Operator's Manual

Radius VSM™

Patient-Worn Vital Signs Monitor

Masimo

Not For Sale in the USA - For Export Only

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 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: Use of this device must follow the order of a physician.

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

Wireless Radio: Contains: FCC ID: 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
- Body 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 hospitals 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 body 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.

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: 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: 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 in the 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: Do not connect the Radius VSM charger to an electrical outlet controlled by a wall switch or dimmer.

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, 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: 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 Module remains fully charged.

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

Note: 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 may not reflect the actual body temperature when used on patients undergoing treatments that may alter their normal temperature regulation (e.g., therapeutic hypothermia, antipyretics).

CAUTION: Avoid direct heating or cooling of the sensor application site. Localized temperature exposure of the sensor may result in no or incorrect readings.

CAUTION: Rapid or large changes in ambient temperature may cause no or incorrect readings.

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.

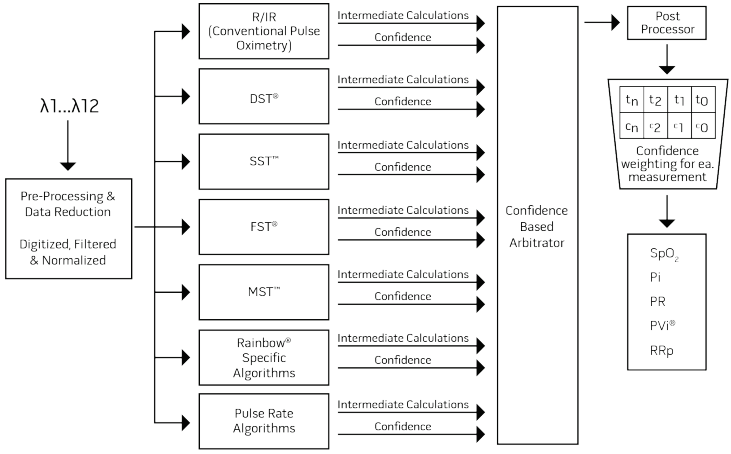
Signal Extraction Technology® (SET®)

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.

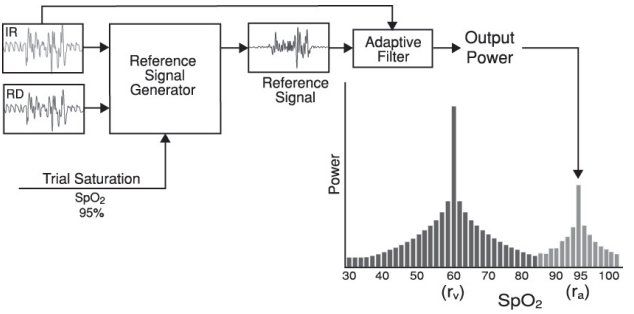
Masimo rainbow SET® Parallel Engines

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].

Citations for Pleth Variability Index (PVi)

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11. *Yu Y., Dong J., Xu Z., Shen H., Zheng J. Pleth Variability Index-Directed Fluid Management in Abdominal Surgery under Combined General and Epidural Anesthesia. J Clin Monit Comput. 2014 Feb 21.*
12. *Desgranges F.P., Desebbe O., Ghazouani A., Gilbert K., Keller G., Chiari P., Robin J.,Bastien O., Lehot J.J., Cannesson M. Br. J. Anaesth 2011 Sep;107(3):329-35.*
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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®)

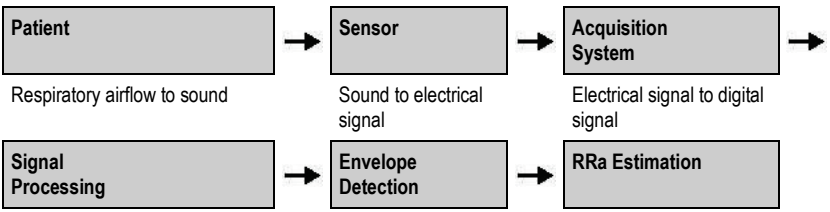
rainbow Acoustic Monitoring (RAM) continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Sensor, which is applied on the patient's neck, translates airflow sounds generated in the upper airway to an electrical signal that can be processed 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 chest. The Radius VSM will process these electrical signals to reproduce the ECG waveform and to provide an estimate of the patient's heart rateand/or respiration rate. The ECG waveform data is also monitored to detect Tachycardia/Bradycardia, Extreme-Tachycardia/Extreme-Bradycardia, Atrial Fibrillation and lethal arrhythmias (i.e. Ventricular Tachycardia, Ventricular Fibrillation, and Asystole).

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 temperature function relies on the principle that the heat flux generated by the body temperature can be inferred by the skin surface temperature to allow for the estimation of the body temperature. The temperature data, which is an adjustment to the sublingual body temperature, is sent to the Radius VSM to be displayed continuously.

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 53.

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

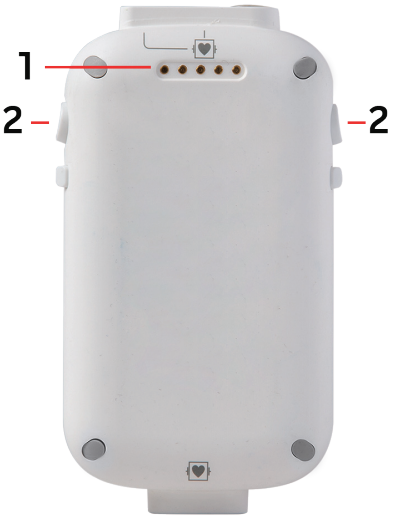
Speaker to provide system sounds and alarms.

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

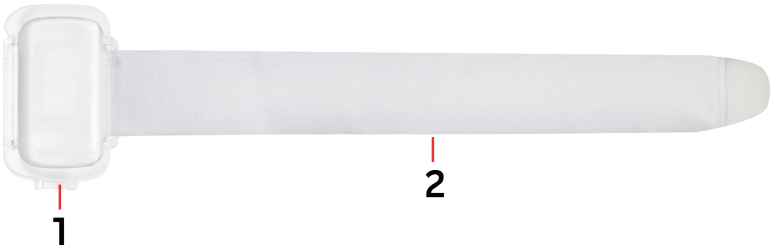
Connections to charge the battery. See ***Battery Charging*** on page 35.

2. Release Buttons

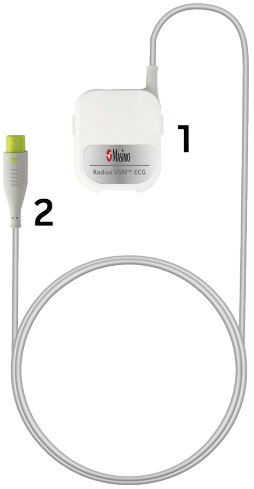
Press to release the tabs securing the Radius VSM to the Armband or charger.

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

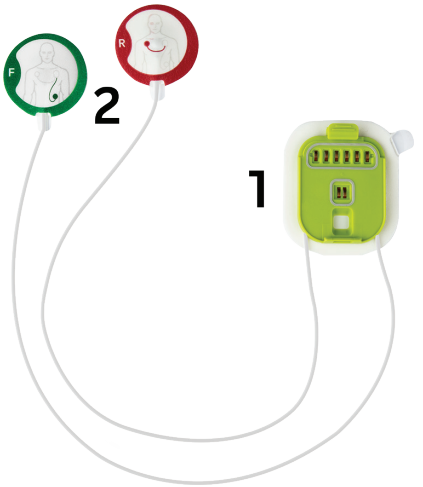
The ECG Module is the reusable part that attaches to the ECG Main Electrode.

The temperature sensor is part of the ECG Module.

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

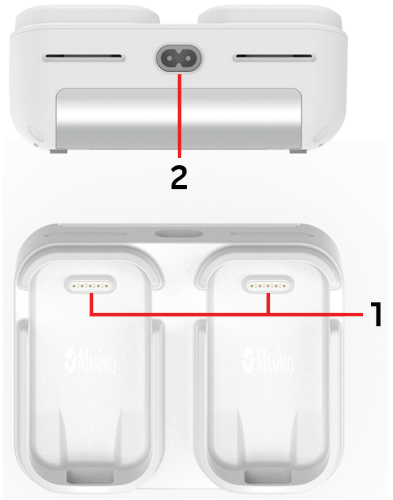
Connects to the Radius VSM.

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. The operator can also be the person the device is attached to and monitoring.

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 27. 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 131.
4. Read the ***Safety Information, Warnings and Cautions*** on page 9.
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 32.
   - For the Radius VSM Charger, connect the charger power cord to a working AC outlet. See ***Radius VSM Charger*** on page 32.
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 53.

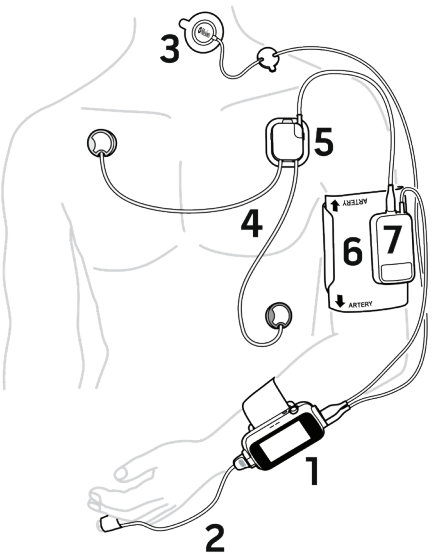
   Device ON: A battery icon displays on the Radius VSM screen, and the *System Status Light* is Green.

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 129.

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 ***Battery Charging*** on page 35.

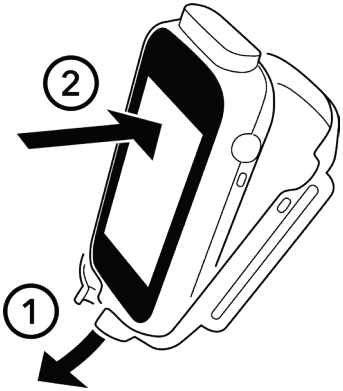
Note: Attach the Radius VSM to the non-dominant arm. However, the Radius VSM can be attached to either arm.

Note: Safety Information, Warnings and Cautions should be read before use. See ***Safety Information, Warnings and Cautions*** on page 9.

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.

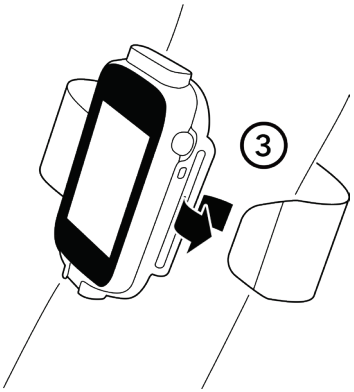
   WARNING: Discontinue and dispose of armband if it appears to be stained or becomes excessively moist to minimize risk of skin irritation.

   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 127.
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

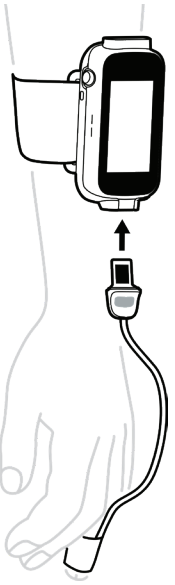
Note: The RRa parameter does not display until an acoustic sensor is connected.

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 31.

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



Attaching an Acoustic Sensor

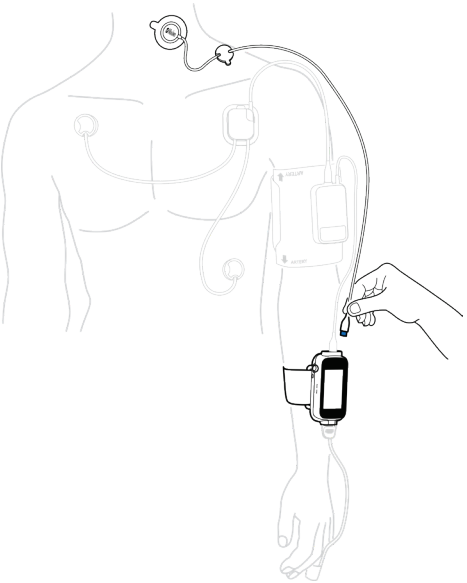
Note: The acoustic sensor should be attached to the same side of the body as the Radius VSM.

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

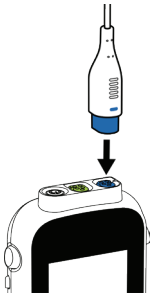
Note: The acoustic sensor is single-patient-use.

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 28.

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 INDEX 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/***.

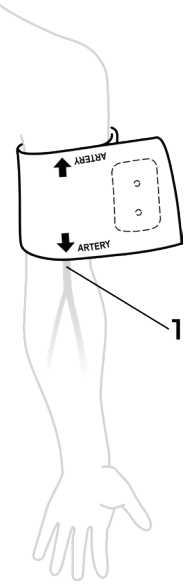
2. Place Cuff on Measurement Site

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.

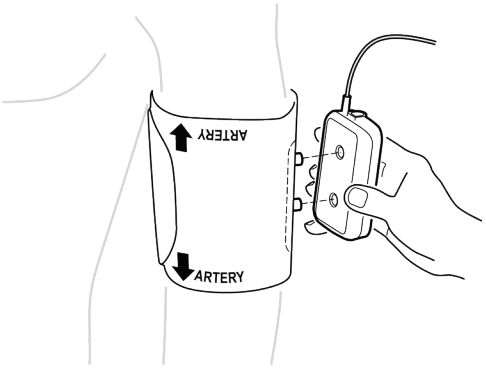
Note: The cuff should fit snugly around the patient's arm for maximum signal quality. The lower edge of the cuff should be located 2 cm (0.8") above the inside bend of the elbow.



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.

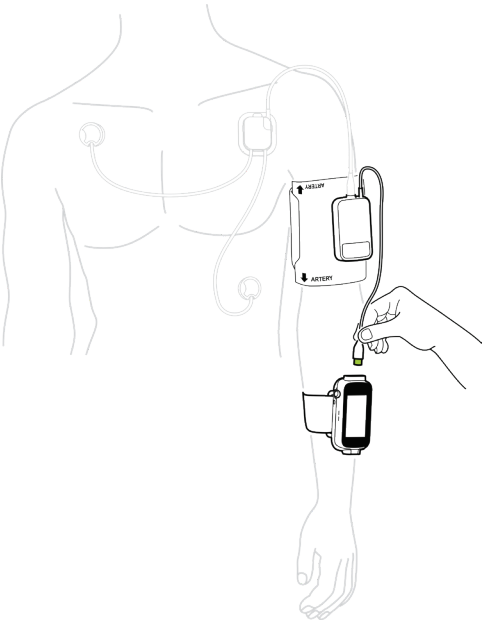


4. Connect the NIBP Module to the Radius VSM

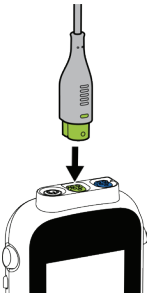
Connect the NIBP Module green cable connector to the green port on Radius VSM.

See ***Front and Top Views*** on page 28.

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 127.
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.

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

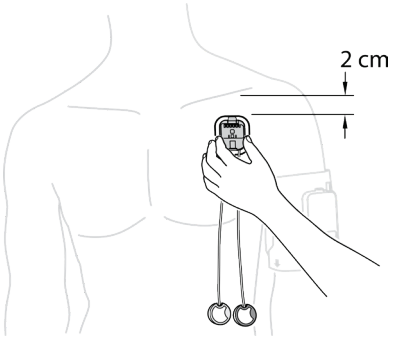
WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

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

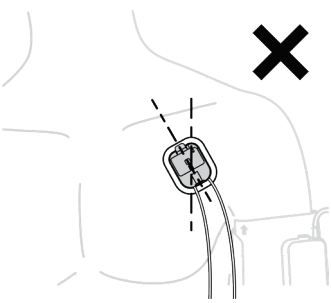
Note: The ECG Electrodes are single-patient-use.

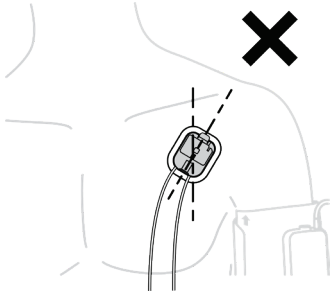
1. Attach main electrode/connector base

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.



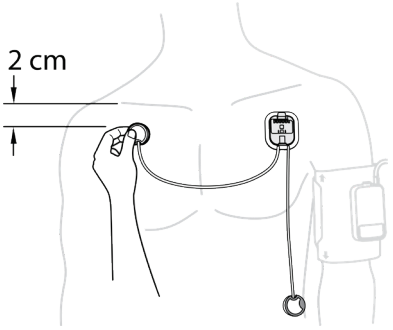
CAUTION: Do not place the main electrode/connector at an angle.





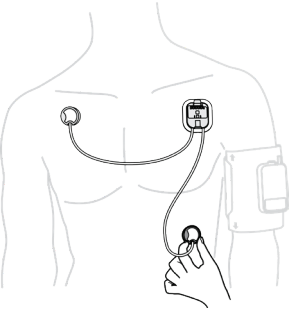
2. Attach second electrode

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.



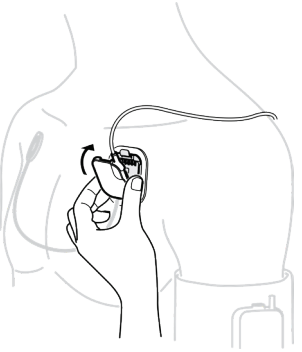
3. Attach third electrode

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

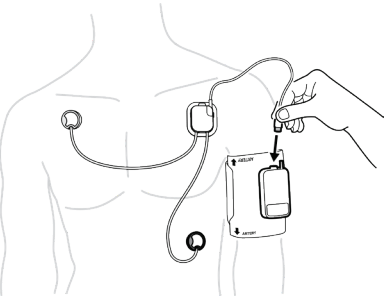
Insert the bottom of the ECG Module into the base and click the top to secure.



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 31.



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 127.
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 58.
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 140. 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.

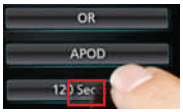
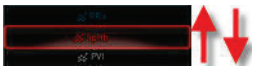
2. Main Menu/Home Button Action menu

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 53.

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.

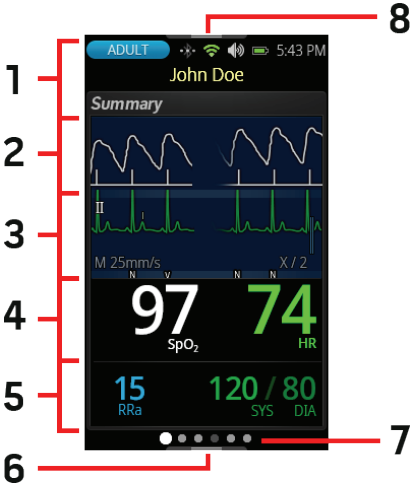
Below is a list of all the different types of controls available on Radius VSM and the various ways to interact with each type of control.

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 139, on page 52.

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.

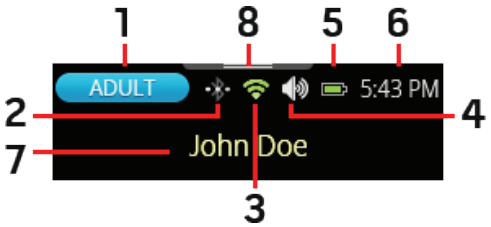
6. Main Menu/Home Button Action Menu Swipe up from the bottom of the screen to display the Main Menu and Home Buttons. See ***Accessing Radius VSM Main Menu Options*** on page 53.

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 11: Alarms and Messages*** on page 95.

About the Status Bar

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



1. Profiles

Displays the current patient Profile.

See ***Chapter 10: Profiles*** on page 93.

2. Bluetooth

Displays Bluetooth connection status.

See ***Bluetooth*** on page 58.

3. WiFi

Displays WiFi connection status.

See ***Wi-Fi*** on page 57.

4. Sound

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

See ***Sounds*** on page 55.

5. Battery Charge Indicator

Displays battery charge remaining.

See ***Battery Charge Indicator*** on page 51.

6. Time

Displays the current time.

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

7. Patient Label

Displays when the patient is admitted.

See ***Appendix A: Radius VSM Operation with Root*** on page 135.

8. Alarm Status/Exception Messages Action Menu

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

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

Battery Charge Indicator

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 53.

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

* Connect the Radius VSM Wearable Monitor to the battery charge adapter to prevent the device from powering OFF and to charge the battery. See ***Battery Charging*** on page 35.

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*.

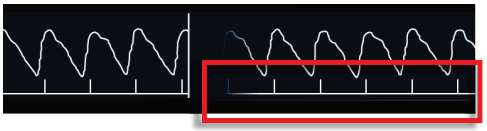
* Radius VSM can be configured to connect to Patient SafetyNet wirelessly by authorized and trained personnel only.

Waveforms

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

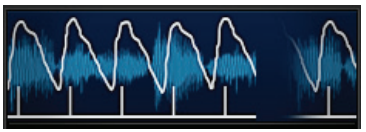
Signal IQ Indicators

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.



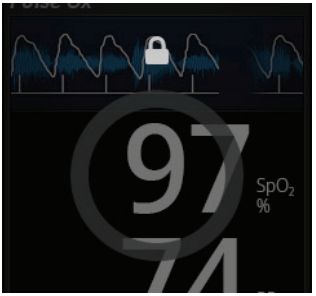
Pleth + Sig IQ + Acoustic View

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 59.



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 28. 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 131.

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:

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 55.

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

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

Trends Settings*, **
See ***Trends*** on page 61.

Profiles*, **
See ***Chapter 10: Profiles*** on page 93.

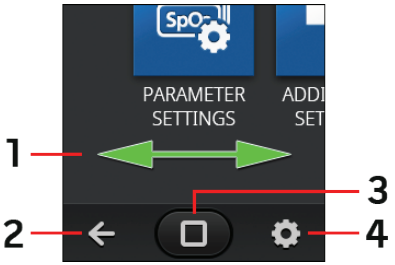
* When Radius VSM is connected to Root, this setting no longer displays on Radius VSM and displays in the Root *Main Menu*. See ***Accessing Root Main Menu Options*** on page 137.

** This icon is neither available nor displayed in the *Main Menu* when *Home Mode Menu Enabled* is ON. See ***Access Control*** on page 59.

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 98.	2 minutes	1, 2, or 3 minutes, Permanent **, ***, or Permanent with Reminder **, ****.

Option	Description	Factory Default Settings	User Configurable Settings
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 59.

** Requires user to have All Mute Enabled turned on in the *Access Control* menu. See ***Access Control*** on page 59.

*** 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 57.

Bluetooth
See ***Bluetooth*** on page 58.

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

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

Access Control **
See ***Access Control*** on page 59.

* This icon is neither available nor displayed in the *Device Settings* menu when *Home Mode Menu Enabled* is ON. See ***Access Control*** on page 59.

** 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
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
Power On Profile	Sets the profile used when the device is powered on. See ***Chapter 10: Profiles*** on page 93.	Previous Profile	Previous Profile or Adult
All Mute Enabled	Enables parameter Alarm Silence menu option. See ***Sounds*** on page 55.	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. See ***Screen Lock Feature*** on page 53.	Off	On or Off
Data Collection Enabled	Enables or disables physical data collection mode.	Off	On or Off
Home Mode Menu Enabled	Enables or disables ability to access parameter alarms and other device settings. See ***Accessing Radius VSM Main Menu Options*** on page 53.	Off	On or Off
Save as Adult	Saves current profile parameter as the Adult Profile.	N/A	Press **Save** to update the profile.
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.
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:

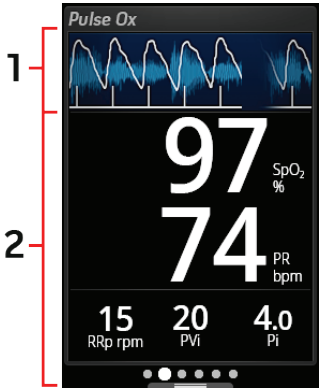
1. From the *Parameter Settings* screen, touch the **About** icon. The following is an example for SpO_2.

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 *
- ***Additional Settings for Pulse Ox*** on page 70

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

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 65.
- ***PVi Settings*** on page 66.
- ***RR Settings*** on page 67.

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 141 *

* 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 141 *

* 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
High Alarm Delay	When a High or Low alarm condition occurs, this feature delays the audible part of an alarm.	NA	0 seconds	0, 10, or 15 seconds
Low Alarm Delay		NA	0 seconds	0, 10, or 15 seconds

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 141 *

* 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 66
- ***Additional Settings for PVi*** on page 67
- ***About Parameter Information*** on page 61
- ***Trend Settings*** on page 141 *

* 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 23. 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 141 *

* 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

Options	Description	Factory Default Settings	User Configurable Settings
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 141 *

* 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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
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

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 70.	APOD	MAX, APOD, NORM
SmartTone	Enable or disable the SmartTone. See ***Sounds*** on page 55.	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)

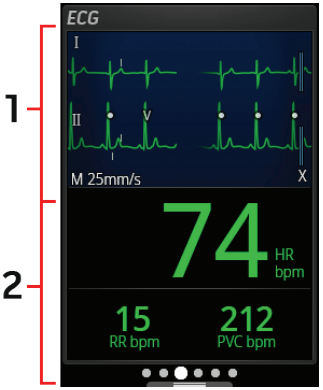
ECG Overview

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.

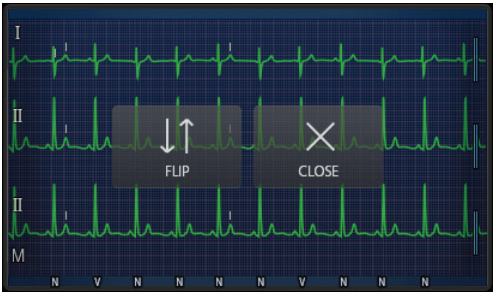
The waveform displays in landscape on the Radius VSM screen.

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.

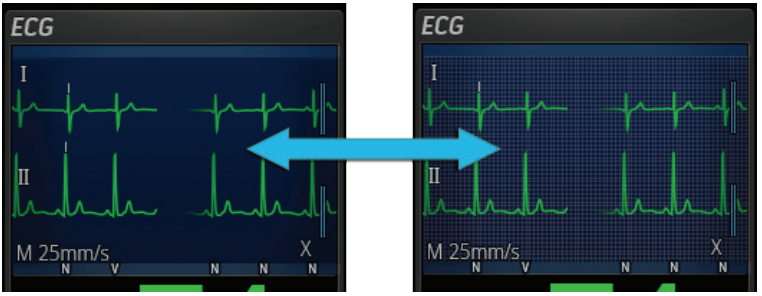


Display Waveform Grid

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 141 *

* 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 141 *

* 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 141 *

* 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 I	Displays the selected ECG lead waveform.	Primary	Primary, I, II, III, aVR, aVL, or aVF
Display Lead II	Displays the selected ECG lead waveform.	Secondary	Secondary, I, II, III, aVR, aVL, or aVF
Gain	Adjust the ECG displayed waveform gain.	5 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.	12.5 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
Extreme Bradycardia HR	Limit to trigger extreme bradycardia detection	40	Off or 20 to 130in steps of 5
Bradycardia HR	Limit to trigger bradycardia detection	50	Off or 25 to 135 in steps of 5
Tachycardia HR	The heart rate limit to trigger Tach detection	120	Off or 55 to 290 in steps of 5

Option	Description	Factory Default Settings	User Configurable Options
Extreme Tachycardia HR	The heart rate limit to trigger extreme Tach detection	180	Off or 60 to 295 in steps of 5
Silence Duration	Sets the amount of time that the alarm is silenced.	2 minutes	30 seconds, 1, 2 or 5 minutes
Arrhythmia Relearn	Initiate for re-learning of rhythm	N/A	Select **Relearn**.
VTach HR	The ventricular heart rate limit to trigger VTach detection	100	15 to 300 in steps of 5
VTach PVC	The PVC run limit to trigger VTach detection	5	3 to 99 in steps of 1
Asystole Threshold	Define the length of time with no Heart Beat is detected	4.00 seconds	2.50 seconds to 4.00 seconds in 0.25 second increments

* Displayed under the *Analysis Settings* when Radius VSM is connected to Root. The *Analysis Settings* are displayed and accessed on Root when Radius VSM is connected to Root.

Additional Settings for ECG

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

Option	Description	Factory Default Settings	User Configurable Options
Lead Code (System)*	Select the region	Code 1	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	Manual	Auto or Manual
Respiration Threshold***	Respiration Rate detection level under Manual Respiration Mode	0 mOhms	-1000 mOhms -10,000 mOhms to 1000 mOhms to 10,000 mOhms in 1000 mOhms steps

* For additional information, see ***Lead System*** on page 78.

** When I or II is selected, RR parameter displays on the *ECG Screen*.

*** Setting available when Respiration Mode is set to Masimo.

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.

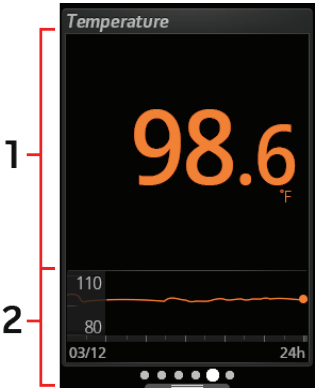
Chapter 7: Temperature

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 body temperatures that are approximations of oral 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. See ***Chapter 7: Temperature*** on page 81.

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 NIBP feature works by noninvasively monitoring the pressure changes during cuff inflation to determine arterial blood 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 87 **

* 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 ***MAP Settings*** on page 85.
   - 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

Options	Description	Alarm Priority	Factory Default Settings	User Configurable Settings
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

MAP Settings

From the *Mean Arterial Pressure Settings* screen, access the following screens:

MAP Alarms on page 85

About Parameter Information on page 61

MAP Alarms

From the *Mean Arterial Pressure* 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	48 to 163 in steps of 1, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	50	Off, or 47 to 162 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 86

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 14: Service and Maintenance*** on page 127.

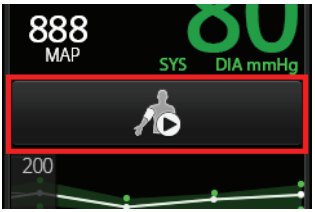
Note: This section is provided as a reference and intended for qualified service professionals only and is password protected.

Blood Pressure Measurements

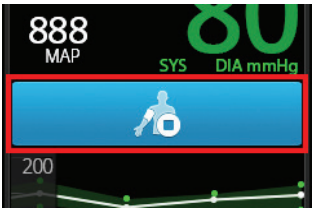
To select the proper cuff and attach to the measurement site, see ***Attaching the Noninvasive Blood Pressure Cuff and Module to the Patient*** on page 39.

Spot Check NIBP Measurement

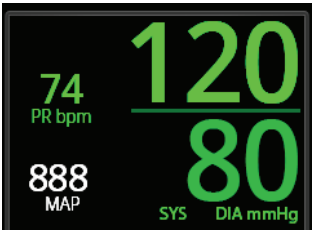
1. Properly place the blood pressure cuff on patient. See ***Attaching the Noninvasive Blood Pressure Cuff and Module to the Patient*** on page 39.
2. Touch the *Start* button to begin measurement.



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* 

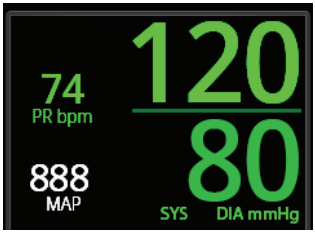
in the *Main Menu*.
4. Open the *Intervals* settings.
5. On the *Intervals* screen, change *Set Mode* to *Schedule*. The set mode can also be changed using the action menu. Press **OK** to confirm.

   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.



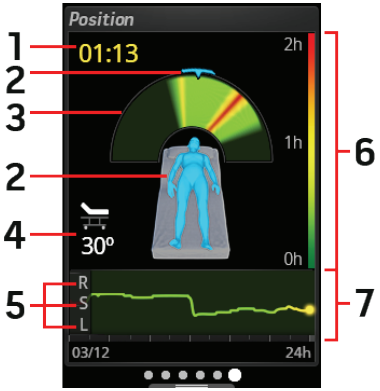
Chapter 9: Position Monitoring

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: Profiles

The following chapter contains information about profiles and profile settings.

Profiles Overview

Radius VSM contains a *Profiles* screen which lets the user customize settings:

- **Adult**
  Adult profile is the factory default profile. Displays in the Status bar as *ADULT* and the color of the Profile button turns Blue.

Note: If no changes are made to the profile settings, Radius VSM automatically resets to the default *Adult* profile after the device is powered off and on again.

The active profile displays in the *Status Bar*. See ***About the Status Bar*** on page 50. In the following example, the *Adult* profile is active.

To restore all Radius VSM settings to factory default settings, see ***Access Control*** on page 59.

Profiles Settings

The Radius VSM can be configured for various patient types through the Profiles option located under the main menu options. See Accessing Main Menu Options.

Use the *Profiles Settings* screen to select patient type.

Option	Description	Factory Default Setting	Configurable Settings
Profile Name	Identifies the profile currently active on Radius VSM.	Adult	Adult, *Adult
Configure Profile	Configure profile options.	NA	Edit **

* Profile can be modified through the *Configure Profile* screen.

** Select to access the *Configure Profile* screen.

Configure Profile

Use the *Configure Profile* screen to select the following options for the profile.

Option	Description	Factory Default Setting	Configurable Settings
NIBP Cuff Size	Select the NIBP cuff size for the profile.	Large	Small, Medium, Large

Chapter 11: 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

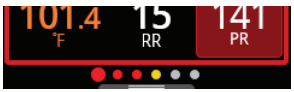
The following table describes visual alarm behaviors.

	**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).

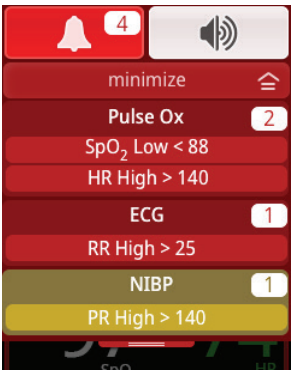
	**High Priority Alarm** The example shown here is a SpO_2 Low alarm for Pulse Ox. The border of the entire Radius VSM display is illuminated, and the explanation of the alarm is shown in the Status Bar (SpO_2 Low) with the effected system (Pulse Ox).
	**Medium Priority Alarm** The example shown here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

When Radius VSM is connected to Root through Bluetooth connection, audible alarms will sound on Radius VSM and Root. Audible alarms can be temporarily silenced by touching the Alarm Silence button on Radius VSM or Root. Visual alarms will continue to display on Radius VSM until the alarm condition has been addressed. For alarm management on Root, see ***Operator's Manual*** for ***Root***.

When Radius VSM is connected to Patient SafetyNet (and not communicating to Root through Bluetooth), audible alarms will sound on Radius VSM and Patient SafetyNet. Audible alarms can be temporarily silenced by touching the Radius VSM Alarm Silence button. Visual alarms will continue to display on Radius VSM until the alarm condition has been addressed.

Note: In the event of temporary loss of power to Radius VSM, the Root will restore alarm setting 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 95.