Operator's Manual

Radius VSM™

Patient-Worn Vital Signs Monitor

Masimo

For Sale in the USA

These operating instructions provide the necessary information for proper operation of the Radius VSM. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of Radius VSM are prerequisites for its proper use. Do not operate Radius VSM without completely reading and understanding these instructions. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

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

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

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

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

Wireless Radio: Contains: FCC ID: VKF-MWM2 | Contains IC: 7362A-MWM2

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MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1:2005, CAN/CSA C22.2 No. 60601-1:2014, and applicable Particular (IEC 60601-2-27, IEC 80601-2-30, IEC 80601-2-49, ISO 80601-2-61, ISO 80601-2-56) and related Collateral (IEC 60601-1-8:2006) Standards for which the product has been found to comply by Intertek.

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

Contents

About This Manual

This manual explains how to set up and use the Radius VSM™. Important safety information relating to general use of Radius VSM 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 VSM ("System") is a wearable, battery operated, patient monitoring system which is capable of continuous multimodal measurements through interconnection of the following technologies:

- Masimo SET® Pulse Oximetry
- Acoustic Respiration Rate (RRa) and Respiration Rate from the Pleth (RRp)
- ECG Heart Rate, Respiration Rate and Arrhythmia detection
- Noninvasive blood pressure
- Skin temperature
- Posture/physical orientation detection

Intended Use/Indication for Use

The Radius VSM and accessories are intended to be used as both a wearable multi-parameter patient monitor and an accessory to a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospital and healthcare facilities.

The Radius VSM and accessories are indicated for the monitoring of hemodynamic (including ECG, arrhythmia detection, non-invasive blood pressure, SpO_2, Pulse Rate, PVi, heart rate, and temperature), and respiratory (e.g., impedance, acoustic, and pleth-based respiration rate) physiological parameters along with the orientation and activity of adults.

The Radius VSM and accessories are indicated for the non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate (PR) of well or poorly perfused adults during both no motion and motion conditions.

The Radius VSM and accessories are indicated for continuous monitoring of skin temperature of adults.

The Radius VSM and accessories are indicated for monitoring of the orientation and activity of patients including those susceptible to pressure ulcers.

The Radius VSM and accessories are indicated for the continuous non-invasive monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) of adults during no motion conditions.

PVi may be used as a noninvasive dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.

Devices with Masimo technology are only indicated for use with Masimo accessories.

Contraindications

Radius VSM is contraindicated for patients who may have an allergic reaction to the adhesives or ECG gel.

Safety Information, Warnings and Cautions

CAUTION: Radius VSM is to be operated by, or under the supervision of, a clinician. Read this manual, accessory directions for use, all precautionary information, and specifications before use.

Failure to follow these instructions may increase the potential residual risk of the following:

- Possible wrong or delayed treatment decision due to overreliance.
- Electrical, Fire, or Mechanical Injury.
- Skin irritation due to potential allergic reaction.
- Cross-contamination due to reuse of disposable parts.

Safety Warnings and Cautions

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

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

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

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

WARNING: Keep Radius VSM and accessories away from small children. Small items may become a choking hazard.

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

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

WARNING: To avoid patient injury, ensure that the Radius VSM and accessories are not positioned where wires could become entangled around the patient, or cause choking, strangulation, or inhibit circulation in extremities.

WARNING: Do not use the Radius VSM in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide to avoid risk of explosion.

WARNING: Do not use Radius VSM during magnetic resonance imaging (MRI) or in an MRI environment.

- The device contains ferromagnetic materials that can be attracted by the MR magnet core that can make it a risk of projectile injury.
- Metal components can heat up during MR scanning that can present thermal injury and burns.
- Artifacts can be created in the MR image.
- Strong magnetic fields may prevent the device from operating properly.

WARNING: The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.

WARNING: Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.

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

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

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

CAUTION: To ensure patient electrical isolation, only connect to Masimo devices that have been designed for Radius VSM.

CAUTION: Ensure the device is adequately spaced from the patient's head to minimize exposure to audible alarms.

Note: Clear the trend data before monitoring a new patient using Radius VSM.

Note: Do not monitor more than a single patient at a time on Radius VSM.

Note: Use and store the Radius VSM in accordance with specifications. See the Specifications chapter in this manual.

ECG

WARNING: Secure all electrodes to the patient. Conductive parts of electrodes must not contact earth or other conductive parts to avoid patient injury.

WARNING: To protect from electric shock, always remove the electrodes and completely disconnect Radius VSM before bathing the patient.

WARNING: If skin irritation is noticed, discontinue use of the electrodes.

Noninvasive Blood Pressure

WARNING: Frequently check the blood pressure monitoring site to ensure adequate circulation to prevent patient injury.

WARNING: Do not apply the cuff to a limb that is on the same side of a mastectomy.

WARNING: Do not use or stop blood pressure measurements if the patient appears to be affected by the pressurization of the cuff due to a physical condition (e.g., pregnant, pre-eclamptic)

WARNING: Avoid too frequent blood pressure measurements to prevent injury to the patient due to blood flow interference.

WARNING: Do not attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arterio-venous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.

CAUTION: Do not apply the blood pressure cuff over a wound to avoid further injury.

Performance Warnings and Cautions

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

WARNING: Radius VSM has not been validated for use in pediatric population.

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

WARNING: Radius VSM is not intended to be used as an apnea monitor. Do not rely on the respiration monitoring for detection of cessation of breathing.

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

WARNING: PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.

WARNING: Always ensure settings including alarm limits and alarm speaker volume are appropriate for each patient and facility's protocol and environment prior to use. Devices in which the alarm speaker is not working or the alarm speaker volume setting is not distinguishable from the facilities ambient noise should not be used.

WARNING: Radius VSM may be used during defibrillation; however, the display may require up to 5 seconds to return to normal operation.

WARNING: Radius VSM is not intended for use during electrocautery.

WARNING: When the Radius VSM is connected via Bluetooth to Root, Radius VSM audible alarms will be provided on the Root.

WARNING: Always check that speaker is functional prior to use to avoid the potential for not detecting an audible alarm.

WARNING: When used independently, avoid placing Radius VSM against a surface that may cause the alarm to be muffled. This may result in the inability to detect the audible alarms.

WARNING: Radius VSM may not fully charge in a high ambient temperature environment.

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

WARNING: Properly apply sensors according to sensor's directions for use. Misapplied sensor or sensors that become partially dislodged may cause no or incorrect readings.

WARNING: Select a well perfused site for monitoring, very low perfusion at the monitored site may result in no or incorrect readings.

WARNING: Do not use Radius VSM on patients that have been injected with dyes or any substance containing dyes, the change usual blood pigmentation may cause no or incorrect readings.

WARNING: Displayed parameter(s) may not be accurate when a low SIQ message is provided. Clinicians should consider additional information to supplement values to completely understand the patient's condition.

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

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

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

- Improper sensor application or use of incorrect sensor.
- Blood pressure cuff inflated or constricting the same arm as the sensor site.
- Intravascular dyes such as indocyanine green or methylene blue.
- Arterial catheter
- Venous congestion
- Abnormal venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg position).
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Moisture, birthmarks, skin discoloration, nail aberration, deformed fingers, or foreign objects in the light path.
- Elevated levels of bilirubin.
- Physiological conditions that can significantly shift the oxygen disassociation curve.
- A physiological condition that may affect vasomotor tone or changes in vasomotor tone.

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

- Elevated levels of COHb and/or MetHb. Note: High levels of COHb or MetHb may occur with a seemingly normal SpO_2.
- Severe anemia.
- Very low arterial perfusion.
- Hypocapnic or Hypercapnic conditions.
- Excessive motion.
- Vasospastic disease such as Raynaud's.
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Peripheral vascular disease.
- EMI radiation interference.

WARNING: PVi may not accurately reflect the fluid responsiveness due to the following conditions:

- When not on mechanical ventilation.
- Under mechanical ventilation with a tidal volume less than 8 mL/kg.
- Venous congestion.
- Abnormal venous pulsations (e.g. tricuspid valve regurgitation, Trendelenburg position).
- Conditions that may affect peripheral arterial blood flow (e.g., Hypotension, severe vasoconstriction, severe anemia, or hypothermia.)
- When applied to a site other than a finger.
- Low perfusion.
- Motion.

WARNING: Inaccurate RRa measurements may be caused by:

- Improper sensor application or use of use of incorrect sensor.
- Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. Cardiac arrhythmias, intra-aortic balloon, etc.).
- Motion artifact.
- Excessive ambient or environmental noise.

WARNING: Inaccurate RRp readings may additionally be caused by:

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

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 can cause inaccurate readings and/or pressure injury.

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

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

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Radius VSM, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

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

CAUTION: If using Radius VSM 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 or no measurements.

CAUTION: If the Low Perfusion message is frequently displayed, find a better perfused monitoring site.

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

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

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

CAUTION: The Radius VSM is has the ability to operate across the facility's network. Unanticipated failure or alteration of network components (including but not limited to: disconnection or malfunctioning of a networking device/switch/router/ethernet cable) may result in loss of supplemental notifications. Altering or making changes to the Hospital Network should be done with proper knowledge.

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

- Wired Network Connection

  During Ping Test, passing result if:

  a. At least 98% of packets have latency ≤ 30 milliseconds, and

  b. No more than 2 % packets loss.

- Wireless Network Connection

  During Ping Test, passing result if:

  a. At least 98% of packets have latency ≤ 100 milliseconds,

  b. No more than 2 % packets loss, and

  c. Primary access point signal strength at least -67 dBm.

CAUTION: The wireless quality of services may be influenced by the presence of other devices that may create radio frequency interference (RFI). Some RFI devices to consider are as follows: electrocautery equipment, diathermy, cellular telephones, wireless PC and tablets, pagers, RFID, MRI, electrically powered wheelchair, etc. When used in the presence of potential RFI devices, consideration should be taken to maximize separation distances and to observe for any potential signs of interference such as loss of communication or reduced Wi-Fi signal strength.

CAUTION: Network performance may be affected by changes in the network.

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

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

CAUTION: To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time Radius VSM is used.

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

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

Note: Physiological conditions that result in loss of pulsatile signal may result in no SpO_2 and RRp readings.

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

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

Note: Always charge Radius VSM when it is not in use to ensure that the Radius VSM battery remains fully charged.

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

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

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

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

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

ECG Performance

WARNING: Properly apply electrodes according to electrodes' directions for use. Misapplied electrode or electrodes that become partially dislodged may cause no or incorrect readings.

WARNING: Ensure that the electrical connections are properly connected to the Radius VSM to prevent no or incorrect readings.

WARNING: Avoid placing the electrodes over compromised skin, excessive hair, implants, ports, subcutaneous or dermal fillers or scar tissue, as this may result in incorrect readings.

WARNING: The output power of the Radius VSM and other sources of radio frequency energy, when used in the proximity of a pacemaker, can be sufficient to interfere with pacemaker performance. Due to the shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring any paced patient. In order to minimize the possibility of interference, position electrodes, electrode wires, and the Radius VSM as far away from the pacemaker as possible. Consult the pacemaker manufacturer for information on the RF susceptibility of their products and the use of their products with the Masimo ECG System.

WARNING: Pacemakers that create fusion beats (pace pulse on top of the QRS complex) may not be detected by the monitor's QRS detector.

WARNING: For paced patients who exhibit only intrinsic rhythm, the monitor can erroneously count pace pulses as QRS complexes when the algorithm first encounters them, resulting in missed detection of cardiac arrest. The risk of missing cardiac arrest can be reduced by monitoring these patients with the low heart rate limit at or slightly above the basic/demand pacemaker rate. A low heart rate alarm notifies you when the patient begins pacing. Proper detection and classification of the paced rhythm can then be determined.

WARNING: Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Make sure that pace pulses are detected correctly by checking the pace pulse markers on the display. Keep pacemaker patients under close observation.

WARNING: ECG signal detection can be affected by the following:

- Improper electrode application.

- Conditions that may increase skin impedance (e.g. dry skin).
- Weak heart (ECG) signals.
- Excessive movement.
- Electrode or electrodes placement over skin injuries or hair.
- Abnormal heart rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, ventricular tachycardia/fibrillation, seizures etc.).
- EMI radiation interference.

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

- Improper electrode application.
- Excessive motion.
- Abnormal heart rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, ventricular tachycardia/fibrillation, seizures etc.).
- EMI radiation interference.

WARNING: During complete heart block or pacemaker failure (to pace or capture), tall P-waves (greater than 1/5 of the average R-wave height) can be erroneously counted by the arrhythmia algorithm, resulting in missed detection of cardiac arrest.

CAUTION: Applying excessive pressure to electrodes may lead to decreased signal quality, decreased ECG reliability, and poor adhesion.

CAUTION: The conductive parts of electrodes or connectors should not contact other conductive parts including earth ground.

CAUTION: Replace the electrode when a reading cannot be obtained; review troubleshooting steps listed in the troubleshooting section.

CAUTION: Use the electrodes immediately after opening to prevent gel from drying out.

CAUTION: Do not use unapproved conductive gel with the electrodes as it may cause skin irritations or lack of adhesion.

CAUTION: Do not allow electrode gel to contact the electrode connector as this may cause impedance problems and inaccurate ECG readings.

CAUTION: Check electrodes and placement after patient movement to ensure proper connection.

Note: During defibrillation, monitoring may be temporarily interrupted or distorted. It may take several seconds for the ECG trace to reappear on the screen. After defibrillation, the device will continue to monitor as before; the device settings will not be affected.

Noninvasive Blood Pressure

WARNING: Before applying the cuff on the patient, confirm the cuff size is appropriate. Incorrect cuff size may result incorrect blood pressure measurements.

WARNING: When a blood pressure measurement error code occurs, any blood pressure values reported should be disregarded.

CAUTION: If the blood pressure cuff is on the same limb as the Radius VSM monitoring equipment, avoid securing the Radius VSM too tight as it may cause constriction of the blood volume used in determining your blood pressure.

Note: Blood pressure measurements can be affected by the patient's position, physiological condition, and environmental factors.

Note: Physiological conditions that can affect blood pressure measurements include, but are not limited to, cardiac arrhythmias, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, trembling, and shivering.

Temperature Performance

WARNING: Radius VSM provides the skin temperature and does not reflect the actual body temperature.

Cleaning and Service Warnings and Cautions

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

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

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

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

CAUTION: Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the display.

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

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

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

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

Compliance Warnings and Cautions

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

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

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

WARNING: Do not incinerate the Radius VSM. The device contains a battery should be properly disposed according to local laws and regulations.

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

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

Note: Use Radius VSM in accordance with the Environmental Specifications section in the Operator's Manual.

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: 2015. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

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: When using Radius VSM consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

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

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

Chapter 1: Technology Overview

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

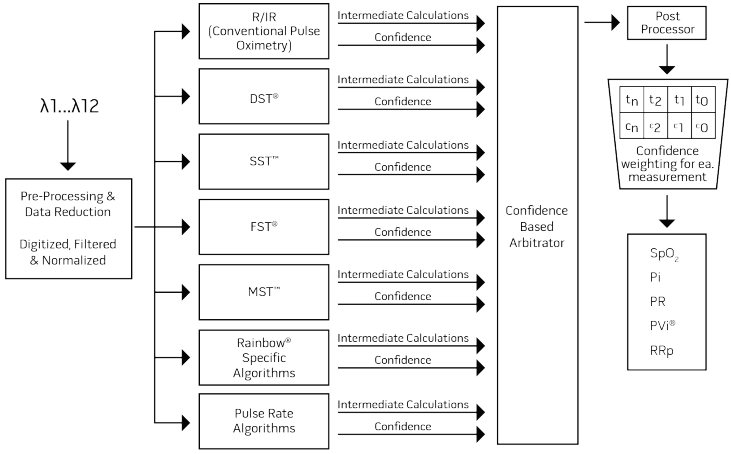
Signal Extraction Technology® (SET®)

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

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

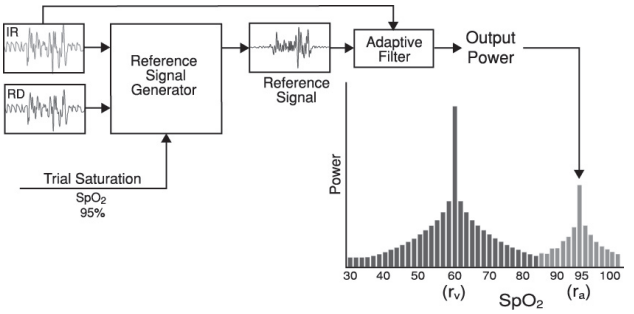
Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.



Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (SpO2)

Pulse oximetry is governed by the following principles:

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

Successful Monitoring for SpO2, PR and Pi

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

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

Functional Oxygen Saturation (SpO2)

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

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

General Description for Pulse Rate (PR)

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

General Description for Perfusion Index (Pi)

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

General Description for Pleth Variability Index (PVi)

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

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

PVi may be used as a noninvasive dynamic indicator of fluid responsiveness of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.

One study found that the accuracy of PVi in determining fluid responsiveness was dependent on perfusion index (Pi). The study found that PVi reliably predicted fluid responsiveness only in patients with a Pi >4% [15].

The utility of PVi has been evaluated in clinical studies [1-11]. Technical and clinical factors that may affect PVi include probe malposition, probe site, patient motion, skin incision, spontaneous breathing activity, lung compliance, open pericardium, use of vasopressors or vasodilators, low perfusion index, subject age, arrhythmias, left or right heart failure, and tidal volume [12-14]. Other studies have found that the use of vasopressors may reduce the accuracy of PVi in predicting fluid responsiveness [16, 17].

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General Description for Respiration Rate (RRp)

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

Signal IQ

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

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

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

rainbow Acoustic Monitoring® (RAM®)

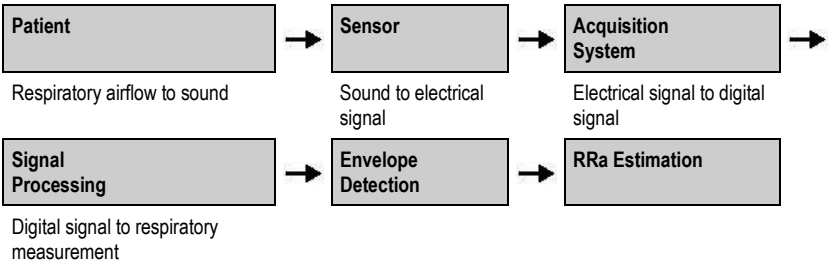
rainbow Acoustic Monitoring (RAM) continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Sensor, which is applied on the patient's neck, translates airflow sounds generated in the upper airway to an electrical signal that can be processed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

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

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

rainbow Acoustic Monitoring Architecture

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



Patient

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

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

Sensor

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

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

Acquisition System

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

Signal Processing

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

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

Citations

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Electrocardiogram (ECG)

The Masimo Radius VSM ECG System acquires electrical signals from the patient through multiple electrodes placed on the patient's skin. The Radius VSM will process these electrical signals to reproduce the ECG waveform and to provide an estimate of the patient's heart rate and/or respiration rate. The ECG waveform data is monitored to detect for the following:

- Heart Rate
- Respiration Rate
- Lethal Arrhythmias - Asystole, Ventricular Tachycardia, Ventricular Fibrillation
- Non-lethal Arrhythmias - Arterial Fibrillation (longer than 30 seconds)

Electrodes

The Masimo Radius VSM ECG system uses a proprietary electrode and cable assembly. The electrodes are place on specific location of the patient torso to measure the electrical potential on the surface of the

skin. These electrodes make passive measurements of the electrical potential caused by the electrical activity of the heart muscles.

Signal Acquisition

The hardware and software processing of the acquired waveform is designed to remove known causes of interference and to monitor the status of the measurement system. Interference from external radio frequency sources and power lines can interfere with proper processing of the signals. The patient may also be a source of additional noise signals through non-cardiac muscle contractions or movement, the use of a cardiac pacemaker, or patient motion. The system is also designed to detect if a lead has fallen off the patient or has otherwise become unusable.

Temperature

The Radius VSM provides a direct mode surface temperature of the skin where the Radius VSM Multi-Functional Reusable Pod is applied. The displayed temperature may require time to equilibrate after initial application (up to 10 minutes).

Chapter 2: System Components

This chapter contains the description of the Radius VSM physical features.

General System Description

The Radius VSM system includes these components:

- Radius VSM Patient-Worn Vital Signs Monitor
- Root Battery Charging Adapter or Radius VSM Charger
- Armband
- SpO_2 Sensor
- Acoustic Sensor
- NIBP Module
- NIBP Cuff
- ECG Module
- ECG Electrodes

Radius VSM Patient-Worn Vital Signs Monitor

Front and Top Views

1. Power Button/System Status Light

Turns the device On and Off and provides an operational status light. See ***About the System Status Light*** on page 54.

2. Green Accessory Port *

Connection for NIBP or ECG Module.

3. Blue Accessory Port *

Connection for acoustic (RAM) sensor.

4. Release Buttons

Press to release the tabs securing the Radius VSM to the Armband or charger.

5. Speaker

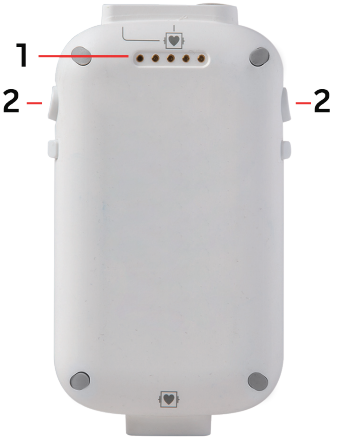
Speaker to provide system sounds and alarms.

6. Patient Cable Port

Connection for a patient cable or sensor.

* The NIBP/ECG/RAM connectors are color-coded for ease of identifying compatible Radius VSM accessory ports.

Rear View



1. Charging Connector Pins

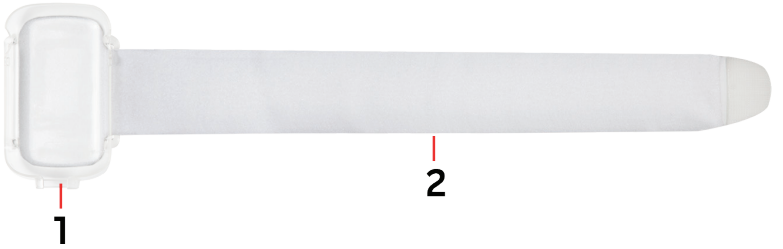
Connections to charge the battery. See ***Battery Charging*** on page 35.

2. Release Buttons

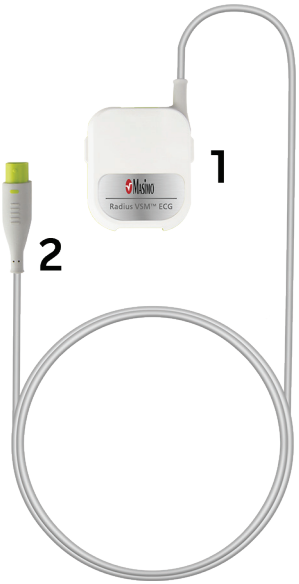
Press to release the tabs securing the Radius VSM to the Armband or charger.

Radius VSM Armband

The cradle ***(1)*** is part of the Armband ***(2)***. The Radius VSM locks in the cradle. The armband is a disposable accessory. See ***Securing Radius VSM to the Patient and attaching a Sensor*** on page 36.



ECG Module



1. ECG Module

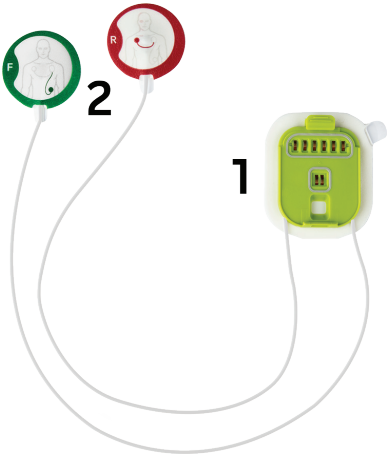
The ECG Module is the reusable part that attaches to the ECG Main Electrode.

ECG Module includes a temperature sensor and an integrated patient orientation and activity sensor.

2. ECG Module Connector

Connects to the NIBP Module or the Radius VSM.

ECG Electrodes and Temperature Sensor



1. ECG Main Electrode

The ECG Electrodes and Main Connector are the disposable parts that attach to the patient's chest and the ECG Module.

2. ECG Electrodes

The ECG Electrodes attach to the patient's chest.

Noninvasive Blood Pressure Module

The NIBP Module is a reusable item of the Radius VSM system.

Front and Top Views

1. Power Light

On when connected to Radius VSM and powered on.

2. Connector

The ECG Module connects here.

3. NIBP Module Cable

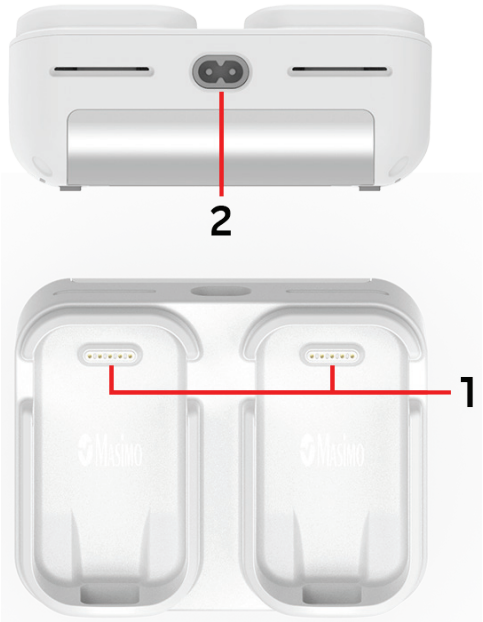
Connects to the Radius VSM.

Rear View

1. NIBP Module NIB Connections

Connects the NIBP Module to the Cuff.

Radius VSM Charger



1. Charging Connector Pins

Connections to charge the Radius VSM battery. See ***Battery Charging*** on page 35.

2. Power Entry Module

Connection for the AC power cord.

Radius VSM Root Battery Charging Adapter

The Radius VSM Battery Charging Adapter fits into the docking station on Root.

1. Radius VSM Pocket

Store the Radius VSM when not used or when charging.

2. Charging Connector Pins

Connections to charge the Radius VSM battery. See ***Battery Charging*** on page 35.

Chapter 3: Basic Setup and Use

This chapter contains information about setup and basic use of Radius VSM.

Preparation for Use

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

1. Remove the Radius VSM and accessories from the packaging and check for signs of shipping damage.
2. Confirm that you have all system components. See ***General System Description*** on page 29. Check all items against the packing list. Save all packing materials, invoice, and shipping information. These may be required to process a claim with the carrier.
3. If anything is missing or damaged, contact the Technical Service Department. See ***Return Procedure*** on page 133.
4. Read the ***Safety Information, Warnings and Cautions*** on page 11.
5. Charge the Radius VSM battery. See ***Battery Charging*** on page 35.

Battery Charging

The Radius VSM should be fully charged before use.

1. Prepare the charger.
   - To charge using Root, attach the Battery Charging Adapter to Root. See ***Radius VSM Root Battery Charging Adapter*** on page 33.
   - For the Radius VSM Charger, connect the charger power cord to a working AC outlet. See ***Radius VSM Charger*** on page 33.
2. Place the Radius VSM into the charger and click into place.
3. Verify Radius VSM is charging:

   Device OFF: The Radius VSM *System Status Light* flashes. See ***About the System Status Light*** on page 54.

   Device ON: A battery icon displays on the Radius VSM screen, and the *System Status Light* is Green.

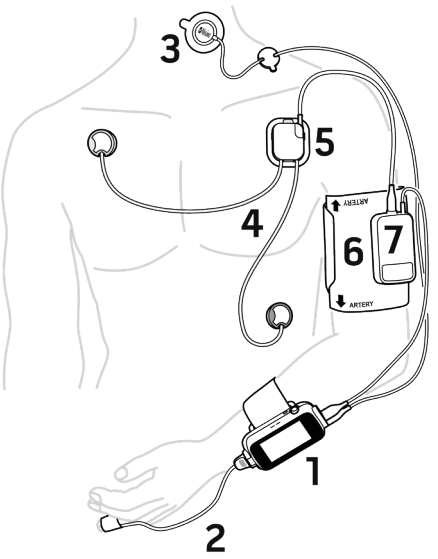
   

4. When charged, remove the Radius VSM from the charger.
   - When Radius VSM is Off, the *System Status Light* stops flashing and illuminates steadily to indicate that the battery is charged.

   For additional battery information, See ***Battery Operation and Maintenance*** on page 131.

Note: The lithium batteries provided with the Radius VSM are sealed with a pressure-regulated valve so that gases do not escape during normal charging or discharging. In case of abnormal charging, pressure can build up inside the battery that may result in typically sealed gases to be vented. This risk to the patient is minimized since battery charging is done when the device is separated from the patient. In case of abnormally high discharge currents, the current is limited via hardware and software controls.

Radius VSM System Setup



1. Radius VSM Patient-Worn Vital Signs Monitor and Armband
2. Pulse Ox Sensor
3. Acoustic Sensor
4. ECG Electrodes
5. ECG Module
6. NIBP Cuff
7. NIBP Module

To setup the Radius VSM system for monitoring, follow these steps:

1. Attach the Radius VSM Patient-Worn Vital Signs Monitor ***(1)***. See ***Securing Radius VSM to the Patient and attaching a Sensor*** on page 36.
2. Attach a Pulse Ox sensor ***(2)***. See ***Attaching a Pulse Ox Sensor*** on page 38.
3. Attach an acoustic sensor ***(3)*** for respiration monitoring. See ***Attaching an Acoustic Sensor*** on page 39.
4. Attach the ECG Electrodes ***(4)*** and the ECG Module ***(5)***. See ***Attaching the ECG Module and Electrodes to the Patient*** on page 42.
5. Attach the NIBP Cuff ***(6)*** and NIBP Module ***(7)***. See ***Attaching the Noninvasive Blood Pressure Cuff and Module to the Patient*** on page 39.
6. Power On the Radius VSM. See Powering Radius VSM ON and OFF.

Securing Radius VSM to the Patient and attaching a Sensor

Charge the Radius VSM before placing on the patient. See Initial Battery Charging.

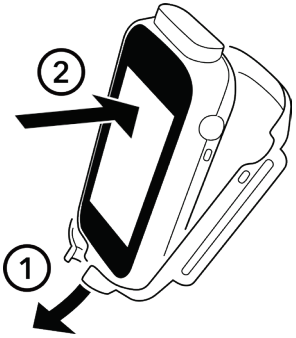
Note: Attach the Radius VSM to the non-dominant arm. However, the Radius VSM can be attached to either arm.

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

Note: The armband is single-patient-use.

1. Remove the armband from the packaging.

2. Place the Radius VSM into the cradle ***(1)*** then snap the top to secure ***(2)***.



3. Place the armband on the arm; making sure the armband fabric is between the cradle and the arm.

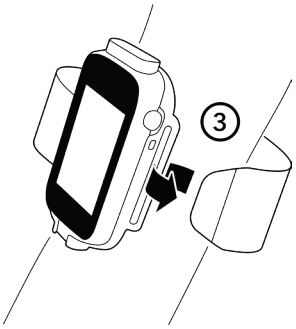
   WARNING: Discontinue and dispose of armband if it appears to be stained or becomes excessively moist to minimize risk of skin irritation.

   CAUTION: If the device is applied directly to the skin, select a site that is free from skin irritation or signs of chafing.

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

   Note: The cradle and Radius VSM should be attached so the Masimo logo is at the top.

4. Pull the armband through the slot in the cradle ***(3)***.



5. Check to ensure the armband fits comfortably around the patient's arm. Fold the end of the armband over the armband fabric to secure.

   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: Secure the armband so that it does not slide off the arm.

Removing Radius VSM from Patient

1. Disconnect the Pulse Ox sensor.
2. Disconnect the acoustic sensor.
3. Disconnect the NIBP or ECG Module connector.
4. Remove the armband with the Radius VSM from the patient's arm.
5. Press the release buttons on the Radius VSM and remove from the cradle.
6. Disinfect and clean the Radius VSM. See ***Cleaning*** on page 129.
7. Charge the Radius VSM. See ***Battery Charging*** on page 35.
8. Dispose of the armband according to local laws and regulations.
   WARNING: To avoid possible cross-contamination, do not reuse the armband.

Attaching a Pulse Ox Sensor

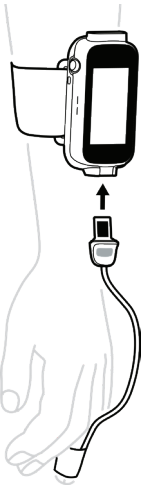
Note: The RRa parameter does not display until an acoustic sensor is connected.

Note: The Pulse Ox sensor is single-patient-use.

For a list of compatible sensors, visit ***http://www.masimo.com/***.

1. Attach the Pulse Ox sensor to the patient's finger. See the sensor *Directions for Use* for proper application.
2. Connect the sensor to Radius VSM. See ***Front and Top Views*** on page 32.

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



Attaching an Acoustic Sensor

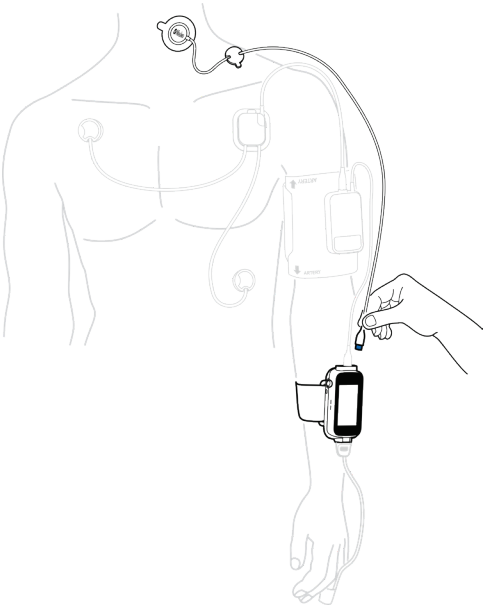
Note: The acoustic sensor should be attached to the same side of the body as the Radius VSM.

Note: Radius VSM only displays the RRa parameter when the acoustic sensor is connected.

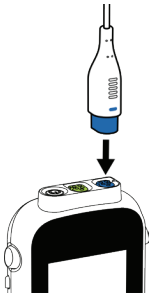
Note: The acoustic sensor is single-patient-use.

1. Attach the acoustic sensor to the patient. See the sensor *Directions for Use* for proper application
2. Connect the sensor blue cable connector to the blue port on the Radius VSM. See ***Front and Top Views*** on page 29.

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



Match the blue connector to the blue port of the Radius VSM.



Attaching the Noninvasive Blood Pressure Cuff and Module to the Patient

1. Select the Correct Cuff Size

Note: The cuff is single-patient-use.

Wrap the cuff around the arm.

The index line 

should align within the cuff range markings 

.

If the index line does not fit within the range markings, select a larger or smaller cuff. For a list of compatible NIBP cuffs, visit ***http://www.masimo.com/***.

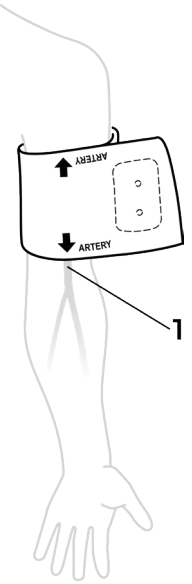
2. Place Cuff on Measurement Site

Note: The cuff can be used on either arm, but should be on the same arm as Radius VSM.

Locate the brachial artery in the middle of the inner arm. Wrap the cuff around the arm, making sure the Artery-mark is aligned over the located brachial artery **(1)** as shown.

If possible, do not wrap the cuff over the patient's clothing.

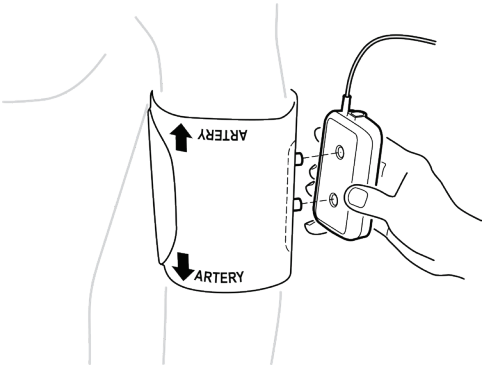
Note: The cuff should fit snugly around the patient's arm for maximum signal quality. The lower edge of the cuff should be located 2 cm (0.8") above the inside bend of the elbow.



3. Attach the NIBP Module to the Cuff

Position the Module on the cuff with the cable pointing upwards as shown.

Press the module on the cuff nibs until fully seated.

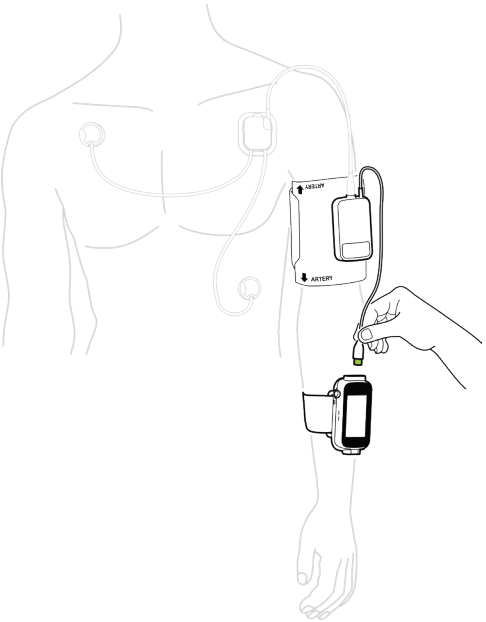


4. Connect the NIBP Module to the Radius VSM

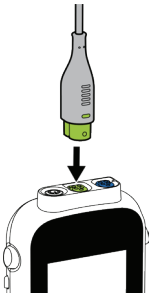
Connect the NIBP Module green cable connector to the green port on Radius VSM.

See ***Front and Top Views*** on page 29.

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



Match the green connector to the green port of Radius VSM.



Removing the NIBP Module and Cuff

1. Disconnect the NIBP Module connector from Radius VSM.
2. Disconnect the ECG Module connector.
3. Pull the NIBP Module off of the Cuff nibs.
4. Remove the cuff.
5. Clean the NIBP Module. See ***Cleaning*** on page 129.
6. Dispose of the cuff according to local laws and regulations.

   WARNING: To avoid possible cross-contamination, do not reuse the cuff.

Attaching the ECG Module and Electrodes to the Patient

The instructions below are for attaching the ECG Electrodes to the patient, the ECG Module to the electrodes, and the ECG Module to the NIBP Module. The ECG Module can also be connected directly to the Radius VSM (the NIBP Module cannot be connected to Radius VSM).

Note: ECG Module includes a temperature sensor and an integrated patient orientation and activity sensor.

Skin Preparation

Good electrode-to-skin contact is important for the ECG signal as the skin conducts electricity poorly.

1. Select sites with skin that is without impairment of any kind.
2. Remove hair from the skin as necessary.
3. Wash with soap and water and leave no soap residue.

   Note: It is not recommended to use ether or pure alcohol because this dries the skin and increases the resistance.
4. Dry skin thoroughly.

Attaching the Electrodes

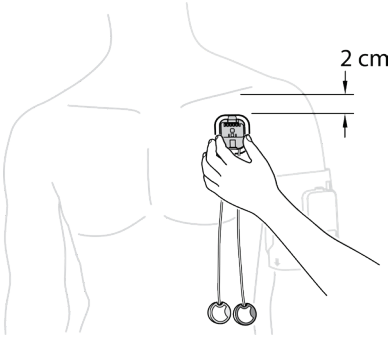
WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Note: The ECG Electrodes should be oriented to the same side of the body as the Radius VSM.

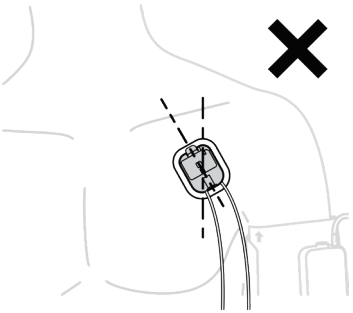
Note: The ECG Electrodes are single-patient-use.

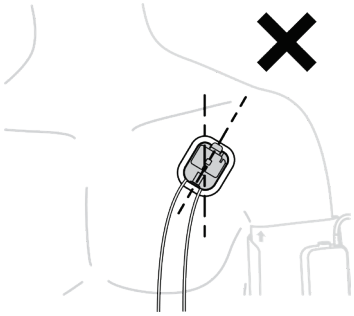
1. Attach main electrode/connector base

Attach the main (left upper limb) electrode/connector base in the mid line of the collarbone approximately 2 cm (0.8") below the patient's left collarbone.



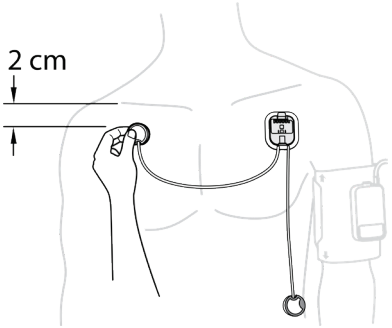
CAUTION: Do not place the main electrode/connector at an angle.





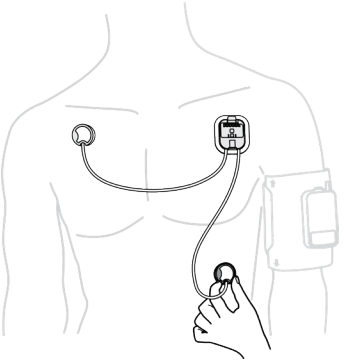
2. Attach second electrode

Attach the second (right upper limb) electrode in the mid line of the collarbone approximately 2 cm (0.8") below the patient's right collarbone.



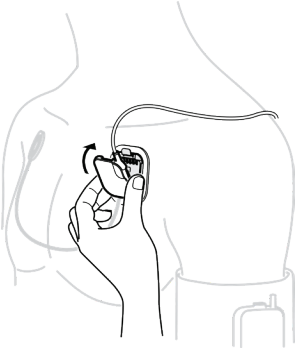
3. Attach third electrode

Attach the third (left lower limb) electrode along the anterior axillary line (outer edge of belly), between the last rib and the pelvic bone as shown.



4. Attach ECG module

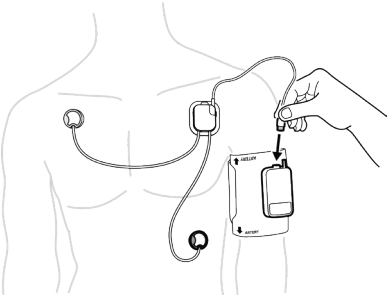
Insert the bottom of the ECG Module into the base and click the top to secure.



5. Connect ECG Module to Radius VSM

Connect the ECG Module green cable connector to the green port on the NIBP Module.

See ***Front and Top Views*** on page 32.



Removing the ECG Module and Electrodes

1. Disconnect the ECG Module from the Radius VSM NIBP Module or Radius VSM.
2. Release the tab and remove the ECG Module from the ECG Electrodes.
3. Remove the electrodes from the patient.

   CAUTION: Do not to dispose of the reusable ECG Module when removing the disposable ECG Electrodes.
4. Clean the ECG Module. See ***Cleaning*** on page 129.
5. Dispose of the ECG Electrodes according to local laws and regulations.

Powering Radius VSM ON and OFF

To Power ON Radius VSM:

1. Press and hold the Power Button for more than two (2) seconds.
2. The Radius VSM powers ON.

To Power OFF Radius VSM:

1. Press and hold the Power Button for more than two (2) seconds.
2. The Radius VSM powers OFF.

Connecting Radius VSM with Root

In order connect the Radius VSM to Root via Bluetooth connection, perform the following steps:

1. Enable Bluetooth Connectivity on Root. See the Operator's Manual for Root.
2. Power On the Radius VSM.
3. Dock the the Radius VSM to the Root that you intend to make the Bluetooth connection.
4. Allow enough time for the Root to acknowledge the Radius VSM is docked. The user will hear a beep tone to indicate that the Bluetooth connection between Root and Radius VSM has been established.
5. Verify that the Bluetooth Mac address on Radius VSM matches the Mac Address listed on Root. See ***Bluetooth*** on page 59.
6. You can verify the Bluetooth connection is successful when the Root screen begins to display the Radius VSM's measurement data.

WARNING: When the Radius VSM 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 VSM is within approximately a 7m radius and line of sight of Root.

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

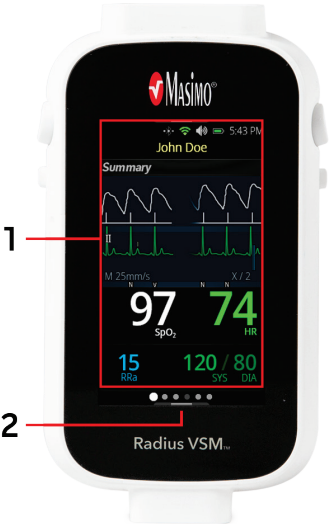
Locating Radius VSM

The Radius VSM has the ability to be located by sounding a tone. With Radius VSM connected to Root, go to the *About* screen on Root and select *Locator*. See ***About Root*** on page 142. If Radius VSM is within range of Root and connected, it will sound a tone.

Chapter 4: Operation

The information in this chapter assumes that Radius VSM is set up and ready for use. This chapter provides necessary information for proper operation of the device. Do not operate Radius VSM without completely reading and understanding these instructions.

Using the Touchscreen and Home Button



1. Main Screen

Is the main monitoring screen. Touch a value or icon on the Display View to access settings and other screens.

See ***About the Main (Summary) Screen*** on page 49.

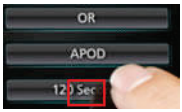
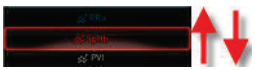
2. Main Menu/Home Button Action menu

Swipe up from the bottom of the screen to view the Main Menu and home button.

See ***Accessing Radius VSM Main Menu Options*** on page 54.

Using the Touchscreen Interface

Using the gestures described below, the user is able to customize the viewing experience, including displaying the highest priority parameters and measurements. Feature navigation availability is dependent on which medical devices are connected to Radius VSM.

Action	Illustration	Example	Description
Touch			Touch and release. Action performed once finger is released.
Touch and Hold			Touch and hold. Action is performed once hold duration is reached. Can also move (drag) items while holding (when allowed).
Swipe			Touch and swipe (left, right, up or down) and release.

Action	Illustration	Example	Description
Flick			Touch and quickly swipe (left, right, up or down), and release.

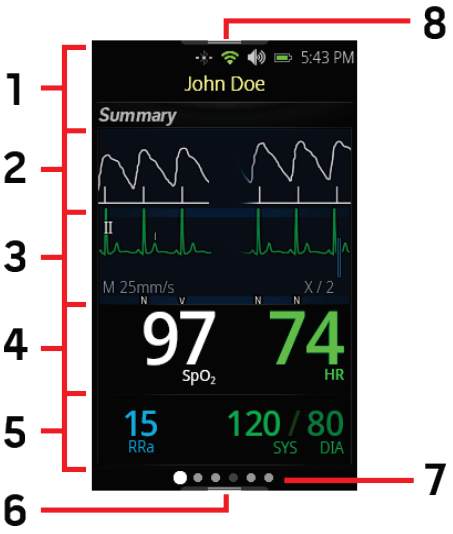
Below is a list of all the different types of controls available on Radius VSM and the various ways to interact with each type of control.

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

Control	Applicable Actions	Description
Button	Touch	• Performs action (as defined by the button description)
Icon Menu	Touch tile	• Opens menu specified by tile
	Swipe left or right (anywhere)	• Scrolls icons left or right
	Touch bottom indicator icon	• Quickly centers tile corresponding to indicator icon
Window	Touch parameter or measurement	• Opens parameter or measurement menu
	Touch and hold	• Enables parameter and measurement drag and drop
Alert Silence icon	Touch	• Silences all audible alerts
Other Status Bar icons	Touch	• Opens relevant menu
Back Arrow	Touch	• Exits menu, abandons any changes

About the Main (Summary) Screen

The *Summary Screen* displays information and parameters from the Radius VSM system. The information and parameters displayed on the *Summary Screen* are a direct result of connected accessories. The *Summary Screen* can be composed of the following items.



1. Status Bar Displays messages, profile, alarm status, and battery information. Includes patient. See ***About the Status Bar*** on page 50.

2. Waveform Displays pleth waveform and signal confidence. See ***Signal IQ Indicators*** on page 53.

3. ECG Waveform Displays ECG waveform with an ECG Module connected. Touch the waveform to access the settings. See ***ECG Waveform Settings*** on page 76.

4. Pulse Ox Parameters Displays parameter values. Touch the parameter to access the settings directly. See ***Pulse Ox Settings*** on page 63.

5. NIBP Measurements Displays blood pressure measurements with an NIBP Module connected. Touch the parameter to access the settings directly. See ***Noninvasive Blood Pressure (NIBP) Settings*** on page 84.

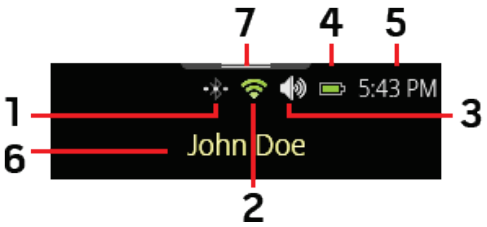
6. Main Menu/Home Button Action Menu Swipe up from the bottom of the screen to display the Main Menu and Home Buttons. See ***Accessing Radius VSM Main Menu Options*** on page 54.

7. System Screens Indicates multiple screens are available for viewing on Radius VSM. Swipe left or right to view system screens.

8. Alarm Status/Exception Messages Action Menu Swipe down from the top of the screen to display the alarm status and system messages. See ***Chapter 10: Alarms and Messages*** on page 93.

About the Status Bar

The *Status Bar* is visible at the top of the Radius VSM display.



1. Bluetooth

Displays Bluetooth connection status.

See ***Bluetooth*** on page 59.

2. WiFi

Displays WiFi connection status.

See ***Wi-Fi*** on page 58.

3. Sound

This icon does **not** indicate the actual volume level of the alarm or pulse tone.

See ***Sounds*** on page 56.

4. Battery Charge Indicator

Displays battery charge remaining.

See ***Battery Indicator and State of Charge*** on page 51.

5. Time

Displays the current time.

See ***Localization*** on page 57.

6. Patient Label

Displays when the patient is admitted.

See ***Appendix A: Radius VSM Operation with Root*** on page 137.

7. Alarm Status/Exception Messages Action Menu

Swipe down from top of the screen to view action menu.

See ***About Alarms*** on page 93.

Battery Indicator and State of Charge

When Radius VSM is On, the Battery Charge Indicator displays the remaining battery charge as follows:

Note: The System Status Light also indicates battery charging status. See ***About the System Status Light*** on page 54.

Note: When Radius VSM goes into low battery mode, there is approximately 15 minutes of battery life left.

Icon	Status
	The Radius VSM Wearable Monitor is running on battery power. To view battery charge in percentage, see ***Radius VSM Battery*** on page 59.
	When the battery charge reaches a low battery level*: • The Battery Charge Status Indicator icon will change color (Red). • A “Low Battery” message appears. • Approx. 15 min. of battery life remains

The below table provides an estimate of the expected runtime at different battery charge levels:

Estimated Battery Life Remaining	Estimated Run Time (w/ECG, RAM & SpO_2 Continuous monitoring, NiBP Scheduled every 30 minutes with wireless communication with Patient SafetyNet)	Inhibited Functionality
100%	> 10 hours	None
75%	< 8 hours	None
50%	< 5 hours	None
25%	< 3 hours	None
10%	< 1 hour	None
Low Battery*	< 0.5 hours	NiBP

Note: As the performance of all batteries will decline with age, these runtimes may be reduced over the use life of the battery.

* Connect the Radius VSM Wearable Monitor to the battery charge adapter to prevent the device from powering OFF and to charge the battery. See Initial Battery Charging.

Wi-Fi Connection Status

The wireless icon in the Status Bar on Radius VSM displays the current connection status. See ***About the Status Bar*** on page 50.

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

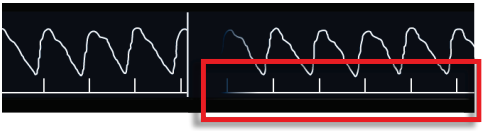
* Radius VSM can be configured to connect to Patient SafetyNet wirelessly by authorized and trained personnel only.

Waveforms

The following section contains examples of the waveforms viewable on the *Main Screen* and *Pulse Ox* screen.

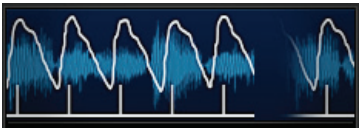
Signal IQ Indicators

With a Pulse Ox sensor connected, the signal IQ (SIQ) indicators are displayed as vertical bars for each individual pulsation. The height of the bar provides an assessment of the confidence in the SpO_2 measurement displayed.



Pleth + Sig IQ + Acoustic View

The RRa waveform is located above the parameter values. Acoustic Respiratory Rate (RRa) must be available for this feature to be shown. With an acoustic sensor connected to Radius VSM, the Pleth waveform, signal IQ indicators, and acoustic waveform displays.



Screen Lock Feature

To prevent unintended changes to the settings of Radius VSM the device has a feature that can be enabled to lock the screen after 60 seconds with no interaction. To enable or disable this feature, see ***Access Control*** on page 60.

Unlock Screen

When locked, the screen dims and a ring appears.

To unlock, press and hold on the center of the screen to fill the ring. When the ring is filled, the screen unlocks.

About the System Status Light

The System Status Light is part of the On/Off button and located on the top of the device. See ***Front and Top Views*** on page 29. The System Status Light provides visual indications of battery charging progress and Radius VSM operation. The light illuminates different colors depending on the state of the device.

Light Status	Indication
None	Radius VSM is off.
Green	Radius VSM is on.
	Radius VSM is connected to the charging adapter and battery charging is complete.
Solid Orange	Radius VSM is connected to the charging adapter and the battery is charging.
Flashing Orange	Radius VSM is powering down after pressing and holding the On/Off button.
Flashing Red	Radius VSM internal fault. Service is required. See ***Contacting Masimo*** on page 134.

Accessing Radius VSM Main Menu Options

To access the *Main Menu*, swipe up from the bottom of the Radius VSM screen.

The *Main Menu* options are:The *Main Menu* options are:

Pulse Ox Settings*
See ***Pulse Ox Settings*** on page 63.

ECG Settings*
Displayed on devices with ECG connected.
See ***ECG Settings*** on page 74.

Temperature Settings*
Displayed on devices with ECG Connected.
See ***Temperature Settings*** on page 81.

Noninvasive Blood Pressure Settings*
Displayed on devices with NIBP connected.
See ***Noninvasive Blood Pressure (NIBP) Settings*** on page 84.

Activity Monitoring Settings*
Displayed on devices with ECG connected.
See ***Position Monitoring Settings*** on page 92.

Sounds

See ***Sounds*** on page 56.

Device Settings

See ***Device Settings*** on page 56.

About

See ***About*** on page 60.

Trends Settings*

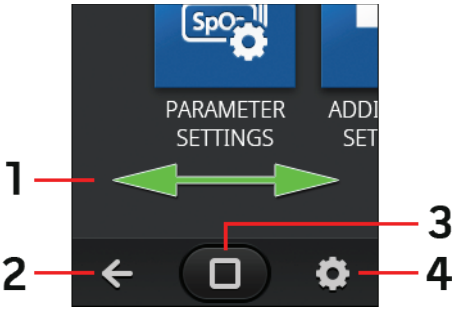
See ***Trends*** on page 61.

* When Radius VSM is connected to Root, this setting no longer displays on Radius VSM and displays in the Root *Main Menu*. See ***Accessing Root Main Menu Options*** on page 139.

Navigating the Main Menu

Once the *Main Menu* screen is displayed, users can access additional screens, information and settings.

1. Swipe the screen left or right to pan through the available menu icons.
2. Touch the arrow at the bottom left corner of the touchscreen to navigate to the previous screen.
3. To return to the *Main Screen*, press the *Home Button* at the bottom the touchscreen at any time.
4. Touch the gear icon to return to the *Main Menu*.



Display Timeout

When viewing any of the menu screens, and no user interaction occurs within one (1) minute, the display returns to the *Main Screen*.

Navigating Through Menus

- When configuring settings, all changes must be confirmed by selecting *OK*.
- To cancel the changes, select *Cancel*.
- Any screen requiring selection of option(s) will time out after one (1) minute of inactivity and return to the *Main Screen*.

Sounds

Use the *Sounds* screen to control the volume of sounds and duration of audio pause on Radius VSM. The Sound icon appears on the status bar. See ***About the Status Bar*** on page 50.

Option	Description	Factory Default Settings	User Configurable Settings
Alarm Volume*	Sets the alarm volume level.	4 (Highest volume)	1 to 4 - Slide towards the left to decrease volume.
Pulse Tone Volume	Sets the pulse tone volume level.	3	0 to 4 - Slide towards the left to decrease volume and to silence.
Audio Pause Duration*	Sets the length of time that the audible alarm remains silenced, when Audio Pause is enabled. See ***Audio Pause*** on page 96.	2 minutes	1, 2, or 3 minutes, Permanent **,***, or Permanent with Reminder **,****.
SmartTone*	Allows the audible pulse to continue to beep when the pleth graph shows signs of motion.	Off	On or Off

* This setting is neither available nor displayed in the *Sounds* menu when *Home Mode Menu Enabled* is ON. See ***Access Control*** on page 60.

** Requires user to have All Mute Enabled turned on in the *Access Control* menu. See ***Access Control*** on page 60.

*** 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.

Device Settings

The *Device Settings* menu allows the user to view and customize settings for Radius VSM.

The *Device Settings* options are:

Localization *, **

See ***Localization*** on page 57.

Wi-Fi

See ***Wi-Fi*** on page 58.

Bluetooth

See ***Bluetooth*** on page 59.

Radius VSM Battery

See ***Radius VSM Battery*** on page 59.

Brightness

See ***Brightness*** on page 59.

Access Control **

See ***Access Control*** on page 60.

* This icon is neither available nor displayed in the *Device Settings* menu when *Home Mode Menu Enabled* is ON. See ***Access Control*** on page 60.

** When Radius VSM is connected to Root, this setting does not display.

Localization

Use the *Localization* screen to configure settings related to local time, language and geography. The time appears on the status bar. See ***About the Status Bar*** on page 50.

Option	Description	Factory Default Settings	User Configurable Settings
Language	Selects the language display for Root.	English	Choose from English, Japanese (日本語), French (Français), German (Deutsch), Italian (Italiano), Spanish (Español), Simplified Chinese (简体中文), Danish (Dansk), Swedish (Svenska), Portuguese (Português), Dutch (Nederlands), Norwegian (Norsk), or Polish (Polski).
Date	Set the current date.	N/A	month, date, and year
Time	Set the current time.	N/A	hour, minutes, and AM or PM
Date Format	Set the display format for current date.	mm/dd/yy	mm/dd/yy or dd/mm/yy

Option	Description	Factory Default Settings	User Configurable Settings
Time Format	Set the display format for current time.	12 hour	12 or 24 hour
Line Frequency	Set to match regional power line frequency.	60 Hz	50 Hz or 60 Hz

Wi-Fi

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

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

Use the *Wi-Fi* screen to enable or disable Wi-Fi connectivity. When Radius VSM is connected to a Wi-Fi network, the Wi-Fi icon on the Status Bar indicates the status of the connection. See ***Wi-Fi Connection Status*** on page 52. The Wi-Fi icon on the Status Bar also indicates the strength of the connection. See ***About the Status Bar*** on page 50.

Option	Description	Factory Default Settings	User Configurable Settings
Wi-Fi	Enables or disables Wi-Fi connectivity.	Off	On or Off
Status*	Displays connected wireless network status.	NA	NA
MAC Address*	Displays the Radius VSM MAC Address.	NA	NA
SSID*	SSID for the wireless network Radius VSM is connected with.	NA	NA
Destination IP Address*	Displays the IP address Radius VSM is connected to.	NA	NA
* Additional fields in the *Wi-Fi* screen display read-only settings about the Wi-Fi connection that cannot be configured by the user. These items can be used to verify the connection with Masimo Patient SafetyNet.			

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

Bluetooth

Use the *Bluetooth* screen to enable or disable Bluetooth connectivity. To connect Radius VSM to Root using Bluetooth and verify the connection, see ***Connecting Radius VSM with Root*** (on page 45). When Bluetooth connectivity is enabled, the Bluetooth icon appears in the Status Bar. See ***About the Status Bar*** on page 50.

Option	Description	Factory Default Settings	User Configurable Settings
Bluetooth	Enables or disables Bluetooth connectivity.	Off	On or Off
MAC Address	Displays the Radius VSM MAC Address	NA	NA
Forget Root	Unpairs with the connected Root device.	NA	Press **Clear**.
Additional fields in the *Bluetooth* screen display read-only settings about the Bluetooth connection that cannot be configured by the user.			

Radius VSM Battery

Use the Battery screen to view the specific percentage of charge remaining in Radius VSM's battery. The Battery icon appears in the Status Bar. See ***About the Status Bar*** on page 50.

Option	Description
Battery Level	Provides a read-only display of battery percentage of charge.

Brightness

Use the *Brightness* screen to adjust the brightness of Radius VSM's display.

Option	Description	Factory Default Settings	User Configurable Settings
Brightness	Adjust the brightness level of the display manually.	4	1 (dimmest), 2, 3, 4 (brightest)

Access Control

The *Access Control* screen contains configurable options and settings that require a password to view or change.

To enter Access Control

1. When the screen displays, enter the following: **6 2 7 4**
   Asterisks (****) will be displayed.
   To undo an entry, press *Backspace*.
2. Press the return key to access the password-protected screen.

Note: The password will have to be entered every time this screen is accessed.

Option	Description	Factory Default Settings	User Configurable Settings
All Mute Enabled	Enables parameter Alarm Silence menu option. See ***Sounds*** on page 56.	Off	On or Off
Lock Alarm Volume	Sets the lowest alarm volume level.	Off	3, 4, or Off
Lockscreen Enabled	Allows the user to lock the touchscreen to prevent accidental changes.	Off	On or Off
Data Collection Enabled	Enables or disables physical data collection mode.	Off	On or Off
Factory Defaults	Options are restored to factory values.	N/A	Press **Restore**.

About

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

Option *	Description
Serial Number	Displays the serial number for the device.
MCU	Displays the version number of the device board software.
Processor	Displays the version number of the system level software.
MSX Tech Board	Displays the version number for the Masimo technology board.
EGC Tech Board	Displays the version number of the ECG Module.

Option *	Description
NIBP Tech Board	Displays the version number for the NIBP Module.

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

Trends

Trend settings allow the user to configure the Y-axis maximum and Y-axis minimum for each parameter. The maximum and minimum possible values differ depending on the selected parameter.

Trend Settings

Use the *Trend Settings* screen to configure Trend Views on the *Main Screen* and trend data storage on Radius VSM.

Option	Description	Factory Default Settings	User Configurable Settings
Default Duration	Sets the time duration displayed in trend lines.	2 hours	15, 30, or 45 minutes 1, 2, 4, 8, 12, or 24 hours
Clear Trends	Deletes all stored trend data.	N/A	Press **Clear** to delete all stored trend data.
Temperature	Y-axis Min	93.2 ºF	93.4 ºF to 103.9 ºF in increments of 0.1
		34.0 ºC	34.0 ºC to 39.9 ºC in increments of 0.1
	Y-axis Max	104 ºF	93.3 ºF to 104 ºF in increments of 0.1
		40.0 ºC	34.1 ºC to 40.0 ºC in increments of 0.1
NIBP	Y-axis Min	40	40 to 220 in steps of 10
	Y-axis Max	230	50 to 230 in steps of 10

About Parameter Information

Additional information about each parameter is available.

To access additional information about parameters:

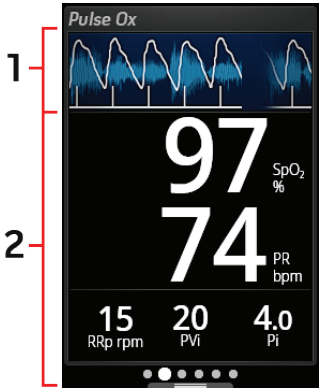
1. From the *Parameter Settings* screen, touch the **About** icon. The following is an example for SpO_2.

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

Chapter 5: Pulse OX

Pulse Ox Screen

The *Pulse Ox Screen* is composed of the following:



1. Waveform

Displays the waveform and signal confidence. See ***Waveforms*** on page 52.

2. Parameter Field

Displays parameter values. Touch the parameter to access the settings screen. See ***Pulse Ox Settings*** on page 63.

The Pulse OX waveform and parameters also display on the *Summary Screen*.

Pulse Ox Settings

The *Pulse OX* menu allows the user to view and customize settings by changing any of the following options:

- ***Parameter Settings (see below)***
- ***3D Alarms*** on page 97 *
- ***Additional Settings for Pulse Ox*** on page 70

* When connected with Root, this setting displays on Root and not on Radius VSM.

In the *Parameter Settings* screen, swipe left or right to access and select the desired parameter icon.

- ***SpO2 Settings*** on page 63.
- ***PR Settings*** on page 65.
- ***Pi Settings*** on page 66.
- ***PVi Settings*** on page 66.
- ***RR Settings*** on page 67.
- ***Aggregate RR Settings*** on page 70.

SpO2 Settings

From the *SpO2 Settings* screen, access any of the following screens:

- ***SpO2 Alarms*** on page 64
- ***Additional Settings for SpO2*** on page 64
- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 143 *

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

SpO2 Alarms

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

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

Additional Settings for SpO2

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

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time*	The length of time over which the system calculates the average of all data points.	8 seconds	2-4, 4-6, 8, 10, 12, 14, or 16 seconds**
FastSat	See ***FastSat Overview*** on page 65.	Off	Off or On

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

** For the 2 and 4 second settings the averaging time may range from 2-4 and 4-6 seconds, respectively.

FastSat Overview

FastSat enables rapid tracking of arterial oxygen saturation changes. Arterial oxygen saturation data is averaged using pulse oximeter averaging algorithms to smooth the trend.

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

PR Settings

From the *PR Setting*s screen, access any of the following screens:

- ***PR Alarms*** on page 65
- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 143 *

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

PR Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	High	140 bpm	35 bpm to 235 bpm, in steps of 5 bpm
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	50 bpm	30 bpm to 230 bpm, in steps of 5 bpm
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 sec, 1, 2 or 5 minutes

Pi Settings

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

- ***Pi Alarms*** on page 66
- ***Additional Settings for Pi*** on page 66
- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 143 *

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

Pi Alarms

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

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

Additional Settings for Pi

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

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

PVi Settings

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

- ***PVi Alarms*** on page 67
- ***Additional Settings for PVi*** on page 67
- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 143 *

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

PVi Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	2 to 99, in steps of 1, or Off When set to Off, alarms are disabled.
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	Off or 1 to 98 in steps of 1 When set to Off, alarms are disabled.
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds or 1, 2, 5, or 10 minutes

Additional Settings for PVi

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

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

RR Settings

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

- ***RRa Settings*** on page 67
- ***RRp Settings*** on page 69

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. When the respiratory rate is determined by the acoustic signal, the *Main Screen* labels respiratory rate as *RRa*, as shown below.

Note: Radius VSM can monitor RRa or RRp but not both simultaneously.

RRa is active when the following conditions are all met:

- RRa is installed on the Radius VSM.
- A dual rainbow cable is connected.
- An acoustic sensor is connected.

Note: See the Directions for Use provided with the acoustic sensor.

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

- ***RRa Alarms*** on page 68
- ***Additional Settings for RRa*** on page 68
- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 143 *

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

RRa Alarms

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

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

Additional Settings for RRa

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

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time	The length of time over which the system calculates the average of all data points.	Slow	Slow, Medium, Fast, Trending, or No Averaging
Freshness	The duration of time that, during interference, the system displays the last valid reading.	5 minutes	0, 1, 5, 10, or 15 minutes

RRp Settings

When using a pulse oximetry or pulse CO-Oximetry sensor with Radius VSM, respiration rate can be determined by the plethysmographic waveform (RRp). This method measures respirations per minute (rpm) based on cyclic variation in photoplethysmogram (i.e. pleth or PPG) to establish a respiration rate measurement. When using a pulse oximetry or pulse CO-Oximetry sensor, RRp alarms and RRp settings are active and the *Main Screen* labels respiratory rate as *RRp*, as shown below.

Note: Radius VSM can monitor RRa or RRp but not both simultaneously.

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

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

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

- ***RRp Alarms*** on page 69
- ***Additional Settings for RRp*** on page 70
- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 143 *

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

RRp Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	High	30 breaths per minute	6 to 69 breaths per minute in steps of 1 breaths per minute, or Off
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	6 breaths per minute	Off, or 5 to 68 breaths per minute in steps of 1 breaths per minute
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 seconds or 1, 2, or 5 minutes
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	NA	30 seconds	0, 10, 15, 30, or 60 seconds

Additional Settings for RRp

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

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time	The length of time over which the system calculates the average of all data points.	Slow	Slow, Medium, Fast, Trending, or No Averaging
Freshness	The duration of time that, during interference, the system displays the last valid reading.	5 minutes	0, 1, 5, 10, or 15 minutes

Aggregate RR Settings

From the *aggRR Settings* screen, access the following option:

- ***About Parameter Information*** on page 61

Additional Settings for Pulse Ox

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

Option	Description	Factory Default Settings	User Configurable Settings
Sensitivity Mode	Change Sensitivity Mode. See ***Sensitivity Modes Overview*** on page 71.	APOD	MAX, APOD, NORM
SmartTone	Enable or disable the SmartTone. See ***Sounds*** on page 56.	Off	On, Off
SpO_2 low % limit	Set the SpO_2 low limit alarm. See ***SpO2 Settings*** on page 63.	Off	Off or 1% to 98% in steps of 1%

Sensitivity Modes Overview

Three sensitivity levels enable a clinician to tailor the response of Radius VSM to the needs of the particular patient situation. Sensitivity Modes are accessed through the *Action Menu*. See Action Menu.

The sensitivity levels are as follows:

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

Chapter 6: Electrocardiogram (ECG)

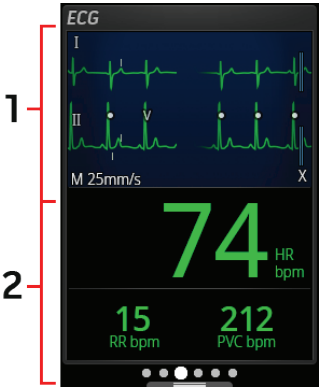
ECG Overview

Through multiple electrodes attached to the patient, the Masimo Radius VSM ECG System provides visual ECG waveforms and an estimate of the patient's heart rate. The counting of Premature Ventricular Contractions (PVCs) per minute is also provided.

When Radius VSM is connected to a Masimo device, in addition to the ECG display on Radius VSM, ECG information also displays on the Masimo device screen.

ECG Screen

The *ECG Screen* is composed of the following:



1. ECG Waveform

Displays the ECG waveform and allows access to waveform settings. Touch the waveform to access the settings. See ***ECG Waveform Settings*** on page 76.

ECG waveforms also display on the *Summary Screen*.

2. ECG Parameter Field

Displays parameter values. Touch the parameter to access the settings screen. See ***ECG Settings*** on page 74.

Note: The Respiration Rate (RR) parameter displays when Respiration Lead settings are set to I or II under ***Additional Settings for ECG*** on page 78.

Rotate Waveform

In additional to the normal waveform display, the waveform on the *ECG Screen* can be rotated and viewed in landscape mode.

Rotate Waveform

Touch the waveform to display controls to rotate the waveform.

Select rotate left or right to view the waveform in the desired orientation.

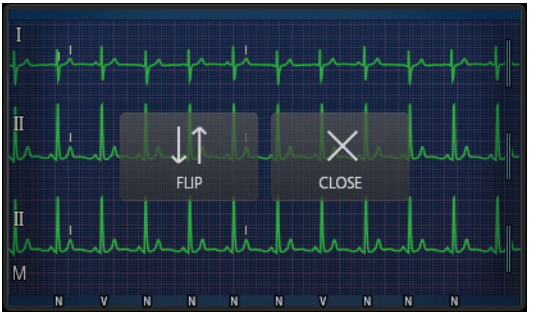
The waveform displays in landscape on the Radius VSM screen.

The parameters do not display, only the waveform.

Note: The landscape display reverts back to the *ECG Screen* automatically after 20 seconds.

To manually exit the landscape display and return to the ECG Screen, touch the waveform and select **Close**.

Select **Flip** to flip the waveform over.

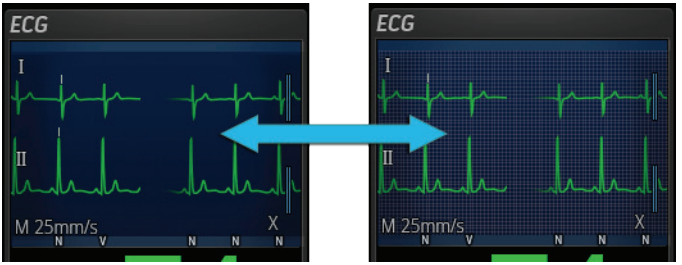


Display Waveform Grid

A grid can be displayed on the waveform in the *ECG Screen*.

Toggle Grid On and Off

To toggle the grid ON or OFF for the waveform in both the *ECG Screen* and the rotated view, touch and hold the waveform for 2 seconds.



ECG Settings

The *ECG* menu allows the user to view and customize settings for the ECG Module by changing any of the following options:

- ***ECG Parameter Settings*** on page 75.
- ***ECG Waveform Settings*** on page 76.
- ***Analysis Settings*** on page 77*
- ***Arrhythmia Settings*** on page 77.
- ***Additional Settings for ECG*** on page 78.

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

ECG Parameter Settings

1. In the *Parameter Settings* screen, swipe left or right to access the desired parameter.
2. Select the desired parameter icon.
   - See ***HR Settings (ECG)*** on page 75.
   - See ***RR Settings (ECG)*** on page 75.
   - See ***PVC Settings (ECG)*** on page 76.

   Note: RR settings display when Respiration Lead settings are set to I or II under ***Additional Settings for ECG*** on page 78.

HR Settings (ECG)

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

- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 143 *

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

RR Settings (ECG)

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

- ***RR Alarms*** on page 76
- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 143 *

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

RR Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	30 rpm	6 rpm to 119 rpm in steps of 1, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	High	6 rpm	Off, or 5 rpm to 118 rpm in steps of 1 When set to Off, alarm is disabled
Silence Duration	Sets the amount of time that the alarm is silenced.	NA	2 minutes	30 sec, 1, 2 or 5 minutes
Apnea Timeout	Set no-breath timeout	High	40 seconds	10, 15, 20, 25, 30, 35, or 40 seconds
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	NA	30 seconds	30 seconds or 1, 2 or 5 minutes

PVC Settings (ECG)

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

- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 143 *

* This setting is only available and displayed on Root when Radius VSM is connected to Root.

ECG Waveform Settings

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

Option	Description	Factory Default Settings	User Configurable Options
Display Lead 1	Displays the selected ECG lead waveform.	Primary	Primary, I, II, III, aVR, aVL, or aVF
Display Lead 2	Displays the selected ECG lead waveform.	Secondary	Secondary, I, II, III, aVR, aVL, or aVF
Gain	Adjust the ECG displayed waveform gain.	10 mm/mV	1.25, 2.5, 5, 10, 20, or 40 mm/mV

Option	Description	Factory Default Settings	User Configurable Options
Speed (Sweep Speed)	Adjust the wave speed.	25 mm/sec	6.25, 12.5, or 25 mm/sec
Beat Annotation	Enable ECG wave annotation with beat labels on the screen.	Off	On or Off
Pacer Detection	Enable pacer detection	On	On or Off
Pacer Lead	Assigned leads for pacer detection	I & II & III	I, II, III, I & II, I & III, II & III, or I & II & III
Mode (Waveform)	Select the type of waveform displayed on the screen	Monitoring	Monitoring or Diagnostic
Notch Filter	Reduces the electrical noise produced by the mains power supply.	On	On or Off
Tremor Filter *	Reduces the muscle noise.	Off	On or Off

* Setting available when Mode (Waveform) is set to Diagnostic.

Analysis Settings

The *Analysis Settings* are displayed and accessed on Root when Radius VSM is connected to Root. These settings are the same as listed under *Arrhythmia Settings* when Radius VSM is NOT connected to Root.

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

Option	Description	Factory Default Settings	User Configurable Options
Primary Analysis Lead	Select the primary lead	II	I, II, III, aVR, aVL, or aVF
Secondary Analysis Lead	Select the secondary lead	III	Off, or I, II, III, aVR, aVL, aVF

Arrhythmia Settings

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

Option	Description	Factory Default Settings	User Configurable Options
Arrhythmia Relearn	Initiating this feature resets the baseline ECG data in the classification of arrhythmias so that the ECG baseline can be made more current. This feature can be useful when ECG electrodes are applied to new patients or after a significant change in an ECG pattern.	N/A	Select **Relearn**.

Option	Description	Factory Default Settings	User Configurable Options
Primary Analysis Lead	Select the primary lead	II	I, II, III, aVR, aVL, or aVF
Secondary Analysis Lead	Select the secondary lead	Off	Off, or I, II, III, aVR, aVL, aVF
VTach HR	The ventricular heart rate limit to trigger VTach detection	100	15 to 300 in steps of 5
VTach Run	The PVC run limit to trigger VTach detection	5	3 to 99 in steps of 1
Brady HR	Limit to trigger bradycardia detection	50	Off or 25 to 135 in steps of 5
Extreme Brady HR	Limit to trigger extreme bradycardia detection	40	Off or 20 to 130 in steps of 5
Tachy HR	The heart rate limit to trigger Tach detection	120	Off or 55 to 290 in steps of 5
Extreme Tachy HR	The heart rate limit to trigger extreme Tach detection	180	Off or 60 to 295 in steps of 5
Asystole Threshold	Define the length of time with no Heart Beat is detected	4.0 seconds	2.50 seconds to 5.00 seconds in 0.25 second increments

Additional Settings for ECG

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

Option	Description	Factory Default Settings	User Configurable Options
Lead System*	Select the region	Code 2	Code 1 (European) or Code 2 (US)
Respiration Lead	Select the source lead to measure respiration rate	Off	Off, I, or II
Respiration Mode	Select the detection method for respiration rate	Auto	Auto or Manual

Option	Description	Factory Default Settings	User Configurable Options
Respiration Threshold	Respiration Rate detection level under Manual Respiration Mode	0 mOhms	-1000 mOhms to 10,000 mOhms in 1000 mOhms steps
Tremor Filter	Applies a filter to help remove high frequency noise to help remove artifacts for tremor like movements.	Off	On or Off

***** For additional information, see ***Lead System*** on page 79.

Lead System

The following table identifies the lead electrodes and neutral electrode, their identification, color and position.

Lead System	Code 1 (European)		Code 2 (US)		Electrode Position on the Body *
	Electrode Identifier	Electrode Color Code	Electrode Identifier	Electrode Color Code	
Limb	R	Red	RA	White	Right Arm
	L	Yellow	LA	Black	Left Arm
	F	Green	LL	Red	Left Leg

* See ***Radius VSM System Setup*** on page 36 for ECG Electrode application.

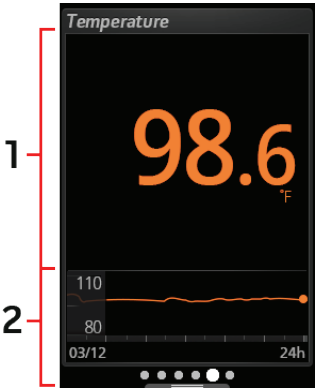
Chapter 7: Temperature

Temperature Overview

Temperature measurements are provided to the Radius VSM from a temperature sensor built into the ECG Module. The temperature sensor is designed to continuously provide skin temperatures. When Radius VSM is connected to a compatible Masimo device, temperature data also displays on the Masimo device screen.

Temperature Screen

The *Temperature Screen* is composed of the following:



1. Temperature Display

Displays the measured temperature. Touch the temperature to access the settings screen. See ***Temperature Settings*** on page 81.

The temperature reading also displays on the *Summary Screen*.

2. Trends

Displays trend for temperature. Touch the trend to access the settings screen. See ***Temperature Settings*** on page 81.

Temperature Settings

Note: The *Temperature Settings* is **ONLY** available when an ECG Module and Electrodes are connected to Radius VSM.

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

- ***Temperature Alarms*** on page 81
- ***Additional Settings*** on page 82
- ***Trends*** on page 61
- ***About Parameter Information*** on page 61.

Temperature Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	Off	93.4 °F to 103.9 °F, in increments of 0.1, or Off 34.2 °C to 39.9 °C, in increments of 0.1, or Off When set to Off, alarms are disabled.
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	Off or 93.3 °F to 103.8 °F in increments of 0.1 Off or 34.1 °C to 39.8 °C, in increments of 0.1 When set to Off, alarms are disabled.
Silence Duration	Sets the amount of time that the alarm is silenced.	N/A	2 minutes	30 seconds or 1, 2, or 5 minutes

Additional Settings

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

Options	Description	Factory Default Settings	User Configurable Settings
Unit of Measure	The unit of measure for temperature.	°F	°F, °C

Chapter 8: Noninvasive Blood Pressure (NIBP)

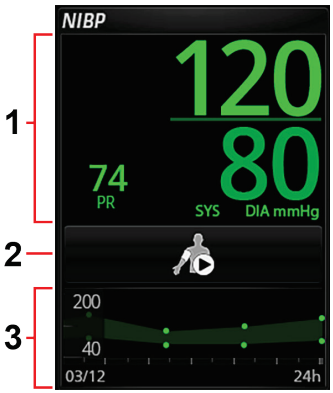
NIBP Overview

The Radius VSM blood pressure measurements rely on the oscillometric method, which relies on the principle that the amplitude of the cuff pressure changes can be used to determine arterial blood pressure. The pressure measured when the blood flow is effectively constricted is used to estimate the systolic pressure and the pressure measured when the blood flow is allowed to fill the ventricular chamber is used to estimate the diastolic pressure.

When Radius VSM is connected to a Masimo device, in addition to the NIBP display on Radius VSM, NIBP information also displays on the Masimo device screen.

NIBP Screen

The *NIBP Screen* is composed of the following:



1. NIBP Parameter Display

Displays the NIBP parameters. Touch the parameters to access the settings screen. See ***Noninvasive Blood Pressure (NIBP) Settings*** on page 84.

2. Start/Stop NIBP Measurement

Start/Stop NIBP Measurement button. See ***Blood Pressure Measurements*** on page 87.

3. Trends

Displays trend for NIBP. Touch the trend to access the settings screen. See ***Noninvasive Blood Pressure (NIBP) Settings*** on page 84.

Patient Conditions

When measuring the patient's blood pressure, it is recommended that the patient be in Normal Use position, as described below.

Ensure that the following conditions are met before taking the patient's blood pressure:

- Patient is comfortably seated
- Patient's legs are uncrossed
- Patient's feet are flat on the floor
- Patient's back and arms are supported
- The middle of the cuff is at the level of the right atrium of the heart

CAUTION: Blood pressure measurements can be affected by the patient's position, physiological condition, and environmental factors.

Note: Physiological conditions that can affect blood pressure measurements (e.g, cardiac arrhythmias, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, trembling, and shivering).

Note: It is recommended that the clinician ask the patient to relax and not speak during measurement.

Note: It is recommended that 5 minutes elapse before the first reading is taken.

Noninvasive Blood Pressure (NIBP) Settings

The *NIBP* menu allows the user to view and customize settings for the NIBP module by changing any of the following options:

- ***Parameter Settings for Noninvasive Blood Pressure (NIBP)*** on page 84.
- ***Intervals Settings for NIBP*** on page 86 *
- ***Additional Settings for NIBP*** on page 86
- ***Calibration*** on page 86 **

* This setting displays only when scheduled NIBP measurement has been enabled.

** This setting is NOT available on Root when Radius VSM is connected to Root.

Parameter Settings for Noninvasive Blood Pressure (NIBP)

1. In the *NIBP Settings* screen, swipe left or right to access the desired parameter.
2. Select the desired parameter icon.
   - See ***SYS/DIA Settings*** on page 84.
   - See ***Pulse Rate (PR)*** on page 85.

SYS/DIA Settings

From the *Systolic/Diastolic Settings* screen, access the following screens:

SYS/DIA Alarms on page 84

Trend Settings on page 61

About Parameter Information on page 61

SYS/DIA Alarms

From the *Systolic/Diastolic Settings* screen, touch *Alarms*, and then change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
Systolic High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	220	60 to 229 in steps of 1, or Off When set to Off, alarm is disabled
Systolic Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	75	Off, or 61 to 228 in steps of 1 When set to Off, alarm is disabled
Diastolic High Limit	The High Limit is upper threshold that triggers an alarm.	Medium	110	42 to 129 in steps of 1, or Off When set to Off, alarm is disabled
Diastolic Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	41	Off, or 41 to 128 in steps of 1 When set to Off, alarm is disabled

Pulse Rate (PR)

From the *Pulse Rate Settings* screen, access the following screens:

Pulse Rate Alarms on page 85

About Parameter Information on page 61

Pulse Rate Alarms

From the *Pulse Rate Settings* screen, touch *Alarms*, and then change any of the following options:

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
High Limit	High Limit is the upper threshold that triggers an alarm.	Medium	120	40 to 235 in steps of 5, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	50	Off, or 35 to 230 in steps of 5 When set to Off, alarm is disabled

Intervals Settings for NIBP

Intervals measurement mode takes blood pressure measurements once every defined interval for the defined duration. Interval and Duration settings can be customized to accommodate a facilities protocol.

Note: Interval measurement scheduling is performed on Root thought the *NIBP Settings* in the Main Menu.

WARNING: Too frequent blood pressure measurements can cause injury to the patient due to blood flow interference.

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

Option	Description	Factory Default Settings	User Configurable Options
Set Mode	Set the interval measurement mode.	Manual	Manual or Schedule
Auto Restart	Allows Root to automatically restart the NIBP schedule on a newly connected Radius VSM if an NIBP schedule was previously active, e.g. swapping Radius VSM during a shift change.	Off	Off ot On
Interval: Duration	Set the time between measurements for a scheduled amount of time.	Measurement Interval: 15 min Measurement Duration: 24 hr	5, 10, 15, 30, 45 minutes, or 1, 2, 4, 8, 12 hours 30, 45 minutes, or 1, 2, 4, 8, 12, 24 hours
Start Schedule*	Select to start or stop the NIBP scheduled measurements	NA	NA

* Displays **Stop** when an NIBP measurement schedule is running.

Additional Settings for NIBP

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

Option	Description	Factory Default Settings	User Configurable Options
Measurement Timeout	Set the measurement timeout value.	15 minutes	5, 10, 15, 30, 60, or 90 minutes

Calibration

The *Calibration* option on the *NIBP* menu allows a qualified service professional to access calibration settings and tools for the NIBP module. For more information, see ***Chapter 13: Service and Maintenance*** on page 129.

Note: This section is provided as a reference and intended for qualified service professionals only and is password protected.

Blood Pressure Measurements

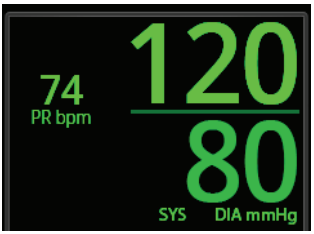
To select the proper cuff and attach to the measurement site, see ***Attaching the Noninvasive Blood Pressure Cuff and Module to the Patient*** on page 39.

Spot Check NIBP Measurement

1. Properly place the blood pressure cuff on patient. See ***Attaching the Noninvasive Blood Pressure Cuff and Module to the Patient*** on page 39.
2. Touch the *Start* button to begin measurement.

3. Wait for measurement to complete or touch the *Stop* button to stop measurement.

4. Wait for measurement values to appear to ensure that the NIBP measurement is complete.



Schedule NIBP Measurement

Schedule measurement mode takes blood pressure measurements once every defined interval for the defined duration. A patient profile can have up to five (5) schedules. The schedules run consecutively, when one schedule ends the next one begins automatically.

To perform Scheduled blood pressure measurements:

Note: Interval measurement scheduling is performed on Root thought the *NIBP Settings* in the Main Menu.

1. Ensure that the correct patient profile is selected before measurement.
2. Properly place the blood pressure cuff on the patient. See ***Attaching the Noninvasive Blood Pressure Cuff and Module to the Patient*** on page 39.
3. To enable *Schedule* mode, select *NIBP Settings* 

in the *Main Menu*.
4. Open the *Intervals* settings.
5. On the *Intervals* screen, change *Set Mode* to *Schedule*. The set mode can also be changed using the action menu. Press **OK** to confirm.

   WARNING: Too frequent blood pressure measurements can cause injury to the patient due to blood flow interference.
6. Press the **Start Schedule** button.
7. On the NIBP screen, touch the *Sched* button to begin measurement.

8. Blood pressure measurements will be performed at the set intervals. To stop the current measurement, touch the *Stop* button.

Note: Touching the *Stop* button only stops the current measurement, the next scheduled measurement will still be performed by Radius VSM. To stop the remaining scheduled measurements, select **Stop Schedule** from the *Intervals* settings screen.

9. After an interval measurement has completed and values appear, the next interval measurement will begin and repeat until the set duration time has elapsed.

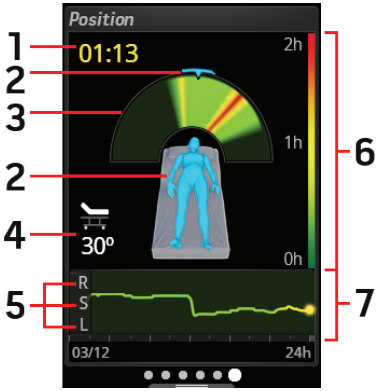
Chapter 9: Position Monitoring

Position Monitoring Overview

The ECG Module also includes a noninvasive position and activity sensor designed to continuously monitor patient movement and activity, including patient falls. When Radius VSM is connected to a compatible Masimo device, position and activity data is also displayed on the Masimo device screen

Position Monitoring Screen

Patient position is shown as a graphical representation along with the elapsed time the patient has been in that position on the *Position Screen*. The *Position Screen* is composed of the following:



When a position is not allowed, the trend view shows the position grayed out.

1. Time in Current Position

Elapsed time in hours and minutes (HH:MM) patient is in current position. See ***Position Monitoring Settings*** on page 92.

2. Patient Current Position

Shows patient current position. If patient is sitting or standing/walking, a message is displayed at the top of the *Position* window.

3. Time in Position Color Chart

Color chart for length of time in each position. See ***Position Monitoring Settings*** on page 92.

4. Head of Bed Angle

Patient's current incline angle.

5. Patient Position in Trend

R = Right Side, S = Supine, L = Left. See ***Position Monitoring Settings*** on page 92.

6. Time in Position Color Key

Color key for length of time in position vs. severity. See ***Position Monitoring Settings*** on page 92.

7. Trend Graph

Displays time in position over a period of time. See ***Position Monitoring Settings*** on page 92.

Position Monitoring Settings

Note: The *Position Settings* display on devices **ONLY** when an ECG Sensor is connected to Radius VSM.

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

- ***Position Monitoring Alarms*** on page 92
- ***Additional Settings for Position Monitoring*** on page 92
- ***About Parameter Information*** on page 61

Position Monitoring Alarms

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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
Position Duration	Maximum amount of time patient should be in one position.	Low	2 hours	1 to 4 hours in 0.5 hour steps
Positions Allowed	A user set configuration for indicating that a certain patient position is allowed or not allowed. When On, position is allowed, when Off, position is not allowed.	Low	All	All, Left Only, Supine Only, Right Only, Left Supine, Left/Right Supine, or Right Supine
Fall Detection Alarm	Alarms when a fall-like movement occurs.	High	On	On or Off

Additional Settings for Position Monitoring

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

Options	Description	Factory Default Settings	User Configurable Settings
Clear Sensor History	Clears sensor data and trend history.	NA	Select to clear history

Chapter 10: Alarms and Messages

About Alarms

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

The *Alarm Silence* and *Audio Pause* icons are minimized and are not displayed on the screen during monitoring. When an alarm is triggered, the *Alarm Status/Exception Messages Action Menu* at the top of the display expands, displaying the *Alarm Silence* and *Audio Pause* icons. The *Alarm Status/Exception Messages Action Menu* can be minimized by swiping upwards from the bottom of the menu.

Note: When minimized, the visible tab for the *Alarm Status/Exception Messages Action Menu* illuminates the color of the highest alarm priority.

The *Alarm Silence* icon is an indicator as well as a functional button. The icon indicates the presence of alarms, and can be used to temporarily suspend audible alarms for a pre-configured amount of time (Silence Duration). If multiple alarms are present, the number of alarms display in the *Alarm Silence* icon.

Silence Duration configurations vary across different parameters and measurements. For more information about Silence Duration, refer to ***Pulse Ox Settings*** on page 63.

Icon Appearance	Description	Visual Alarms
	There are currently no active alarms, and no alarms have been silenced.	No
	There is currently an active alarm that has **not** been silenced.	Yes
	There is currently an active alarm that has been silenced.	Yes

Alarms Interface

Alarms have different priority levels and come from different sources.

Audible Alarms

The following table describes audible alarm behaviors.

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

Visual Alarms

Visual alarms are displayed on the Radius VSM Screen.

Main Screen

The following table describes visual alarm behaviors.

	**Parameter Level:** The example shown here is an RR alarm (RR High) for the ECG system as the reading exceeds the upper alarm limit. Note that the RR parameter as well as the Window are illuminated red, and the explanation of the alarm is shown at the top of the Window (RR High) with the effected system (ECG).
	**System Level:** The example shown here is a "Sensor Off Patient" alarm. Note that the border of the window is red and the explanation of the alarm is shown in the Status Bar (Sensor Off Patient).
	**High Priority Alarm** The example shown here is a SpO_2 Low alarm for Pulse Ox. The border of the entire Radius VSM display is illuminated, and the explanation of the alarm is shown in the Status Bar (SpO_2 Low) with the effected system (Pulse Ox).

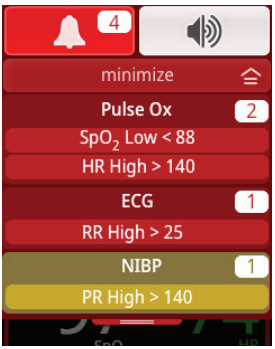
	**Medium Priority Alarm** The example shown here is an SpO_2 High alarm for Pulse Ox. The border of the entire Radius VSM display is illuminated, and the explanation of the alarm is shown in the Status Bar (SpO_2 High) with the effected system (Pulse Ox).

Multiple Alarm Notifications

Multiple alarms may occur at one time on Radius VSM. When one or more systems attached to Radius VSM have alarms present, the user is notified the following ways:

	**Alarm Silence Icon:** The *Alarm Silence* icon displays the number of active alarms. This number displays even when alarms are silenced.
	**System Screens:** The example shown indicates there are active alarms for other systems connected to Radius VSM. Note that the dots at the bottom of the screen illuminate Red and Yellow, indicating there are high and medium priority alarms for these systems. Swipe left or right on the screen to view the system screens for the active alarms.

To view the multiple alarms, perform the following:

	**Alarm Status/Exception Messages Action Menu List:** The example shown displays a list of alarm messages in the *Alarm Status/Exception Messages Action Menu*. To view the list of active alarms and messages, swipe down on the *Alarm Status/Exception Messages Action Menu* to expand.
	The numbers next to the system header indicate the number of active alarms for that particular system.  Swipe up to close the *Alarm Status/Exception Messages Action Menu*. **Note:** The *Alarm Status/Exception Messages Action Menu* minimizes automatically after a few seconds with no interaction.

Alarm Management

The Radius VSM is responsible for the detection, processing, and generation of alarm signals for an alarm condition. The Radius VSM will always provide a visual indication of an alarm condition. However, when connected to Root through a Bluetooth connection, the audible alarms can be transferred to the Root to prevent redundant alarming on the Radius VSM and Root. Even though alarm conditions are reflected on the Root, the alarm signals are generated by the Radius VSM. Therefore, the Radius VSM

generated audible alarms on the Root can be temporarily silenced by touching the Alarm Silence icon on the Root or the Radius VSM. Visual alarms will continue to be displayed on Radius VSM until the alarm condition has been addressed or acknowledged for latched alarms. For alarm management on Root, see ***Operator's Manual*** for ***Root***.

The Radius VSM is also compatible to the Masimo Patient SafetyNet. When connected to Patient SafetyNet, audible and visual alarms generated by the Radius VSM are also presented on the Patient SafetyNet in addition to the Radius VSM to provide additional supplemental awareness.

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

Silencing Alarms

To silence or dismiss alarms:

- Touch the *Alarm Silence* button.
- If the alarm is for a specific parameter, touch the alarming parameter. Parameters are highlighted when in an alarm state. This will not work if multiple alarms are present.
- Audible alarms that are suspended by pressing the *Alarm Silence* button can be unsuspended by pressing the *Alarm Silence* button again.

To silence audible alarms

Touch the *Alarm Silence* icon (or the highlighted value) once to silence the audible alarm. If multiple alarms are preset, the audible alarm is silenced for all.

The audible alarm is now silenced for the Silence Duration. A countdown timer displays as shown. The length of time that a audible alarm remains silenced can be changed using the Silence Duration feature located in the *Alarms* menu for available parameters. For more information about Silence Duration, refer to ***Pulse Ox Settings*** on page 63.

Audio Pause

Audio Pause temporarily suspends all audible alarms on Radius VSM. When it is active, visual alarms are not impacted and will still display. The Audio Pause icon is located on the right side of the *Alarm Status Action Menu*. See ***About Alarms*** on page 93.

By default, *Audio Pause* is inactive (alarms audible), and the icon appears in as follows:

To activate *Audio Pause*, press the icon. It will turn red and the remaining *Audio Pause* Duration time counts down next to the icon. The default duration for *Audio Pause* is 120 seconds. In the example

below, *Audio Pause* is activated, and there are 15 seconds left until *Audio Pause* is inactive again (alarms audible again).

To configure *Audio Pause*, see ***Sounds*** on page 56.

Note: When *Audio Pause* is activated, powering off and then powering on Radius VSM will return *Audio Pause* to its default inactive state.

3D Alarms

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

Desat Index on page 98

About Desat Index on page 97

Pi Delta on page 98

About Pi Delta on page 98

About Desat Index

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

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

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

To set a 3D Desat Index Alarm see ***Desat Index*** on page 98.

Desat Index

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

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

About Pi Delta

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

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

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

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

Pi Delta

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

Options	Description	Factory Default Settings	User Configurable Settings
Percent Change	The change in Pi from the baseline that, if maintained for the Timeout length, will trigger audible and visual alarms.	50%	10% to 99%, in steps of 1%

Options	Description	Factory Default Settings	User Configurable Settings
Timeout	The length of time over which the percent change in Pi is monitored.	None	None or 1, 5, 30 minutes, 1, 4, 8, 12, 24, 36, 48 hours

Radius VSM Messages

The following section lists common messages, their potential causes, and next steps related to the Radius VSM device.

Alarm Message	Description	Alarm Priority	Next Step
Low battery	Battery charge is low.	Medium	Charge battery by docking into battery charger.

Pulse Ox Messages

The following section lists common messages, their potential causes, and next steps related to Pulse Ox operation of the Radius VSM System.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Replace Cable or *(RAM) Replace Cable*	The patient cable is non-functional or the patient monitoring time of the cable has expired.	Replace the patient cable.
(Pulse CO-Ox) Cable Near Expiration or *(RAM) Cable Near Expiration*	Patient cable has less than 10% of patient monitoring time remaining.	Replace with new patient cable.
(Pulse CO-Ox) No Cable Connected or *(RAM) No Cable Connected*	Cable not attached or not fully inserted into the connector.	Disconnect and reconnect cable into connector.
(Pulse CO-Ox) Incompatible Cable	Not a proper cable.	Replace with a proper cable.
(Pulse CO-Ox) Replace Sensor or *(RAM) Replace Sensor*	• Reusable sensor has used all its available patient monitoring time. • Sensor is non-functional. • Defective sensor.	Replace sensor.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Sensor Near Expiration or *(RAM) Sensor Near Expiration*	Reusable sensor has less than 10% patient monitoring time remaining.	Replace with new reusable sensor.
(Pulse CO-Ox) No Sensor Connected or *(RAM) No Sensor Connected*	• Sensor not fully inserted into the connector. May be an incorrect sensor or a defective sensor or cable. • Device is searching for patient's pulse. • Sensor is disconnected from patient cable. Sensor connected upside down into patient cable.	• Disconnect and reconnect sensor. See the instructions for use provided with the sensor. • Disconnect and reconnect the sensor into the Patient Cable connector. • Check to see if the sensor LED is flashing. Disconnect and reconnect the sensor. If the LED fails to operate, replace the sensor.
(Pulse CO-Ox) Incompatible Sensor or *(RAM) Incompatible Sensor*	• Not a proper Masimo sensor. • Sensor is attached to a device without an appropriate parameter installed.	• Replace with a proper Masimo sensor. • Use a compatible sensor. Contact your local Masimo Representative to learn more about optional parameter upgrades.
(Pulse CO-Ox) Replace Adhesive Sensor or *(RAM) Replace Adhesive Sensor*	When a single-patient-use sensor is used, the adhesive portion of the sensor is non-functional, or the patient monitoring time of the adhesive portion of the sensor has expired.	Replace the adhesive portion of the sensor.
(Pulse CO-Ox) Adhesive Near Expiration or *(RAM) Adhesive Near Expiration*	Disposable sensor has less than 10% patient monitoring time remaining.	Replace with new disposable sensor.
(Pulse CO-Ox) 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.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Incompatible Adhesive Sensor or *(RAM) Incompatible Adhesive Sensor*	• Not a proper Masimo sensor. • Sensor is attached to a device without an appropriate parameter installed.	• Replace with a proper Masimo sensor. • Use a compatible sensor. Contact your local Masimo Representative to learn more about optional parameter upgrades.
(Pulse CO-Ox) Sensor Initializing or *(RAM) Sensor Initializing*	Device is checking the sensor for proper function and performance.	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.
(Pulse CO-Ox) Sensor Off Patient or *(RAM) Sensor Off Patient*	• Sensor off patient. • Sensor not connected to patient properly. Sensor is damaged.	• Disconnect and reconnect sensor. Reattach sensor. • Properly reapply the sensor to the patient and reconnect the sensor to the device or patient cable. If the sensor is damaged, replace the sensor.
(RAM) RAM Check Sensor	RAM unable to collect data through RAM Sensor.	Ensure proper sensor application. Check that no object is pulling on the sensor cable, which may cause the sensor to peel off.
(Pulse CO-Ox) Low Perfusion Index	Signal strength is too weak.	Move sensor to better perfused site. See on page 105.
(Pulse CO-Ox) Low Signal IQ	Indicates low signal confidence in the value displayed due to poor signal strength.	Ensure proper sensor application. Move sensor to a better perfused site. See ***Signal IQ Indicators*** on page 53.
(*Pulse CO-Ox*) *Pulse Search*	Device is searching for pulse.	If device fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.
(Pulse CO-Ox) Interference Detected or *(RAM) Interference Detected*	• High intensity light (pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight) or other monitor displays. • Incorrect monitor line frequency setting (Hz).	• Place a Masimo Optical Light Shield over the sensor. • Adjust the Line Frequency to the correct Hz setting. See ***Device Settings*** on page 56.
(Pulse CO-Ox) SpO_2 Only Mode	Occurs during an unsuccessful sensor initialization/pulse search routine or during monitoring.	See the directions for use provided with your sensor. Use a Masimo light shield to cover the sensor and adjust the sensor.

Message	Potential Causes	Next Steps
"- -" (Dashes shown as parameter value - Invalid parameter alarm)	Unable to provide a parameter value.	Check patient's vital condition.

Electrocardiogram Messages

The following section lists common messages, their potential causes, and next steps related to ECG operation of the Radius VSM System.

Alarm Message	Description	Alarm Priority	Next Step
Low HR	HR has decreased below the set lower limit.	High	Check patient's vital condition.
High HR	HR has increased above the set upper limit.	High	Check patient's vital condition.
Low RR	RR has decreased below the set lower limit.	High	Check patient's vital condition.
High RR	RR has increased above the set upper limit.	High	Check patient's vital condition.
Asystole Detected	Asystole event detected.	High	Check patient's vital condition.
VTach	Ventricular Tachycardia is detected	High	Check patient's vital condition.
VTach / VFib	Ventricular Fibrillation / Tachycardia is detected	High	Check patient's vital condition.
Bradycardia	Bradycardia is detected	High	Check patient's vital condition.
Extreme Bradycardia	Extreme Bradycardia is detected	High	Check patient's vital condition.
Tachycardia	Tachycardia is detected	High	Check patient's vital condition.
Extreme Tachycardia	Extreme Tachycardia is detected	High	Check patient's vital condition.
ECG Inop	ECG Module unable to obtain readings.	High	Verify electrode leads placement. Ensure skin is properly prepared. See ***Attaching the ECG Module and Electrodes to the Patient*** on page 42.
ECG Module Disconnect	ECG Module is disconnected from the Radius VSM Patient-Worn Vital Signs Monitor.	High	Check module connections.

Alarm Message	Description	Alarm Priority	Next Step
ECG Lead (Lead Identifier) Off	ECG electrode is disconnected from the patient.	High	Check electrode connection to the patient. Ensure skin is properly prepared. See ***Attaching the ECG Module and Electrodes to the Patient*** on page 42.
Replace ECG Sensor	• Defective ECG sensor • Expired ECG sensor	High	Replace the ECG Sensor.
Apnea	Apnea is detected	High	Check patient's vital condition.
Atrial Fibrillation	Atrial Fibrillation is detected	Medium	Check patient's vital condition.

NIBP Messages

The following section lists common messages, their potential causes, and next steps related to NIBP operation of the Radius VSM System.

Message	Potential Causes	Alarm Priority	Next Steps
No Cuff	Cuff disconnected	High	• Check that the NIBP Module is properly connected to the cuff and the Radius VSM. • Check that the correct size cuff is being applied. • Check that the cuff is in the correct position. • Check that there is no excessive clothing between arm and cuff. • Retake another measurement. • Check that the cuff is not leaking air. • If problem still persists, contact Customer Service.
Replace Cuff	Leaking cuff	High	
Check Cuff (Overpressure)	May be due to a faulty cuff	High	
Check Cuff (Inflate Timeout)	May be a blockage in the air supply	High	
Check Cuff (Weak Signal)	Weak or no signal measured during blood pressure measurement	High	
Retake NIBP Measurement (Motion Detected)	Motion may be affecting ability to take measurement	High	
Retake NIBP Measurement (Interference)	Weak signal when measurement is being taken	High	
Check NIBP (Module Error)	Device requires service	High	• Contact Masimo Technical Support. See ***Chapter 13: Service and Maintenance*** on page 129.

Temperature Messages

The following section lists common messages, their potential causes, and next steps related to Temperature operation of the Radius VSM System.

Alarm Message	Description	Alarm Priority	Next Step
Temperature High	Temperature has increased above the set high limit.	Medium	Check patient's vital condition.
Temperature Low	Temperature has decreased below the set lower limit.	Medium	Check patient's vital condition.
Replace Temperature Sensor	Sensor has expired.	Medium	Replace the ECG sensor.

Position Monitoring Messages

The following section lists common messages, their potential causes, and next steps related to Position Monitoring operation of the Radius VSM System.

Message	Potential Causes	Alarm Priority	Next Steps
Turn Due	Patient has overstayed in a given position beyond the time limit set forth by user.	NA*	Physically check patient's condition and move the patient to a new position.
Restricted Position	Patient is currently violating one of two possible restricted zones.	NA*	Physically check patient's condition and move the patient to an allowed position.
Fall Detected	Radius VSM sensor has detected a fall-like movement.	High	Physically check patient's condition, and acknowledge the alarm on Masimo device screen.

* Visual alarm only.

Chapter 11: Troubleshooting

Troubleshooting Measurements

The following section lists possible measurement symptoms, the potential cause, and next steps.

For additional information, see ***Safety Information, Warnings and Cautions*** on page 11.

Symptom	Potential Causes	Next Steps
Low SIQ message displayed (Low signal quality).	• Sensor is damaged or not functioning. • Improper sensor type or application. • Excessive motion. • Low perfusion.	• Verify Sensor type and size and re-apply sensor. See *Directions for Use* for Sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Minimize or eliminate motion at the monitoring site. • Set to Maximum Sensitivity. See ***Sensitivity Modes Overview*** on page 71.
Difficulty obtaining a reading.	• Inappropriate sensor or sensor size. • Improper sensor type or application. • Low perfusion. • Excessive motion artifact. • Excessive ambient or strobing light. • Low battery/ not plugged into AC power supply. • Interference from line frequency-induced noise.	• Allow time for parameter reading to stabilize. • Verify sensor type and size and re-apply sensor. See *Directions for Use* for sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Verify the device and sensor are configured with the parameter. • Verify proper sensor and sensor size for the patient. • Shield the sensor from excessive or strobing light. • Minimize or eliminate motion at the monitoring site. • Connect AC power supply. • Verify and set 50 or 60Hz menu setting. See ***Localization*** on page 57.

Symptom	Potential Causes	Next Steps
Parameter readings displayed as dashes.	• Parameter may not have stabilized. • Device may not be configured with the parameter. • Sensor is not compatible with the parameter.	• Allow time for parameter reading to stabilize. • Verify sensor type and size and re-apply sensor. See *Directions for Use* for sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Verify the device and sensor are configured with the parameter.
Dimly Lit Parameters	• Low signal quality.	• Assess the patient. • Verify sensor type and size and re-apply sensor. See *Directions for Use* for sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Minimize or eliminate motion at the monitoring site. • Set to MAX Sensitivity. See ***Sensitivity Modes Overview*** on page 71.
Parameter Values Do Not Correlate With Clinical Assessment or Arterial Blood Gas Measurements	• Low perfusion. • Sensor displacement.	• Check for error messages. See ***Chapter 10: Alarms and Messages*** on page 93. • Check placement of sensor or if it is too tight. Reapply sensor or select a new site. Set to MAX sensitivity and confirm that the sensor is securely placed on the patient. See *Directions for Use* for sensor.
Unexpected Parameter Readings	• Low SIQ or Pi values. • Inappropriate sensor size or sensor measurement location.	• Reposition sensor to site with strong SIQ and Pi. Average readings taken from three different sites to improve accuracy. Submit blood sample for laboratory CO-Oximetry test for comparison. • Verify proper sensor for patient size. Verify proper sensor site. See *Directions for Use* for sensor.

Troubleshooting ECG Measurements

Symptom	Potential Causes	Next Steps
Difficulty obtaining a reading	• Improper electrode or electrodes application. • Poor electrode contact. • Excessive Motion Artifact. • ECG signal is weak. • Electrical continuity. • Interference from line frequency-induced noise.	• Allow time for parameter reading to stabilize. • Check for electrode gel dry out. • Use appropriate skin prep. • Check the placement of the electrode. Re-apply electrodes or move to a different site. • Check all electrode, leadwire and ECG module cable connections. • Replace electrodes. • Minimize or eliminate motion at the monitoring site. • Check line frequency filter on equipment.
Intermittent Signal	• Electrical continuity. • Poor electrode contact. • Interference. • Cabling.	• Check all electrode, leadwire and ECG module cable connections. • Check for electrode gel dry out. • Remove all possible static charge, touch metal (bedrail) prior to touching the patient. • Replace electrodes.
Motion Artifact	• Excessive Motion Artifact. • Poor electrode contact. • Electrical continuity. • Interference from line frequency-induced noise. • Cabling.	• Check the placement of the electrode. Re-apply electrodes or move to a different site avoiding large muscle masses. • Check for electrode gel dry out. • Check all electrode, leadwire and ECG module cable connections. • Minimize or eliminate motion at the monitoring site. • Replace electrodes.
Low Amplitude	• Equipment. • Patient physiology. • Electrical continuity. • Skin impedance.	• Adjust monitor settings to increase ECG amplitude. • Change lead selection. • Check all electrode, leadwire and ECG module cable connections. • Check for electrode gel dry out.
Parameter readings displayed as dashes.	• Parameter may not have stabilized or may be out of range.	• Allow time for parameter reading to stabilize. • Verify electrode placement or move to a different site. • Replace electrodes.

Symptom	Potential Causes	Next Steps
Unexpected Parameter Readings	• Inappropriate electrode measurement location.	• Compare pulse rate with other means. • Verify proper electrodes site. See ***Attaching the ECG Module and Electrodes to the Patient*** on page 42 for electrode placement.

Troubleshooting Radius VSM

The following section lists possible Radius VSM symptoms, potential causes, and next steps.

For more information, see ***Chapter 10: Alarms and Messages*** on page 93.

Symptom	Potential Causes	Next Steps
Device does not turn on	• Depleted Battery. • Internal failure.	• Charge the battery. • Contact Masimo Service. See ***Contacting Masimo*** on page 134.
System failure technical alarm active (continuous speaker tone)	• Internal failure.	• To silence an alarm, press the Alarm Silence button. If alarm continues to sound, turn off the Radius VSM. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
Speaker does not work	• Device audible settings may be incorrect. • Internal failure.	• Turn Radius VSM Off and On. • Check that Alarms have not been silenced. • Check the device is not in All Mute. • Check that the device speaker is not being muffled. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
Device screen is blank	• The device is Off. • Battery may be depleted. • Internal failure.	• Turn Radius VSM Off and On. • Charge the battery. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
Touchscreen/Buttons do not respond when pressed	• EMI (Electro Magnetic Interference) • Internal failure.	• Relocate the device from other devices that may cause electromagnetic interference. • Contact Masimo service. See See ***Contacting Masimo*** on page 134.

Symptom	Potential Causes	Next Steps
Battery run time significantly reduced	• Battery not fully charged. • Battery damaged. • Battery capacity effected.	• Check battery charge level indicator. • Check battery is fully charged. • Replace battery. See ***Contacting Masimo*** on page 134. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
Battery does not charge	• Charging Connector makes poor connection. • Battery damaged. • Internal failure.	• Ensure device is seated properly in charging adapter. • Replace battery. See ***Contacting Masimo*** on page 134. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
Device does not detect that patient cable is connected	• Cable connector not properly connected to the device. • Damaged connector. • Damaged cable. • Cable expired. • Internal failure.	• Remove and reconnect cable. • Ensure the connector is fully connected to the device. • Replace cable. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
Device does not detect that the sensor is connected	• Sensor not properly connected to device. • Improper placement of sensor. • Damaged sensor. • Sensor expired. • Internal failure.	• Remove and reconnect sensor. • Ensure the connector is fully connected to the device. • Reapply sensor to the patient. Refer to sensor *Directions For Use*. • Replace sensor. • Turn Radius VSM Off and On. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
Device does not detect that ECG module is connected	• Connection between the module and ECG module is not properly connected. • Damaged connector. • Damaged ECG module cable. • Internal failure.	• Remove and reconnect the ECG module cable. • Ensure the connector is fully connected to the device. • Replace ECG module cable. • Contact Masimo service. See ***Contacting Masimo*** on page 134.

Symptom	Potential Causes	Next Steps
Device does not detect that the electrodes are connected	• Electrodes not properly connected to device. • Improper placement of electrodes. • Damaged electrodes. • Accessory connector makes a poor connection. • Internal failure.	• Remove and reconnect electrodes. • Ensure the connector is fully connected to the device. • Reapply electrodes to the patient. • Replace electrodes. • Check ECG module cable connection. • Turn Radius VSM Off and On. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
ECG Board fails to operate	• Internal failure.	• Turn Radius VSM Off and On. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
Device does not detect that NIBP module is connected	• Connection between the device and NIBP module is not properly connected. • Damaged connector. • Damaged NIBP module cable. • Internal failure.	• Remove and reconnect the NIBP module cable. • Ensure the connector is fully connected to the device. • Replace NIBP module. • Contact Masimo service. See ***Contacting Masimo*** on page 134.
Device does not communicate to other external devices through wireless connection	• External device is not compatible. • Wi-Fi is not turned on and/or not correctly configured. • Location does not have wireless availability. • Connected network is not available. • Internal failure.	• Check external device compatibility. • Check that the wireless feature is on and correctly configured. See ***Wi-Fi*** on page 58. • Check wireless availability for location. • Check network settings and availability. • Contact Masimo service. See ***Contacting Masimo*** on page 134.

Chapter 12: Specifications

Radius VSM Device Specifications

Pulse Oximetry Specifications

Display Range and Display Resolution

Measurement	Display Range	Resolution
SpO_2 (Functional Oxygen Saturation)	0% to 100%	1%
PR (Pulse Rate)	25 bpm to 240 bpm	1 bpm
Pi (Perfusion Index)	0.0 to 0.99	0.01
	1.0 to 9.9	0.1
	10 to 20	1
PVi (Pleth Variability Index)	0 to 100	1
RRa (Acoustic Respiration Rate)	4 rpm to 70 rpm	1 rpm
RRp (Respiration Rate from the Pleth)	4 rpm to 70 rpm	1 rpm

The emitted wavelengths range from 600 nm to 1000 nm and the peak optical power is less than 15 mW. Information about the wavelength range can be especially useful to clinicians.

Accuracy (ARMS)* [1]

Oxygen Saturation (SpO_2)		
No Motion [2] (SpO_2 from 70% to 100%)	Adults	1.5%[1]
Motion [3] (SpO_2 from 70% to 100%)	Adults	1.5%[1]
Low perfusion [4] (SpO_2 from 70% to 100%)	Adults	2%

[1] 1.5% A_{RMS} with RD SET Disposable Sensors.

Pulse Rate (PR)		
Range	25 bpm to 240 bpm	
No motion	Adults	3 bpm
Motion [5]	Adults	5 bpm

Pulse Rate (PR)		
Low Perfusion	Adults	5 bpm

Respiratory Rate (RRa) [6]		
Range of 4 rpm to 70 rpm	Adults	1 rpm

Respiratory Rate (RRp) [7]		
Range	4 rpm to 70 rpm	
No Motion	Adults	3 rpm A_{RMS}*, ± 1 rpm mean error

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

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

SpO2 Performance Specifications

Accuracy testing for SpO_2 was performed on healthy adult subjects. The tables below provides A_{RMS} (Accuracy Root Mean Square) values measured using the Masimo Rainbow SET Technology with Masimo RD SET disposable sensors in clinical studies under no motion conditions. The Bland-Altman plots provided in the operator's manual are for the sensors identified in the respective plots. Bland-Altman plots for sensors not listed in the tables below are available in the Directions for Use (DFU) for those sensors. See the sensor DFU for the Bland-Altman plots for the respective compatible sensor.

Measurement A_{RMS} Values for Disposable (RD SET Series) Sensors	
SpO_2 Accuracy Range (%)	A_{RMS} (%)
70-80	0.83
80-90	1.11
90-100	1.53
70-100	1.15

The table below provides the upper 95% and lower 95% limits of agreement. The differences between measurements by the two methods are used to calculate the mean and standard deviation. The lower 95% limit of agreement is the mean minus 1.96 standard deviation and the upper 95% limit of agreement is the mean plus 1.96 standard deviation. These limits are expected to contain 95% of the differences between measurements between the two methods in controlled environments.

SpO_2 Upper and Lower Limits of Agreement (LoA)*	
Upper 95% LoA	2.27%
Lower 95% LoA	-2.29%

** See Bland and Altman. Agreement between methods of measurement with multiple observations per individual. Journal of Biopharmaceutical Statistics (2007) vol. 17 pp. 571-582.*

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

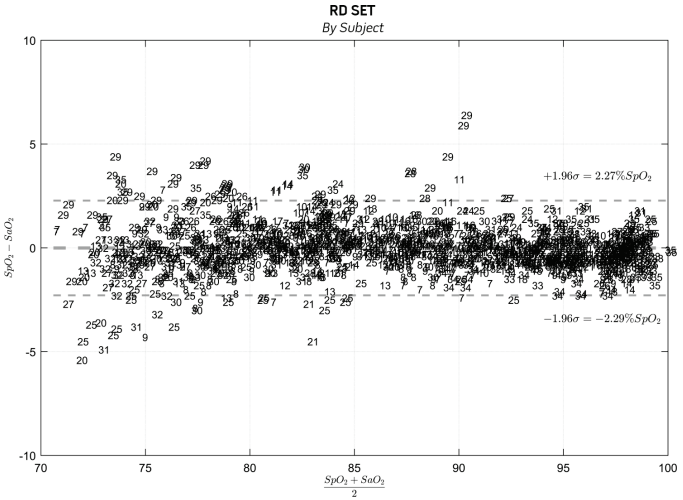


Figure 1: Disposable (RD SET Series) Sensors (ARMS 70-100%)

RRp Performance Specifications

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

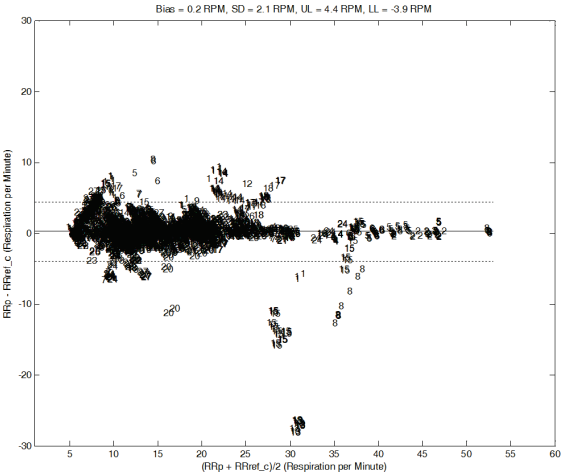


Figure 2: Subject by Subject Bland-Altman plot of RRp with respect to RRref_c

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

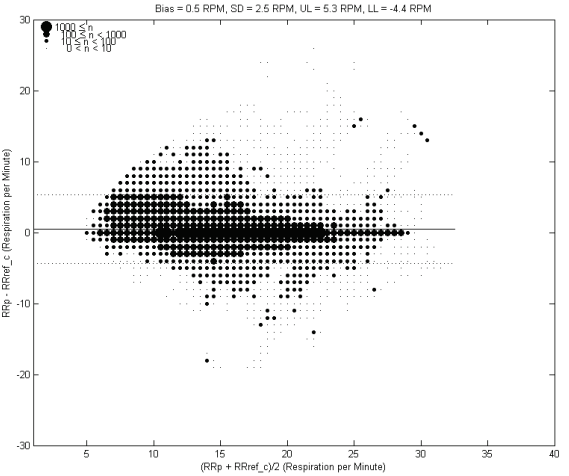


Figure 3: Bland-Altman plot of RRp with respect to RRref_c

Electrical

Battery Electrical Specifications	
Type	Lithium ion
Run Time	10 hours [8]
Charging Time	4 hours [9]
Battery Storage Life	Approx. 5 years from the date of purchase
Battery Life Cycle	Approx. 2 years or 500 complete charge/discharge cycles

Battery Storage Requirements	
Storage Length*	Required Storage Temperature
1 Month	-10°C to 55°C
6 Months	-10°C to 45°C
1 Year	-10°C to 25°C
Storage Humidity	10% to 80% non-condensing

* After 12 months storage duration, battery shall go through 1 full discharge and 1 full charge. After cycling, set battery to SOC 35+/-5%.

Physical Characteristics

Radius VSM Physical Characteristics	
Dimensions	10.9 cm x 5.8 cm x 2.1 cm (4.28” x 2.28” x 0.83”)
Weight	122 g (0.27 lbs.)
Expected Service Life	5 Years

Display

Item	Description
Size	2.6" (6.6 cm)
Display Update Rate	1 second
Type	TFT LCD
Resolution	240x410

Alarms

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

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

* When volume is set to the highest level.

Wireless Specifications

Communication (Wi-Fi)	
Type	WLAN Radio: IEEE 802.11 a/b/g/n
Frequency	2.4 GHz - 802.11b/g/n: 2412-2472 MHz 5.0 GHz - 802.11a/n: 5150-5250 MHz, 5250-5350 MHz, 5470-5725 MHz, 5725-5825 MHz
Max Peak Output Power	WLAN 18dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	OFDM, BPSK, QPSK, CCK
Modulation Signals	Analog and Digital
Available Data Rates	802.11a - 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11b - 1, 2, 5.5, 11 Mbps 802.11g - 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11n – MCS 0-7 HT20/HT40

Communication (Bluetooth)	
Type	Bluetooth and Bluetooth LE
Frequency	2402-2480 MHz
Max Peak Output Power	Bluetooth; 8.2 dBm Bluetooth LE; 4.75 dBm

Communication (Bluetooth)	
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	Bluetooth; DH5, 2DH5, 3DH5 Bluetooth LE; GFSK
Modulation Signals	Analog and Digital
Available Data Rates	Bluetooth 1, 2, 3 Mbps

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

Radio Certification ID	
USA	FCC ID: VKF-MWM2
Canada	IC: 7362A-MWM2
Europe	EU Radio Equipment Directive (RED 2014/53/EU) EN 300 328:V2.1.1 EN 301 893:V2.1.1 EN 301 489-1:V2.2.0 EN 301 489-17 V3.1.1 EN 62311 2008

ECG Specifications

Display Range and Display Resolution

Measurement	Display Range	Resolution
HR (Heart Rate)	15 bpm to 300 bpm	1 bpm
RR (Respiration Rate)	4 rpm to 120 rpm	1 rpm
PVC (Premature Ventricular Contractions)	0 min to 99 min	1 min

Accuracy (ARMS)*

Heart Rate (HR)	
Range of 15 bpm to 300 bpm	≤ 2 BPM or ≤ 1% (whichever is greater)

Respiration Rate (RR)	
Range of 0, 4 rpm to 120 rpm	≤ 1 rpm

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

ECG Performance Characteristics

Parameter	Specification
Active Patient Signal - Leads Off Sensing/Noise Suppression	Active Electrode < 100 nA Drive/Reference Electrode < 1 µA
Tall T-wave Rejection Capability	70% of a R/T >= 1 mV QRS (monitoring mode)
Heart Rate - Averaging	4 to 16 RR Intervals
Heart Rate - Update Rate	≤ 1 second
Heart Rate - Response Time	≤ 10 seconds
High Heart Rate - Time to Alarm	≤ 10 seconds
Pacemaker Pulse Rejection Capability	Amplitude: ± 2 mV to ± 700 mV Width: 0.1 ms to 2.0 ms
Pacemaker Pulse Rejection Disabling	NA
Sweep Speeds	25 mm/second (default) 12.5 mm/second 6.25 mm/second
Monitoring ECG Bandwidth	0.67 Hz to 40 Hz (Adults)
Diagnostic ECG Bandwidth	0.05 Hz to 150 Hz

Physical Characteristics

ECG Module Physical Characteristics	
Dimensions	4.7 cm x 4.06 cm (1.85” x 1.60”)
Cable Length	50 cm (19.7”)
Weight	20 g (0.04 lbs.)

Noninvasive Blood Pressure (NIBP) Specifications

Display Range

Measurement	Patient Population	Display Range
Systolic	Adult	60 to 230 mmHg
Diastolic	Adult	40 to 130 mmHg
Pulse Rate (PR)	Adult	30 to 240 bpm

Accuracy

Pressure Transducer	
Between 0 mmHg and 300 mmHg	±3 mmHg
Blood Pressure [10], [11]	
Meets ANSI/AAMI SP10 and ISO 81060-2 (Mean difference of ≤5 mmHg with a standard deviation of ≤8 mmHg)	

Pressure Range

Weight	Patient Category	Initial Pressurization	Maximum Pressure
Greater than 75 lbs (34 kg)	Adult	0 mmHg	300 mmHg

Physical Characteristics

NIBP Module Physical Characteristics	
Dimensions	9.3 cm x 5.5 cm x 2.9 cm (3.66” x 2.17” x 0.86”)
Cable Length	72.6 cm (28.6”)
Weight	111 g (0.24 lbs.)

Temperature Specifications

Display Range and Display Resolution

Measurement	Display Range	Resolution
Temperature	25.0°C to 43.0°C (77.0°F to 109.4°F)	0.1 °C or °F

Accuracy

Temperature		
Laboratory[1]	25°C to 43°C (77°F to 109.4°F)	±0.3°C (±0.54 °F)
Application Site	Chest	

[1] Laboratory temperature is equivalent to skin temperature.

Temperature Measuring Time

Temperature Measuring Time	Time
Recommended Minimum Temperature Measuring Time	10 mins.
Temperature Update Rate	Every 1 min.

Position Monitoring Specifications

Display Range

Measurement	Display Range
Patient Recline Angle [12]	-180° to 180°
Time in Current Position	0:00 to 99:59

Radius VSM Charger Specifications

Physical Characteristics

Radius VSM Battery Charger Physical Characteristics	
Dimensions	22.9 cm x 9.4 cm x 5.4 cm (9.0" x 3.7" x 2.1")
Weight	203 g (0.45 lbs.)

Environmental

Environmental Conditions	
Operating Temperature	0°C to 40°C (32°F to 104°F)
Storage/Transport Temperature	-20°C to 60°C [13] (-4°F to 140°F)

Environmental Conditions	
Operating Humidity	10% to 95%, non-condensing
Storage/Transport Humidity	10% to 95%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1060 mbar (540 hPa to 1060 hPa)

Compliance

EMC Compliance
IEC 60601-1-2:2014, Class B

Safety Standards Compliance
ANSI/AAMI ES 60601-1:2005+A1:2012
AAMI EC57:2012
CAN/CSA C22.2 No. 60601-1:2014
IEC 60601-1:2005 + A1:2012
IEC 60601-1-6:2010 + A1:2013
IEC 60601-1-8:2006 + A1:2012
IEC 60601-1-11:2015
IEC 60601-2-25:2011
IEC 60601-2-27:2011
IEC 80601-2-30:2018
IEC 80601-2-49:2018
ISO 80601-2-56:2017 + A1:2018
ISO 80601-2-61:2017

Equipment Classification per IEC 60601-1	
Type of Protection	Internally powered (Battery power)
Degree of Protection of Electrical Shock	Defibrillation proof CF-Applied Part
Protection against harm from liquid ingress	
NIBP Module	IP22, Protected from objects greater than 12 millimeters and water spray less than 15 degrees from vertical.

Equipment Classification per IEC 60601-1	
Radius VSM Patient-Worn Vital Signs Monitor, ECG Module	IP24, Protected from objects greater than 12 millimeters and water spray from any direction.
Mode of Operation	Continuous

Guidance and Manufacturer's Declarations - Electromagnetic Compatibility

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 (Radiated) Emissions CISPR 11	Group 1/Class B	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.

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	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	Performed over 0.15-80 MHz
	6 Vrms	6 Vrms	Performed on the following ISM (industrial, scientific and medical) bands of frequency: The bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz

Electromagnetic Immunity			
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Radius VSM, including cables, than the recommendation separation distance calculated from the equation applicable to the frequency of the transmitter.
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.			

* U_T: Rated voltage for the equipment

Test Specifications for Enclosure Port Immunity to RF Wireless Communication Equipment

Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-395	TETRA 400	Pulse modulation **(b)** 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM **(c)** +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation **(b)** 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation **(b)** 18 Hz	2	0.3	28
870						
930						

Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3. 4. 35: UMTS	Pulse modulation **(b)** 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation **(b)** 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation **(b)** 217 Hz	0.2	0.3	9
5500						
5785						

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

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

Recommended Separation Distances

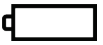
Recommended separation distances between portable and mobile RF communications equipment and the Radius VSM.	
Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**
	80 MHz to 2.7 GHz $d = 0.6\sqrt{P}$
0,01	0.06
0,1	0.19
1	0.6
10	1.9
100	6

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

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC		Separate collection for electrical and electronic equipment (WEEE)
	Defibrillation-proof. Type CF Applied Part	FCC ID:	Identifies unit has been registered as a radio device
Rx ONLY	**Caution:** Federal law restricts this device to sale by or on the order of a licensed physician.		ETL Intertek certification See ***Declarations on Page 1*** for certifications
EC REP	Authorized representative in the European community		Federal Communications Commission (FCC) Licensing
IP22	Protected from objects greater than 12 millimeters and water spray less than 15 degrees from vertical	IP24	Protected from objects greater than 12 millimeters and water spray from any direction
	Not made with natural rubber latex		Recyclable
	Non-Sterile		Do not use if package is damaged
	Manufacturer	####	Masimo reference number
	Date of manufacture YYYY-MM-DD	SN	Serial number
MD	Medical Device	LOT	Lot code
	Bluetooth	REF	Catalog number (model number)
	Storage temperature range		Keep dry
	Atmospheric pressure limitation		Fragile, handle with care

Symbol	Description	Symbol	Description
	Storage humidity limitation		Class II Equipment
	NIBP		Battery, General
	Artery symbol and arrow should be placed over brachial or femoral artery		Arm Circumference
	Cuff index line must fall within range markings for an accurate measurement		Index Line
	This equipment contain specific radio equipment that has been certified to the Technical Regulator Certification under the Radio Law.		China Restriction of Hazardous Substances
	The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual	-	--
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Citations

[1] Refer to sensor DFU for specific sensor performance specifications.

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

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

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

[5] Masimo rainbow SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator.

[6] Respiration rate accuracy for the Masimo Acoustic Respiration Sensor and Instrument has been validated for the range of 4 to 70 breaths per minute for adult patients in bench top testing. Clinical

validation for up to 61 breaths per minute was also performed with the Masimo Acoustic Respiration Sensor and Instrument.

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

[8] This represents approximate run time using a fully charged battery with Masimo SET pulse oximetry, Acoustic respiratory rate, ECG, skin temperature and posture orientation being continuously monitored and the NIBP measurement being made periodically (4 times/hour), no alarm or pulse tones active, display not active, Wi-Fi is on and connected to Masimo Patient SafetyNet.

[9] The battery recharge time shall be no longer than 4 hours to reach 80% charge capacity at operating temperature of 25°C (77°F) ambient temperature and might not charge completely under elevated ambient temperature.

[10] The pressure transducer accuracy was bench-top tested against a maximum error of less or equal to ±3 mmHg (±0.4 kPa) over an environmental temperature condition of 10 °C to 40 °C and 15% to 85% relative humidity (non-condensing), per IEC 80601-2-30.

[11] The blood pressure accuracy performance has been clinically validated on 89 adult volunteers. The mean difference for systolic and diastolic were -1.23 mmHg and -2.67 mmHg, respectively. The standard deviation of differences for systolic and diastolic are 7.32 mmHg and 7.13 mmHg, respectively. This meets the acceptance criteria of mean ≤5 mmHg and standard deviation of ≤ 8 mmHg per the ISO 80601-2 standard.

[12] Angle determined based upon a reference plane where the device is flat in the horizontal position. No calibration required.

[13] If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20°C to +30°C, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.

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

Chapter 13: Service and Maintenance

Cleaning

The Radius VSM, NIBP Module and ECG Module are reusable devices. The devices are supplied and used non-sterile. The devices 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 Radius VSM Charger and Root Battery Charging Adapter should also be cleaned periodically or according to local and governmental regulations to minimize the risk of cross-contamination.

WARNING: Before cleaning, read ***Cleaning and Service Warnings and Cautions*** on page 19.

WARNING: Before cleaning, make sure the device is off and is not applied to the patient.

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

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

To clean the Radius VSM System components follow the instructions below:

- Wipe the outer surfaces using a dampened soft cloth twice with one of the recommended cleaning solutions listed below, or until the surfaces are free of any visible residue.

  Note: Pay particular attention to crevices and hard to reach areas. Use a soft bristled brush to gently remove any visible residue from crevices as necessary.
- Repeat the above cleaning step using a fresh wipe.
- Allow the device to dry thoroughly before using again.

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 solvents or cleaning agents:

- 70% Isopropyl Alcohol
- Glutaraldehyde
- 10% bleach (sodium hypochlorite) to 90% water solution
- Quaternary ammonium chloride
- Accelerated Hydrogen Peroxide (e.g. Oxivir Tb)

Using the recommended cleaning solutions on the Radius VSM display panel will not affect the performance of the devices.

WARNING: Do not attempt to clean or re-use single-use accessories on multiple patients.

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

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 VSM fails any of the described tests, discontinue its use and refer to ***Chapter 11: Troubleshooting*** on page 105.

Before performing the following tests, do the following:

- Disconnect any sensors or patient cables.
- Ensure that the Radius VSM battery is charged.

Power-On Self-Test

To conduct a Power-On Self-Test

1. Charge and power on the Radius VSM. See ***Powering Radius VSM ON and OFF*** on page 45.
2. Upon powering on, the Masimo logo should display.

   Note: If the Radius VSM does not pass the Power-On Self-Test, a system failure technical alarm will be activated.

Touchscreen Function Test

To conduct a Touchscreen Function Test

1. Charge and power on the Radius VSM. See ***Powering Radius VSM ON and OFF*** on page 45.
2. Perform the gestures outlined in Using the Touchscreen Interface.

Speaker Test

To conduct a Speaker Test

1. With Radius VSM fully charged and powered on, enter the *Sounds* settings. See ***Sounds*** on page 56.
2. Increase and decrease the Alarm Volume and Pulse Tone Volume levels. The speaker should respond and sound in relationship to the adjustment.
   - If the speaker does not sound, see ***Chapter 11: Troubleshooting*** on page 105.

Alarm Limit Test

To Conduct an Alarm Limit Test

1. Connect a sensor to the Radius VSM. Place the sensor on a finger to obtain an SpO_2 value.
2. Change the Low SpO_2 Alarm parameter to a value two points above the currently displayed value. See ***SpO2 Alarms*** on page 64.
3. Verify that the audible alarm sounds and the visual alarm displays with the set alarm limit.
4. Silence the alarm. See ***Chapter 10: Alarms and Messages*** on page 93.
5. Reset the Low SpO_2 alarm limit to the original settings.

Battery Test

To Conduct a Battery test

1. Dock the Radius VSM on the Battery Charging Adapter. Make sure the connection pins of the Radius VSM are in contact with the adapter.
2. Verify that the Radius VSM is charging. The System Status Light flashes to indicate that the Radius VSM is charging. See ***Front and Top Views*** on page 29.
3. Un-dock the Radius VSM from the Battery Charging Adapter.
4. Turn Radius VSM on and confirm operation.

Maintenance

Battery Operation and Maintenance

The Radius VSM includes a lithium ion rechargeable battery.

Before using the Radius VSM, the battery should be fully charged. See ***Battery Charging*** on page 35.

The Radius VSM battery requires approximately 4 hours for charging.

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

CAUTION: The battery is not user replaceable, contact Masimo Service if the battery needs to be replaced.

Note: Always store the Radius VSM on the charger. Do not place it on a conductive surface where the connection pins may be shorted.

NIBP Calibration

The *Calibration* screen contains calibration procedures that require a password to access.

To enter the Calibration menu:

1. When the *Enter Password* screen displays, enter the following: **4 2 5 8**
   To undo an entry, press *Backspace*.
2. Press the return key to access the password-protected screen to view available options.
   Note: The password will have to be entered every time this screen is accessed.

Manometer

Note: This section is provided as a reference and intended for authorized service personnel only.

Pass Criteria

International standards for automated NIBP devices require that the maximum static pressure accuracy shall be ± 3mmHg or 2% of the reading, whichever is greater. This is a stringent requirement and all test equipment must be in excellent working order to properly perform this test. It is important to verify the calibration before changing it. Historical data has shown that the transducers rarely need to be re-calibrated although we still suggest that the calibration be verified annually.

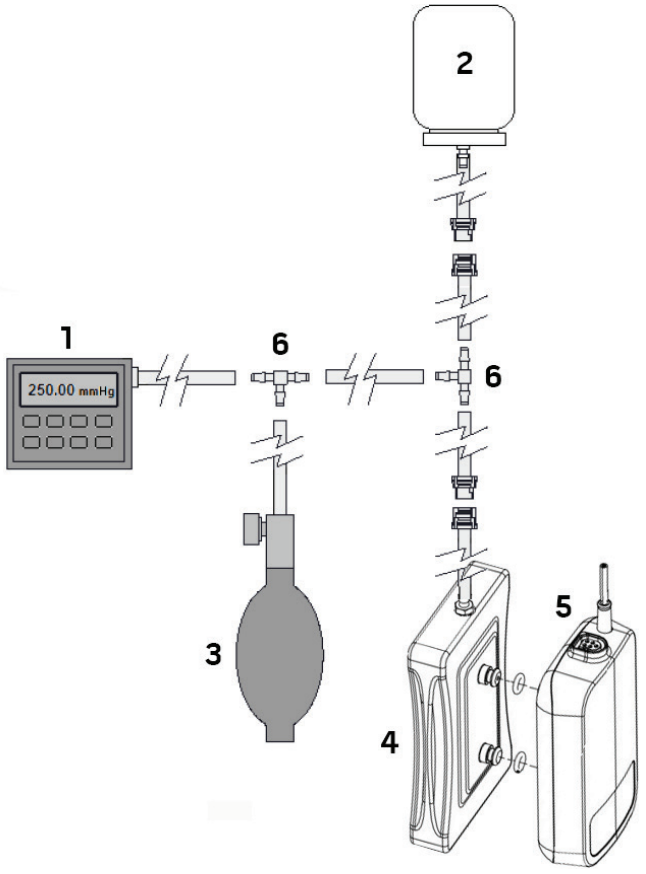
Equipment

- Calibrated Manometer*
- Pneumatic "T" Adapters
- Masimo NIBP Module adapter fixture
- 500mL bottle
- Hand Bulb
- Connection Tubing

*Verify the manometer has been calibrated within the last 12 months. Calibration accuracy shall be within ±0.02% to ±0.25% FS (Full Scale) and a measurement uncertainty of ±1 LSD (Least Significant Digit).

Procedure

1. Connect the manometer **(1)**, 500mL bottle **(2)** and hand bulb **(3)** together with the Service Adapter **(4)** (the NIBP Module **(5)** attached to one side and the NIBP cuff attached to the other side of the Service Adapter) using "T" adapters **(6)** and connection tubing.



2. Power ON the manometer.
   - Verify the manometer has been zeroed.
   - Set the unit of measurement to mmHg.
   - Verify the manometer has been calibrated.
3. Power ON the Radius VSM and enter the *Calibration* menu.
4. Press **Manometer**.
5. Press **Start**.
6. Apply various pressures (0mmHg to 280mmHg) to the NIBP module with the hand bulb.
7. Compare the NIBP module pressure to the manometer pressure:
   - If the NIBP module pressure and manometer pressure differ WITHIN the ±3mmHg tolerance, then the NIBP module has PASSED the calibration test and no further action is needed. Go to step 7.
   - If the NIBP module pressure and manometer pressure differ BEYOND the ±3mmHg tolerance, contact Masimo Technical Services. See ***Masimo Technical Services*** on page 134.
8. Disconnect the manometer, 500mL bottle and hand bulb from the Masimo NIBP Module adapter fixture.
9. Power OFF the manometer.

Repair Policy

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

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

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

Return Procedure

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

- A letter describing in detail any difficulties experienced with the Radius VSM. 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 VSM 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 VSM has been decontaminated for bloodborne pathogens.
- Return the Radius VSM to the shipping address listed in ***Contacting Masimo*** on page 134 below.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

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

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product (Radius VSM™) and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 24 months and any batteries for six (6) months from the original date the Product was obtained by the end-user purchaser.

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

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

Exclusions

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

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

Limitation of Warranty

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

Sales & End-User License Agreement

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

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3. Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Masimo's prior written consent; except that the Software and all of Purchaser’s rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.
4. U.S. Government Rights: If Purchaser is acquiring Software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the Software and documentation are deemed to be “commercial software” and “commercial computer software documentation,” respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the Software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this Agreement.

Appendix A: Radius VSM Operation with Root

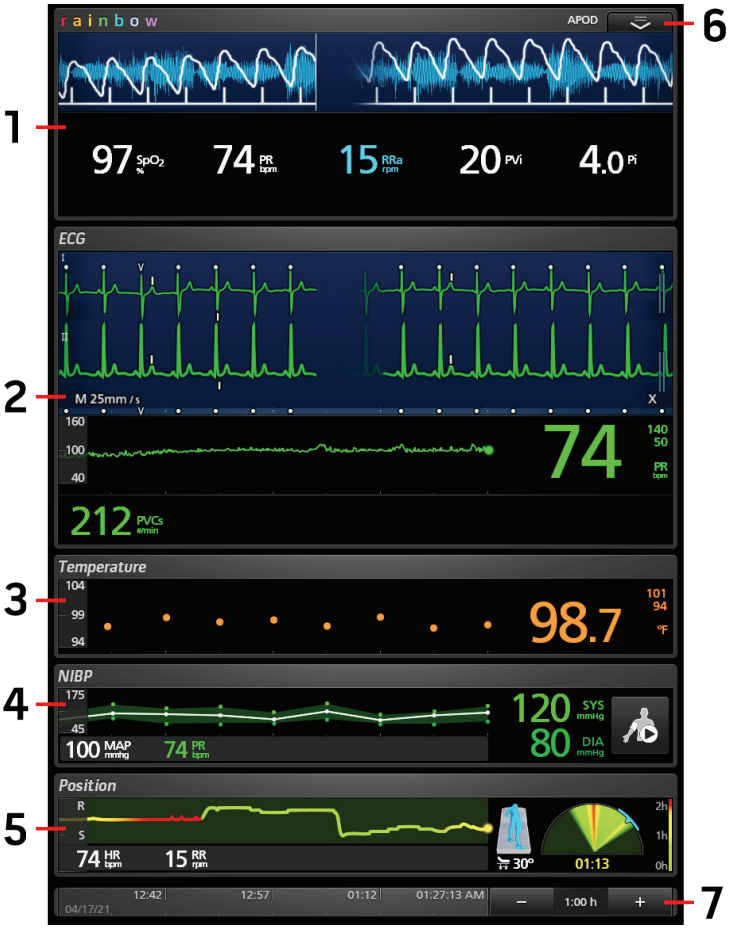
Overview

The following information outlines Radius VSM operation when connected to Root. Additional data, displays and settings may be available on Root that are not available directly on the Radius VSM device. This section discusses this Root specific information and is intended to be used with the ***Operator's Manual, Root®*** or ***Operator's Manual, Root® with noninvasive blood pressure and temperature***.

Operation

About the Root Main Screen

The following is an example of the Root *Main Screen* with Radius VSM connected:



Ref.	Feature	Description
1	Pulse Ox Window	Displays the pulse oximeter parameter information from Radius VSM. See ***Chapter 4: Operation*** on page 47.
2	ECG Window	Displays the ECG information from Radius VSM. See ***Chapter 6: Electrocardiogram (ECG)*** on page 73.
3	Temperature Window	Displays the Temperature information from Radius VSM. See ***Chapter 7: Temperature*** on page 81.
4	NIBP Window	Displays the NIBP information from Radius VSM. See ***Chapter 8: Noninvasive Blood Pressure (NIBP)*** on page 83.
5	Position Monitoring Window	Displays the Position Monitoring information from Radius VSM. See ***Chapter 9: Position Monitoring*** on page 91.
6	Action Menu	Provides access to settings and view modes. See ***About the Action Menu*** on page 138.
7	Trend View Controls	Provides the ability to modify the Trend View display. See ***Trend View Controls*** on page 139.

About the Action Menu

The *Action Menu* provides access to settings and view modes directly from the *Main Screen*. To expand the *Action Menu*, select the arrow in the upper right corner of the window.

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

The *rainbow Action Menu* provides access to the following settings:

- **Waveform** - Opens the *Waveform Settings*. See ***Waveform Settings*** on page 141.
- **Sensitivity** - Cycles through the available sensitivity modes, APOD, NORM and MAX. See ***Sensitivity Modes Overview*** on page 71.
- **Trend View** - Displays values in Trend View.
- **Analog** - Displays values as a needle pointing to graduations in a circular array around a dial.

When Schedule mode is configured through Root by authorized personnel, the *NIBP Action Menu* provides access to the following settings:

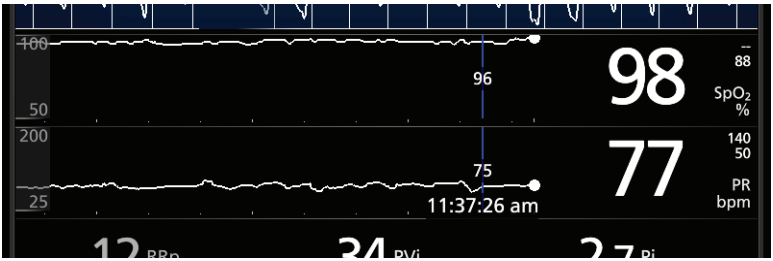
- **Intervals** - Opens the intervals setting screen. See ***Schedule NIBP Measurement*** on page 87.

Refer to the ***Operator's Manual, Root®*** or ***Operator's Manual, Root® with noninvasive blood pressure and temperature*** for additional information.

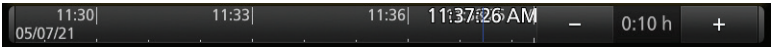
Trend View Controls

Trend View data can be manipulated using the touchscreen as follows:

Trend View Example



Trend View Controls



1. Touch the + or - buttons on the *Trend View Controls* to change the time range of *Trend View* data displayed on the screen. Select from 0:10h (10 minutes) to 24:00h (24 hours).
2. Use a pinch gesture with two fingers on the *Trend View* display or the *Trend View Controls* to zoom in and out of the data displayed on the screen. Select from 0:10h (10 minutes) to 24:00h (24 hours) in increments of 0:01h.
3. Swipe the *Trend View* display or *Trend View Controls* left or right to scroll the *Trend View* data forward or backward in time.
4. Tap the *Trend View* display or *Trend View Controls* in a specific spot to view the values at that time (shown in the examples).

Accessing Root Main Menu Options

To access the *Main Menu* options of the Root, press/select the **Main Menu** icon at the bottom right corner of the Root touchscreen.

The Radius VSM settings on the Root are similar to the settings on Radius VSM. For complete Root operating instructions, refer to the ***Operator's Manual, Root®*** or ***Operator's Manual, Root® with noninvasive blood pressure and temperature***.

With Radius VSM connected to the Root, the settings in the *Main Menu* options change as follows:

Layout

See ***Root Layout with Radius VSM*** on page 140.

Pulse Ox Settings

See ***Pulse Ox Settings*** on page 63.

ECG Settings

Displayed on devices with ECG connected.

See ***ECG Settings*** on page 74.

Temperature Settings

Displayed on devices with ECG Connected.

See ***Temperature Settings*** on page 81.

Noninvasive Blood Pressure Settings

Displayed on devices with NIBP connected.

See ***Noninvasive Blood Pressure (NIBP) Settings*** on page 84.

Activity Monitoring Settings

Displayed on devices with ECG connected.

See ***Position Monitoring Settings*** on page 92.

About

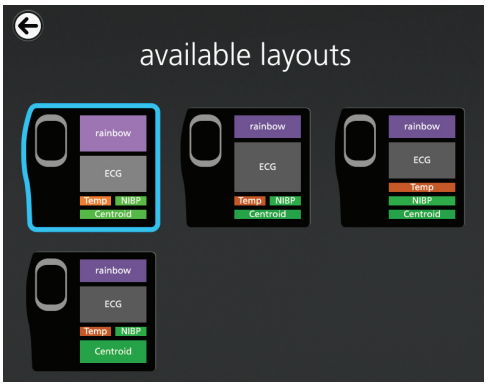
See ***About Root*** on page 142.

Trends Settings

See ***Trend Settings*** on page 143.

Root Layout with Radius VSM

When the Radius VSM is connected to Root, the user will have the option to select from several pre-configured layouts. Image below shows possible layout options available on Root with the Radius VSM connected.



Waveform Settings

Note: This setting displays on Root with Radius VSM connected.

Waveform Settings are located within the *rainbow Settings* for the *Pulse OX* feature of Radius VSM when connected to Root. Use the *Waveform Settings* to set the waveforms displayed in the *Pulse OX* window on the Root *Main Screen*.

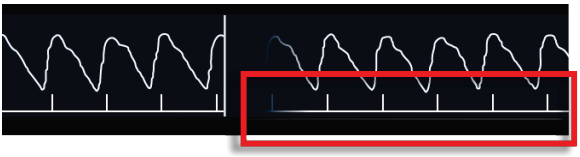
Option	Description	Factory Default Settings	User Configurable Settings
Waveform Mode	Change the Waveform View.	Pleth + Sig IQ + Acoustic	Pleth + Sig IQ, Pleth + Sig IQ + Acoustic, PVi Pleth + Sig IQ, PVi Pleth + Sig IQ + Acoustic, or Acoustic

Waveform Mode

The following section contains examples of some of the waveforms viewable on the *Main Screen*.

Signal IQ Indicators

Signal IQ (SIQ) indicators are displayed as vertical bars for each individual pulsation. The height of the bar provides an assessment of the confidence in the SpO_2 measurement displayed.

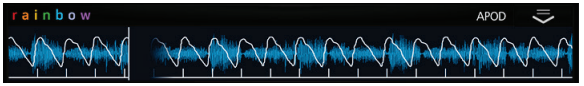


Acoustic Waveform View

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

Pleth + Sig IQ + Acoustic View

The waveform is located above the parameter values. This view contains the Pleth waveform, signal quality indicators, and acoustic waveform (if RRa is available).



About Root

Use the *About* screen on Root to view the serial number as well as software and hardware version information about Radius VSM and accessories. These details may be helpful during troubleshooting.

The below fields are read-only and cannot be configured by the user, unless otherwise noted.

Item	Description
Radius VSM	
Serial Number	Displays the serial number for the device.
Processor	Displays processor version number.
Build Number	Displays build number.
MAC Address	Displays the Radius VSM Bluetooth MAC address.
MSX Tech Board	Displays the version number for the Masimo technology board.
ECG Tech Board	Displays the version number for the Masimo ECG module board.
NIBP Tech Board	Displays the version number for the Masimo NIBP module board.
RSSI	Displays the Bluetooth received signal strength indicator (RSSI).
Locator	Select **Activate** to sound a tone on Radius VSM.

Trends

Trend settings allow the user to configure the Y-axis maximum and Y-axis minimum for each parameter. The maximum and minimum possible values differ depending on the selected parameter.

Trend Settings

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

Option	Description	Factory Default Settings	User Configurable Settings
SpO_2	Y-axis Min	50	0 to 95 in steps of 5
	Y-axis Max	100	5 to 100 in steps of 5
PR	Y-axis Min	25	25 to 235 in steps of 5
	Y-axis Max	200	30 to 240 in steps of 5
Pi	Y-axis Min	0.0	0.0 to 19.0 in increments of 1.0
	Y-axis Max	20.0	1.0 to 20.0 in increments of 1.0
PVi	Y-axis Min	0	0 to 99 in steps of 1
	Y-axis Max	30	1 to 100 in steps of 1
RRa	Y-axis Min	0	0 to 119 in steps of 1
	Y-axis Max	35	1 to 120 in steps of 1
RRp	Y-axis Min	0	0 to 119 in steps of 1
	Y-axis Max	35	1 to 120 in steps of 1
Temperature	Y-axis Min	80.0 ºF	80.0 ºF to 109.9 ºF in increments of 0.1
		26.7 ºC	26.7 ºC to 43.2 ºC in increments of 0.1
	Y-axis Max	110.0 ºF	80.1 ºF to 110.0 ºF in increments of 0.1
		43.3 ºC	26.8 ºC to 43.3 ºC in increments of 0.1
NIBP	Y-axis Min	20	20 to 259 in steps of 1
	Y-axis Max	260	21 to 260 in steps of 1
HR (ECG)	Y-axis Min	30	30 to 295 in steps of 5
	Y-axis Max	200	35 to 300 in steps of 5
PVC (ECG)	Y-axis Min	0	0 to 69 in steps of 1
	Y-axis Max	35	1 to 70 in steps of 1

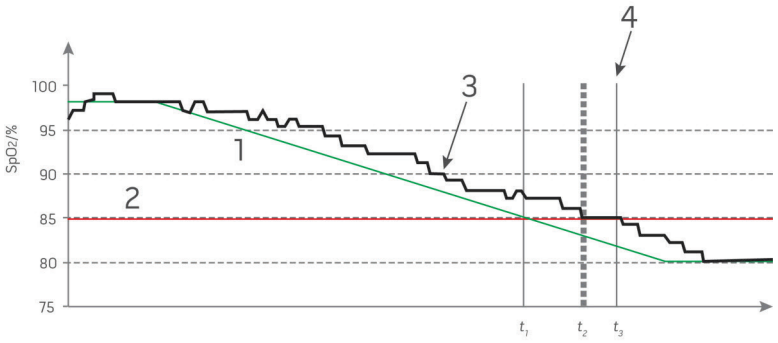
Blood Pressure Measurements using Root

When Radius VSM is connected to Root, blood pressure measurements can be performed directly from Root. Operation is similar to Radius VSM. See ***Blood Pressure Measurements*** on page 87.

Appendix B: Concepts of Alarm Response Delay

Concepts of Alarm Response Delay

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



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

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

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

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

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

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