Radius-7™ Wearable Pulse CO-Oximeter

Operator's Manual

These operating instructions intend to provide the necessary information for proper operation of the Radius-7 Wearable Pulse CO-Oximeter. The Operator's Manual describes how Radius-7 information is displayed when used with Root, including display details as well as accessing and changing user-configurable settings. For additional information related to Root, refer to the Operator's Manual for Root.

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 the Radius-7 Wearable Pulse CO-Oximeter are prerequisites for proper use.

Do not operate the Radius-7 Wearable Pulse CO-Oximeter without completely reading and understanding these instructions.

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

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.

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

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MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH ANSI/AAMI ES 60601-1:2005,
CAN/CSA C22.2 No. 60601-1:2008, and applicable Particular
(IEC 60601-2-49:2011, EN/ISO 80601-2-61:2011 and related
Collateral (ANSI/AAMI/IEC 60601-1-8:2006) Standards for
which the product has been found to comply by UL.

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

Contents

About this Manual

This manual explains how to set up and use the Radius-7 Wearable Pulse CO-Oximeter. Important safety information relating to general use of the Radius-7 appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device or damage to other property.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Features and Indications for Use

Product Description

The Radius-7 is a non-invasive device that measures arterial oxygen saturation (SpO2), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI®) along with optional measurements of hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet®), Acoustic Respiration Rate (RRa®) and Pleth Respiration Rate (RRp™).

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

- Patient wearable device for continuous monitoring when the patient is ambulatory.
- Bluetooth radio for transfer of parameter data to the Root patient monitoring and connectivity platform.
- Masimo SET® and rainbow®SET technology performance.
- SpO2 and pulse rate monitoring in motion and low perfusion environments.
- Continuous and non-invasive monitoring of carboxyhemoglobin (SpCO), methemoglobin (SpMet), and total hemoglobin (SpHb).
- Respiration rate determined by the acoustic (RRa) or plethysmographic waveform (RRp).

Indications for Use

The Radius-7 and accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Radius-7 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.

Safety Information, Warnings and Cautions

CAUTION: Radius-7 Wearable Pulse CO-Oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

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. Injury to personnel or equipment damage could occur.

WARNING: Do not start or operate the Radius-7 unless the setup was verified to be correct.

WARNING: To ensure safety, only use Masimo authorized devices with Radius-7.

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: Explosion Hazard: 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.

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 cabling 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 Charger 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

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: Radius-7 is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.

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

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.

WARNING: Misapplied sensor or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

WARNING: With very low perfusion at the monitored site, the reading may read lower than core arterial oxygen saturation.

WARNING: Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site.

WARNING: Excessive venous pulsations may cause erroneous low SpO2 readings (e.g. tricuspid valve regurgitation,Trendelenburg position).

WARNING: Interfering Substances: Dyes or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.

WARNING: SpO2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

WARNING: If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

WARNING: Inaccurate SpO2 readings may be caused by:

- Improper sensor application.
- Elevated levels of COHb and MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Intravascular dyes such as indocyanine green or methylene blue.
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin.
- Severe anemia.
- Low arterial perfusion.
- Motion artifact.

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

- Improper sensor application.
- Intravascular dyes, such as indocyanine green or methylene blue.
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Elevated PaO_2 levels.
- Elevated levels of bilirubin.
- Low arterial perfusion.
- Motion artifact.
- Low arterial oxygen saturation levels.
- Elevated carboxyhemoglobin levels.
- Elevated methemoglobin levels.
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Vasospastic disease such as Raynaud's.
- Elevate altitude
- Peripheral vascular disease.
- Liver disease.
- EMI radiation interference.

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

- Improper sensor application.
- Intravascular dyes such as indocyanine green or methylene blue.
- Abnormal hemoglobin levels.
- Low arterial perfusion.
- Low arterial oxygen saturation levels.
- Elevated total bilirubin levels.

- Motion artifact.
- SpCO readings may not be provided if SpO2 readings are less than 90%
- SpCO readings may not be provided if SpMet readings are greater than 2%

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

WARNING: Inaccurate respiration rate measurements may be caused by:

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

CAUTION: Do not place the Radius-7 on 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 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: To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time Radius-7 is used.

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.

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 (SpO2) 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.

Cleaning and Service Warnings and Cautions

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

WARNING: Electric Shock Hazard: The battery in the Battery Module should not be removed from the Radius-7.

WARNING: Do not incinerate the Radius-7 Battery Module.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the Radius-7 for servicing.

CAUTION: Electrical Shock: Before cleaning Radius-7, always turn it off and physically disconnect it from Root.

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: Changes or modifications not expressly approved by Masimo shall void the warranty for this 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 instructions.

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.

Chapter 1- Technology Overview

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

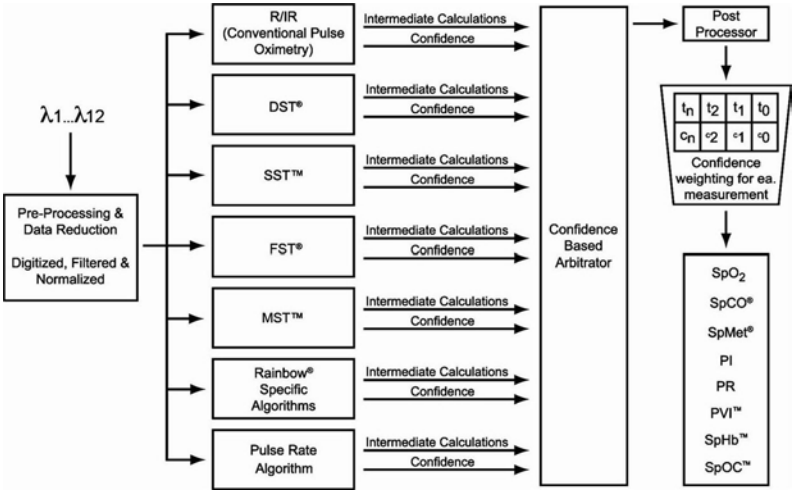
Signal Extraction Technology® (SET®)

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.

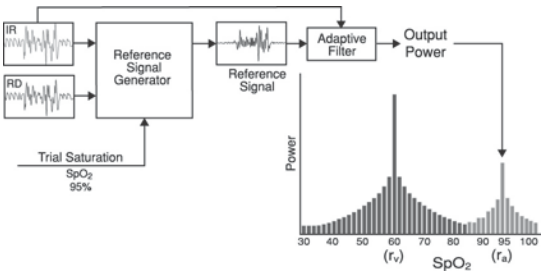
Masimo rainbow SET Parallel Engines

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 SpO2 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 SpO2 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 that dyshemoglobins are not capable of transporting oxygen, but are recognized as oxygenated hemoglobins by conventional pulse oximetry.

General Description for Perfusion Index (PI)

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

General Description for 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 Pleth Variability Index (PVI)

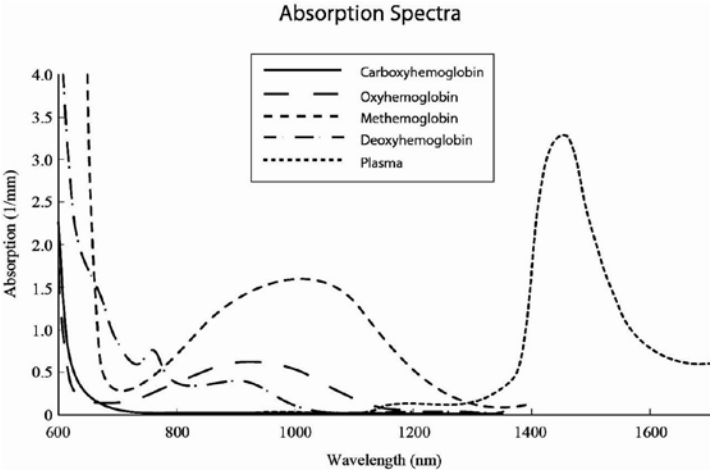
The pleth variability index (PVI) is a measure of the dynamic changes in the perfusion index (PI) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI is displayed as a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

The utility of PVI is unknown at this time and requires further clinical studies. Technical factors that may affect PVI include probe malposition and patient motion.

rainbow Pulse CO-Oximetry Technology

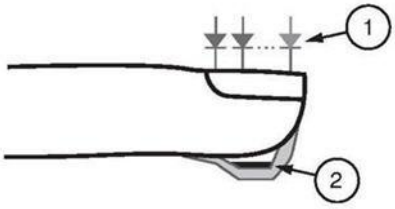
rainbow Pulse CO-Oximetry technology is governed by the following principles:

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



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

The Radius-7 utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to a diode (detector). Signal data is obtained by passing various visible and infrared lights (LEDs, 500 to 1400nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the Radius-7 for calculation.



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

Once the 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 (SpCO [%]), methemoglobin (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. The maximum skin surface temperature is measured to be less than 41 ° C (106° F) in a minimum 35 ° C (95 ° F) ambient. This is verified by Masimo sensor skin temperature test procedures.

General Description for Total Hemoglobin (SpHb)

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

General Description for SpOC

Oxygen (O_2) is carried in the blood in two forms, either dissolved in plasma or combined with hemoglobin. The oxygen content calculated by the Pulse CO-Oximeter is referred to as SpOC and is measured in units of ml O_2/dL blood.

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

SpOC (ml/dL*) = 1.31 (ml O2/g) x SpHb (g/dL) x SpO2 + 0.3 (ml O2/dL)

*When ml O2/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.

General Description for Carboxyhemoglobin (SpCO)

Pulse CO-Oximetry is a continuous and non-invasive method of measuring the levels of carboxyhemoglobin concentration (SpCO) in arterial blood. The device displays the data as a percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

General Description for Methemoglobin (SpMet)

Pulse CO-Oximetry is a continuous and non-invasive method of measuring the levels of methemoglobin concentration (SpMet) in arterial blood. The device displays the data as a percentage value for the SpMet.

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™)

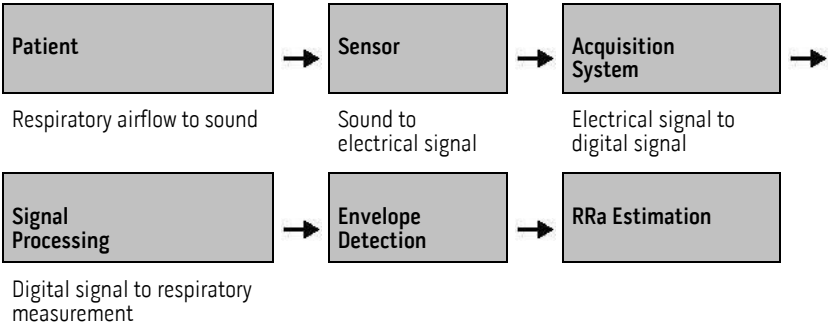
rainbow Acoustic Monitoring (RAM) continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Sensor, which is applied on the patient's neck, translates airflow sounds generated in the upper airway to an electrical signal that can be processed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

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].

Acoustic 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.

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[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.

In Vivo Adjustment™

The In Vivo Adjustment feature lets clinicians manually adjust one or more clinical parameters to match that of a corresponding laboratory reference for continuous trending. To remind clinicians that the feature is active, an offset value displays alongside the adjusted parameter value.

In Vivo Adjustment for a parameter can be turned on by accessing the In Vivo screen in the settings menu of that parameter. After enabling the feature, set an offset value. Once the feature is enabled, a positive or a negative offset value appears on the main display underneath the parameter value.

The In Vivo offset is set to zero for any of the following:

- Cable or sensor is disconnected from instrument.
- Sensor goes off patient causing a sensor initialization to occur.
- Eight hours has elapsed since the In Vivo value was activated.
- Restoration of factory defaults.
- The user turns off In Vivo.

Offset Value

When In Vivo Adjustment is activated for a specific parameter, the offset value appears beneath that specific parameter on the secondary display connected to the device. A positive value means that the displayed parameter value has been increased (according to a laboratory reference value as entered by a clinician) and a negative value means the displayed parameter value has been decreased (according to a laboratory reference value as entered by a clinician).

In Vivo Adjustment can be set to On or Off. The factory default setting is Off. If set to On, the parameter value is adjusted and an offset value appears. The offset value is set by the user.

Note: When In Vivo Adjustment is enabled for a specific parameter, the alarm states for that parameter are based on the offset values as opposed to the measured values. Check the alarm limits each time In Vivo Adjustment is enabled.

Signal IQ® (SIQ)

The display provides a visual indicator of the plethysmogram signal quality and an alert when the displayed SpO_2 values are not based on adequate signal quality. The signal quality indicator displayed is called the Signal IQ. The Signal IQ can be used to identify the occurrence of a patient's pulse and the associated signal quality of the measurement.

The Signal IQ is shown as a "pulse bar" indicator, where the peak of the bar coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the device locates the arterial pulsation. The pulse tone (when enabled) coincides with the peak of the Signal IQ bar. As saturation increases or decreases, the pulse tone will ascend or descend accordingly, for each 1% change in saturation.

The height of the Signal IQ bar indicates the quality of the measured signal. A high vertical bar indicates that the SpO_2 measurement is based on a good quality signal. A small vertical bar indicates that the SpO_2 measurement is based on data with low signal quality. When the signal quality is very low the accuracy of the SpO_2 measurement may be compromised. A "Low Signal IQ" is indicated by a bar height of two bars or less and the bars turn red. When this occurs, proceed with caution and do the following:

- Assess the patient.
- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site to maintain accurate readings. Also, misalignment of the sensor's emitter and detector can result in smaller signals.
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred.

After performing the above, if the "Low Signal IQ" indication occurs frequently or continuously, obtaining an arterial blood specimen for oximetry analysis may be considered to verify the oxygen saturation value.

Adaptive Threshold Alarm (ATA)

The Adaptive Threshold Alarm (ATA) feature is an optional feature that helps reduce the frequency of non-actionable alarms.

ATA establishes the alarm limit threshold based upon the patient-specific baseline value of the SpO2 parameter which is determined from the recent history of SpO2 values. An Adaptive Threshold Limit is continuously determined for the patient and SpO2 values outside the Adaptive Threshold Limit trigger an audible alarm. The Adaptive Threshold Limit is bound by the standard SpO2 low alarm limit and the Rapid Desat low alarm limit. SpO2 values that exceed the Rapid Desat limit, whether it occurs rapidly or not, will activate an audible alarm.

Prior to activating ATA, please review and select the appropriate standard low alarm limit and other alarm settings. Once ATA is selected, the Rapid Desat Alarm protection is always active. If the ATA low alarm limit is violated, ATA generates an audible alarm.

It is important to note that once activated, ATA has the following automatic safety features:

Reminder Tones

If an SpO2 value from a patient drops below the standard low alarm limit set by the user, a visual alert will display and a reminder tone will repeat every 15 minutes as long as the condition persists. If the SpO2 value drops below the ATA low alarm limit, an audible alarm will be activated.

Rapid Desat Alarm Protection

The Rapid Desat feature is always active when ATA is turned on. This means that deep desaturations (5% or 10%) from the standard SpO2 low alarm limit immediately generate an audible alarm. When used with ATA, it also serves as absolute low alarm limit protection. SpO2 values exceeding the Rapid Desat low alarm limit, whether rapid or not, will activate an audible alarm. The user can change the Rapid Desat default setting from 5% to 10%. ATA does not allow a Rapid Desat default setting of 0%.

When ATA is turned Off, the device uses the standard alarm limits and standard alarm delays.

FastSat® (FST®)

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 the Radius-7 is set to FastSat On, the averaging algorithm evaluates all the saturation values providing an averaged saturation value that is a better representation of the patient's current oxygenation status. With FastSat, the averaging time is dependent on the input signal.

Sensitivity Modes

Three sensitivity levels enable a clinician to tailor the response of the Radius-7 to the needs of the particular patient situation. The sensitivity levels are as follows:

- **NORM (Normal Sensitivity)**

  NORM is the recommended sensitivity mode for patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).

- **APOD® (Adaptive Probe Off Detection Sensitivity®)**

  APOD is the recommended sensitivity mode where there is a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.

- **MAX (Maximum Sensitivity)**

  MAX is recommended sensitivity mode for patients with low perfusion or when a low perfusion message displays in APOD or NORM mode. MAX mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.

Chapter 2- System Components

General System Description

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

1. Instrument Module
2. Battery Module
3. Armband
4. Battery Charging Adapter

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

Sensor compatibility:

Refer to www.masimo.com for available Acoustic and M-LNCS sensors. Refer to sensor's *Direction for Use* for detailed sensor information.

Radius-7 Instrument Module

The Instrument Module connects both optical and acoustic rainbow sensors and has a Bluetooth radio to connect with Root.

Front View

The following table describes the features of the Instrument Module:

Ref.	Feature	Description
1	Acoustic Sensor Connector	An acoustic sensor can be connected to Radius-7 via this connector. **CAUTION:** Refer to the *Directions for Use* for the sensor before applying it on patients.

Ref.	Feature	Description
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	rainbow SET Sensor Connector	A rainbow SET sensors can be connected to Radius-7 via this connector. **CAUTION:** Refer to the *Directions for Use* for the sensor before applying it on patients.

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.

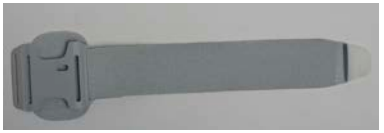
Front View

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 in the Operator's Manual.

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.

Without Battery Module docked

The following table describes the features of the Battery Module:

Ref.	Feature	Description
1	Battery Pocket	The Battery Pocket can be used to store the entire Radius-7 or Instrument Module separately.
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 36* in the Operator's Manual.

Chapter 3- Setup

The following 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 81 of the Operator's Manual.

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* section of the Operator's Manual.
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 36* of the Operator's Manual.

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.
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 *Battery Operation and Maintenance* on page 82 of the Operator's Manual.
5. Once sufficiently charged you may undock the Battery Module by pressing the Release Buttons on the Battery Module.
6. Enable Bluetooth Connectivity on Root. See Operator's Manual for Root.

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 been has been established.
4. Verify that the Bluetooth Mac address on Radius-7 matches the Mac Address listed on Root. See *Navigating the Main Menu* on page 42 in the Operator's Manual.
5. Undock 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 7 m radius and line of sight of Root.

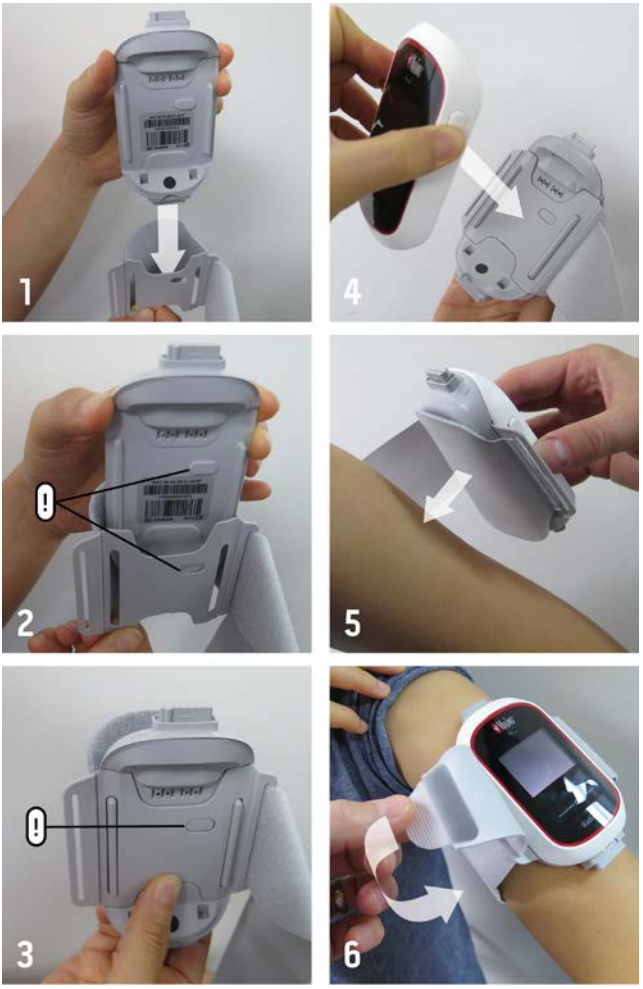
   CAUTION: When using multiple Radius-7 and Root systems, re-dock the Battery Module to Root to ensure proper pairing before connecting the Radius-7 to the patient.

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 *Chapter 2- System Components* on page 31 in the Operator's Manual 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 above.
3. The ▭ shaped hole in the Armband plastic should fit over the matching key on the front side of the Instrument Module.
4. Connect the Battery Module 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.

   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: 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.
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.
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 81* of the Operator's Manual.
8. Return the Battery Module to the battery charging adapter for charging. See *Charging the Radius-7 Battery Module on page 36* of the Operator's Manual.
9. Store the Instrument Module in the Battery Pocket of the Battery Charging Adapter.

Chapter 4- Operation

Using the Touchpad

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

Note: The display panel is not a touch screen.

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

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

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

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

About the Main Screen

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, 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.

Navigating the Main Menu

From the Main Screen, touch and hold the Touchpad to access the Main Menu.

Use the Touchpad *Swipe* gesture to scroll through the Main Menu Options. Use the *Touch* gesture to select the Main Menu Option. Use the same gestures to adjust settings.

The Main Menu options are:

Main Menu Options	Description	Default	Options
Waveform	Allows the user to choose if the waveform will be displayed on the screen.	Off	On or Off
Brightness	Change the brightness of the Display Panel.	100%	25%, 50%, 75% and 100%
About	Hardware and software information about the device including Bluetooth Mac Address .	N/A	N/A

Navigating Radius-7 Settings on Root

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

- Sensitivity Mode settings
- Parameter Alarm settings
- In vivo settings
- Additional settings including Averaging time and FastSat.

The following section describes how Radius-7 settings may be configured with Root when connected via Bluetooth. See ***Connecting Radius-7 to Root via Bluetooth*** on page 36 of the Operator's Manual for information on how to pair Radius-7 with Root. For general information on Root, see Operator's Manual for Root

Configuring Sensitivity Modes

There are two ways to access sensitivity settings menu on Root:

1. From the Main Screen on Root, press on the Sensitivity icon displayed on the top of the screen to toggle through sensitivity configuration options.

   Or
2. Press the gear icon on the bottom right-hand corner of the Main Screen on Root to access the Main Menu, press the Rainbow tile to access the Rainbow menu. In the Rainbow menu select the Additional Settings tile to select Sensitivity Mode.

Options	Description	Factory Default	Configuration Options
Sensitivity Modes	Defines the sensitivity level for which the device will operate. See *Sensitivity Modes on page 30* of the Operator's Manual.	APOD	MAX, APOD, or NORM

Configuring Parameters

Each parameter displayed on Root and Radius-7 can be configured in its respective menu on Root. Configurable options include Alarm Settings, In Vivo Adjustment, 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.

In the Rainbow menu select the Parameter tile to see all available parameters to be configured, and finally press any parameter tile to access the settings menu for that parameter.

Each parameter's settings menu may include the following options:

Option	Description
About	A brief explanation about the parameter.
Alarms	Configure high/low alarm limits, caution ranges for SpO2, Rapid Desat limit threshold, alarm delay, Adaptive Threshold Alarm. See *Adaptive Threshold Alarm (ATA) on page 29* of the Operator's Manual.
In Vivo	For SpO2, SpHb, SpCO, SpMet only enable In Vivo Adjustment and set the offset amount. See *In Vivo Adjustment™* on page 27 of the Operator's Manual.
Additional Settings	For SpO2, PI, PVI, SpHb and RRa configure averaging time and other settings.

SpO2 Settings

About

An informational read-only screen appears with an explanation about SpO2.

Alarms

Option	Description	Factory Default	Configuration Options
High Limit	High Limit is the upper threshold that triggers an alarm.	Off	2% to 99% in steps of 1%, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	88%	1% to 98% in steps of 1%
Rapid Desat	Sets the Rapid Desat limit threshold to the selected amount below the Low Alarm Limit. When SpO2 value falls below rapid desat limit the audio and visual alarm are immediately triggered without respect to the alarm delay.	-10%	-5%, or -10%, or Off
Alarm Desat	When an alarm condition is met, this feature delays the audible part of an alarm	5 seconds	0, 5, 10, or 15 seconds
Adaptive Threshold Alarm (ATA)	ATA establishes patient-specific limit thresholds based upon the baseline value of the parameter. See *Adaptive Threshold Alarm (ATA)* on page 29 of the Operator's Manual.	Off	On or Off

In Vivo

Option	Description	Factory Default	Configuration Options
Enabled	See *In Vivo Adjustment™ on page 27* of the Operator's Manual.	Off	On or Off
Offset Amount	See *In Vivo Adjustment™* on page 27 of the Operator's Manual.	0 when turned On	Adjust difference of ± 6%, in steps of 0.1%

Additional Settings

Option	Description	Factory Default	Configuration Options
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	Enable/disable FastSat feature for rapid tracking of oxygen saturation changes. When enabled, the averaging algorithm evaluates all saturation values, providing an averaged saturation value that is a better representation of the patient's current oxygenation status.	Off	On or Off

PR Settings

About

An informational read-only screen appears with an explanation about PR.

Alarms

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

PI Settings

About

An informational read-only screen appears with an explanation about PI.

Alarms

Option	Description	Factory Default	Configuration Options
High Limit	High Limit is the upper threshold that triggers an alarm.	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.	Off	Step size: 0.03 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 18 in steps of 1, or Off

Additional Settings

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

PVI Settings

About

An informational read-only screen appears with an explanation about PVI.

Alarms

Option	Description	Factory Default	Configuration Options
High Limit	High Limit is the upper threshold that triggers an alarm.	Off	2 to 99 in steps of 1, or Off When set to Off, alarms are disabled.
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Off	1 to 98 in steps of 1, or Off When set to Off, alarms are disabled.

Additional Settings

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

SpHb Settings

About

An informational read-only screen appears with an explanation about SpHb.

Alarms

Option	Description	Factory Default	Configuration Options
High Limit	High Limit is the upper threshold that triggers an alarm.	17.0 g/dL (11.0 mmol/L)	2.0 g/dL to 24.5 g/dL in steps of 0.1 g/dL, or Off (2.0 mmol/L to 15.0 mmol/L in steps of 0.1 mmol/L, or Off) When SpHb Precision is set to 1.0, the values are rounded to the nearest whole number. When set to Off, alarm is disabled.
Low Limit	Low Limit is the lower threshold that triggers an alarm.	7.0 g/dL (4.0 mmol/L)	1.0 g/dL to 23.5 g/dL in steps of 0.1 g/dL. or Off (1.0 mmol/L to 14.5 mmol/L, in steps of 0.1 mmol/L, or Off) When SpHb Precision is set to 1.0, values are rounded to the nearest whole number. When set to Off, alarm is disabled.

In Vivo

Option	Description	Factory Default	Configuration Options
In Vivo Calibration	See *In Vivo Adjustment™* on page 27 of the Operator's Manual.	Off	On or Off
In Vivo Calibration Offset	See *In Vivo Adjustment™ on page 27* of the Operator's Manual.	0 when turned On	± 3 g/dL in steps of ± 0.1 g/dL

Additional Settings

Option	Description	Factory Default	Configuration 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.	Venous	Arterial or Venous
Precision	Allows the user to set the decimal for SpHb.	0.1	0.1, 0.5, or 1.0 (whole numbers)
Unit of Measure	Displays total hemoglobin (SpHb) as g/dL (grams per deciliter) or mmol/L (millimoles per liter).	g/dL	mmol/L or g/dL

SpCO Settings

About

An informational read-only screen appears with an explanation about SpCO

Alarms

Option	Description	Factory Default	Configuration Options
High Limit	High Limit is the upper threshold that triggers an alarm.	10	2% to 98%, in steps of 1%, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Off	1% to 97%, in steps of 1%, or Off When set to Off, alarm is disabled.

In Vivo

Option	Description	Factory Default	Configuration Options
Enabled	See *In Vivo Adjustment™ on page 27* of the Operator's Manual.	Off	On or Off
Offset Amount	See *In Vivo Adjustment™ on page 27* of the Operator's Manual.	0 when turned On	± 9% in steps of ± 0.1%

SpMet Settings

About

An informational read-only screen appears with an explanation about SpMet

Alarms

Option	Description	Factory Default	Configuration Options
High Limit	High Limit is the upper threshold that triggers an alarm.	10	1% to 2%, 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.	Off	0.1% to 2%, in steps of 0.1% 2.5% to 99%, in steps of 0.1%, or Off When set to Off, alarm is disabled.

In Vivo

Option	Description	Factory Default	Configuration Options
Enabled	See *In Vivo Adjustment™ on page 27* of the Operator's Manual.	Off	On or Off
Offset Amount	See *In Vivo Adjustment™* on page 27 of the Operator's Manual.	0 when turned On	± 3% in steps of ± 0.1%

SpOC Settings

About

An informational read-only screen appears with an explanation about SpOC

Alarms

Option	Description	Factory Default	Configuration Options
High Limit	High Limit is the upper threshold that triggers an alarm.	Off	2% to 34%, in steps of 1%, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Off	1% to 33%, in steps of 1%, or Off When set to Off, alarm is disabled.

Respiration Rate Settings

The Radius-7 can determine respiration rate (RR) either by the acoustic signal (RRa) or by the plethysmographic waveform (RRp).

RRa Settings

When using an acoustic sensor, respiration rate (RR) is determined by the acoustic (RRa) signal. See *rainbow Acoustic Monitoring™ (RAM™) on page 25* of the Operator's Manual. When the respiratory rate is determined by the acoustic signal, RRa alarms and RRa settings are active, and the parameter label displays as RRa.

RRa is active under the following conditions:

- RRa is installed on Radius-7.
- Acoustic sensor is connected.

About

An informational read-only screen appears with an explanation about RRa

Alarms

Option	Description	Factory Default	Configuration Options
High Limit	High Limit is the upper threshold that triggers an alarm.	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.	6 breaths per minute	5 to 68 breaths per minute in steps of 1 breath per minute, or Off
Respiratory Pause	The duration of time that triggers an alarm if no breaths are detected	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	30 seconds	0, 10, 15, 30 or 60 seconds

Additional Settings

Option	Description	Factory Default	Configuration Options
Averaging Time	The length of time over which the system calculates the average of all data points.	Slow	No, Fast, Medium, Slow or Trending

Option	Description	Factory Default	Configuration Options
Freshness	The duration of time that, during interference, the system displays the last valid reading.	5 minutes	0, 1, 5, 10, or 15 minutes

RRp Settings

When using a pulse oximetry or pulse CO-Oximetry sensor with Radius-7, respiration rate can be determined by the plethysmographic waveform (RRp). This method measures a patient's respiratory rate based on plethysmographic amplitude changes that correspond to the respiratory cycle. When using a pulse oximetry or pulse CO-Oximetry sensor, RRp alarms and RRp settings are active and the parameter label displays as RRp.

Note that the Radius-7 can monitor RRa or RRp but not both simultaneously. RRp is active under the following conditions:

- RRp is installed on the Radius-7.
- Pulse oximetry or pulse CO-Oximetry sensor is connected.
- Acoustic sensor is not connected.

About

An informational read-only screen appears with an explanation about RRp

Alarms

Option	Description	Factory Default	Configuration Options
High Limit	High Limit is the upper threshold that triggers an alarm.	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.	6 breaths per minute	5 to 68 breaths per minute in steps of 1 breath per minute, or Off
Alarm Delay	When a High or Low alarm condition occurs, this feature delays the audible part of an alarm	30 seconds	0, 10, 15, 30 or 60 seconds

Additional Settings

Option	Description	Factory Default	Configuration Options
Averaging Time	The length of time over which the system calculates the average of all data points.	Slow	No, Fast, Medium, Slow or Trending

Option	Description	Factory Default	Configuration Options
Freshness	The duration of time that, during interference, the system displays the last valid reading.	5 minutes	0, 1, 5, 10, or 15 minutes

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	Audible Characteristics	Visual Characteristics
High	571 Hz tone, 10 pulse bursts	Flashing Red
Medium	550 Hz tone, 3 pulse bursts	Flashing Yellow

The conditions and priorities are provided below:

Parameter	High Limit Alarm	Low Limit Alarm
SpO2	Medium	High
PR	High	High
PI	Medium	Medium
SpCO	High	Medium
SpMet	High	Medium
SpHb	High	High
SpOC	Medium	High
PVI	Medium	Medium
RRa	High	High
RRp	High	High

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.

The following are the factory default settings and configuration options for Alarms:

Option	**Description**	**Factory Default Setting**	**Configurable Settings on Root**
Alarm Volume	Sets the alarm volume level.	Highest volume	Slide towards the left to decrease volume to silence.
Pulse Tone Volume	Sets the pulse tone volume level.	Highest volume	Slide towards the left to decrease volume to silence.
Audio Pause Duration	Sets the length of time that the audible alarm remains silenced, when Audio Pause is enabled.	2 minutes	1, 2, 3 minutes, Permanent*, Permanent with Reminder*. If *Permanent* is selected, there will be no audible alarms, but visual alarms will still display. If *Permanent with Reminder* is selected, a tone will sound every three (3) minutes as a reminder that *Permanent* is active. *Requires user to have All Mute Enabled in the Access Control menu. See Operator's Manual for Root.

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.

Messages

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

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. Check connection between the Instrument Module and Battery Module. Redock the Battery Module on Root to re-establish Bluetooth connectivity.
Speaker failure message	Device requires service.	Contact Masimo Tech Support. See *Contacting Masimo on page 84* of the Operator's Manual.
• (Pulse CO-Ox) Replace Sensor, or • (RAM) Replace Sensor	Reusable sensor has used all of its available monitoring time • Sensor is non-functional. • Defective sensor.	Replace sensor.
• (Pulse CO-Ox) Incompatible Sensor, or • (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.

Alarm Message	Description	Next Step
• (Pulse CO-Ox) Replace Adhesive Sensor, or • (RAM) Replace Adhesive Sensor	When a single-patient-use sensor is used, the adhesive portion of the sensor is non-functional, or the life of the adhesive portion of the sensor has expired.	Replace the adhesive portion of the sensor.
• (Pulse CO-Ox) Replace Cable, or • (RAM) Replace Cable	Defects in the Instrument Module	Return the device for servicing.
• (Pulse CO-Ox) Incompatible Adhesive Sensor, or • (RAM) Incompatible Adhesive Sensor	Not a compatible Masimo Adhesive 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) No Adhesive Sensor Connected, or • (RAM) No Adhesive Sensor Connected	When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.	Ensure the adhesive portion is firmly connected to the sensor.
• (Pulse CO-Ox) Interference Detected, or • (RAM) Interference Detected	High intensity light such as pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight, or other monitor displays.	Place a Masimo Optical Light Shield over the sensor.
(Pulse CO-Ox) Low Perfusion Index	Signal too small.	Move sensor to better perfused site.

Alarm Message	Description	Next Step
(Pulse CO-Ox) Low Signal IQ	Low signal quality.	Ensure proper sensor application. Move sensor to a better perfused site. See *Signal IQ® (SIQ)* on page 28 of the Operator's Manual.
Low SpCO SIQ message	SpCO measurement reading is obscured.	Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor.
Low SpMet SIQ message	SpMet measurement reading is obscured.	Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor.
Low SpHb SIQ message	SpHb measurement reading is obscured.	Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor.
• (Pulse CO-Ox) No Sensor Connected, or • (RAM) No Sensor Connected	Sensor not fully inserted into the connector.	Disconnect and reconnect sensor. See the instructions for use provided with your sensor.
	Incompatible or defective sensor.	Replace with a compatible Masimo sensor.
	Device is searching for patient's pulse.	Disconnect and reconnect the sensor to the Instrument Module.
(Pulse CO-Ox) 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.

Alarm Message	Description	Next Step
(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.
• (Pulse CO-Ox) Sensor Off Patient, or • (RAM) Sensor Off Patient	Sensor off patient.	Disconnect and reconnect sensor. Reattach sensor.
	Sensor not connected to patient properly. Sensor is damaged.	Properly reapply the sensor on the patient and reconnect the sensor to the Instrument Module. If the sensor is damaged, replace the sensor.

Chapter 6- Troubleshooting

Troubleshooting Measurements

Symptom	Potential Causes	Next Steps
Low signal quality.	Sensor is damaged or not functioning. Improper sensor type or application. Excessive motion. Low perfusion.	• Verify Sensor type and size and re-apply sensor. See *Directions for Use* for Sensor. • Check and see if blood flow to the site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace Sensor. • Minimize or eliminate motion at the monitoring site. • Set to Maximum Sensitivity. See *Sensitivity Modes* on page 30 of the Operator's Manual.
Difficulty obtaining a reading.	Interference from line frequency induced noise. Misaligned sensor Inappropriate sensor or sensor size. Excessive ambient or strobing light. Excessive motion.	• Verify/set 50/60hz menu setting. See Operator's Manual for Root. • Verify Sensor type and size and re-apply sensor. See *Directions for Use* for Sensor. • Check and see if blood flow to the site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Minimize or eliminate motion at the monitoring site. • Shield the sensor from excessive or strobing light.

Symptom	Potential Causes	Next Steps
SpCO reading displays as dashes.	SpCO parameter may have not stabilized.	• Allow time for parameter reading to stabilize. • Verify Sensor type and size and re-apply sensor. See *Directions for Use* for Sensor. • Check and see if blood flow to the site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace Sensor. • Submit blood sample for laboratory CO-Oximetry test for comparison. • Check patient conditions indicated to affect SpCO accuracy.

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 the Main Menu* on page 42 of the Operator's Manual. If the condition persists, issue requires service. See *Contacting Masimo* on page 84 of the Operator's Manual
Touchpad does not respond to gestures.	Internal failure.	Requires service. See *Contacting Masimo* on page 84 of the Operator's Manual.
Speaker makes no sound when device is not connected to Root.	Internal failure	Requires service. See *Contacting Masimo* on page 84 of the Operator's Manual.

Symptom	Potential Cause	Next Step
Unable to pair with Root	Bluetooth not enabled on Root. Internal failure.	1. Check if Bluetooth is enabled on Root. See the Operator's Manual for Root. 2. Check if Bluetooth is enabled on Radius-7 by accessing the About panel on the Main Menu. See *Connecting Radius-7 to Root via Bluetooth on page 36* of the Operator's Manual. 3. Verify the Mac address on Radius-7 matches the one on Root. The Mac address on Radius-7 can be found by accessing the About panel on the Main Menu of Radius-7. For information on accessing the Mac address listed on Root refer to Operator's Manual for Root. 4. Re-dock the Battery Module on Root to pair the device with Root. 5. Call Service.

Chapter 7- Specifications

Measurement Range

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

Accuracy

Oxygen Saturation (SpO_2) [1]		
No Motion [1] (SpO2 from 60% to 80%)	Adults, Pediatrics	3%
No Motion [2] (SpO2 from 70% to 100%)	Adults, Pediatrics	2%

Motion [3] (SpO_2 from 70% to 100%)	Adults, Pediatrics	3%
Low perfusion [4] (SpO_2 from 70% to 100%)	Adults, Pediatrics	2%
Pulse Rate (PR)		
Range	25 to 240 bpm	
No motion	Adults, Pediatrics	3 bpm
Motion [5]	Adults, Pediatrics	5 bpm
Low Perfusion	Adults, Pediatrics	3 bpm
Carboxyhemoglobin Level (SpCO) [1]		
Range of 1% to 40%	Adults, Pediatrics	3%
Methemoglobin Level (SpMet) [1]		
Range 1% to 15%	Adults, Pediatrics	1%
Total Hemoglobin SpHb [6]		
Range of 8 g/dL to 17 g/dL	Adults, Pediatrics	1 g/dL
Respiratory Rate (RRa, RRp) [7]		
Range of 4 to 70 bpm	Adults, Pediatrics	1 breath per minute

Resolution

Parameter	Resolution
$\%SpO_2$	1%
%SpCO	1%
%SpMet	0.1%

Parameter	Resolution
SpHb g/dL	0.1 g/dL
Pulse Rate	1 beats per minute
Respiration Rate	1 breaths per minute

Electrical

Battery Module of Radius-7	
Type	Lithium ion
Capacity	12 hours
Charging Time	≤ 6 hours

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

Environmental

Radius-7 Environmental Conditions:

Environmental Conditions	
Operating Temperature	41°F to 104°F (5°C to 40°C)
Transport/Storage Temperature	-4°F to 122°F (-20°C to 50°C) [8]
Operating Humidity	10% to 95%, non-condensing
Non-Operating Humidity	10% to 95%, non-condensing
Operating Altitude	540 mbar to 1060 mbar at ambient temperature and humidity

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

Physical Characteristics

Item	Description
Dimensions	5.1" x 2.8 " x 1.2" (130 mm x 70 mm x 30 mm)
Weight	0.34lbs. (155g)

Alarms

Parameter	Alarm Range
SpO_2	1% to 99%
SpCO	1% to 98%
SpMet	0.1% to 99.5%
SpHb	1.0 g/dL to 24.5 g/dL
RR	5 to 69 breaths per minute
PI	0.03% to 19%
PVI	1% to 99%
Pulse Rate	30 bpm to 235 bpm
SpOC	1 g/dL to 34 g/dL

Alarm Characteristic	Description
Alarm Volume (Set at 100%)	High Priority Medium Priority Medium Priority < High Priority
Sensitivity	NORM, MAX, APOD [8]

Display Indicators

Item	Description
Trend Memory	Max of 6 hours at 2-second resolution
Display Update Rate	1 second
Response Time	< 30 second delay
Type	OLED
Pixels	160 X 128
Dot Pitch	0.073 (W) mm X 0.219 (H) mm

EMC Compliance

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

Safety Standards Compliance

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

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

Radio Compliance

Radio Modes	Bluetooth
Compliance	
USA	FCC ID: VFK-RADIUS FCC parts 15.247
Canada	IC: 7362A-RADIUS RSS-210
Europe	EN 300 328, EN 301 489-17 R&TTE

Guidance and Manufacturer's Declaration- Electromagnetic Emissions

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Suitable for use in all establishments, including domestic environments.

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.
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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
			$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 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 measures may be necessary, such as re-orienting or relocating the ME Equipment. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment			
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 K Hz to 80 MHz d = 1.17*Sqrt (P)	80 MHz to 800 MHz d = 1.17*Sqrt (P)	800 MHz to 2.5GHz d = 2.33*Sqrt (P)
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Symbols

Symbol	Description
	Follow Instructions for Use.
	See Instructions for Use.
	Separate collection for electronic waste.
	Mark of conformity to European Medical Device Directive 93/42/EEC.
	Federal law restricts this device to sale by or on the order of a licensed physician.
	Authorized Representative in the European Community
	Storage Humidity range: 10% to 95% or 15% to 95%.
	Storage temperature range: +70° C to -40° C or -20° C to 50° C. Storage altitude range: +1600hPa to +500hPa.
	Keep dry.
	Fragile/breakable, handle with care.
	Date of Manufacture.
	Manufacturer.

Symbol	Description
	Non-sterile.
	Defibrillation proof Type BF.
IP24	Protection from ingress and particulate matter.
	Catalog number (model number).
	Serial Number.
	UL, LLC. Certification.
	Non-ionizing electromagnetic radiation.
	Federal Communications Commission (FCC) licensing.
	Wireless features can be used in member states with the restriction of indoor use in France.
IC Model	Industry Canada Registered Model.

Citations

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

[2] The Masimo rainbow SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70%-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation which encompasses 68% of the population weight.

[3] The Masimo rainbow SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and touching motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70%-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[4] The Radius-7 has been validated for low perfusion accuracy in bench-top testing against a Biotek Index 2TM simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70%-100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.*

[5] Masimo rainbow SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals ±1 standard deviation which encompasses 68% of the population.

[6] SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8 g/dL to 17 g/dL SpHb against a laboratory CO-Oximeter. The variation equals ±1 standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

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

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

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

Chapter 8 - Service and Maintenance

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

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 36* of the Operator's Manual.

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.

The following tables outline the estimated run times of Radius-7. The time estimates are based on Radius-7 with fully charged Battery Module.

Configuration	Operation Mode	Minimum run time
Radius-7 patient wearable device	Connected to patient	12 hours

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- Setup*** on page 35 of the Operator's Manual.
- 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* of the Operator's Manual.

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* of the Operator's Manual.
2. Use Root to change the High SpO_2 Alarm parameter to a value two points below the currently selected value. See *SpO2 Settings* of the Operator's Manual.
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 82* of the Operator's Manual.
3. Undock 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*** on page 81. Make sure the equipment is fully dry before packing.

To return the device for service, refer to ***Return Procedure*** on page 84.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in ***Cleaning*** on page 81. 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 84 below.

Contacting Masimo

Masimo Corporation
40 Parker
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

Warranty

Masimo warrants to the initial Purchaser for a period of one (1) year from the date of purchase that: each new Product and the Software media as delivered are free from defects in workmanship or materials.

Batteries are warranted for six (6) months.

To request a replacement under warranty, Purchaser must contact Masimo for a returned goods authorization. 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 shall be the responsibility of Purchaser.

Masimo's sole obligation under this warranty is to repair or replace any Product or Software that is covered under warranty.

Exclusions

The warranty does not extend to, and Masimo is not responsible for, repair, replacement, or maintenance needed because of: a) modification of the Product or Software without Masimo's written authorization; b) supplies, devices or electrical work external to the Product or not manufactured by Masimo; c) disassembly or reassembly of the Product by anyone other than an authorized Masimo agent; d) use of the Product with Sensors or other accessories other than those manufactured and distributed by Masimo; e) use of the Product and Software in ways or in environments for which they are not labeled; and f) neglect, misuse, improper operation, accident, fire, water, vandalism, weather, war, or any act of God. This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product. This warranty does not extend to any Product that has been reprocessed, reconditioned or recycled.

This warranty also does not apply to any Products provided to Purchaser for testing or demonstration purposes, any temporary Products Modules or any Products for which Seller does not otherwise receive a usage or purchase fee; all such Products are provided AS-IS without warranty.

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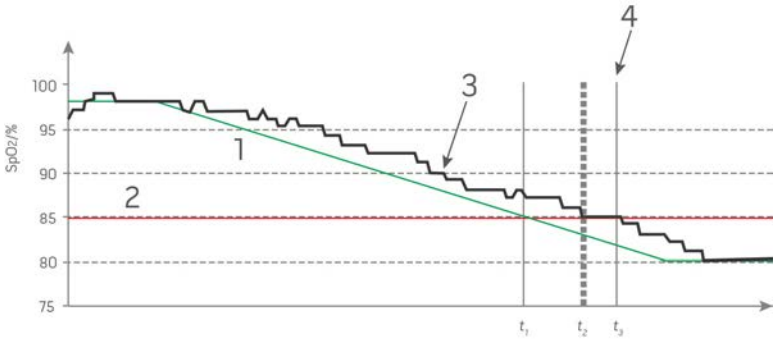
Appendix

Concepts of Alarm Response Delay

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



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

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

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

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

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

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