit has been registered as a radio device
	Non-ionizing electromagnetic radiation	IC Model:	Innovation, Science and Economic Development Canada (ISED)

Symbol	Description	Symbol	Description
	Warning, electricity		Biohazardous Waste
	Electrostatic	 SpO2	Not for continuous monitoring (No alarm for SpO2)
	No parameter alarms		Product contains no PVC (polyvinyl chloride) material
	Caution		Not made with natural rubber latex
	Manufacturer		Catalog number (model number)
	Date of manufacture YYYY-MM-DD		Masimo reference number
	Storage temperature range		Serial number
	Keep dry		Fragile, handle with care
	Storage humidity limitation		Do not use if package is damaged
	Atmospheric pressure limitation		Equipotential Ground Terminal
	AC current		SatShare Interface

Symbol	Description	Symbol	Description
	Fuse		Wireless Symbol level
	Stand-By		Wireless features can be used in member states with the restriction of indoor use in France - Class 2 wireless device
	RS-232 Interface		Iris Connection
	Analog Out Interface		Ethernet
	USB port		Nurse Call Interface
	Less than		Greater than
	China Restriction of Hazardous Substances		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual
	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Citations

[1] 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. This variation equals plus or minus one standard deviation which encompasses 68% of the population weight.

[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. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[4] The Radical-7 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%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.*

[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. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

[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 variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

[7] Respiration rate accuracy for the Masimo Acoustic Respiration Sensor and Instrument has been validated for the range of 4 to 70 breaths per minute for adult and pediatric patients and 4 to 120 breaths per minute for infant and neonatal patients in bench top testing. Clinical validation for up to 61 breaths per minute was also performed with the Masimo Acoustic Respiration Sensor and Instrument.

[8] RRp performance has been clinically validated on 28 healthy, adult volunteers, 59 hospitalized adult patients, and 28 hospitalized pediatric patients (> 2 years of age). The clinical testing included non-randomized studies comparing RRp measurements against manual, clinician-scored capnograms. The clinical testing on hospitalized adult and pediatric patients was conducted using convenience sampling and did not necessarily include all patient conditions found in hospitals and hospital-type settings. The clinical testing results may not be generalized to all patient conditions. RRp performance was validated across the entire range of 4 to 70 RPM through bench testing.

[9] This represents approximate run time with all connectivity options turned off and at the lowest level of brightness using a fully charged battery.

[10] 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.

[11] 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.

[12] Maximum sensitivity mode fixes perfusion limit to 0.02%.

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Chapter 9: Service and Maintenance

The following chapter contains information about cleaning, battery operation, performance verification, service, repair, and warranty.

Cleaning

The Radical-7 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 Radical-7 and physically disconnect the AC power and all patient connections before cleaning.

CAUTION: To avoid permanent damage to the Radical-7, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

To surface clean the Radical-7:

- 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 Radical-7 to dry thoroughly before using again.

CAUTION: To avoid permanent damage to the Radical-7, do not use excessive amounts of liquids to clean the device.

The surfaces of the Radical-7 may be cleaned with the following solvents or cleaning agents:

- 70% isopropyl alcohol
- Glutaraldehyde
- 0.5% sodium hypochlorite water solution
- Accelerated Hydrogen Peroxide solutions (e.g., Oxivir TB)
- Quaternary Ammonium chloride solution

Battery Operation and Maintenance

The Radical-7 Handheld includes a lithium ion rechargeable battery. The Radical-7 Docking Station may include the optional 6.5 amp-hour nickel metal hydride rechargeable battery.

Before using the Radical-7 as a Handheld or as a transport monitor, the Handheld rechargeable battery and the optional Docking Station rechargeable battery must be fully charged. To charge the batteries, refer to ***Initial Battery Charging*** on page 44.

Estimated Run Times of Battery Power

The following tables outline the estimated run times of the battery-powered Radical-7. The time estimates are based on a Radical-7 with fully charged batteries. The time estimates are also based on a Radical-7 with and without the back-light illuminated.

The Radical-7 is always configured to include the Handheld battery. It may optionally be configured to include the Docking Station battery. Determine the configuration of the system before referencing the following tables.

Run Time for Handheld Only

In this configuration, the Radical-7 is configured to only include the Handheld battery (standard configuration). When running on battery power, it is advisable to operate only the Handheld. On battery power, it is possible to operate the Standalone (Handheld attached to the Docking Station with the Handheld battery providing power to the Docking Station). However, the capacity of the Handheld battery pack is not sufficient to support this mode for long periods of time.

For optimal battery run time, configure the device to automatically adjust the brightness. See ***Brightness*** on page 91.

Configuration	Operation Mode	Minimum run time
Handheld only	Handheld, undocked, not connected to AC power	4 hours
Handheld only	Handheld docked, not connected to AC power	1 hour

Replacing the Batteries

Before installing or removing the battery, make sure the AC power cord is removed and power to the Radical-7 is turned off.

To replace the rechargeable Handheld battery

1. Turn off the Radical-7 Handheld off and remove the patient cable connection. If docked, detach the Handheld from the Docking Station.
2. Loosen the closure screw on the battery compartment door and lift out the battery.
3. Take a new battery and place it in the compartment.
4. Tighten the closure screw.
5. Place the Handheld into Docking Station, turn on line power and charge battery.

See ***Battery Operation and Maintenance*** on page 149.

Replacing the Fuses

Should a power problem blow one or both of the fuses in the power entry module on the rear panel, the fuse(s) will need to be replaced. Before starting, the user will need a 5-mm or 3/16-in screwdriver.

To replace the fuse(s)

1. Disconnect device from AC power.
2. Remove AC power cord from the power entry module at the rear of the Docking Station.
3. Using the screwdriver, gently pry loose the fuse cover in the left portion of the power entry module, exposing the fuse holder.
4. Using the screwdriver, gently remove the fuse holder.
5. Note how the fuse(s) are placed in the fuse holder for installation of the new fuse(s).
6. To remove the fuses from the fuse holder, use the edge of the screwdriver blade to pry against the bottom of the metal portion of the fuse where it is secured to the glass portion of the fuse.
7. Place the fuse(s) in the fuse holder, properly orienting the fuse(s). For fuse specifications, see ***Electrical***.

   WARNING: Fire Hazard: To protect against fire hazard, replace only with fuses of same type, current rating, and voltage rating.
8. Slide the fuse holder back into the power entry module and press firmly to make sure it is completely seated.
9. Close the fuse cover and press gently until it seats completely, flush with the back of the Docking Station. The device is ready to be reconnected to AC power. If the fuses blow shortly after replacement, the device requires service.

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 Radical-7 following repairs or during routine maintenance, follow the procedure outlined in this chapter. If the Radical-7 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:

- Place the Handheld into the Docking Station.
- Connect the Docking Station to AC power and fully charge the Handheld battery.
- Disconnect any patient cables or pulse oximetry probes.
- Disconnect any SatShare, serial or analog output cables from the device.
- Set the Radical-7 to Normal operating mode by going to the Main menu and the Home Use feature to *No*.

Power-On Self Test

To conduct a Power-On Self Test

1. Connect the Battery Module to the Device Module. Refer to Setup for instructions on how to connect the Battery Module to the Device Module.
2. Upon connection, the device emits a tone and the Masimo logo displays.

Touchscreen Function Test

To conduct a Touchscreen Function Test

1. Connect the Radical-7 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 Radical-7. 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 71.
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 Radical-7.
2. Use the Patient Cable connector on the Radical-7 to connect the Masimo SET® Tester to the Radical-7.
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 Radical-7.
2. Turn off the Radical-7 and then turn on again. Ensure that there are no audible alarms and that the Audible Alarm feature is not set to silenced.
3. Verify the Nurse Call polarity is set to normal. See ***Access Control*** on page 91.
4. Prepare a digital multi-meter to measure resistance.
5. Connect the common lead of the digital multi-meter to the pin 12 (Nurse Call - Common) of the Analog Output connector on the RDS. See ***Analog Output and Nurse Call Specifications*** on page 136.

6. Connect the positive lead of the digital multi-meter to pin 6 (Nurse Call - Normally Open) of the Analog Output connector on the RDS.
7. Verify that the resistance is greater than 1 Megaohm (open circuit).
8. Trigger an alarm on the Radical-7 (for example, by connecting and disconnecting a sensor while measuring data).
9. Verify that the resistance is less than 35 ohms.

Analog Output Test

To conduct an Analog Output test

1. Disconnect any patient cables, sensors, or accessories from the Radical-7. Turn off the Radical-7 and then turn on again.
2. Connect the common lead of a digital voltmeter to the pin 2 (Ground) of the analog output connector on the Radical-7. Connect the positive lead of the voltmeter to pin 9 (Analog 1) of the analog output connector.
3. On the *device output* screen, on the *analog 1* option, select **0V Output**. See ***Device Output*** on page 94.
4. Verify that the voltmeter measures a voltage of approximately 0V.
5. Change the *analog 1* option to **1V Output**.
6. Verify that the voltmeter measures a voltage of approximately 1.0V.
7. Repeat steps 5 and 6, with the positive lead of the voltmeter connected to pin 15 (*analog 2*). See ***Serial Interface Specifications*** on page 135.
8. Connect a patient cable and sensor and verify that the voltage on pins 9 and 15 are between 0V and 1.0V while measuring a saturation and pulse rate.

Battery Test

To conduct a Battery test

1. Fully charge the Radical-7 by placing the Handheld into the Docking Station and then connect the AC power.
2. Verify that the Handheld Battery Charging indicator is illuminated.
3. When the Radical-7 is fully charged, the Handheld Battery Charging indicator turns off.
4. Turn on the Radical-7 on and verify that the Battery indicator shows a full charge.

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

To return the device for service, refer to ***Return Procedure*** on page 154.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in ***Cleaning*** on page 149. 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 Radical-7. 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 Radical-7 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 Radical-7 has been decontaminated for bloodborne pathogens.
- Return the Radical-7 to the shipping address listed in ***Contacting Masimo*** on page 154 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 (Radical-7® 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.

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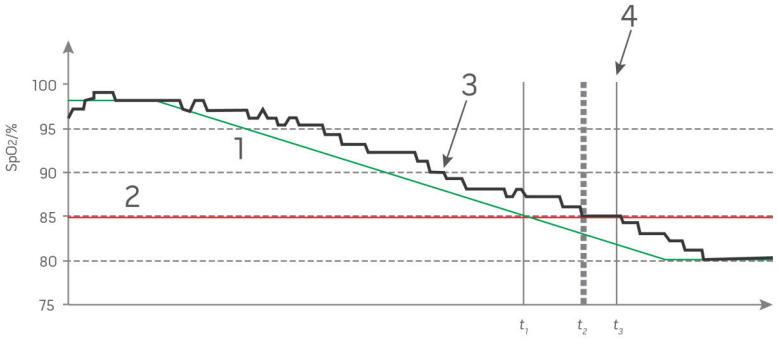
Appendix: Concepts of Alarm Response Delay

Concepts of Alarm Response Delay

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



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

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

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

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

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

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