Operator's Manual

Radius-7®

Wearable Pulse CO-Oximeter®

Masimo

For Sale in the USA

These operating instructions provide the necessary information for proper operation of all models of the Radius-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 Radius-7 are prerequisites for its proper use. Do not operate Radius-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.

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

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings and precautions.

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

Wireless Radio:
Contains: FCC ID: VKF-MWM1 or VKF-MWM2 | Model: Radius-7 | IC: 7362A- MWM1 or 7362A-MWM2

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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 the Radius-7® Wearable Pulse CO-Oximeter®. Important safety information relating to general use of the Radius-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

Product Description

The Radius-7® Wearable Pulse CO-Oximeter® is a noninvasive device that measures arterial oxygen saturation (SpO_{2}), pulse rate (PR), perfusion index (Pi), and Pleth Variability Index (PVi®) along with optional measurements of hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC™), methemoglobin (SpMet®), Acoustic Respiration Rate (RRa®), and Pleth Respiration Rate (RRp®).

The following key features are available for the Radius-7:

- Patient wearable device for continuous monitoring when the patient is ambulatory.
- Bluetooth radio for transfer of parameter data to the Root patient monitoring and connectivity platform.
- Optional Wi-Fi for direct communication throughout the hospital to the Patient SafetyNet™ remote monitoring system.
- Masimo SET® and rainbow® SET technology performance.
- SpO_{2} and pulse rate monitoring in motion and low perfusion environments.
- Continuous and noninvasive monitoring of carboxyhemoglobin (SpCO), methemoglobin (SpMet), and total hemoglobin (SpHb).
- Respiration rate can be determined by the acoustic (RRa) or plethysmographic waveform (RRp).

Indications for Use

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

Contraindications

There are no contraindications.

Safety Information, Warnings and Cautions

CAUTION: Radius-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 should be read before use. Refer to the Operator's Manual for Root for additional safety information, warnings, and cautions.

Safety Warnings and Cautions

WARNING: Do not use Radius-7 if it appears or is suspected to be damaged.

WARNING: Always use Radius-7 in conjunction with Root. Do not use parts from other systems. Injury to personnel or equipment damage could occur.

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

WARNING: Do not start or operate the Radius-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: Only use Masimo authorized devices with Radius-7. Using unauthorized devices with Radius-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 Radius-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 the Radius-7 during magnetic resonance imaging (MRI) or in an MRI environment.

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

WARNING: Electrical Shock Hazard: 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 the Radius-7 while monitoring patient.

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

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

WARNING: The Armband site must be checked frequently or per clinical protocol to ensure adequate securement, circulation and skin integrity.

WARNING: Armbands applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure injury.

WARNING: Discontinue and dispose of Armband if it appears to be stained or becomes excessively moist to minimize risk of skin irritation.

CAUTION: Electrical Shock Hazard: Do not place the Battery Charging Adapter of Radius-7 on or near the patient. Injury to patient could occur.

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

Performance Warnings and Cautions

General

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

WARNING: Always ensure settings including alarms are appropriate for each patient and facility's protocols prior to use.

WARNING: The Radius-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 Radius-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. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

WARNING: Radius-7 is not an apnea monitor.

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

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

WARNING: Do not use during electrocautery. This may affect the accuracy or availability of the parameters and measurements.

WARNING: When the Radius-7 is connected to Root, all audible alarms will be provided on the Root.

WARNING: Always pair Radius-7 with Root.

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

WARNING: Properly apply sensors according to the sensor's directions for use. Misapplied sensor or sensors that become partially dislodged 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: With very low perfusion at the monitored site, the reading may read lower than core arterial oxygen saturation.

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: SpHb measurements in the ranges of 0 to 8g/dL and 17 to 25 g/dL are provided for reference information only. The monitor shall display *Low SpHb SIQ* message along with the SpHb measurement whenever the measurement is displayed in these ranges. Furthermore, the display window also changes color providing a visual alarm to alert the user that the SpHb values are either in the 0 to 8g/dL or 17 to 25 g/dL ranges. Clinicians should consider additional information to supplement SpHb values, including laboratory diagnostic tests using blood samples, to completely understand the patient's condition.

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.

WARNING: Inaccurate SpO_2 readings may be caused by:

- Elevated levels of COHb and/or MetHb.
- Severe anemia.
- Extremely low arterial perfusion.
- Excessive induced motion.
- Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (Quantitative defects such as Thalassemias).

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

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

WARNING: Inaccurate SpCO readings may be caused by:

- Elevated methemoglobin levels in the range of >15%.
- Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (quantitative defects such as Thalassemias).
- Extremely elevated hemoglobin levels.
- Low arterial perfusion.
- Low arterial oxygen saturation levels including altitude induced hypoxemia.
- Motion induced artifact.
- Severe anemia.

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

WARNING: Inaccurate SpMet readings may be caused by:

- Elevated carboxyhemoglobin levels in the range of >3%.
- Hemoglobinopathies (qualitative defects including sickle cell) and Hemoglobin synthesis disorders (quantitative defects such as Thalassemias).
- Extremely elevated hemoglobin levels.
- Low arterial perfusion.
- Low arterial oxygen saturation levels including altitude induced hypoxemia.
- Motion induced artifact.
- Physiological conditions that can significantly shift the oxygen disassociation curve.
- Severe anemia.

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

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

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

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

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

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

CAUTION: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to Radius-7.

CAUTION: In order to maintain Bluetooth connectivity with Root, ensure that the Radius-7 is within approximately 7 m radius and line of sight of Root.

CAUTION: When using Radius-7 in Wi-Fi mode, be aware of the patient's location. Alarms relayed to Patient SafetyNet will not provide patient location.

CAUTION: When using multiple Radius-7 and Root systems, re-dock the Battery Module to Root to ensure proper pairing before connecting the Radius-7 to the patient.

CAUTION: If the Radius-7 and Root become unable to communicate, parameters and measurements will not show on the Root; however, this will not affect Radius-7's ability to monitor the patient.

CAUTION: In order to establish and maintain Radius-7's minimum Quality of Service, the following network specifications should be met before and after installation:

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

Note: Physiological conditions that result in loss of pulsatile signal may result in no SpO_2, SpHb, SpOC, SpCO, SpMet, and RRp readings.

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

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

Note: When the Radius-7 is connected directly via Wi-Fi to Patient SafetyNet, the Radius-7 will provide audible alarms.

Note: Before securing Radius-7 onto the patient, make sure the Battery Module is sufficiently charged.

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

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

Note: The Radius-7 display enters standby mode after 30s of inactivity. The Radius-7 display entering standby mode does not affect the monitoring of the patient.

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

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

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

Patient SafetyNet

Note: The wireless communication status between Radius-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 Radius-7 as these processes may damage the electrical components, potentially leading to patient harm.

WARNING: To avoid electric shock, do not attempt to service the Radius-7 or the Battery Module. Servicing of the Radius-7 should be done by qualified personnel only.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the Radius-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 electric shock, always turn off the Radius-7 and physically disconnect it from Root before cleaning Radius-7.

CAUTION: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the Radius-7. These substances affect the device's materials and device failure can result.

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

CAUTION: To prevent damage, do not soak or immerse Radius-7 in any liquid solution.

Compliance Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

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

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

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

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

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

Chapter 1: Technology Overview

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

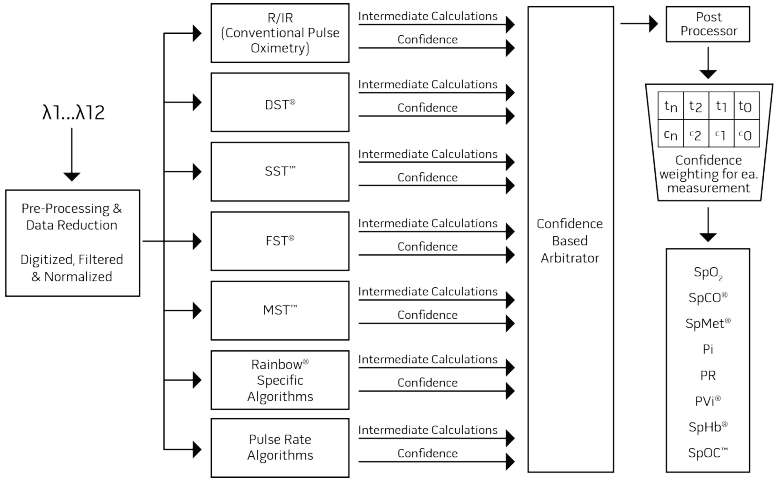
Signal Extraction Technology® (SET®)

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

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

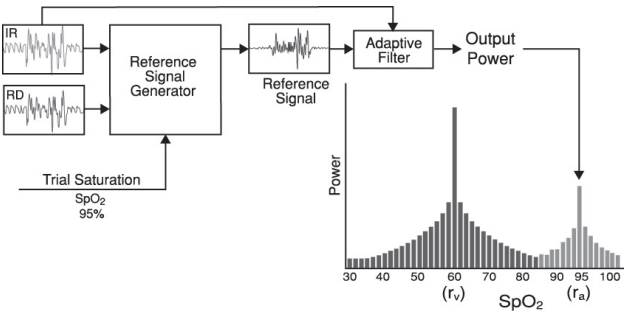
Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.



Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (SpO2)

Pulse oximetry is governed by the following principles:

- Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
- 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 Radius-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)

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2. *Forget P, Lois F, de Kock M. Goal-Directed Fluid Management Based on the Pulse Oximeter-Derived Pleth Variability Index Reduces Lactate Levels and Improves Fluid Management. Anesth Analg. 2010 Oct; 111(4):910-4.*
3. *Zimmermann M., Feibicke T., Keyl C., Prasser C., Moritz S., Graf B.M., Wiesenack C. Accuracy of Stroke Volume Variation Compared with Pleth Variability Index to Predict Fluid Responsiveness in Mechanically Ventilated Patients Undergoing Major Surgery. Eur J Anaesthesiol. 2010 Jun; 27(6):555-61.*
4. *Desebbe O, Boucau C, Farhat F, Bastien O, Lehot JJ, Cannesson M. Anesth Analg. The Ability of Pleth Variability Index to Predict the Hemodynamic Effects of Positive End-Expiratory Pressure in Mechanically Ventilated Patients under General Anesthesia. 2010 Mar 1; 110(3):792-8.*
5. *Tsuchiya M., Yamada T., Asada A. Pleth Variability Index Predicts Hypotension During Anesthesia Induction. Acta Anesthesiol Scand. 2010 May; 54(5):596-602.*
6. *Loupec T., Nanadoumgar H., Frasca D., Petitpas F., Laksiri L., Baudouin D., Debaene B., Dahyot-Fizelier C., Mimoz O. Pleth Variability Index Predicts Fluid Responsiveness in Critically Ill Patients. Crit Care Med. 2011 Feb; 39(2):294-9.*

7. *Fu Q., Mi W.D., Zhang H. Stroke Volume Variation and Pleth Variability Index to Predict Fluid Responsiveness during Resection of Primary Retroperitoneal Tumors in Hans Chinese. Biosci Trends. 2012 Feb; 6(1):38-43.*
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10. *Feissel M., Kalakhy R., Banwarth P., Badie J., Pavon A., Faller J.P., Quenot JP. Plethysmographic Variation Index Predicts Fluid Responsiveness in Ventilated Patients in the Early Phase of Septic Shock in the Emergency Department: A Pilot Study. J Crit Care. 2013 Oct; 28(5):634-9.*
11. *Yu Y., Dong J., Xu Z., Shen H., Zheng J. Pleth Variability Index-Directed Fluid Management in Abdominal Surgery under Combined General and Epidural Anesthesia. J Clin Monit Comput. 2014 Feb 21.*
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13. *Cannesson M. Arterial pressure variation and goal-directed fluid therapy. J Cardiothorac Vasc Anesth. 2010 Jun; 24(3):487-97.*
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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.

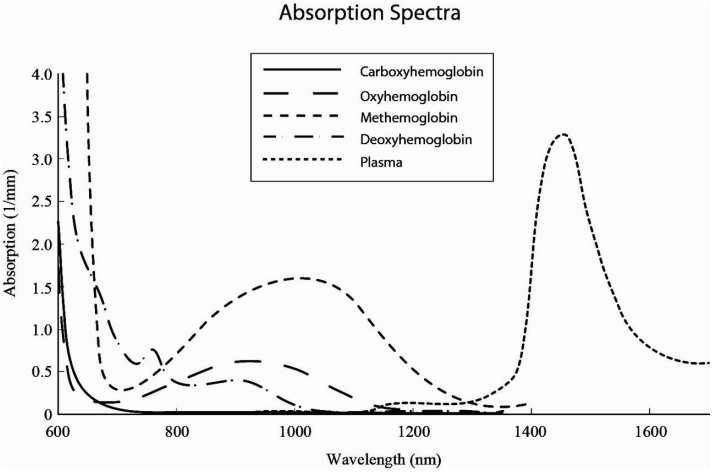
With motion, the plethysmographic waveform is often distorted and may be obscured by noise artifact. Shown as a vertical line, the SpO_2 SIQ coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Signal IQ identifies the timing that the algorithms 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 Main Screen*** on page 40.

rainbow Pulse CO-Oximetry Technology

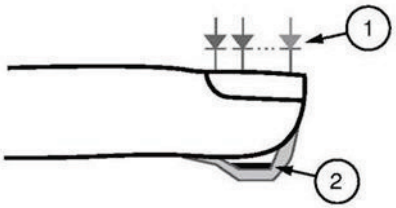
rainbow Pulse CO-Oximetry technology is governed by the following principles:

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

The Radius-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 Radius-7 for calculation.



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

Once Radius-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 Radius-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 Radius-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 71.

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 Radius-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™)

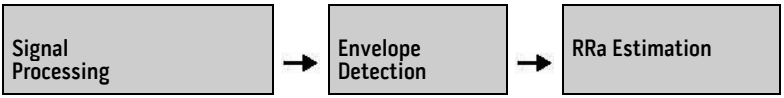
rainbow Acoustic Monitoring (RAM) continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Sensor, which is applied on the patient's neck, translates airflow sounds generated in the upper airway to an electrical signal that can be processed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



Digital signal to respiratory measurement

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

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[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: System Components

This chapter contains the description of the Radius-7 physical features.

General System Description

The Radius-7® Wearable Pulse CO-Oximeter® system consists of the following components:

- Instrument Module
- Battery Module
- Armband
- Battery Charging Adapter

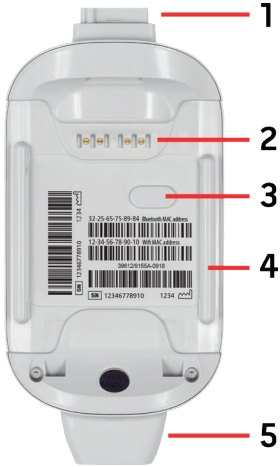
The Battery Charging Adapter docks onto the Root to function as both a charger and holder for the Radius-7. The Battery Module snaps onto the Instrument Module and together they can be strapped onto a patient's arm using the Armband.

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

Radius-7 Instrument Module

The Instrument Module connects both optical and acoustic rainbow sensors.

Radius-7 is available with Bluetooth only, or with Bluetooth and Wi-Fi. Bluetooth enables connection with Root. Wi-Fi enables direct connection with Patient SafetyNet when out of Bluetooth range with Root.



The following table describes the features of the Instrument Module:

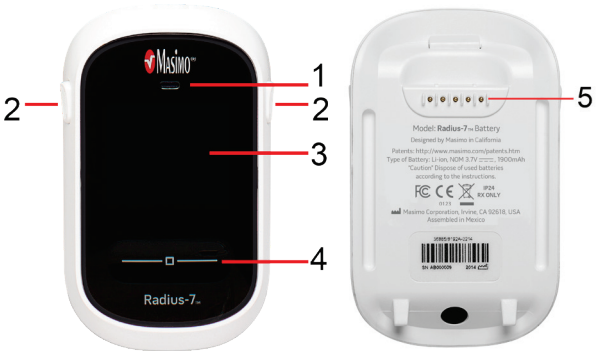
Ref.	Feature	Description
1	Acoustic Sensor Connector	An acoustic sensor can be connected to Radius-7 via this connector. **CAUTION:** Refer to the *Directions for Use* for the sensor before applying it on patients.
2	Contact Pins	The pins provide a data and power connection to the Battery Module.
3	Key for Armband	The key allows for proper positioning of the Armband used to secure Radius-7 to the patient.
4	Wi-Fi Antenna*	Antenna for wireless communication.
5	RD Sensor Connector	RD sensors can be connected to Radius-7 via this connector. **CAUTION:** Refer to the *Directions for Use* for the sensor before applying it on patients.

* Available on Wi-Fi radio equipped models only.

Radius-7 Battery Module

The Battery Module features a Display panel, Touchpad, Speaker and rechargeable lithium-ion battery. The Battery Module is designed to snap onto the Instrument Module.

Front View **Back View**



The following table describes the features of the Battery Module:

Ref.	Feature	Description
1	Speaker	Radius-7 is provided with a speaker to provide alarms in the event the communication to secondary display is lost.
2	Release Buttons	These buttons are used to release the Battery Module from the Instrument Module and Battery Charging Adapter.
3	Display Panel	This display area shows parameter values and visual alarms. If the device is connected to a secondary display, parameter data is displayed continuously on the secondary display.
4	Touchpad	This feature is used to navigate the menu screens and acknowledge alarms.
5	Connection Pins	The pins enable the Battery Module to dock onto the Battery Charging Adapter and provide power and communication to the Battery Module.

Radius-7 Armband

The Armband is used to secure Radius-7 to the patient. The Armband comes in three different sizes; small (11.9"), medium (16.4") and large (25.4"). The Instrument Module and Armband are keyed so that they can only be connected properly in the right orientation. See ***Securing Radius-7 to Patient*** on page 35.

Radius-7 Battery Charging Adapter

The Battery Charging Adapter fits into the docking station on Root and allows the Battery Module to be docked for charging or storage. Once the Battery Charging Adapter is installed on the Root docking station during initial setup, the adapter should not be removed during patient monitoring.

The following table describes the features of the Battery Charging Adapter:

Ref.	Feature	Description
1	Battery Pocket	The Battery Pocket can be used to store the Battery Module or the Instrument Module individually, or the entire Radius-7.
2	Battery Module Connector	The Battery Module Connector allows for docking and charging of the Battery Module. See ***Charging the Radius-7 Battery Module*** on page 33.

Chapter 3: Setting Up

This chapter contains information about setting up Radius-7 before use.

Unpacking and Inspection

To unpack and inspect the device perform the following steps:

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 ***Chapter 8: Service and Maintenance*** on page 105.

Preparation for Use

Prior to setting up the Radius-7 for monitoring, perform the following steps:

1. Confirm that you have all system components:
   - Battery Module (2)
   - Instrument Module
   - Armband
   - Battery Charging Adapter
   - Root
   - Sensors
2. Read the ***Safety Information, Warnings and Cautions*** on page 11.
3. Setup the Root system according to the directions provided in the Operator's Manual for Root.
4. Power on the Root and ensure it is connected to AC power supply. See Operator's Manual for Root.
5. Ensure the Battery Module is fully charged. See ***Charging the Radius-7 Battery Module*** on page 33.

Charging the Radius-7 Battery Module

Before use, the Radius-7 Battery Module needs to be fully charged. To charge the Battery Module for the first time perform the following steps:

1. Attach the Battery Charging Adapter to the Root by aligning the bottom of the adapter with the two groves at the bottom of the docking interface on the Root and snap it in place.
2. Ensure that the Root is powered on and connected to an AC power supply.
3. Dock the Battery Module onto the Battery Charging Adapter.

Note: Charge the Battery Module on the Root System you intend to pair with the Radius-7. Docking the Battery Module onto Root automatically pairs the device with Root. See ***Connecting Radius-7 to Root via Bluetooth*** on page 34.

4. Verify that the Battery Module is charging. A battery icon will be displayed on the Radius-7 screen to indicate that the Battery Module is charging. See ***About the Main Screen*** on page 40.
5. Once sufficiently charged you may un-dock the Battery Module by pressing the Release Buttons on the Battery Module.
6. Enable Bluetooth Connectivity on Root. See Operator's Manual for Root.

For additional battery information, See ***Battery Operation and Maintenance*** on page 105.

Connecting Radius-7 to Root via Bluetooth

In order connect the Radius-7 to Root via Bluetooth connection perform the following steps:

1. Enable Bluetooth Connectivity on Root. See Operator's Manual for Root.
2. Dock the Battery Module of the Radius-7 to the Root that you intend to make the Bluetooth connection.
3. Allow enough time for the Root to acknowledge the Radius-7 is docked. The user will hear a beep tone to indicate that the Bluetooth connection between Root and Radius-7 has been established.
4. Verify that the Bluetooth Mac address on Radius-7 matches the Mac Address listed on Root. See ***Navigating Radius-7 Main Menu*** on page 40.
5. Un-dock the Battery Module from Root and connect it to the Instrument Module to complete Bluetooth connection.
6. You can verify the Bluetooth connection is successful when the Root screen begins to display the Radius-7's measurement data.

WARNING: When the Radius-7 is connected via Bluetooth to Root all audible alarms will be provided on the Root.

CAUTION: In order to maintain Bluetooth connectivity with Root, ensure that the Radius-7 is within approximately a 7m radius and line of sight of Root.

CAUTION: When using multiple Radius-7 and Root systems, re-dock the Battery Module to Root to ensure proper pairing before connecting the Radius-7 to the patient.

Connecting Radius-7 to Patient SafetyNet

To configure Radius-7 to connect to Patient SafetyNet, please use the Masimo Instrument Configuration Tool. See the ***Operator's Manual, Masimo Instrument Configuration Tool*** for directions about connecting Radius-7 to Patient SafetyNet.

The wireless icon in the Status Bar on Radius-7 displays the current connection status. See ***About the Main Screen*** on page 40.

Icon	Description
	A gray icon indicates Radius-7 wireless radio is on, but it is not connected to a wireless network.
	A blue icon indicates Radius-7 is connected to a wireless network, but not communicating with Patient SafetyNet.
	A green icon indicates Radius-7 is connected to a wireless network and communicating directly with Patient SafetyNet.

Securing Radius-7 to Patient

Before securing Radius-7 onto the patient, make sure the Battery Module is sufficiently charged.

Note: Safety Information, Warnings and Cautions should be read before use. See ***Safety Information, Warnings and Cautions*** on page 11.

See ***Chapter 2: System Components*** on page 29 for information on the different components.

To secure the Radius-7 to a patient, follow the instructions below with the help of the visual aid:

1. Remove the Armband from the packaging.
2. Slide the Instrument Module between the Armband fabric and the Armband plastic as shown in the figure (1).
3. The ▭ shaped hole in the Armband plastic should fit over the matching key on the front side of the Instrument Module as shown in the figure (2 & 3).
4. Connect the Battery Module to the Instrument Module (4) securing the Armband Adapter between the Battery Module and the Instrument Module.
5. Select a site on the patient's arm to secure Radius-7. Place the Radius-7 on the arm with the Masimo logo on the top and making sure the Armband fabric is between the Radius-7 and the arm (5).

CAUTION: If the device is being applied directly to the patient's skin, select a site that is free from skin irritation or signs of chaffing.

CAUTION: Only the smooth side of the Armband fabric should make contact with the patient when properly applied.

Note: Do not to dispose of the Radius-7 instrument module when changing the replaceable armband.

Note: The Radius-7 should be oriented so that the Acoustic Sensor connector is the closest connector to the patient's neck.

6. Loop the Armband strap around the patient's arm and thread the strap through the remaining open slot of the Armband plastic from the rear and secure the end of the Armband strap by pressing the tab on the end onto the Armband fabric (6).
7. Check to ensure the strap fits comfortably around the patient's arm.

   WARNING: Armbands applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure injury.

   WARNING: The Armband site must be checked frequently or per clinical protocol to ensure adequate securement, circulation and skin integrity.

   WARNING: Discontinue and dispose of Armband if it appears to be stained or becomes excessively moist to minimize risk of skin irritation.

   CAUTION: Ensure that the Armband does not slide off the arm.
8. Connect sensor(s) to the Instrument Module.
9. See *Directions for Use* for each sensor for proper application of the sensor to the patient.

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

Removing Radius-7 from Patient

To remove the Radius-7 from a patient, perform the following steps:

1. Disconnect sensor(s) from the Instrument Module.
2. Detach the end of the armband strap from the Armband fabric.
3. Un-thread armband strap from Instrument Module slot and remove the Radius-7 from the patient's arm.
4. Press the Release Buttons on the Battery Module, and slide the Battery Module off of the Instrument Module.
5. Undo the key of the armband plastic and slide the Instrument Module away from the Armband.

   Note: Do not to dispose of the Radius-7 instrument module when changing the replaceable armband.
6. Dispose of the armband according to local laws and regulations.

   WARNING: Do not reuse the strap to avoid possible cross contamination.
7. Disinfect and clean the Battery Module and Instrument Module. See ***Cleaning*** on page 105.
8. Return the Battery Module to the battery charging adapter for charging. See ***Charging the Radius-7 Battery Module*** on page 33.
9. Store the Instrument Module in the Battery Pocket of the Battery Charging Adapter.

Chapter 4: Operation

Using the Touchpad

The Touchpad on the Radius-7 is located below the display panel on the Battery Module.

Note: The display panel is not a touch screen.

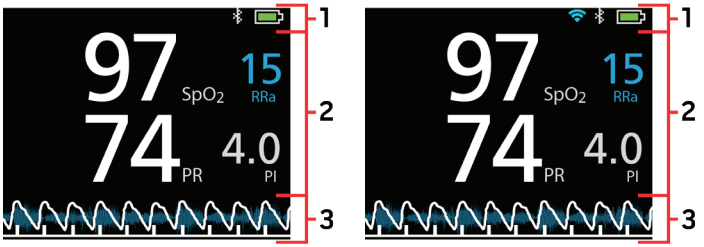
Using the gestures described below, the user is able to view all parameters and measurements, navigate through menu options, and silence/acknowledge alarms on Radius-7.

Action	Description	Function
Touch	Touch and release. Action performed once finger is released.	Select a menu item or action
Touch and Hold	Touch and stay for a prescribed amount of time. Release finger once action had been performed.	Enter and Exit the Main Screen Silence/acknowledge alarms.
Swipe	Touch, move (left, right, up or down) and release.	View all selectable menu options.
Flick	Touch, quickly swipe across (left, right, up or down) and release.	View all selectable menu options. Similar to the Swipe gesture. It allows user to scroll through menu options faster.

After 30 seconds of inactivity on the Touchpad, the Display Panel turns off automatically and switches to Standby mode to conserve power. To turn the Display Panel back on, tap anywhere on the Touchpad.

Note: The Radius-7 display entering Standby mode does not affect the monitoring of the patient.

About the Main Screen



Bluetooth ONLY ***Bluetooth and Wi-Fi***

The Main Screen is composed of the following:

Ref	Feature	Description
1	Status Bar	Visible at the top of the Main Screen and displays Exception Messages, Wi-Fi* connectivity status, Bluetooth connectivity status and battery life.
2	Parameter Display	Majority portion of Main Screen. Displays up to four parameters simultaneously.
3	Waveform Field	Displays SIQ and the pleth waveform with the respiration waveform (blue) in the background.

* Available on Wi-Fi radio equipped models only.

Navigating Radius-7 Main Menu

From the Main Screen, touch and hold the Touchpad on the Battery Module screen to access the Main Menu.

Use the Touchpad *Swipe* gesture to scroll through the Main Menu Options. Use the *Touch* gesture on the Touchpad to select the Main Menu Option that is centered in the window. Use the same gestures to adjust settings.

The Main Menu options are:

Main Menu Options	Description	Default	Options
Back	Returns you to the main screen or previous menu.	N/A	N/A

Main Menu Options	Description	Default	Options
Waveform	Allows the user to choose if the waveform will be displayed on the screen.	On	On or Off
Brightness	Allows the user to change the brightness of the Display Panel.	4	1 through 4 in steps of 1
Display Timeout	Allows the user to choose the amount of time before the display turns off.	30 seconds	10, 30, 60, or 120 seconds
About	Hardware and software information about the device including Wi-Fi Bluetooth Mac Address.	N/A	N/A
Power	Restarts the Radius-7	N/A	N/A

Navigating Radius-7 Settings on Root

The following settings on Radius-7 can be configured with Root:

- Parameter settings including alarms and trends. See ***Configuring Parameters*** on page 42.
- Additional settings including Averaging time and FastSat. See ***Additional Settings*** on page 43.

The Radius-7 settings may be configured with Root when connected via Bluetooth. See ***Connecting Radius-7 to Root via Bluetooth*** on page 34 for information on how to pair Radius-7 with Root. For general information on Root, see Operator's Manual for Root.

About the Action Menu

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

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

- **Sensitivity** - Selecting this option cycles through the available sensitivity modes: APOD, NORM and MAX. See ***Sensitivity Modes Overview*** on page 42.
- **Trend View** - Displays values in *Trend View*. See ***Trends*** on page 60.
- **Analog View** - Displays values in an analog gauge style view.

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

Sensitivity Modes Overview

Three sensitivity levels enable a clinician to tailor the response of Radius-7 to the needs of the particular patient situation. Sensitivity Modes are accessed through the *Action Menu* or through Additional Settings. See ***About the Action Menu*** on page 41 or ***Additional Settings*** on page 43.

The sensitivity levels are as follows:

- **NORM (Normal Sensitivity)**
  NORM is the recommended sensitivity mode for patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).
- **APOD® (Adaptive Probe Off Detection® Sensitivity)**
  APOD is the recommended sensitivity mode for situations which there is a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.
- **MAX (Maximum Sensitivity)**
  MAX is the recommended sensitivity mode for patients with low perfusion or when a *low perfusion* message displays in APOD or NORM mode. MAX mode is not recommended for care areas where patients are not monitored visually, such as medical-surgical floors. It is designed to display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.

Configuring Parameters

Each parameter displayed on Root and Radius-7 can be configured in its respective menu on Root. Configurable options include Alarm Settings and Averaging Time.

There are two ways to access any parameter's settings menu on Root:

1. From the Main Screen on Root, press on any of the parameters displayed in the rainbow window to access its respective settings menu.

   Or

2. Press the gear icon  on the bottom right-hand corner of the Main Screen on Root to access the Main Menu. Then press the rainbow tile  to access the rainbow menu. See ***rainbow Parameter Settings*** on page 43.

rainbow Parameter Settings

The *rainbow* menu allows the user to view and customize settings for rainbow parameters:

Parameter Settings

See ***Parameter Settings*** on page 44.

3D Alarms

See ***3D Alarms*** on page 64.

Additional Settings

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

Additional Settings

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

Option	Description	Default Setting	Configurable Settings
Sensitivity Mode	Change Sensitivity Mode. See ***Sensitivity Modes Overview*** on page 42.	APOD	MAX, APOD, NORM
SmartTone	Enable or disable the SmartTone.	Off	On, Off
SpO_2 low % limit	Set the SpO_2 low limit alarm. See ***SpO2 Settings*** on page 44.	Off	Off, 1% to 98%

Parameter Settings

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 44.
- See ***PR Settings*** on page 46.
- See ***Pi Settings*** on page 47.
- See ***PVi Settings*** on page 49.
- See ***Respiration Rate (RR) Settings*** on page 50.
- See ***SpHb Settings*** on page 54.
- See ***SpOC Settings*** on page 57.
- See ***SpMet Settings*** on page 57.
- See ***SpCO Settings*** on page 58.

SpO2 Settings

From the *SpO_2 Settings* screen, change any of the following options:

SpO2 Alarms on page 45

Additional Settings for SpO2 on page 46

About Parameter Information on page 59

Desat Index on page 64

About Desat Index on page 64

Trends on page 60

SpO2 Alarms

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

Option	Description	Alarm Priority	Factory Default Settings	User 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%
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	Off	Off or 1 to 10 in steps of 1
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	4	Off or 1 to 10 in steps of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, 1, or 2 minutes
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%	-5%, or -10%, or Off
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 46.	Off	Off or On

* With FastSat the averaging time is dependent on the input signal.

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 Radius-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.

PR Settings

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

PR Alarms on page 46

About Parameter Information on page 59

Trends on page 60

PR Alarms

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

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
High Limit	High Limit is the upper threshold that triggers an alarm.	High	140 bpm	35 bpm to 235 bpm, in steps of 5 bpm

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	50 bpm	30 bpm to 230 bpm, steps of 5 bpm
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	20	Off or 5 to 25 in steps of 5
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	10	Off or 5 to 25 in steps of 5
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, or 1, 2, or 5 minutes

Pi Settings

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

Pi Alarms on page 48

Additional Settings for Pi on page 49

About Parameter Information on page 59

Pi Delta on page 65

About Pi Delta on page 65

Trends on page 60

Pi Alarms

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

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	Step size: 0.04 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 19 in steps of 1, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	0.30	Step size: 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
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	Off	Off or 0.01 to 0.09 in increments of 0.01 0.1 to 1.0 in increments of 0.1
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	0.30	Off or 0.01 to 0.09 in increments of 0.01 0.1 to 1.0 in increments of 0.1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, or 1, 2, or 5 minutes

Additional Settings for Pi

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

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

PVi Settings

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

PVi Alarms on page 49

Additional Settings for PVi on page 50

About Parameter Information on page 59

Trends on page 60

PVi Alarms

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

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	40	2 to 99 in steps of 1, or Off When set to Off, alarms are disabled.
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	5	Off or 1 to 98 in steps of 1 When set to Off, alarms are disabled.
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	5	Off or 1 to 10 in steps of 1

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	3	Off or 1 to 10 in steps of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, or 1, 2, 5, or 10 minutes

Additional Settings for PVi

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

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

Respiration Rate (RR) Settings

Radius-7 can determine Respiration Rate (RR) either by the acoustic signal (RRa) or the plethysmographic waveform (RRp). For more information, see:

RRa Settings on page 51

RRp Settings on page 53

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

RRa Alarms on page 51

RRp Alarms on page 53

Additional Settings for RRa on page 52

Additional Settings for RRp on page 54

About Parameter Information on page 59

Trends on page 60

RRa Settings

When using an acoustic sensor, Respiration Rate (RR) is determined by the acoustic (RRa) signal. See ***rainbow Acoustic Monitoring™ (RAM™)*** on page 26. When the respiratory rate is determined by the acoustic signal, the *Main Screen* labels respiratory rate as *RRa*, as shown below.

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

RRa is active under the following conditions:

- RRa is installed on the Radius-7.
- An acoustic sensor is connected.

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

RRa Alarms on page 51

Additional Settings for RRa on page 52

About Parameter Information on page 59

RRa Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	Configurable Options
High Limit	High Limit is the upper threshold that triggers an alarm.	High	30 breaths per minute	6 to 69 breaths per minute in steps of 1 breath 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 68 breaths per minute in steps of 1 breath per minute
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	5	Off or 1 to 7 in steps of 1

Options	Description	Alarm Priority	Factory Default Settings	Configurable Options
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	2	Off or 1 to 7 in steps of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds or 1, 2 or 5 minutes
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	Trending, No Averaging, Fast, Medium, or Slow
Freshness	The duration of time that, during interference, the system displays the last valid reading.	5 minutes	0, 1, 5, 10, or 15 minutes

RRp Settings

When using a pulse oximetry or pulse CO-Oximetry sensor with Radius-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 Radius-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 Radius-7.
- Pulse oximetry or pulse CO-Oximetry sensor is connected.
- Acoustic sensor is not connected.

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

RRp Alarms on page 53

Additional Settings for RRp on page 54

RRp Alarms

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

Options	Description	Alarm Priority	Factory Default	Configurable Options
High Limit	High Limit is the upper threshold that triggers an alarm.	High	30 breaths per minute	6 to 69 breaths per minute in steps of 1 breath 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 68 breaths per minute in steps of 1 breath per minute
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	5	Off or 1 to 7 in steps of 1

Options	Description	Alarm Priority	Factory Default	Configurable Options
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	2	Off or 1 to 7 in steps of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds or 1, 2, or 5 minutes
Alarm Delay	When an alarm condition is met, 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	No Averaging, Fast, Medium, Slow, Trending
Freshness	The duration of time that, during interference, the system displays the last valid reading.	5 minutes	0, 1, 5, 10, or 15 minutes

SpHb Settings

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

SpHb Alarms on page 55

Additional Settings for SpHb on page 56

About Parameter Information on page 59

Trends on page 60

SpHb Alarms

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

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
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 g/dL to 24.5 g/dL in steps of 0.1 g/dL, or Off (2.0 mmol/L to 15.0 mmol/L in steps of 0.1 mmol/L, or Off) (20 g/L to 245 g/L in steps of 1 g/L, or Off) When SpHb Precision is set to 1.0, the values are rounded to the nearest whole number. 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)	1.0 g/dL to 23.5 g/dL in steps of 0.1 g/dL. or Off (1.0 mmol/L to 14.5 mmol/L, in steps of 0.1 mmol/L, or Off) (10 g/L to 235 g/L in steps of 1 g/L, or Off) When SpHb Precision is set to 1.0, values are rounded to the nearest whole number. When set to Off, alarm is disabled.
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	1.0 g/dL Off (mmol/L) (10 g/L)	Off or 0.1 g/dL to 2.5 g/dL in increments of 0.1 Off or 0.1 mmol/L to 1.5 mmol/L in increments of 0.1 Off or 1 g/L to 25 g/L in increments of 1

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	2.0 g/dL Off (mmol/L) (20 g/L)	Off or 0.1 g/dL to 2.5 g/dL in increments of 0.1 Off or 0.1 mmol/L to 1.5 mmol/L in increments of 0.1 Off or 1 g/L to 25 g/L in increments of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, or 1, 2, or 5 minutes

Additional Settings for SpHb

Option	Description	Factory Default Settings	User Configurable Options
Averaging Time	The length of time over which the system calculates the average of all data points.	Medium	Short, Medium, or Long
Calibration	Provides an arterial or venous value that displays on the main screen.	Arterial	Arterial or Venous
Unit of Measure*	Displays total hemoglobin (SpHb) as g/dL (grams per deciliter), mmol/L (millimoles per liter), or g/L (grams per liter). Unit of Measure cannot be changed during active monitoring.	g/dL	g/dL, mmol/L, or g/L
Precision (units of g/dL and mmol/L)	Allows the user to set the decimal for SpHb. **Note:** When unit is g/L, Precision is always 1 (whole numbers).	0.1	0.1, 0.5, or 1.0

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

SpOC Settings

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

SpOC Alarms on page 57

About Parameter Information on page 59

Trends on page 60

SpOC Alarms

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

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	25	2% to 34%, 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	10	Off or 1% to 33%, in steps of 1% When set to Off, alarm is disabled.
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	Off	Off or 1 to 4 in steps of 1
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	2	Off or 1 to 4 in steps of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, or 1, 2, or 5 minutes

SpMet Settings

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

SpMet Alarms on page 58

About Parameter Information on page 59

Trends on page 60

SpMet Alarms

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

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
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 When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	Off or 0.1% to 2%, in steps of 0.1% 2.5% to 99%, in steps 0.5% When set to Off, alarm is disabled.
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	1.0	Off or 0.1 to 2.0 in increments of 0.1 2.5 to 10.0 in increments of 0.5
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	Off	Off or 0.1 to 2.0 in increments of 0.1 2.5 to 10.0 in increments of 0.5
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, or 1, 2, or 5 minutes

SpCO Settings

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

SpCO Alarms on page 59

About Parameter Information on page 59

Trends on page 60

SpCO Alarms

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

Option	Description	Alarm Priority	Factory Default Settings	User Configurable Options
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.
High Caution Range	Provides an early indicator for a parameter approaching the high limit threshold value that triggers an alarm.	NA	3	Off or 1 to 10 in steps of 1
Low Caution Range	Provides an early indicator for a parameter approaching the low limit threshold value that triggers an alarm.	NA	Off	Off or 1 to 10 in steps of 1
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds, or 1, 2, or 5 minutes

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.

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.

Trend Settings

Use the *Trend Settings* screen under each Parameter Setting screen to configure Trend Views on Root.

Option	Description	Factory Default Setting	User Configurable Settings
Default Duration*	Sets the time duration displayed in trend lines.	2 hours	15, 30, or 45 minutes 1, 2, 4, 8, 12, or 24 hours
Clear Trends*	Deletes all stored trend data.	N/A	Press **Clear** to delete all stored trend data.
SpO_2	Y-axis Min	50	0 to 95 in steps of 5
	Y-axis Max	100	5 to 100 in steps of 5
PR	Y-axis Min	25	25 to 235 in steps of 5
	Y-axis Max	200	30 to 240 in steps of 5
SpHb g/dL	Y-axis Min	5.0 g/dL	0.0 to 24.9 g/dL in increments of 0.1
	Y-axis Max	20.0 g/dL	0.1 to 25.0 g/dL in increments of 0.1
SpHb mmol/L	Y-axis Min	3.1 mmol/L	0.0 to 15.4 mmol/L in increments of 0.1
	Y-axis Max	12.4 mmol/L	0.1 to 15.5 mmol/L in increments of 0.1
SpHb g/L	Y-axis Min	50 g/L	0 to 249 g/L in steps of 1
	Y-axis Max	200 g/L	1 to 250 g/L in steps of 1
RRa	Y-axis Min	0	0 to 69 in steps of 1

Option	Description	Factory Default Setting	User Configurable Settings
	Y-axis Max	35	1 to 70 in steps of 1
RRp	Y-axis Min	0	0 to 69 in steps of 1
	Y-axis Max	35	1 to 70 in steps of 1
SpCO	Y-axis Min	0	0 to 99 in steps of 1
	Y-axis Max	40	1 to 100 in steps of 1
SpMet	Y-axis Min	0.0	0.0 to 99.5 in increments of 0.5
	Y-axis Max	15.0	1.0 to 100.0 in increments of 0.5
Pi	Y-axis Min	0.0	0.0 to 19.0 in increments of 1.0
	Y-axis Max	20.0	1.0 to 20.0 in increments of 1.0
PVi	Y-axis Min	0	0 to 99 in steps of 1
	Y-axis Max	30	1 to 100 in steps of 1
SpOC	Y-axis Min	0	0 to 34 in steps of 1
	Y-axis Max	20	1 to 35 in steps of 1

*Available under the Root Main Menu Settings screen. For information about viewing and manipulating Trend Settings on Root, refer to the Root Operator's Manual.

Chapter 5: Alarms and Messages

About Alarms

The Radius-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.*

Alarm Priorities

There are two priorities for alarms:

- High
- Medium

The following are the audible and visual characteristics for different alarm priorities:

Alarm Priority	Alarm Status Color	Audio Alarm Description
High Priority	Flashing red	571 Hz tone, 10-pulse burst, pulse spacing: 0.25s, 0.25s, 0.50s, 0.25s, repeat time:10s
Medium Priority	Flashing yellow	550 Hz tone, 3-pulse burst, pulse spacing: 0.375s, 0.375s, repeat time: 7s

Alarm Management

In order to minimize accidental changes to Radius-7's critical settings, alarm management is restricted to Root.

When Radius-7 is connected to Root, audible alarms will sound on Root but not Radius-7. In this case, audible alarms can be temporarily silenced on Root. Visual alarms will display on both Radius-7 and Root until the alarm condition has been addressed. For alarm management on Root, see Operator's Manual for Root.

When Radius-7 is not connected to Root, audible alarms will sound on Radius-7. Audible alarms can be temporarily silenced by touching and holding the Touchpad for 2 seconds. Visual alarms will continue to display on Radius-7 until the alarm condition has been addressed.

When Radius-7 is connected to Patient SafetyNet (and not communicating to Root through Bluetooth), audible alarms will sound on Radius-7 and Patient SafetyNet. Audible alarms can be temporarily silenced by touching and holding the Touchpad on Radius-7 for 2 seconds. Visual alarms will continue to display on Radius-7 until the alarm condition has been addressed.

Note: In the event of temporary loss of power to Radius-7, the Root will restore alarm setting to Radius-7 through the re-established Bluetooth connection. If the Radius-7 is used without a Bluetooth connection to Root, then the alarm settings will be restored to the factory default.

3D Alarms

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

Desat Index on page 64

About Desat Index on page 64

Pi Delta on page 65

About Pi Delta on page 65

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 64.

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. Radius-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 Radius-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 65. 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

Options	Description	Factory Default Settings	User Configurable Settings
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

Messages

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

Alarm Message	Description	Next Step
(Pulse CO-Ox) Replace Cable *or* *(RAM) Replace Cable*	• Defects in the Instrument Module	• Return the device for servicing.
(Pulse CO-Ox) No Sensor Connected *or* *(RAM) No Sensor Connected*	• Sensor not fully inserted into the connector.	• Disconnect and reconnect sensor. See the instructions for use provided with your sensor.
	• Incompatible or defective sensor.	• Replace with a compatible Masimo sensor.
	• Device is searching for patient's pulse.	• Disconnect and reconnect the sensor to the Instrument Module.
(Pulse CO-Ox) Replace Sensor *or* *(RAM) Replace Sensor*	• Sensor has used all of its available monitoring time • Sensor is non-functional. • Defective sensor.	• Replace sensor.
(Pulse CO-Ox) Incompatible	• Not a compatible Masimo sensor.	• Replace with a compatible Masimo sensor.

Alarm Message	Description	Next Step
Sensor *or* *(RAM) Incompatible Sensor*	• Sensor is attached to a device without an appropriate parameter installed.	• Use a compatible sensor. Contact your local Masimo Representative to learn more about optional parameter upgrades.
(Pulse CO-Ox) Sensor Near Expiration *or* *(RAM) Sensor Near Expiration*	• Sensor has less than 10% patient monitoring time remaining.	• Replace sensor.
(Pulse CO-Ox) No Adhesive Sensor Connected *or* *(RAM) No Adhesive Sensor Connected*	• The adhesive portion of the sensor is not connected.	• Ensure the adhesive portion is firmly connected to the sensor.
(Pulse CO-Ox) Replace Adhesive Sensor *or* *(RAM) Replace Adhesive Sensor*	• When a disposable or resposable sensor is used, the adhesive portion of the sensor is non-functional, or the life of the adhesive portion of the sensor has expired.	• Replace the adhesive portion of the sensor.
(Pulse CO-Ox) Incompatible Adhesive Sensor	• Not a compatible Masimo disposable or resposable sensor.	• Replace with a compatible Masimo disposable or resposable sensor.
or *(RAM) Incompatible Adhesive Sensor*	• Sensor is attached to a device without an appropriate parameter installed.	• Use a compatible sensor. Contact your local Masimo Representative to learn more about optional parameter upgrades.
(Pulse CO-Ox) Adhesive Near Expiration *or* *(RAM) Adhesive Near Expiration*	• Disposable or resposable sensor has less than 10% patient monitoring time remaining.	• Replace with new disposable or resposable sensor.

Alarm Message	Description	Next Step
(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 on the patient and reconnect the sensor to the Instrument Module. If the sensor is damaged, replace the sensor.
(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) Sensor Initializing	• Device is checking the sensor for proper functioning 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.
(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.
(Pulse CO-Ox) Interference Detected *or* *(RAM) Interference Detected*	• High intensity light such as pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight, or other monitor displays.	• Place a Masimo Optical Light Shield over the sensor.
(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.
(Pulse CO-Ox) Low Perfusion Index	• Signal strength is too weak.	• Move sensor to better perfused site.

Alarm Message	Description	Next Step
(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*** on page 22.
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 SpHb*** on page 24.
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***.
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 24.
"- -" (Dashes shown as parameter value)	• Unable to provide a parameter value.	• Check patient's vital condition.
Low battery	• Battery charge is low.	• Charge Battery Module by docking into Battery Charging Adapter on Root and powering Root with AC line power. Replace Battery Module if necessary.
Device disconnected	• Device has lost Bluetooth connectivity with Root.	• Check if Bluetooth is enabled on Root. See the Operator's Manual for Root. • Check connection between the Instrument Module and Battery Module. • Re-dock the Battery Module on Root to re-establish Bluetooth connectivity.
Speaker Failure	• Device requires service.	• Contact Masimo Tech Support. See ***Contacting Masimo*** on page 107.

Chapter 6: Troubleshooting

Troubleshooting Measurements

Symptom	Potential Causes	Next Steps
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 and see if blood flow to the site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace Sensor. • Minimize or eliminate motion at the monitoring site. • Set to Maximum Sensitivity. See ***Sensitivity Modes Overview*** on page 42.
Difficulty obtaining a reading.	• Interference from line frequency induced noise. • Misaligned sensor • Inappropriate sensor or sensor size. • Excessive ambient or strobing light. • Excessive motion.	• Verify/set 50/60hz menu setting. See Operator's Manual for Root. • Verify Sensor type and size and re-apply sensor. See Directions for Use for Sensor. • Check and see if blood flow to the site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Minimize or eliminate motion at the monitoring site. • Shield the sensor from excessive or strobing light.

Symptom	Potential Causes	Next Steps
SpCO reading displays as dashes.	• SpCO parameter may have not stabilized.	• Allow time for parameter reading to stabilize. • Verify Sensor type and size and re-apply sensor. See Directions for Use for Sensor. • Check and see if blood flow to the site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace Sensor. • Submit blood sample for laboratory CO-Oximetry test for comparison. • Check patient conditions indicated to affect SpCO accuracy.
SpHb reading is dim and "Low SpHb SIQ" message displays.	• The SpHb reading is outside of the accuracy range. See ***Chapter 7: Specifications*** on page 75. • 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 and see if blood flow to the site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace Sensor. • Minimize or eliminate motion at the monitoring site. • Submit blood sample for laboratory CO-Oximetry test for comparison. • Check patient conditions indicated to affect SpHb accuracy.

Troubleshooting Radius-7

Symptom	Potential Cause	Next Step
Device turns on but Display Panel is blank.	The viewing contrast is not correct	• Adjust the brightness setting. See ***Navigating Radius-7 Main Menu*** on page 40. • If the condition persists, issue requires service. See ***Contacting Masimo*** on page 107.
Touchpad does not respond to gestures.	Internal failure	• Requires service. See ***Contacting Masimo*** on page 107.
Speaker makes no sound when device is not connected to Root.	Internal failure	• Requires service. See ***Contacting Masimo*** on page 107.
Unable to pair with Root	• Bluetooth not enabled on Root • Internal failure	1. Check if Bluetooth is enabled on Root. See the Operator's Manual for Root. 2. Check if Bluetooth is enabled on Radius-7 by accessing the About panel on the Main Menu. See ***Connecting Radius-7 to Root via Bluetooth*** on page 34. 3. Verify the Mac address on Radius-7 matches the one on Root. The Mac address on Radius-7 can be found by accessing the About panel on the Main Menu of Radius-7. For information on accessing the Mac address listed on Root refer to Operator's Manual for Root. 4. Re-dock the Battery Module on Root to pair the device with Root. 5. Call Service.
Intermittent Connection with Root	• Presence Monitoring is enabled on Root • Environmental interference	1. Check to see if Presence Monitoring feature is enabled. Refer to the Operator's Manual for Root. 2. Ensure Presence Monitoring feature is disabled when using Radius-7 with Root. 3. Check for sources of potential environmental interference. See ***Compliance Warnings and Cautions*** on page 17.

Radius-7 Error Codes

The following section lists possible Radius-7 error codes and potential causes. Contact Masimo Service if any of these error codes appear. See ***Contacting Masimo*** on page 107.

Code	Name
1	Instrument Module (IB) Crystal fault
2	Instrument Module (IB) Watchdog fault
3	Instrument Module (IB) RAM fault
4	Instrument Module (IB) ROM fault
5	Instrument Module (IB) Processor fault
6	Instrument Module (IB) Temperature out of range
7	Voltage out of range
8	MX Technology Board fault
11	Bluetooth fault
51	Battery Module (BB) Crystal fault
52	Battery Module (BB) Watchdog fault
53	Battery Module (BB) RAM fault
54	Battery Module (BB) ROM fault
55	Battery Module (BB) Processor fault
56	Battery Module (BB) Temperature out of range
57	Voltage out of range
58	Battery Gauge fault
59	Battery Charger fault

Chapter 7: Specifications

Measurement Range

Measurement	Display Range
SpO_2 (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 70 rpm
SpHb (Hemoglobin)	0.0 g/dL to 25.0 g/dL 0 g/L to 250 g/L (0.0 mmol/L to 15.5 mmol/L)
SpCO (Carboxyhemoglobin)	0% to 99%
SpMet (Methemoglobin)	0.0% to 99.9%
SpOC (Oxygen Content)	0 ml of O_2/dL to 35 ml of O_2/dL of blood
RRp (Respiration Rate)	0 rpm to 70 rpm

Accuracy (ARMS*)

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

Low perfusion [4] (SpO_2 from 70% to 100%)	Adults, Pediatrics	2%
Pulse Rate (PR)		
Range	25 to 240 bpm	
No motion	Adults, Pediatrics	3 bpm
Motion [5]	Adults, Pediatrics	5 bpm
Low Perfusion	Adults, Pediatrics	3 bpm
Carboxyhemoglobin Level (SpCO) [1]		
Range of 1% to 40%	Adults, Pediatrics	3%
Methemoglobin Level (SpMet) [1]		
Range 1% to 15%	Adults, Pediatrics	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
Respiratory Rate (RRp) [8]		
Range	4 rpm to 70 rpm	
No motion	Adults, Pediatrics (>2 years of age)	3 rpm A_{RMS}* $\pm$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.

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

ARMS Performance Specifications

The tables below provides A_{rms} (Accuracy Root Mean Square) values measured using the Masimo rainbow SET Technology, which is included in the Radius-7, with Masimo rainbow sensors in clinical studies under no motion conditions. This SpO_2 data is representative of data obtained from Masimo rainbow SET Technology and compatible Masimo sensors.

The below Bland-Altman plots represent the correlation of the (SpO_2 + SaO_2)/2 versus (SpO_2 - SaO_2) under no motion with an upper 95% and lower 95% limits of agreement.

Measurement Arms Values for rainbow Reuse (DCI) Sensors	
SpO_2 Accuracy Range (%)	Arms (%)
60-70	2.00
70-80	1.61
60-80	1.83

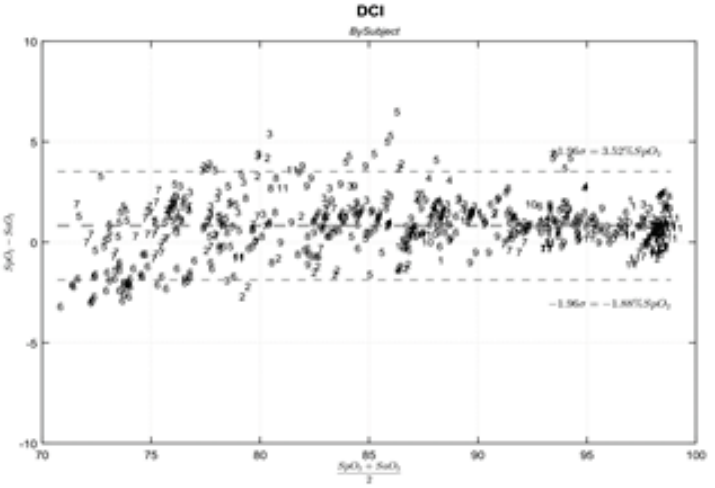


Figure 1: rainbow Reuse Sensors (Arms 60-80%)

Measurement Arms Values for rainbow Reuse (DCI) Sensors	
SpO_2 Accuracy Range (%)	Arms (%)
70-80	1.88
80-90	1.72
90-100	1.21
70-100	1.63

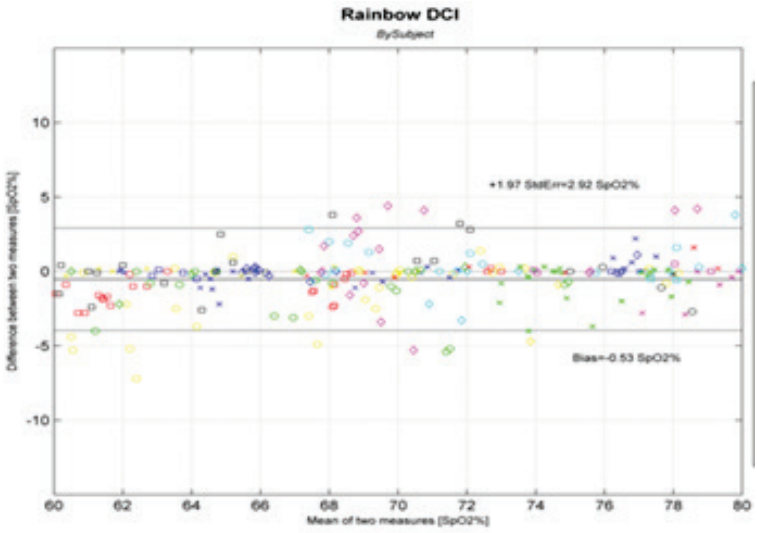


Figure 2: rainbow Reuse Sensors (Arms 70-100%)

Measurement Arms Values for rainbow Adhesive (R1 Series) Sensors	
SpO_2 Accuracy Range (%)	Arms (%)
60-70	3.42
70-80	2.49
60-80	2.99

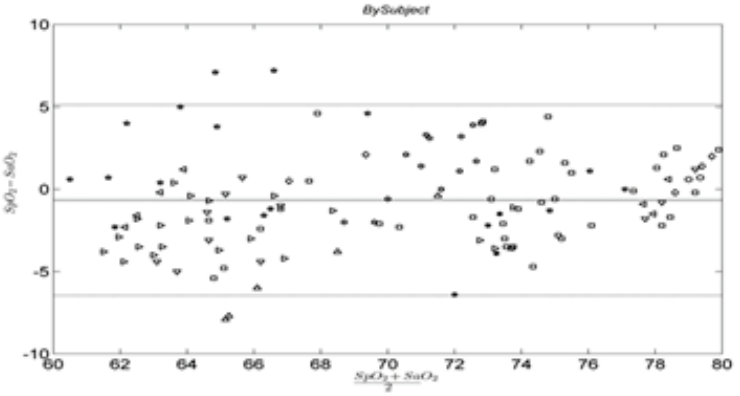


Figure 3: rainbow R1 Series (Arms 60-80%)

Measurement Arms Values for rainbow Adhesive (R1 Series) Sensors	
SpO_2 Accuracy Range (%)	Arms (%)
70-80	2.47
80-90	1.80
90-100	1.57
70-100	1.98

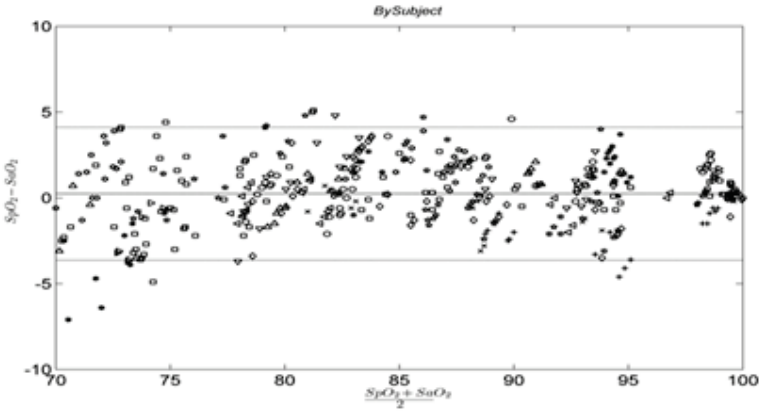


Figure 4: rainbow R1 Series (Arms 70-100%)

RRp Performance Specifications

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

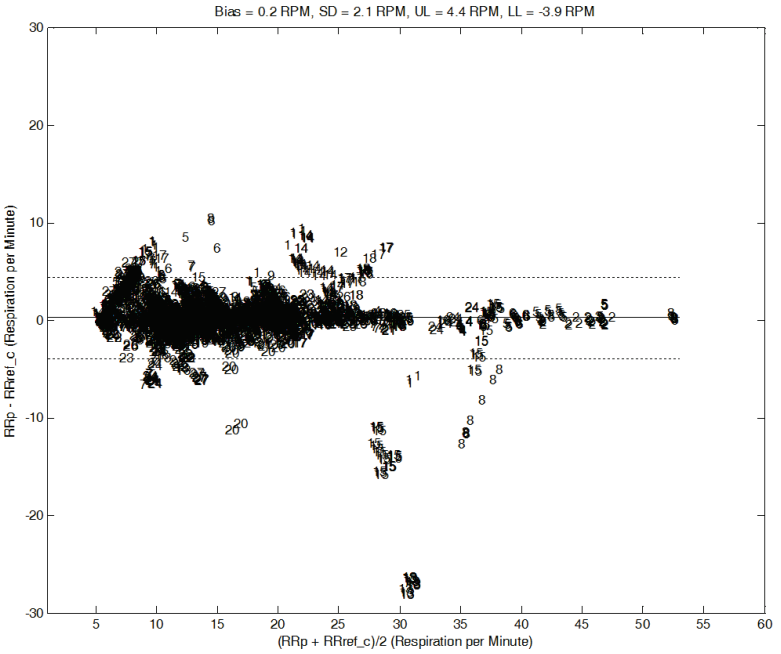


Figure 1: Subject by Subject Bland-Altman plot of RRp with respect to RRref_c

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

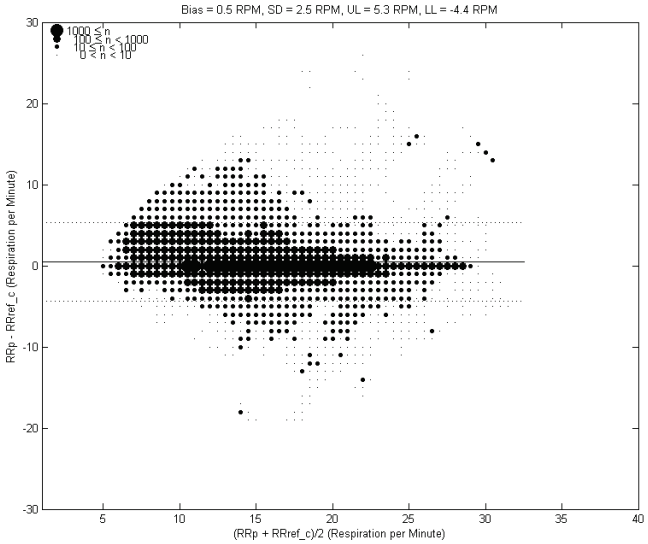


Figure 2: Bland-Altman plot of RRp with respect to RRref_c

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

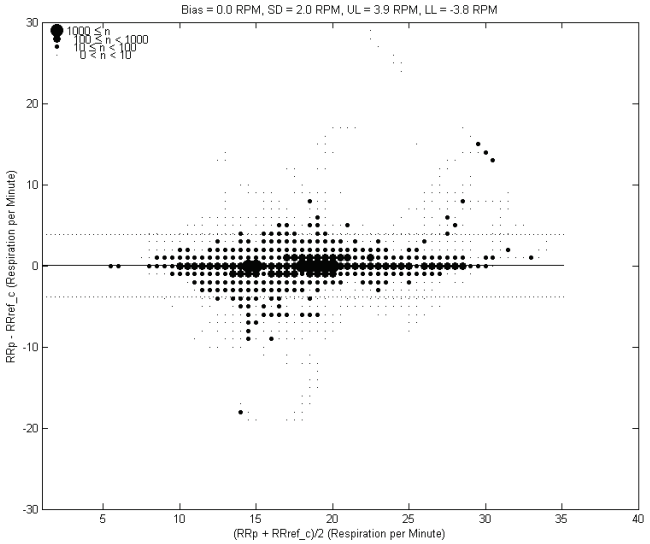


Figure 3: Bland-Altman plot of RRp with respect to RRref_c

Medical Conditions

Adult Medical Conditions

Medical Conditions from Clinical Study of Hospitalized Adult Patients

	N		N
Autoimmune		**Musculoskeletal and Connective Tissue (Cont.)**	
Psoriasis	1	End stage arthritis and osteonecrosis, bitateral hips	1
Cardiovascular		Fasciotomy wounds of right foot and tibia.	1
Atrial Septal Defect	1	Idiopathic scoliosis and kyphoscoliosis	1

Medical Conditions from Clinical Study of Hospitalized Adult Patients

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
Hiatal Hernia	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
Neurological	

Medical Conditions from Clinical Study of Hospitalized Adult Patients

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	
Cholecystitis	1

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
Subdural Hematoma	1

Medical Conditions from Clinical Study of Hospitalized Adult Patients

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

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

Medical Conditions from Clinical Study of Hospitalized Adult Patients

Degenerative arthritis of hip	1
Degenerative Joint Disease	1
Dupuytrens Contracture (Right Hand)	1
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
Chronic Constipation	1

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

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
congenital deformity of hip (joint)	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
Peritoneal/Retroperitoneal	

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

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

Radius-7 Battery Module	
Type	Lithium ion
Run Time	≥ 12 hours (continuous Masimo SET monitoring, Display off, Bluetooth on, Wi-Fi off)
Charging Time	≤ 6 hours

Note: For information on Root Battery see Specifications in the Operator's Manual for Root

Environmental

Radius-7 Environmental Conditions	
Operating Temperature	41°F to 95°F (5°C to 35°C)
Storage Temperature	-40°F to 158°F (-40°C to 70°C)
Operating Humidity	10% to 95%, non-condensing
Storage Humidity	10% to 95%, non-condensing
Atmospheric Pressure	540 mbar to 1060 mbar

For Environmental Specifications for Root with Battery Charging Adapter see Operator's Manual for Root.

Physical Characteristics

Item		Description
Dimensions		4.97" x 2.5" x 1.1" (126.2 mm x 63.2 mm x 27.2 mm)
Weight		
	Battery Module	0.21 lbs. (93g)
	Instrument Module	0.15 lbs. (67g)

Alarms

Alarm Priority	Alarm Status Color	Audio Alarm Description
High Priority	Flashing red	571 Hz tone, 10-pulse burst, pulse spacing: 0.25s, 0.25s, 0.50s, 0.25s, repeat time:10s
Medium Priority	Flashing yellow	550 Hz tone, 3-pulse burst, pulse spacing: 0.375s, 0.375s, repeat time: 7s

Alarm Characteristic	Description
Alarm Volume*	High Priority: 75 dB (min) Medium Priority: 70 dB (min)
Sensitivity	NORM, MAX, APOD [9]

* When volume is set to the highest level.

Display Indicators

Item	Description
Data Update Rate	1 second
Type	OLED
Pixels	160 X 128
Dot Pitch	0.073 (W) mm X 0.219 (H) mm

EMC Compliance

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

Safety Standards Compliance

Safety Standards Compliance
ANSI/AAMI ES 60601-1:2005
CAN/CSA C22.2 No. 60601-1:2008
IEC 60601-1:2005
EN 60601-1:2006
ANSI/AAMI/IEC 60601-1-8:2006
IEC 60601-2-49:2011
EN/ISO 80601-2-61:2011

Equipment Classification per IEC 60601-1	
Type of Protection	Internally powered (battery powered)
Degree of Protection against Electrical Shock	Defibrillation Proof Type BF-Applied Part
Protection against harm from Water and Particulate Matter	IP24 (Protection from solid foreign objects ≥12.5 mm diameter and against ingress from splashing water)
Mode of Operation	Continuous
Environment	Not suitable for use in the presence of flammable anesthetics

Wireless Specifications

Bluetooth ONLY Models: Radius7

Communication (Bluetooth)	
Type	Bluetooth
Frequency	2402-2480 MHz
Max Peak Output Power	Bluetooth 1.3 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	DH5
Modulation Signals	Analog and Digital
Available Data Rates	Bluetooth 1 Mbps

Radio Compliance	
USA	FCC ID: VKF-RADIUS Model: Radius-7
Canada*	IC: 7362A-RADIUS IC Model: RADIUS RSS-247
Europe	EN 301 489-17: EN 300 328 V2.2.0 EN 301 489-1 V2.1.1 EN 301 489-17 V3.1.1 EN 301 893 V2.0.7 R & TTE Directive

* 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.

Bluetooth WITH Wi-Fi Models: Radius-7 with Wi-Fi

Communication (Bluetooth)	
Type	Bluetooth
Frequency	2402-2480 MHz
Max Peak Output Power	Bluetooth 1.3 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	DH5
Modulation Signals	Analog and Digital
Available Data Rates	Bluetooth 1 Mbps

Communication (Wi-Fi)	
Type	WLAN Radio: IEEE 802.11 a/b/g
Frequency	802.11a: 5180-5240 MHz, 5745-5825 MHz 802.11b/g: 2412-2462 MHz
Max Peak Output Power	WLAN 17 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	OFDM, BPSK, CCK
Modulation Signals	Analog and Digital
Available Data Rates	802.11a - 6, 9, 12, 18, 24, 36, 48, 54 Mbps. 802.11b - 1, 2, 5.5, 11 Mbps. 802.11g - 6, 9, 12, 18, 24, 36, 48, 54 Mbps.

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-MWM1 Model: Radius-7
Canada*	IC: 7362A-MWM1 IC Model: MWM1 RSS-247
Europe	EU Radio Equipment Directive (RED 2014/53/EU) EN 300 328 V2.1.1:2016 EN 301 893 V2.1.1:2017 EN 301 489-17 V3.1.1:2012 EN 62311:2008
Japan	TELEC

* 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 2	The ME Equipment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	Suitable for use in all establishments, including domestic environments.

Guidance and Manufacturer's Declaration- Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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			
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
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 = 1.17*Sqrt (P)	800 MHz to 2.5GHz d = 2.33*Sqrt (P)
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC		ETL Intertek certification See ***Declarations on Page 1*** for certifications
	Non-Sterile	IP24	Protection from ingress and particulates and water spray from any direction
	Defibrillation-proof. Type BF applied part		Separate collection for electrical and electronic equipment (WEEE)
EC REP	Authorized representative in the European community		Recyclable
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician	FC	Federal Communications Commission (FCC) Licensing
	Non-ionizing electromagnetic radiation	FCC ID:	Identifies unit has been registered as a radio device
	Warning, electricity	IC Model:	Innovation, Science and Economic Development Canada (ISED)
	Electrostatic		Biohazardous Waste
	No parameter alarms	 SpO2	Not for continuous monitoring (No alarm for SpO_2)

Symbol	Description	Symbol	Description
	Caution		Product contains no PVC (polyvinyl chloride) material
	Manufacturer		Not made with natural rubber latex
	Date of manufacture YYYY-MM-DD		Catalog number (model number)
	Storage temperature range		Masimo reference number
	Keep dry		Serial number
	Storage humidity limitation		Fragile, handle with care
	Atmospheric pressure limitation		Do not use if package is damaged
	Nurse Call Interface		Equipotential Ground Terminal
	AC current		SatShare Interface
	Fuse		Wireless Symbol level
	Stand-By		Wireless features can be used in member states with the restriction of indoor use in France-Class 2 wireless device
	RS-232 Interface		Iris Connection

Symbol	Description	Symbol	Description
	Analog Out Interface		Ethernet
>	Greater than		USB port
<	Less 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 male and female 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 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 ±1 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 ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[4] The Radius-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 ±1 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 ±1 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 laboratory CO-Oximeter. The variation equals ±1 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 device has been validated for the range of 4 to 70 breaths per minute in bench top testing. Clinical validation for up to 30 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] Maximum sensitivity mode fixes perfusion limit to 0.02%.

**Registered trademark of Fluke Biomedical Corporation, Everett, Washington.*

Chapter 8: Service and Maintenance

Cleaning

The Radius-7 is a reusable device. The device is supplied and used non-sterile.

The Radius-7 should be cleaned before and after it has been applied to a patient and/or in accordance with local and governmental regulations to minimize the risk of cross-contamination.

The Battery Charging Adapter should also be cleaned periodically or according to local and governmental regulations to minimize the risk of cross-contamination.

CAUTION: Check the enclosure for possible cracks or opening before cleaning.

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

The outer surfaces can be cleaned either with a soft cloth dampened with a mild detergent and warm water solution or they can be wiped down with the following cleaning solutions:

- Cidex Plus (3.4% glutaraldehyde)
- 10% bleach solution
- ≤ 70% Isopropyl Alcohol solution

Using the recommended cleaning solutions on the display panel will not affect the performance of the Radius-7.

WARNING: Do not attempt to clean or re-use the arm band on multiple patients.

WARNING: Discontinue and dispose of arm band if it appears to be stained or becomes excessively moist to minimize risk of skin irritation.

Battery Operation and Maintenance

The Radius-7 includes a Battery Module containing a lithium ion rechargeable battery.

Before using the Radius-7, the Battery Module should be fully charged. See ***Charging the Radius-7 Battery Module*** on page 33.

The Battery Module requires approximately 6 hours for charging.

Memory effects of the battery may shorten run-time. When Battery Module run time is significantly reduced, it is advisable to completely discharge and fully recharge the Battery Module.

Note: Always store the Battery Module on the Root. Do not place it on a conductive surface where the connection pins may be shorted.

Safety Checks

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 by trained personnel at regular intervals or in accordance with local and governmental regulations.

Before conducting Safety Checks examine the device. Look for cracks or possible openings in the enclosure. If the device appears or is suspected to be damaged, return for Servicing.

To conduct Safety Checks follow the procedure outlined in this chapter. If Radius-7 fails any of the described tests, discontinue its use and refer to the Troubleshooting section.

Before performing the following tests, do the following:

- Disconnect any sensors or patient cables.
- Disconnect the Battery Module from the Instrument Module. See ***Chapter 3: Setting Up*** on page 33.
- Ensure that the Battery Module is charged.

Speaker, Display and Touchpad Function Test

To Conduct a Speaker, Display and Touchpad Function Test

1. Snap the Battery Module onto the front side of the Instrument Module.
2. Upon connection, verify the Radius-7 emits a tone and the Masimo logo is displayed on the screen.
3. Follow instructions for using the Touchpad. See ***Using the Touchpad*** on page 39.

Alarm Limit Test

To Conduct an Alarm Limit Test

1. Pair the Radius-7 device to Root. See ***Connecting Radius-7 to Root via Bluetooth*** on page 34.
2. Use Root to change the High SpO_2 Alarm parameter to a value two points below the currently selected value. See ***SpO_2 Settings*** on page 44.
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.

Battery Test

To Conduct a Battery test

1. Dock the Battery Module on the Battery Charging Adapter on Root. Make sure the connection pins of the Battery Module are in contact with the adapter.
2. Verify that the Battery Module is charging. A battery icon will be displayed on the Radius-7 screen to indicate that the Battery is charging. See ***Battery Operation and Maintenance*** on page 105.
3. Un-dock the Battery Module from Root and connect to the Instrument Module.
4. Upon connection, verify the device emits a tone and the device turns on.

Repair Policy

Masimo or an authorized service department must perform warranty repair and service. Do not use malfunctioning equipment. Have the device repaired.

Clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in Cleaning. Make sure the equipment is fully dry before packing.

To return the device for service, refer to ***Return Procedure*** on page 107.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in Cleaning. Make sure the equipment is fully dry before packing. Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number. Package the equipment securely, in the original shipping container if possible, and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the Radius-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 Radius-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 Radius-7 has been decontaminated for bloodborne pathogens.
- Return the Radius-7 to the shipping address listed in ***Contacting Masimo*** on page 107 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 (Radius-7® Wearable Pulse CO-Oximeter®) and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months and any batteries for six (6) months from the original date the Product was obtained by the end-user purchaser.

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

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

Exclusions

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

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

Limitation of Warranty

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

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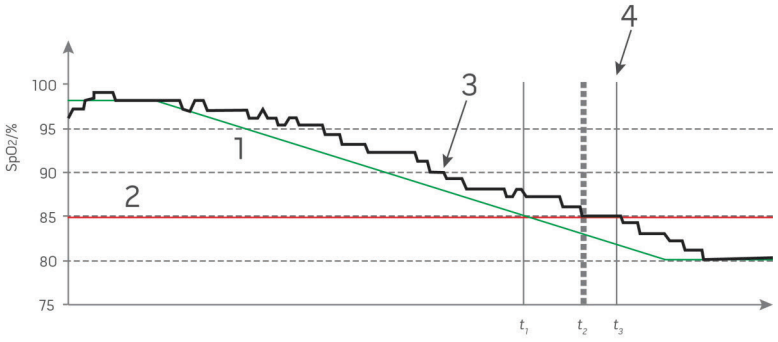
Appendix: Concepts of Alarm Response Delay

Concepts of Alarm Response Delay

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



Reference	Definition	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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