# Radius-7® Wearable Pulse CO-Oximeter®

**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.

**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-Radius and VKF-MWM1 | Model: Radius-7 | Contains: IC: 7362A-Radius and 7362A-MWM1 | IC Model: Radius and MWM1

Masimo Corporation
52 Discovery
Irvine, CA 92618, USA       $C \epsilon$
Tel.: 949-297-7000
Fax.: 949-297-7001       **0123**
www.masimo.com

EU authorized representative for Masimo Corporation:

EC REP
MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

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.

314933

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

®, Masimo®, Pulse CO-Oximeter®, Radius-7®, Root®, Adaptive Probe Off Detection®, APOD®, Discrete Saturation Transform®, DST®, FastSat®, FST®, PVi®, RAM®, rainbow®, rainbow Acoustic Monitoring®, rainbow Resposable®, RRa®, SET®, Signal Extraction Technology®, Signal IQ®, SpCO®, SpHb®, SpMet®, and X-Cal® are federally registered trademarks of Masimo Corporation.

SpOC™ is a trademark of Masimo Corporation. All other trademarks and registered trademarks are property of their respective owners.

The use of the trademark Patient SafetyNet™ is under license from University HealthSystem Consortium.

# 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®), and Acoustic Respiration Rate (RRa®).

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 (RR) is measured by acoustic signal (RRa).

## Indications for Use

The Masimo Radius-7® Wearable Pulse CO-Oximeter® and Accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO$_2$), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radius-7® Wearable Pulse CO-Oximeter® and accessories are indicated for use with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type 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. As with most hemoglobin data, Radius-7 trend data should be scrutinized in light of a specific patient condition. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional data.

**WARNING:** 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, and SpCO) 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 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.

**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, and SpMet 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.
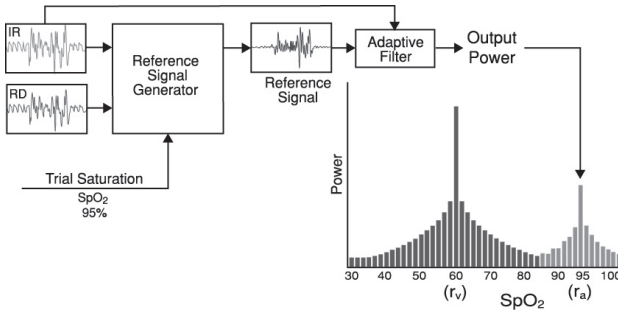
## Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.
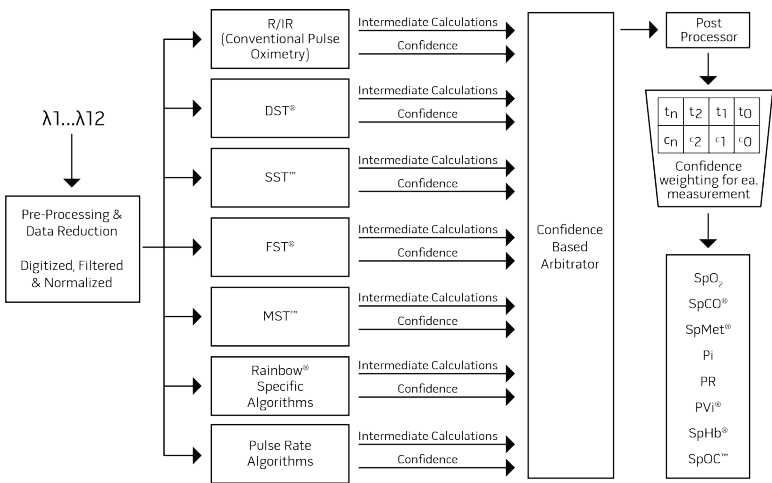
## Masimo SET® DST

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)

1. *Cannesson M., Desebbe O., Rosamel P., Delannoy B., Robin J., Bastien O., Lehot J.J. Pleth Variability Index to Monitor the Respiratory Variations in the Pulse Oximeter Plethysmographic Waveform Amplitude and Predict Fluid Responsiveness in the Operating Theatre.  Br J Anaesth. 2008 Aug;101(2):200-6.*

2. *Forget P, Lois F, de Kock M. Goal-Directed Fluid Management Based on the Pulse Oximeter-Derived Pleth Variability Index Reduces Lactate Levels and Improves Fluid Management. Anesth Analg. 2010 Oct;111(4):910-4.*

3. *Zimmermann M., Feibicke T., Keyl C., Prasser C., Moritz S., Graf B.M., Wiesenack C. Accuracy of Stroke Volume Variation Compared with Pleth Variability Index to Predict Fluid Responsiveness in Mechanically Ventilated Patients Undergoing Major Surgery.  Eur J Anaesthesiol. 2010 Jun; 27(6):555-61.*

4. *Desebbe O, Boucau C, Farhat F, Bastien O, Lehot JJ, Cannesson M. Anesth Analg. The Ability of Pleth Variability Index to Predict the Hemodynamic Effects of Positive End-Expiratory Pressure in Mechanically Ventilated Patients under General Anesthesia. 2010 Mar 1;110(3):792-8.*

5. *Tsuchiya M., Yamada T., Asada A. Pleth Variability Index Predicts Hypotension During Anesthesia Induction. Acta Anesthesiol Scand. 2010 May; 54(5):596-602.*

6. *Loupec T., Nanadoumgar H., Frasca D., Petitpas F., Laksiri L., Baudouin D., Debaene B., Dahyot-Fizelier C., Mimoz O. Pleth Variability Index Predicts Fluid Responsiveness in Critically Ill Patients. Crit Care Med. 2011 Feb; 39(2):294-9.*

7.   *Fu Q., Mi W.D., Zhang H. Stroke Volume Variation and Pleth Variability Index to Predict Fluid Responsiveness during Resection of Primary Retroperitoneal Tumors in Hans Chinese. Biosci Trends. 2012 Feb; 6(1):38-43.*

8.   *Haas S., Trepte C., Hinteregger M., Fahje R., Sill B., Herich L., Reuter D.A. J. Prediction of Volume Responsiveness using Pleth Variability Index in Patients Undergoing Cardiac Surgery after Cardiopulmonary Bypass.   Anesth. 2012 Oct; 26(5):696-701.*

9.   *Byon H.J., Lim C.W., Lee J.H., Park Y. H., Kim H.S., Kim C.S., Kim J.T. Br. J. Prediction of fluid Responsiveness in Mechanically Ventilated Children Undergoing Neurosurgery.   Anaesth 2013 Apr; 110(4):586-91.*

10.  *Feissel M., Kalakhy R., Banwarth P., Badie J., Pavon A., Faller J.P., Quenot JP. Plethysmographic Variation Index Predicts Fluid Responsiveness in Ventilated Patients in the Early Phase of Septic Shock in the Emergency Department: A Pilot Study.   J Crit Care. 2013 Oct; 28(5):634-9.*

11.  *Yu Y., Dong J., Xu Z., Shen H., Zheng J.   Pleth Variability Index-Directed Fluid Management in Abdominal Surgery under Combined General and Epidural Anesthesia. J Clin Monit Comput. 2014 Feb 21.*

12.  *Desgranges F.P., Desebbe O., Ghazouani A., Gilbert K., Keller G., Chiari P., Robin J.,Bastien O., Lehot J.J., Cannesson M. Br. J. Anaesth 2011 Sep;107(3):329-35.*

13.  *Cannesson M. Arterial pressure variation and goal-directed fluid therapy.   J Cardiothorac Vasc Anesth. 2010 Jun; 24(3):487-97.*

14.  *Takeyama M, Matsunaga A, Kakihana Y, Masuda M, Kuniyoshi T, Kanmura Y. Impact of Skin Incision on the Pleth Variability Index. J Clin Monit Comput 2011 Aug; 25(4):215-21.*

# Signal IQ

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

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

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

## 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.

### Absorption Spectra
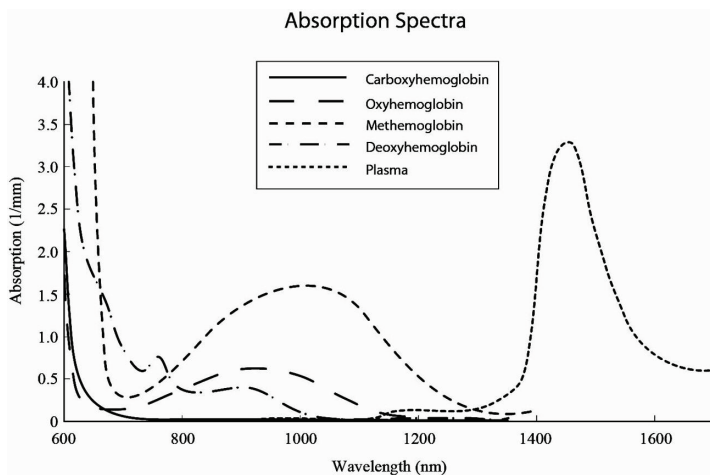


The Radius-7 uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma.

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
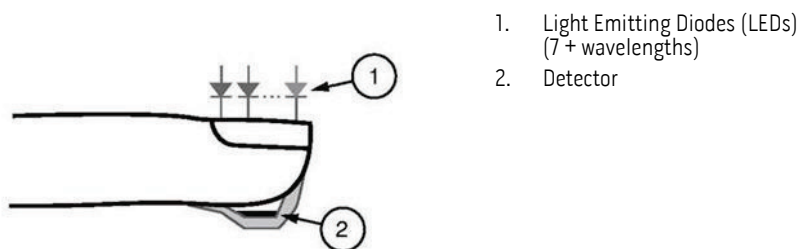
Once Radius-7 receives the signal from the sensor, it utilizes proprietary algorithms to calculate the patient's functional oxygen saturation ($SpO_2$ [%]), blood levels of carboxyhemoglobin saturation (SpCO [%]), methemoglobin saturation (SpMet [%]), total hemoglobin concentration (SpHb [g/dL]) and 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:

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

*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.

| Patient | → | Sensor | → | Acquisition System | → |
|---|---|---|---|---|---|
| Respiratory airflow to sound | | Sound to electrical signal | | Electrical signal to digital signal | |

| Signal Processing | → | Envelope Detection | → | RRa Estimation |
|---|---|---|---|---|
| Digital signal to respiratory measurement | | | | |
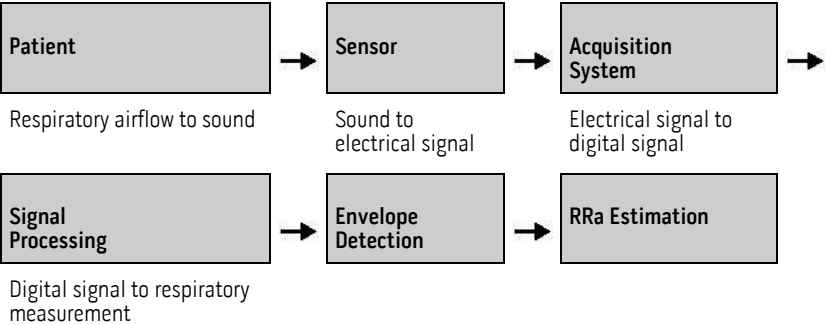
## Patient

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

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

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

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

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

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

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

# Chapter 2: 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.
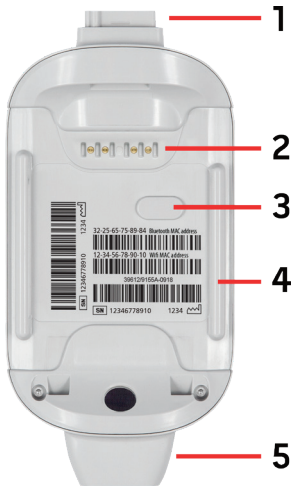


The following table describes the features of the Instrument Module:

| Ref. | Feature | Description |
|---|---|---|
| 1 | Acoustic Sensor Connector | An acoustic sensor can be connected to Radius-7 via this connector.<br>**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.<br>**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**
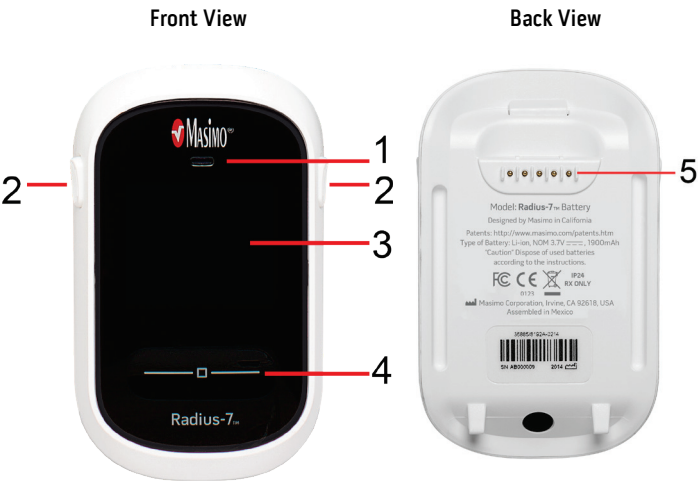
The following table describes the features of the Battery Module:

| 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 37.

## 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 35. |

# 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 95.

## 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 35.

## 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 36.

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 42.

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 95.

## 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 42.

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 42.

| 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 95.

8.  Return the Battery Module to the battery charging adapter for charging. See ***Charging the Radius-7 Battery Module*** on page 35.

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.
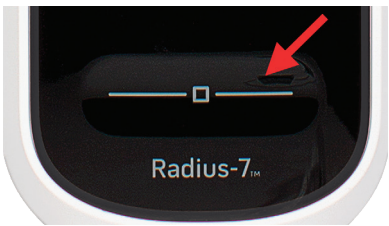


**Note:** The display panel is not a touch screen.

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<br><br>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**
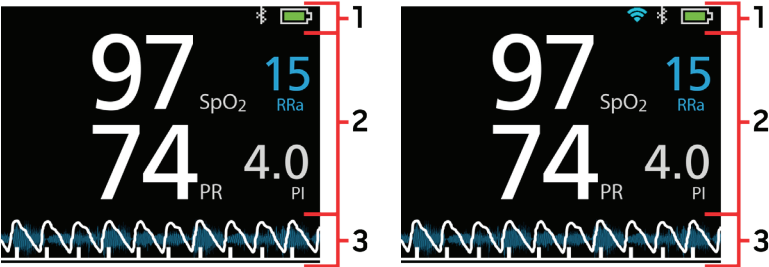
The Main Screen is composed of the following:

| 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 th 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 44.

- Additional settings including Averaging time and FastSat. See **Additional Settings** on page 45.

The Radius-7 settings may be configured with Root when connected via Bluetooth. See **Connecting Radius-7 to Root via Bluetooth** on page 36 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 44.

- **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 43 or **Additional Settings** on page 45.

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 45.

# rainbow Parameter Settings

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

**Parameter Settings**

See *Parameter Settings* on page 46.

**3D Alarms**

See *3D Alarms* on page 64.

**Additional Settings**

See *Additional Settings* on page 45.

# Additional Settings

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

| Option | Description | Default Setting | Configurable Settings |
|--------|-------------|-----------------|-----------------------|
| Sensitivity Mode | Change Sensitivity Mode.<br>See *Sensitivity Modes Overview* on page 44. | APOD | MAX, APOD, NORM |
| SmartTone | Enable or disable the SmartTone. | Off | On, Off |
| $SpO_2$ low % limit | Set the $SpO_2$ low limit alarm.<br>See *SpO2 Settings* on page 46. | Off | Off, 1% to 98% |

# Parameter Settings

[SpO₂ settings icon]

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 46.
- See **PR Settings** on page 48.
- See **Pi Settings** on page 49.
- See **PVi Settings** on page 51.
- See **Respiration Rate (RR) Settings** on page 52.
- See **SpHb Settings** on page 54.
- See **SpOC Settings** on page 57.
- See **SpMet Settings** on page 58.
- See **SpCO Settings** on page 59.

## SpO2 Settings

From the *SpO₂ Settings* screen, change any of the following options:

**SpO2 Alarms** on page 47

**Additional Settings for SpO2** on page 48

**About Parameter Information** on page 60

**Desat Index** on page 65

**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<br><br>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 48. | 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 48

**About Parameter Information** on page 60

**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 50

**Additional Settings for Pi** on page 51

**About Parameter Information** on page 60

**Pi Delta** on page 66

**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 51

**Additional Settings for PVi** on page 52

**About Parameter Information** on page 60

**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<br><br>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<br><br>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). For more information, see:

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

## RRa Settings

RRa is active when the following conditions are all met:

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

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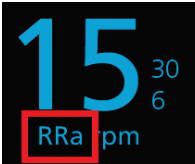
From the *RR Settings* screen, access any of the following screens:

**RRa Alarms** on page 53

**Additional Settings for RRa** on page 54

**About Parameter Information** on page 60

## 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 |
| 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 |

| Options | Description | Alarm Priority | Factory Default Settings | Configurable Options |
|---------|-------------|----------------|--------------------------|----------------------|
| 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 |

## 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 60

**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<br><br>(11.0 mmol/L)<br><br>(170 g/L) | 2.0 g/dL to 24.5 g/dL in steps of 0.1 g/dL, or Off<br><br>(2.0 mmol/L to 15.0 mmol/L in steps of 0.1 mmol/L, or Off)<br><br>(20 g/L to 245 g/L in steps of 1 g/L, or Off)<br><br>When SpHb Precision is set to 1.0, the values are rounded to the nearest whole number.<br><br>When set to Off, alarm is disabled. |
| Low Limit | Low Limit is the lower threshold that triggers an alarm. | High | 7.0 g/dL<br><br>(4.0 mmol/L)<br><br>(70 g/L) | 1.0 g/dL to 23.5 g/dL in steps of 0.1 g/dL. or Off<br><br>(1.0 mmol/L to 14.5 mmol/L, in steps of 0.1 mmol/L, or Off)<br><br>(10 g/L to 235 g/L in steps of 1 g/L, or Off)<br><br>When SpHb Precision is set to 1.0, values are rounded to the nearest whole number.<br><br>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<br>Off<br>(mmol/L)<br>(10 g/L) | Off or 0.1 g/dL to 2.5 g/dL in increments of 0.1<br><br>Off or 0.1 mmol/L to 1.5 mmol/L in increments of 0.1<br><br>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<br><br>Off (mmol/L)<br><br>(20 g/L) | Off or 0.1 g/dL to 2.5 g/dL in increments of 0.1<br><br>Off or 0.1 mmol/L to 1.5 mmol/L in increments of 0.1<br><br>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.<br><br>**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 60

**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<br><br>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%<br><br>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 60

**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 60

**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<br><br>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%<br><br>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 SpO₂.



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<br>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. |
| SpO₂ | 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 |

| Option | Description | Factory Default Setting | User Configurable Settings |
|---|---|---|---|
| | 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 |
| | 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 | 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 65

***About Desat Index*** on page 64

***Pi Delta*** on page 66

***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 65.

## 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 66. The feature includes a user-selectable Pi Delta Alarm. This allows the clinician to request an audible and visual alarm if perfusion at the monitored site decreases by a specified level (delta) over a specified window of time. Three of the variables are selectable by the user within established ranges as noted in Pi Delta Alarms.

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

## Pi Delta

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

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

## Messages

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

| Alarm Message | Description | Next Step |
|---------------|-------------|-----------|
| *(Pulse CO-Ox) Replace Cable*<br><br>*or*<br><br>*(RAM) Replace Cable* | • Defects in the Instrument Module | • Return the device for servicing. |
| *(Pulse CO-Ox) No Sensor Connected*<br><br>*or*<br><br>*(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. |

| Alarm Message | Description | Next Step |
|---|---|---|
| *(Pulse CO-Ox) Replace Sensor*<br><br>*or*<br><br>*(RAM) Replace Sensor* | • Sensor has used all of its available monitoring time<br>• Sensor is non-functional.<br>• Defective sensor. | • Replace sensor. |
| *(Pulse CO-Ox) Incompatible Sensor*<br><br>*or*<br><br>*(RAM) Incompatible Sensor* | • Not a compatible Masimo sensor. | • Replace with a compatible Masimo 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*<br><br>*or*<br><br>*(RAM) Sensor Near Expiration* | • Sensor has less than 10% patient monitoring time remaining. | • Replace sensor. |
| *(Pulse CO-Ox) No Adhesive Sensor Connected*<br><br>*or*<br><br>*(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*<br><br>*or*<br><br>*(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* | • Not a compatible Masimo disposable or resposable sensor. | • Replace with a compatible Masimo disposable or resposable sensor. |

| Alarm Message | Description | Next Step |
|---|---|---|
| *Adhesive Sensor*<br><br>*or*<br><br>*(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*<br><br>*or*<br><br>*(RAM) Adhesive Near Expiration* | • Disposable or resposable sensor has less than 10% patient monitoring time remaining. | • Replace with new disposable or resposable sensor. |
| *(Pulse CO-Ox) Sensor Off Patient*<br><br>*or*<br><br>*(RAM) Sensor Off Patient* | • Sensor off patient.<br>• Sensor not connected to patient properly. Sensor is damaged. | • Disconnect and reconnect sensor. Reattach sensor.<br>• 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. |

| Alarm Message | Description | Next Step |
|---|---|---|
| *(Pulse CO-Ox) Interference Detected*<br><br>*or*<br><br>*(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) SpO₂ 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. |
| *(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. |

| Alarm Message | Description | Next Step |
|---|---|---|
| *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.<br><br>• Check connection between the Instrument Module and Battery Module.<br><br>• 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 97. |

# Chapter 6: Troubleshooting

## Troubleshooting Measurements

| Symptom | Potential Causes | Next Steps |
|---|---|---|
| *Low signal quality.* | • Sensor is damaged or not functioning.<br>• Improper sensor type or application.<br>• Excessive motion.<br>• Low perfusion. | • Verify Sensor type and size and re-apply sensor. See Directions for Use for Sensor.<br>• Check and see if blood flow to the site is restricted.<br>• Check the placement of the sensor. Re-apply sensor or move to a different site.<br>• Replace Sensor.<br>• Minimize or eliminate motion at the monitoring site.<br>• Set to Maximum Sensitivity. See **Sensitivity Modes Overview** on page 44. |
| *Difficulty obtaining a reading.* | • Interference from line frequency induced noise.<br>• Misaligned sensor<br>• Inappropriate sensor or sensor size.<br>• Excessive ambient or strobing light.<br>• Excessive motion. | • Verify/set 50/60hz menu setting. See Operator's Manual for Root.<br>• Verify Sensor type and size and re-apply sensor. See Directions for Use for Sensor.<br>• Check and see if blood flow to the site is restricted.<br>• Check the placement of the sensor. Re-apply sensor or move to a different site.<br>• Minimize or eliminate motion at the monitoring site.<br>• 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.<br><br>• Verify Sensor type and size and re-apply sensor. See Directions for Use for Sensor.<br><br>• Check and see if blood flow to the site is restricted.<br><br>• Check the placement of the sensor. Re-apply sensor or move to a different site.<br><br>• Replace Sensor.<br><br>• Submit blood sample for laboratory CO-Oximetry test for comparison.<br><br>• 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.<br><br>• Improper sensor type or application.<br><br>• Excessive motion.<br><br>• Low perfusion. | • Verify Sensor type and size and re-apply sensor. See Directions for Use for Sensor.<br><br>• Check and see if blood flow to the site is restricted.<br><br>• Check the placement of the sensor. Re-apply sensor or move to a different site.<br><br>• Replace Sensor.<br><br>• Minimize or eliminate motion at the monitoring site.<br><br>• Submit blood sample for laboratory CO-Oximetry test for comparison.<br><br>• 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 42.<br>• If the condition persists, issue requires service. See ***Contacting Masimo*** on page 97. |
| Touchpad does not respond to gestures. | Internal failure | • Requires service. See ***Contacting Masimo*** on page 97. |
| Speaker makes no sound when device is not connected to Root. | Internal failure | • Requires service. See ***Contacting Masimo*** on page 97. |
| Unable to pair with Root | • Bluetooth not enabled on Root<br>• Internal failure | 1. Check if Bluetooth is enabled on Root. See the Operator's Manual for Root.<br>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 36.<br>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.<br>4. Re-dock the Battery Module on Root to pair the device with Root.<br>5. Call Service. |
| Intermittent Connection with Root | • Presence Monitoring is enabled on Root<br>• Environmental interference | 1. Check to see if Presence Monitoring feature is enabled. Refer to the Operator's Manual for Root.<br>2. Ensure Presence Monitoring feature is disabled when using Radius-7 with Root.<br>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 97.

| 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 bpm to 70 bpm |
| SpHb (Hemoglobin) | 0.0 g/dL to 25.0 g/dL<br>0 g/L to 250 g/L<br>(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 |

## Accuracy (ARMS*)

| Oxygen Saturation (SpO$_2$) [1] | | |
| --- | --- | --- |
| No Motion [1]<br>(SpO$_2$ from 60% to 80%) | Adults, Pediatrics | 3% |
| No Motion [2]<br>(SpO$_2$ from 70% to 100%) | Adults, Pediatrics | 2% |
| Motion [3]<br>(SpO$_2$ from 70% to 100%) | Adults, Pediatrics | 3% |
| Low perfusion [4]<br>(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 to 70 bpm | Adults, Pediatrics | 1 bpm |

* $A_{RMS}$ 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.

## 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 |
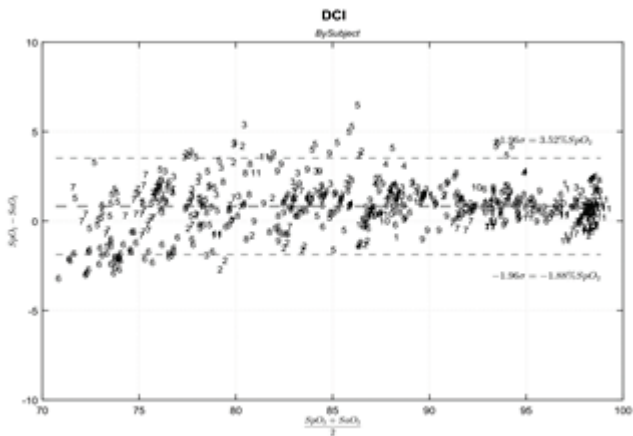


*Figure 1: rainbow Reuse Sensors (Arms 60-80%)*

| Measurement Arms Values for rainbow Reuse (DCI) Sensors | |
|---|---|
| SpO₂ Accuracy Range (%) | Arms (%) |
| 70-80 | 1.88 |
| 80-90 | 1.72 |
| 90-100 | 1.21 |
| 70-100 | 1.63 |
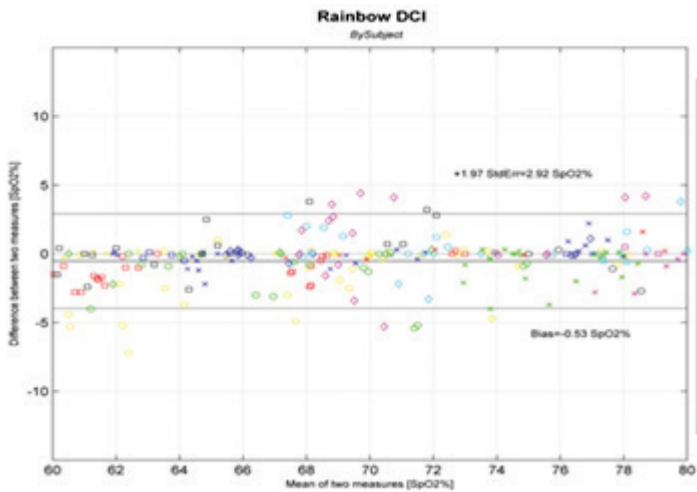


*Figure 2: rainbow Reuse Sensors (Arms 70-100%)*

| Measurement Arms Values for rainbow Adhesive (R1 Series) Sensors | |
|---|---|
| SpO₂ Accuracy Range (%) | Arms (%) |
| 60-70 | 3.42 |
| 70-80 | 2.49 |
| 60-80 | 2.99 |
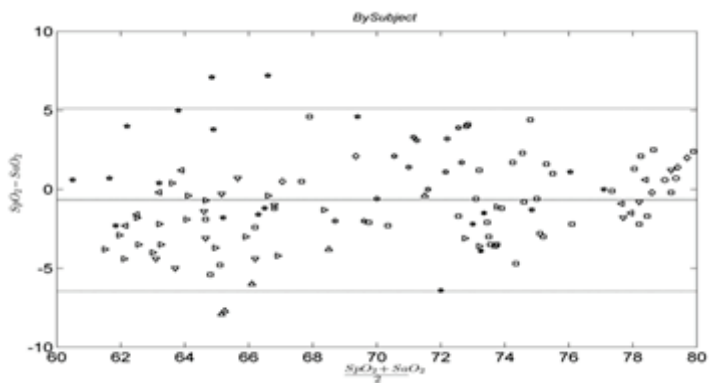


*Figure 3: rainbow R1 Series (Arms 60-80%)*

| 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 |
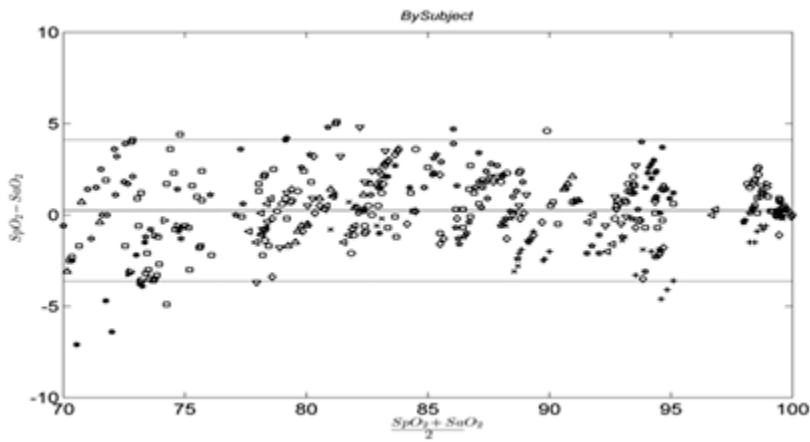


*Figure 4: rainbow R1 Series (Arms 70-100%)*

## Resolution

| Parameter | Resolution |
|---|---|
| SpO$_2$ | 1% |
| PR | 1 bpm |
| RRa | 1 bpm |
| SpHb | 0.1 g/dL |
|  | 1 g/L |

| Parameter | Resolution |
|-----------|------------|
|           | 0.1 mmol/L |
| SpCO      | 1%         |
| SpMet     | 0.1%       |
| SpOC      | 1.0 ml/dl  |

## 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"<br>(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)<br>Medium Priority: 70 dB (min) |
| Sensitivity | NORM, MAX, APOD [8] |

* When volume is set to the highest level.

## Display Indicators

| Item | Description |
| --- | --- |
| Data Update Rate | 1 second |
| Type | OLED |

| Item | Description |
|------|-------------|
| 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) |

| Equipment Classification per IEC 60601-1 | |
|---|---|
| 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 |

| Radio Compliance | |
|---|---|
| Europe | EN 301 489-17:<br>EN 300 328 V2.2.0<br>EN 301 489-1 V2.1.1<br>EN 301 489-17 V3.1.1<br>EN 301 893 V2.0.7<br>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<br>802.11b/g: 2412-2462 MHz |
| Max Peak Output Power | WLAN 17 dBm |

| Communication (Wi-Fi) | |
|---|---|
| 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.<br>802.11b - 1, 2, 5.5, 11 Mbps.<br>802.11g - 6, 9, 12, 18, 24, 36, 48, 54 Mbps. |

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

| Radio Compliance | |
|---|---|
| USA | FCC ID: VKF-MWM1<br>Model: Radius-7 |
| Canada* | IC: 7362A-MWM1<br>IC Model: MWM1<br>RSS-247 |
| Europe | EU Radio Equipment Directive (RED 2014/53/EU)<br>EN 300 328 V2.1.1:2016<br>EN 301 893 V2.1.1:2017<br>EN 301 489-17 V3.1.1:2012<br>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<br>$d = 1.17 \cdot Sqrt (P)$ | 80 MHz to 800 MHz<br>$d = 1.17 \cdot Sqrt (P)$ | 800 MHz to 2.5GHz<br>$d = 2.33 \cdot Sqrt (P)$ |
| 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<br>See **Declarations on Page 1** for certifications |
| NON STERILE | 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 | (PVC symbol, crossed out) | Product contains no PVC (polyvinyl chloride) material |
| (Manufacturer symbol) | Manufacturer | (LATEX symbol, crossed out) | Not made with natural rubber latex |
| (Date of manufacture symbol) | Date of manufacture YYYY-MM-DD | REF | Catalog number (model number) |
| (thermometer symbol) | Storage temperature range | #### | Masimo reference number |
| (umbrella symbol) | Keep dry | SN | Serial number |
| % | Storage humidity limitation | (goblet symbol) | Fragile, handle with care |
| (pressure symbol) | Atmospheric pressure limitation | (crossed package symbol) | Do not use if package is damaged |
| (Nurse Call symbol) | Nurse Call Interface | (ground symbol) | Equipotential Ground Terminal |
| ∿ | AC current | (SatShare symbol) | SatShare Interface |
| (fuse symbol) | Fuse | Y | 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 | RS-232 Interface | (four squares symbol) | 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<br><br>**Note:** eIFU is not available in all countries. | | |

## Citations

*[1] SpO₂, SpCO, and SpMet accuracy was determined by testing on healthy adult male and female volunteers in the range 60% to 100% SpO₂, 0% to 40% SpCO, and 0% to 15% SpMet against a laboratory CO-Oximeter. SpO₂ 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% SaO₂ and 0.5% to 2.5% HbMet with a resultant accuracy of 2.9% SpO₂ 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% SpO₂ 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% SpO₂ 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] 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 Armband on multiple patients.

**WARNING:** Discontinue and dispose of Armband 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 35.

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 35.
- 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 41.

## 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 36.
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 46.
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 95.
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 97.

## 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 97 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.

## Sales & End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

## Restrictions

1.   Copyright Restrictions: The Software and the accompanying written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged, or included with other software, or the written materials is

expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of this Agreement. Nothing in this License provides any rights beyond those provided by 17 U.S.C. §117.

2.  Use Restrictions: Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other device. Purchaser may not disclose, publish, translate, release, distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Software or the written materials.

3.  Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Masimo's prior written consent; except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.

4.  U.S. Government Rights: If Purchaser is acquiring Software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the Software and documentation are deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the Software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this Agreement.

# 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.
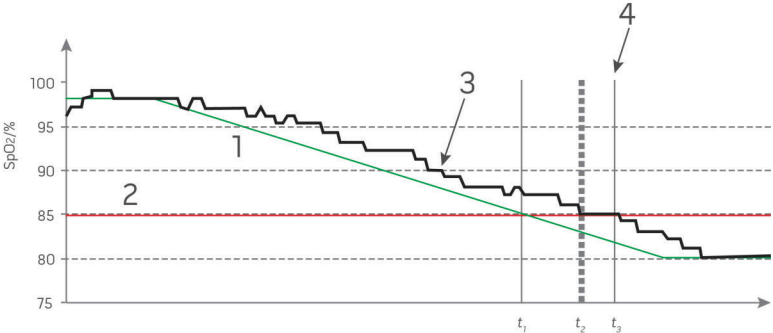


| Reference | Definition | Reference | Definition |
|-----------|------------|-----------|------------|
| 1 | $SaO_2$ | 4 | Alarm Signal Generation |
| 2 | Alarm Limit | $SpO_2$ | Saturation |
| 3 | Displayed $SpO_2$ | t | Time |

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.

# Index

**ᴠMASIMO**®

www.masimo.com