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

To activate *Audio Pause*, press the icon. It will turn red and the remaining *Audio Pause* Duration time counts down next to the icon. The default duration for *Audio Pause* is 120 seconds. In the example below, *Audio Pause* is activated, and there are 15 seconds left until *Audio Pause* is inactive again (alarms audible again).

To configure *Audio Pause*, see ***Sounds*** on page 55.

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

Radius VSM Messages

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

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

Pulse Ox Messages

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

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Replace Cable or *(RAM) Replace Cable*	The patient cable is non-functional or the patient monitoring time of the cable has expired.	Replace the patient cable.
(Pulse CO-Ox) Cable Near Expiration or *(RAM) Cable Near Expiration*	Patient cable has less than 10% of patient monitoring time remaining.	Replace with new patient cable.
(Pulse CO-Ox) No Cable Connected or *(RAM) No Cable Connected*	Cable not attached or not fully inserted into the connector.	Disconnect and reconnect cable into connector.

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

Message	Potential Causes	Next Steps
(Pulse CO-Ox) No Adhesive Sensor Connected or *(RAM) No Adhesive Sensor Connected*	When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.	Ensure the adhesive portion is firmly connected to the sensor.
(Pulse CO-Ox) Incompatible Adhesive Sensor or *(RAM) Incompatible Adhesive Sensor*	• Not a proper Masimo sensor. • Sensor is attached to a device without an appropriate parameter installed.	• Replace with a proper Masimo sensor. • Use a compatible sensor. Contact your local Masimo Representative to learn more about optional parameter upgrades.
(Pulse CO-Ox) Sensor Initializing or *(RAM) Sensor Initializing*	Device is checking the sensor for proper function and performance.	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.
(Pulse CO-Ox) Sensor Off Patient or *(RAM) Sensor Off Patient*	• Sensor off patient. • Sensor not connected to patient properly. Sensor is damaged.	• Disconnect and reconnect sensor. Reattach sensor. • Properly reapply the sensor to the patient and reconnect the sensor to the device or patient cable. If the sensor is damaged, replace the sensor.
(RAM) RAM Check Sensor	RAM unable to collect data through RAM Sensor.	Ensure proper sensor application. Check that no object is pulling on the sensor cable, which may cause the sensor to peel off.
(Pulse CO-Ox) Low Perfusion Index	Signal strength is too weak.	Move sensor to better perfused site. See on page 105.
(Pulse CO-Ox) Low Signal IQ	Indicates low signal confidence in the value displayed due to poor signal strength.	Ensure proper sensor application. Move sensor to a better perfused site. See ***Signal IQ Indicators*** on page 139, on page 52.
(*Pulse CO-Ox*) *Pulse Search*	Device is searching for pulse.	If device fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.

Message	Potential Causes	Next Steps
(Pulse CO-Ox) Interference Detected or *(RAM) Interference Detected*	• High intensity light (pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight) or other monitor displays. • Incorrect monitor line frequency setting (Hz).	• Place a Masimo Optical Light Shield over the sensor. • Adjust the Line Frequency to the correct Hz setting. See ***Device Settings*** on page 56.
(Pulse CO-Ox) SpO_2 Only Mode	Occurs during an unsuccessful sensor initialization/pulse search routine or during monitoring.	See the directions for use provided with your sensor. Use a Masimo light shield to cover the sensor and adjust the sensor.
"- -" (Dashes shown as parameter value - Invalid parameter alarm)	Unable to provide a parameter value.	Check patient's vital condition.

Electrocardiogram Messages

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

Alarm Message	Description	Alarm Priority	Next Step
Low HR	HR has decreased below the set lower limit.	High	Check patient's vital condition.
High HR	HR has increased above the set upper limit.	High	Check patient's vital condition.
Low RR	RR has decreased below the set lower limit.	High	Check patient's vital condition.
High RR	RR has increased above the set upper limit.	High	Check patient's vital condition.
Asystole Detected	Asystole event detected.	High	Check patient's vital condition.
VTach	Ventricular Tachycardia is detected	High	Check patient's vital condition.
VTach / VFib	Ventricular Fibrillation / Tachycardia is detected	High	Check patient's vital condition.
Bradycardia	Bradycardia is detected	High	Check patient's vital condition.
Extreme Bradycardia	Extreme Bradycardia is detected	High	Check patient's vital condition.
Tachycardia	Tachycardia is detected	High	Check patient's vital condition.

Alarm Message	Description	Alarm Priority	Next Step
Extreme Tachycardia	Extreme Tachycardia is detected	High	Check patient's vital condition.
ECG Inop	ECG Module unable to obtain readings.	High	Verify electrode leads placement. Ensure skin is properly prepared. See ***Attaching the ECG Module and Electrodes to the Patient*** on page 42.
ECG Module Disconnect	ECG Module is disconnected from the Radius VSM Patient-Worn Vital Signs Monitor.	High	Check module connections.
ECG Lead (Lead Identifier) Off	ECG electrode is disconnected from the patient.	High	Check electrode connection to the patient. Ensure skin is properly prepared. See ***Attaching the ECG Module and Electrodes to the Patient*** on page 42.
Replace ECG Sensor	Defective ECG sensor Expired ECG sensor	High	Replace the ECG Sensor.
Apnea	Apnea is detected	High	Check patient's vital condition.

NIBP Messages

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

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

Message	Potential Causes	Alarm Priority	Next Steps
Check NIBP (Module Error)	Device requires service	High	• Contact Masimo Technical Support. See ***Chapter 14: Service and Maintenance*** on page 127.

Temperature Messages

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

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

Position Monitoring Messages

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

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

* Visual alarm only.

Chapter 12: Troubleshooting

Troubleshooting Measurements

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

For additional information, see ***Safety Information, Warnings and Cautions*** on page 9.

Symptom	Potential Causes	Next Steps
Low SIQ message displayed (Low signal quality).	• Sensor is damaged or not functioning. • Improper sensor type or application. • Excessive motion. • Low perfusion.	• Verify Sensor type and size and re-apply sensor. See *Directions for Use* for Sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Minimize or eliminate motion at the monitoring site. • Set to Maximum Sensitivity. See ***Sensitivity Modes Overview*** on page 70.
Difficulty obtaining a reading.	• Inappropriate sensor or sensor size. • Improper sensor type or application. • Low perfusion. • Excessive motion artifact. • Excessive ambient or strobing light. • Low battery/ not plugged into AC power supply. • Interference from line frequency-induced noise.	• Allow time for parameter reading to stabilize. • Verify sensor type and size and re-apply sensor. See *Directions for Use* for sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Verify the device and sensor are configured with the parameter. • Verify proper sensor and sensor size for the patient. • Shield the sensor from excessive or strobing light. • Minimize or eliminate motion at the monitoring site. • Connect AC power supply. • Verify and set 50 or 60Hz menu setting. See ***Localization*** on page 57.
Parameter readings displayed as dashes.	• Parameter may not have stabilized. • Device may not be configured with the parameter. • Sensor is not compatible with the parameter.	• Allow time for parameter reading to stabilize. • Verify sensor type and size and re-apply sensor. See *Directions for Use* for sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Verify the device and sensor are configured with the parameter.

Symptom	Potential Causes	Next Steps
Dimly Lit Parameters	• Low signal quality.	• Assess the patient. • Verify sensor type and size and re-apply sensor. See *Directions for Use* for sensor. • Check if blood flow to the sensor site is restricted. • Check the placement of the sensor. Re-apply sensor or move to a different site. • Replace sensor. • Minimize or eliminate motion at the monitoring site. • Set to MAX Sensitivity. See ***Sensitivity Modes Overview*** on page 70.
Parameter Values Do Not Correlate With Clinical Assessment or Arterial Blood Gas Measurements	• Low perfusion. • Sensor displacement.	• Check for error messages. See ***Chapter 11: Alarms and Messages*** on page 95. • Check placement of sensor or if it is too tight. Reapply sensor or select a new site. Set to MAX sensitivity and confirm that the sensor is securely placed on the patient. See *Directions for Use* for sensor.
Unexpected Parameter Readings	• Low SIQ or Pi values. • Inappropriate sensor size or sensor measurement location.	• Reposition sensor to site with strong SIQ and Pi. Average readings taken from three different sites to improve accuracy. Submit blood sample for laboratory CO-Oximetry test for comparison. • Verify proper sensor for patient size. Verify proper sensor site. See *Directions for Use* for sensor.

Troubleshooting ECG Measurements

Symptom	Potential Causes	Next Steps
Difficulty obtaining a reading	• Improper electrode or electrodes application. • Poor electrode contact. • Excessive Motion Artifact. • ECG signal is weak. • Electrical continuity. • Interference from line frequency-induced noise.	• Allow time for parameter reading to stabilize. • Check for electrode gel dry out. • Use appropriate skin prep. • Check the placement of the electrode. Re-apply electrodes or move to a different site. • Check all electrode, leadwire and ECG module cable connections. • Replace electrodes. • Minimize or eliminate motion at the monitoring site. • Check line frequency filter on equipment.

Symptom	Potential Causes	Next Steps
Intermittent Signal	• Electrical continuity. • Poor electrode contact. • Interference. • Cabling.	• Check all electrode, leadwire and ECG module cable connections. • Check for electrode gel dry out. • Remove all possible static charge, touch metal (bedrail) prior to touching the patient. • Replace electrodes.
Motion Artifact	• Excessive Motion Artifact. • Poor electrode contact. • Electrical continuity. • Interference from line frequency-induced noise. • Cabling.	• Check the placement of the electrode. Re-apply electrodes or move to a different site avoiding large muscle masses. • Check for electrode gel dry out. • Check all electrode, leadwire and ECG module cable connections. • Minimize or eliminate motion at the monitoring site. • Replace electrodes.
Low Amplitude	• Equipment. • Patient physiology. • Electrical continuity. • Skin impedance.	• Adjust monitor settings to increase ECG amplitude. • Change lead selection. • Check all electrode, leadwire and ECG module cable connections. • Check for electrode gel dry out.
Parameter readings displayed as dashes.	• Parameter may not have stabilized or may be out of range.	• Allow time for parameter reading to stabilize. • Verify electrode placement or move to a different site. • Replace electrodes.
Unexpected Parameter Readings	• Inappropriate electrode measurement location.	• Compare pulse rate with other means. • Verify proper electrodes site. See ***Attaching the ECG Module and Electrodes to the Patient*** on page 42 for electrode placement.

Troubleshooting Radius VSM

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

For more information, see ***Chapter 11: Alarms and Messages*** on page 95.

Symptom	Potential Causes	Next Steps
Device does not turn on	• Depleted Battery. • Internal failure.	• Charge the battery. • Contact Masimo Service. See ***Contacting Masimo*** on page 131.

Symptom	Potential Causes	Next Steps
System failure technical alarm active (continuous speaker tone)	• Internal failure.	• To silence an alarm, press the Alarm Silence button. If alarm continues to sound, turn off the Radius VSM. • Contact Masimo service. See ***Contacting Masimo*** on page 131.
Speaker does not work	• Device audible settings may be incorrect. • Internal failure.	• Turn Radius VSM Off and On. • Check that Alarms have not been silenced. • Check the device is not in All Mute. • Check that the device speaker is not being muffled. • Contact Masimo service. See ***Contacting Masimo*** on page 131.
Device screen is blank	• The device is Off. • Battery may be depleted. • Internal failure.	• Turn Radius VSM Off and On. • Charge the battery. • Contact Masimo service. See ***Contacting Masimo*** on page 131.
Touchscreen/Buttons do not respond when pressed	• EMI (Electro Magnetic Interference) • Internal failure.	• Relocate the device from other devices that may cause electromagnetic interference. • Contact Masimo service. See See ***Contacting Masimo*** on page 131.
Battery run time significantly reduced	• Battery not fully charged. • Battery damaged. • Battery capacity effected.	• Check battery charge level indicator. • Check battery is fully charged. • Replace battery. See ***Contacting Masimo*** on page 131. • Contact Masimo service. See ***Contacting Masimo*** on page 131.
Battery does not charge	• Charging Connector makes poor connection. • Battery damaged. • Internal failure.	• Ensure device is seated properly in charging adapter. • Replace battery. See ***Contacting Masimo*** on page 131. • Contact Masimo service. See ***Contacting Masimo*** on page 131.
Device does not detect that patient cable is connected	• Cable connector not properly connected to the device. • Damaged connector. • Damaged cable. • Cable expired. • Internal failure.	• Remove and reconnect cable. • Ensure the connector is fully connected to the device. • Replace cable. • Contact Masimo service. See ***Contacting Masimo*** on page 131.

Symptom	Potential Causes	Next Steps
Device does not detect that the sensor is connected	• Sensor not properly connected to device. • Improper placement of sensor. • Damaged sensor. • Sensor expired. • Internal failure.	• Remove and reconnect sensor. • Ensure the connector is fully connected to the device. • Reapply sensor to the patient. Refer to sensor *Directions For Use*. • Replace sensor. • Turn Radius VSM Off and On. • Contact Masimo service. See ***Contacting Masimo*** on page 131.
Device does not detect that ECG module is connected	• Connection between the module and ECG module is not properly connected. • Damaged connector. • Damaged ECG module cable. • Internal failure.	• Remove and reconnect the ECG module cable. • Ensure the connector is fully connected to the device. • Replace ECG module cable. • Contact Masimo service. See ***Contacting Masimo*** on page 131.
Device does not detect that the electrodes are connected	• Electrodes not properly connected to device. • Improper placement of electrodes. • Damaged electrodes. • Accessory connector makes a poor connection. • Internal failure.	• Remove and reconnect electrodes. • Ensure the connector is fully connected to the device. • Reapply electrodes to the patient. • Replace electrodes. • Check ECG module cable connection. • Turn Radius VSM Off and On. • Contact Masimo service. See ***Contacting Masimo*** on page 131.
ECG Board fails to operate	• Internal failure.	• Turn Radius VSM Off and On. • Contact Masimo service. See ***Contacting Masimo*** on page 131.
Device does not detect that NIBP module is connected	• Connection between the device and NIBP module is not properly connected. • Damaged connector. • Damaged NIBP module cable. • Internal failure.	• Remove and reconnect the NIBP module cable. • Ensure the connector is fully connected to the device. • Replace NIBP module. • Contact Masimo service. See ***Contacting Masimo*** on page 131.

Symptom	Potential Causes	Next Steps
Device does not communicate to other external devices through wireless connection	• External device is not compatible. • Wi-Fi is not turned on and/or not correctly configured. • Location does not have wireless availability. • Connected network is not available. • Internal failure.	• Check external device compatibility. • Check that the wireless feature is on and correctly configured. See ***Wi-Fi*** on page 57. • Check wireless availability for location. • Check network settings and availability. • Contact Masimo service. See ***Contacting Masimo*** on page 131.

Chapter 13: Specifications

Radius VSM Device Specifications

Pulse Oximetry Specifications

Display Range and Display Resolution

Measurement	Display Range	Resolution
SpO_2 (Functional Oxygen Saturation)	0% to 100%	1%
PR (Pulse Rate)	25 bpm to 240 bpm	1 bpm
Pi (Perfusion Index)	0.02 to 0.99	0.01
	1.0 to 9.9	0.1
	10 to 20	1
PVi (Pleth Variability Index)	0 to 100	1
RRa (Acoustic Respiration Rate)	4 rpm to 70 rpm	1 rpm
RRp (Respiration Rate from the Pleth)	4 rpm to 70 rpm	1 rpm

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

Accuracy (ARMS)* [1]

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

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

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

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

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

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

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

SpO2 Performance Specifications

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

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

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

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

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

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

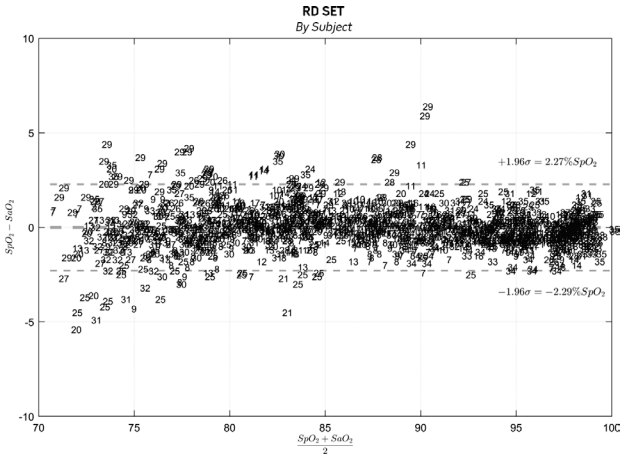


Figure 1: Disposable (RD SET Series) Sensors (ARMS 70-100%)

RRp Performance Specifications

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

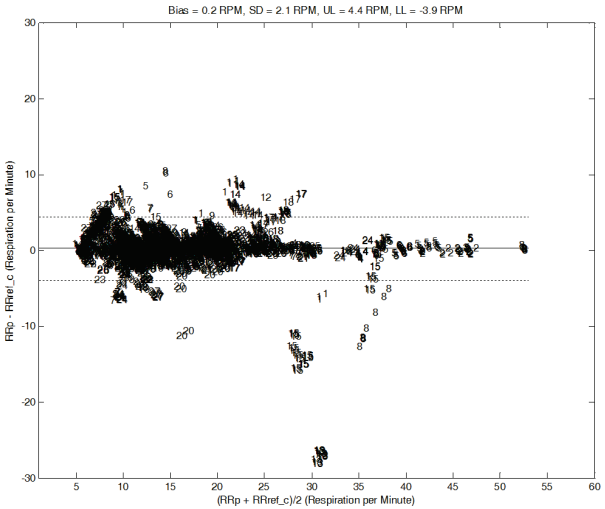


Figure 2: Subject by Subject Bland-Altman plot of RRp with respect to RRref_c

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

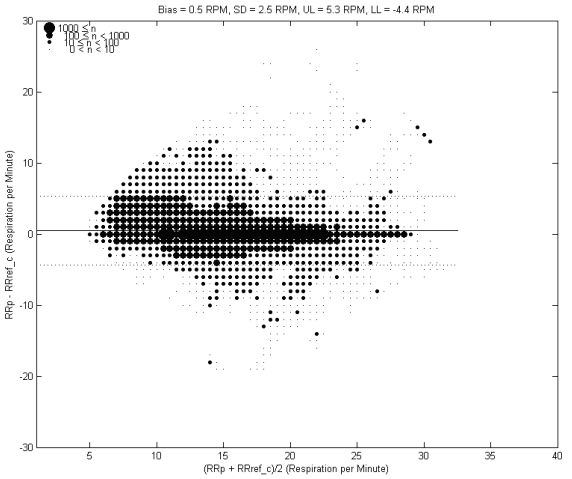


Figure 3: Bland-Altman plot of RRp with respect to RRref_c

Electrical

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

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

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

Physical Characteristics

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

Display

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

Alarms

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

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

* When volume is set to the highest level.

Wireless Specifications

Communication (Wi-Fi)	
Type	WLAN Radio: IEEE 802.11 a/b/g/n
Frequency	2.4 GHz - 802.11b/g/n: 2412-2472 MHz 5.0 GHz - 802.11a/n: 5150-5250 MHz, 5250-5350 MHz, 5470-5725 MHz, 5725-5825 MHz
Max Peak Output Power	WLAN 18dBm

Communication (Wi-Fi)	
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	OFDM, BPSK, QPSK, CCK
Modulation Signals	Analog and Digital
Available Data Rates	802.11a - 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11b - 1, 2, 5.5, 11 Mbps 802.11g - 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11n – MCS 0-7 HT20/HT40

Communication (Bluetooth)	
Type	Bluetooth and Bluetooth LE
Frequency	2402-2480 MHz
Max Peak Output Power	Bluetooth; 8.2 dBm Bluetooth LE; 4.75 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	Bluetooth; DH5, 2DH5, 3DH5 Bluetooth LE; GFSK
Modulation Signals	Analog and Digital
Available Data Rates	Bluetooth 1, 2, 3 Mbps

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

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

ECG Specifications

Display Range and Display Resolution

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

Accuracy (ARMS)*

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

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

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

ECG Performance Characteristics

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

Parameter	Specification
Sweep Speeds	25 mm/second (default) 12.5 mm/second 6.25 mm/second
Monitoring ECG Bandwidth	0.67 Hz to 40 Hz (Adults)
Diagnostic ECG Bandwidth	0.05 Hz to 150 Hz

Physical Characteristics

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

Noninvasive Blood Pressure (NIBP) Specifications

Display Range

Measurement	Patient Population	Display Range
Systolic	Adult	60 to 230 mmHg
Diastolic	Adult	40 to 130 mmHg
MAP	Adult	47 to 163 mmHg
Pulse Rate (PR)	Adult	30 to 240 bpm

Accuracy

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

Pressure Range

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

Physical Characteristics

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

Temperature Specifications

Display Range and Display Resolution

Measurement	Display Range	Resolution
Temperature	0.0°C to 100.0°C (32.0°F to 212.0°F)	0.1 °C or °F

Accuracy

Temperature [12], [13]		
Laboratory	25°C to 43°C (77°F to 109.4°F)	±0.3°C (0.54°F)
Clinical	Measurement Range	36°C to 42°C (96.8°F to 107.6°F)
	Bias	-0.2°C (-0.36°F)
	Limits of Agreement	1.0°C (1.8 °F)
Application Site		Chest

Position Monitoring Specifications

Display Range

Measurement	Display Range
Patient Recline Angle [14]	-180° to 180°
Time in Current Position	0:00 to 99:59

Radius VSM Charger Specifications

Physical Characteristics

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

Environmental

Environmental Conditions	
Operating Temperature	0°C to 40°C (32°F to 104°F)
Storage/Transport Temperature	-20°C to 60°C [15] (-4°F to 140°F)
Operating Humidity	10% to 95%, non-condensing
Storage/Transport Humidity	10% to 95%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1060 mbar (540 hPa to 1060 hPa)

Compliance

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

Safety Standards Compliance
ANSI/AAMI ES 60601-1:2005+A1:2012
AAMI EC57:2012
CAN/CSA C22.2 No. 60601-1:2014
IEC 60601-1:2005 + A1:2012
IEC 60601-1-6:2010 + A1:2013
IEC 60601-1-8:2006 + A1:2012
IEC 60601-1-11:2015
IEC 60601-2-25:2011

Safety Standards Compliance
IEC 60601-2-27:2011
IEC 80601-2-30:2018
IEC 60601-2-47:2012-02
IEC 80601-2-49:2018
ISO 80601-2-56:2017 + A1:2018
ISO 80601-2-61:2017

Equipment Classification per IEC 60601-1	
Type of Protection	Internally powered (Battery power)
Degree of Protection of Electrical Shock	Defibrillation proof CF-Applied Part
Protection against harm from liquid ingress	
Radius VSM Battery Charger	IP21, Protected from objects greater than 12 millimeters and condensation.
NIBP Module	IP22, Protected from objects greater than 12 millimeters and water spray less than 15 degrees from vertical.
Radius VSM Patient-Worn Vital Signs Monitor, ECG Module	IP24, Protected from objects greater than 12 millimeters and water spray from any direction.
Mode of Operation	Continuous

Guidance and Manufacturer's Declarations - Electromagnetic Compatibility

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

Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	Performed over 0.15-80 MHz
	6 Vrms	6 Vrms	Performed on the following ISM (industrial, scientific and medical) bands of frequency: The bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Radius VSM, including cables, than the recommendation separation distance calculated from the equation applicable to the frequency of the transmitter.
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment.			

* U_T: Rated voltage for the equipment

Test Specifications for Enclosure Port Immunity to RF Wireless Communication Equipment

Test Frequency (MHz)	Band (a) (MHz)	Service (a)	Modulation (b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-395	TETRA 400	Pulse modulation **(b)** 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM **(c)** +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation **(b)** 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation **(b)** 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3. 4. 35: UMTS	Pulse modulation **(b)** 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation **(b)** 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation **(b)** 217 Hz	0.2	0.3	9
5500						
5785						

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

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

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC		Separate collection for electrical and electronic equipment (WEEE)
	Defibrillation-proof. Type CF Applied Part	FCC ID:	Identifies unit has been registered as a radio device
Rx ONLY	**Caution:** Federal law restricts this device to sale by or on the order of a licensed physician.		ETL Intertek certification See ***Declarations on Page 1*** for certifications
EC REP	Authorized representative in the European community		Federal Communications Commission (FCC) Licensing
IP21	IP21, Protected from objects greater than 12 millimeters and condensation.	IP22	IP22, Protected from objects greater than 12 millimeters and water spray less than 15 degrees from vertical
IP24	IP24, Protected from objects greater than 12 millimeters and water spray from any direction		Recyclable
	Not made with natural rubber latex		Do not use if package is damaged
	Non-Sterile	####	Masimo reference number
	Manufacturer		Date of manufacture YYYY-MM-DD
SN	Serial number	LOT	Lot code
	Bluetooth	REF	Catalog number (model number)
	Storage temperature range		Keep dry
	Atmospheric pressure limitation		Fragile, handle with care

Symbol	Description	Symbol	Description
	Storage humidity limitation		Class II Equipment
MD	Medical Device		Battery, General
	NIBP		Arm Circumference
	Cuff index line must fall within range markings for an accurate measurement		Index Line
	Artery symbol and arrow should be placed over brachial or femoral artery		China Restriction of Hazardous Substances
	The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual	 209-J00417	This equipment contain specific radio equipment that has been certified to the Technical Regulator Certification under the Radio Law.
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Citations

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

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

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

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

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

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

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

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

[8] This represents approximate run time using a fully charged battery with typical continuous Masimo SET, Acoustic respiratory rate, 3 leads ECG measurements with body temperature and posture orientation, display off, Wi-Fi is on, periodic (4 times/hour) NIBP measurement, and no alarm or pulse tones active.

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

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

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

[12] The laboratory accuracy of the temperature sensor is ±0.3°C (0.54°F) for an input surface temperature range of 25°C to 43°C (77°F to 109.4°F).

[13] The temperature sensor has been validated on 118 subjects, 5 years of age or older, against a reference sublingual clinical thermometer. Results have shown a clinical bias of -0.2°C (-0.36°F) with limits of agreement 1.0°C (1.8°F) in the measurement range 36°C to 42°C (96.8°F to 107.6°F).

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

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

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

Chapter 14: Service and Maintenance

Cleaning

The Radius VSM, NIBP Module and ECG Module are reusable devices. The devices are supplied and used non-sterile. The devices should be cleaned before and after it has been applied to a patient and/or in accordance with local and governmental regulations to minimize the risk of cross-contamination.

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

WARNING: Before cleaning, read ***Cleaning and Service Warnings and Cautions*** on page 17.

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

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

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

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

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

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

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

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

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

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

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

Safety Checks

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed by trained personnel at regular intervals or in accordance with local and governmental regulations.

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

To conduct Safety Checks follow the procedure outlined in this chapter. If Radius VSM fails any of the described tests, discontinue its use and refer to ***Chapter 12: Troubleshooting*** on page 105.

Before performing the following tests, do the following:

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

Power-On Self-Test

To conduct a Power-On Self-Test

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

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

Touchscreen Function Test

To conduct a Touchscreen Function Test

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

Speaker Test

To conduct a Speaker Test

1. With Radius VSM fully charged and powered on, enter the *Sounds* settings. See ***Sounds*** on page 55.
2. Increase and decrease the Alarm Volume and Pulse Tone Volume levels. The speaker should respond and sound in relationship to the adjustment.
   - If the speaker does not sound, see ***Chapter 12: Troubleshooting*** on page 105.

Alarm Limit Test

To Conduct an Alarm Limit Test

1. Connect a sensor to the Radius VSM. Place the sensor on a finger to obtain an SpO_2 value.
2. Change the Low SpO_2 Alarm parameter to a value two points above the currently displayed value. See ***SpO2 Alarms*** on page 64.
3. Verify that the audible alarm sounds and the visual alarm displays with the set alarm limit.
4. Silence the alarm. See ***Chapter 11: Alarms and Messages*** on page 95.
5. Reset the Low SpO_2 alarm limit to the original settings.

Battery Test

To Conduct a Battery test

1. Dock the Radius VSM on the Battery Charging Adapter. Make sure the connection pins of the Radius VSM are in contact with the adapter.

2. Verify that the Radius VSM is charging. The System Status Light flashes to indicate that the Radius VSM is charging. See ***Front and Top Views*** on page 28.
3. Un-dock the Radius VSM from the Battery Charging Adapter.
4. Turn Radius VSM on and confirm operation.

Maintenance

Battery Operation and Maintenance

The Radius VSM includes a lithium ion rechargeable battery.

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

The Radius VSM battery requires approximately 4 hours for charging.

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

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

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

NIBP Calibration

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

To enter the Calibration menu:

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

Manometer

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

Pass Criteria

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

Equipment

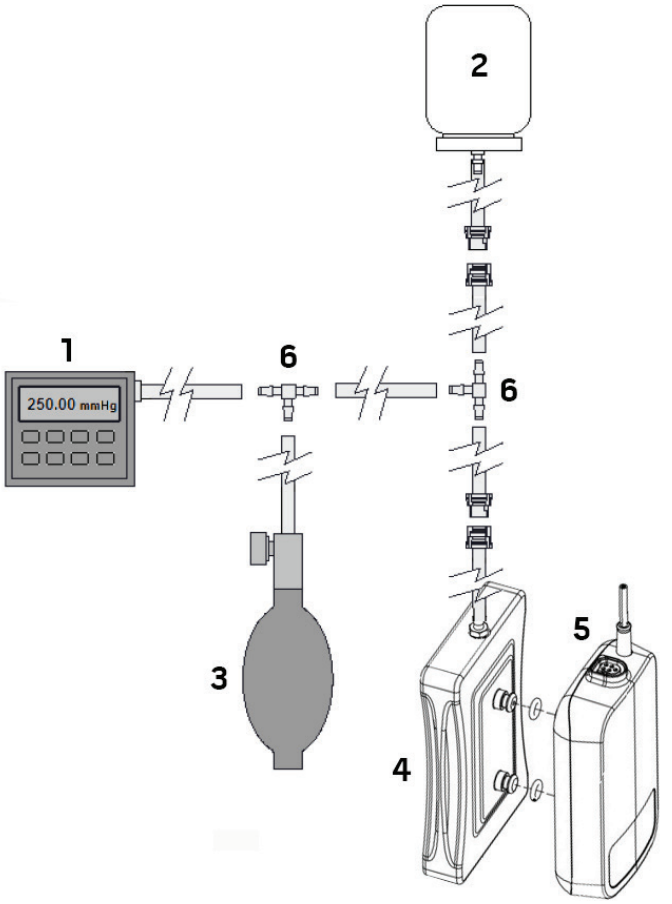
- Calibrated Manometer*
- Pneumatic "T" Adapters
- Masimo NIBP Module adapter fixture
- 500mL bottle

- Hand Bulb
- Connection Tubing

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

Procedure

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



2. Power ON the manometer.
   - Verify the manometer has been zeroed.
   - Set the unit of measurement to mmHg.
   - Verify the manometer has been calibrated.
3. Power ON the Radius VSM and enter the *Calibration* menu.

4. Press **Manometer**.
5. Press **Start**.
6. Apply various pressures (0mmHg to 280mmHg) to the NIBP module with the hand bulb.
7. Compare the NIBP module pressure to the manometer pressure:
   - If the NIBP module pressure and manometer pressure differ WITHIN the ±3mmHg tolerance, then the NIBP module has PASSED the calibration test and no further action is needed. Go to step 7.
   - If the NIBP module pressure and manometer pressure differ BEYOND the ±3mmHg tolerance, contact Masimo Technical Services. See ***Masimo Technical Services*** on page 131.
8. Disconnect the manometer, 500mL bottle and hand bulb from the Masimo NIBP Module adapter fixture.
9. Power OFF the manometer.

Repair Policy

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

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

To return the device for service, refer to ***Return Procedure*** on page 131.

Return Procedure

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

- A letter describing in detail any difficulties experienced with the Radius VSM. Include the RMA number in the letter.
- Warranty information, a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the Radius VSM is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the Radius VSM has been decontaminated for bloodborne pathogens.
- Return the Radius VSM to the shipping address listed in ***Contacting Masimo*** on page 131 below.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001
www.masimo.com

Limited Warranty

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

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

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

Exclusions

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

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

Limitation of Warranty

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

Sales & End-User License Agreement

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

Restrictions

1. Copyright Restrictions: The Software and the accompanying written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged, or included with other software, or the written materials is expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of this Agreement. Nothing in this License provides any rights beyond those provided by 17 U.S.C. §117.
2. Use Restrictions: Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other device. Purchaser may not disclose, publish, translate, release, distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Software or the written materials.
3. Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Masimo's prior written consent; except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.
4. U.S. Government Rights: If Purchaser is acquiring Software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the Software and documentation are deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the Software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this Agreement.

Appendix A: Radius VSM Operation with Root

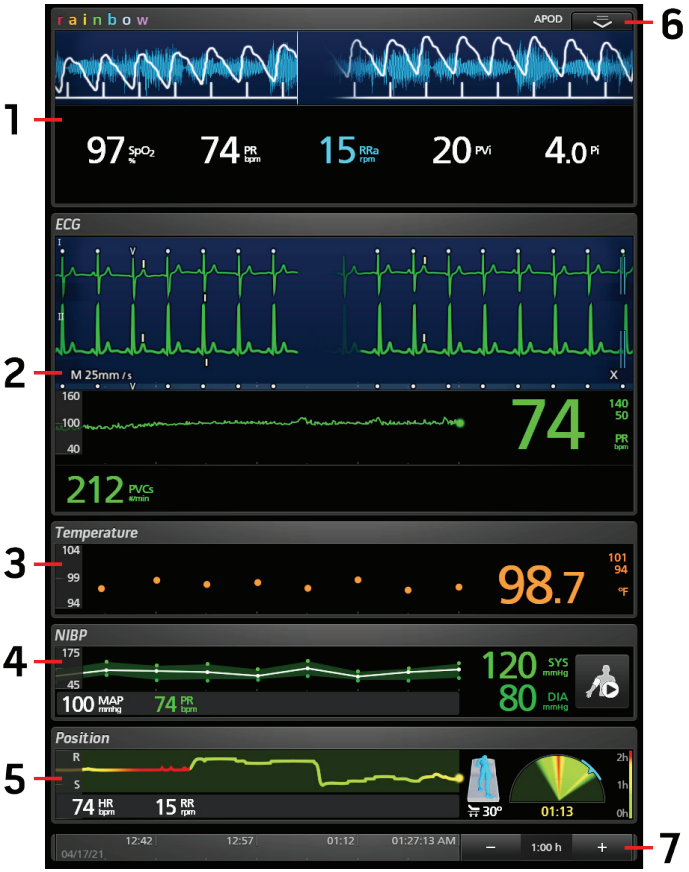
Overview

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

Operation

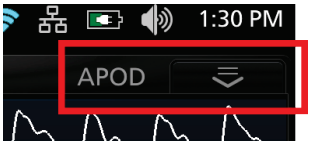
About the Root Main Screen

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



Ref.	Feature	Description
1	Pulse Ox Window	Displays the pulse oximeter parameter information from Radius VSM. See ***Chapter 4: Operation*** on page 47.
2	ECG Window	Displays the ECG information from Radius VSM. See ***Chapter 6: Electrocardiogram (ECG)*** on page 73.
3	Temperature Window	Displays the Temperature information from Radius VSM. See ***Chapter 7: Temperature*** on page 81.
4	NIBP Window	Displays the NIBP information from Radius VSM. See ***Chapter 8: Noninvasive Blood Pressure (NIBP)*** on page 83.
5	Position Monitoring Window	Displays the Position Monitoring information from Radius VSM. See ***Chapter 9: Position Monitoring*** on page 91.
6	Action Menu	Provides access to settings and view modes. See ***About the Action Menu*** on page 136.
7	Trend View Controls	Provides the ability to modify the Trend View display. See ***Trend View Controls*** on page 136.

About the Action Menu



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

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

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

- **Waveform** - Opens the *Waveform Settings*. See ***Waveform Settings*** on page 139.
- **Sensitivity** - Cycles through the available sensitivity modes, APOD, NORM and MAX. See ***Sensitivity Modes Overview*** on page 70.
- **Trend View** - Displays values in Trend View.
- **Analog** - Displays values as a needle pointing to graduations in a circular array around a dial.

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

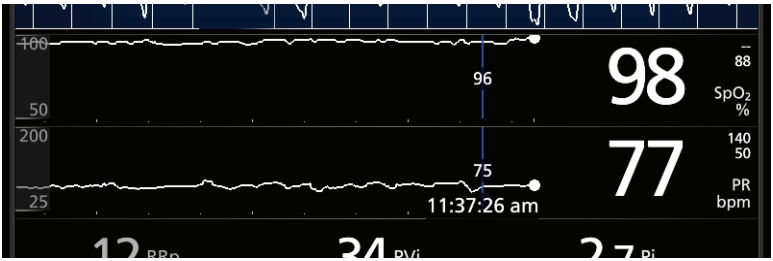
- **Intervals** - Opens the intervals setting screen. See ***Schedule NIBP Measurement*** on page 88.

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

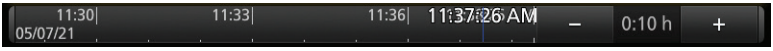
Trend View Controls

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

Trend View Example



Trend View Controls



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

Accessing Root Main Menu Options

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

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

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

Layout

See ***Root Layout with Radius VSM*** on page 138.

Pulse Ox Settings

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

ECG Settings

Displayed on devices with ECG connected.

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

Temperature Settings

Displayed on devices with ECG Connected.

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

Noninvasive Blood Pressure Settings

Displayed on devices with NIBP connected.

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

Activity Monitoring Settings

Displayed on devices with ECG connected.

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

About

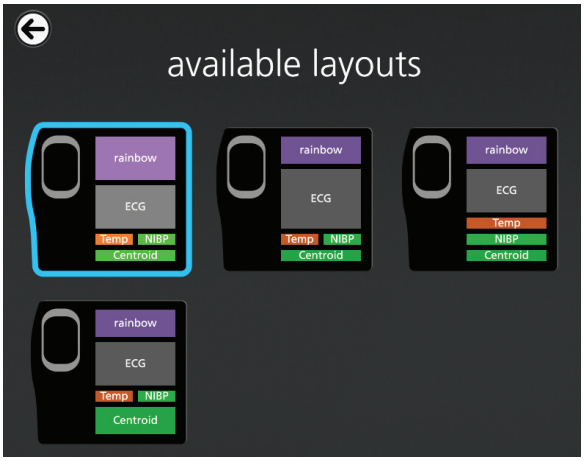
See ***About Root*** on page 140.

Trends Settings

See ***Trend Settings*** on page 141.

Root Layout with Radius VSM

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



Waveform Settings

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

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

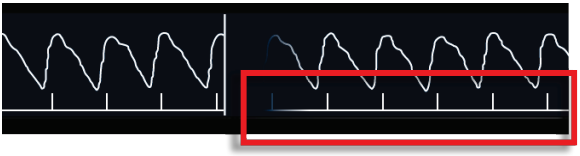
Option	Description	Factory Default Settings	User Configurable Settings
Waveform Mode	Change the Waveform View.	Pleth + Sig IQ + Acoustic	Pleth + Sig IQ, Pleth + Sig IQ + Acoustic, PVi Pleth + Sig IQ, PVi Pleth + Sig IQ + Acoustic, or Acoustic

Waveform Mode

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

Signal IQ Indicators

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

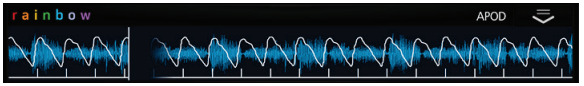


Acoustic Waveform View

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

Pleth + Sig IQ + Acoustic View

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



About Root

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

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

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

Trends

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

Trend Settings

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

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

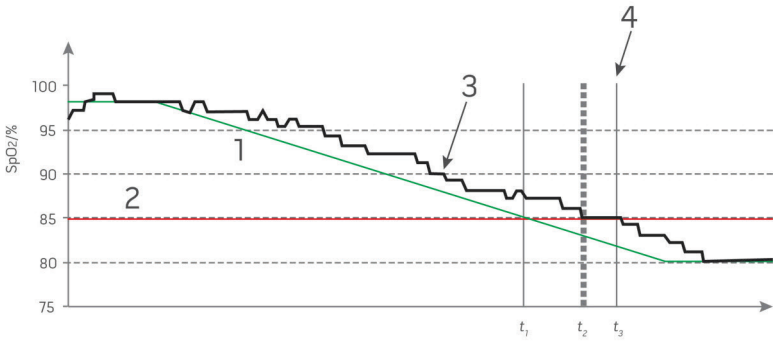
Blood Pressure Measurements using Root

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

Appendix B: Concepts of Alarm Response Delay

Concepts of Alarm Response Delay

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



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

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

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

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

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

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