

Root®

Operator's Manual



These operating instructions intend to provide the necessary information for proper operation of the Root®.

There may be information provided in this manual that is not relevant for your system.

Do not operate Root without completely reading and understanding these instructions.

NOTICE:

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


CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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

Wireless Radio

IC:7362A-RDS7A IC Model: RDS7A

FCC ID: VFK-RDS7A Model - RDS7A

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Medical electrical equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1/CAN/CSA C22.2 No. 601.1

Patents: www.masimo.com/patents.htm

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About this Manual

This manual explains how to set up and use Root. Important safety information relating to general use of Root 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 instrument 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 Intended Use

Product Description and Features

Root is a patient monitoring and connectivity platform to transform care. It offers multiple high-impact innovations for broad applications across the continuum of care.

- Instantly interpretable, high-visibility display of Masimo's breakthrough SET® and rainbow® SET measurements from Masimo's Radical-7® Pulse CO-Oximeter (Radical-7) and the Radius-7™ Wearable Pulse CO-Oximeter (Radius-7).
- Intuitive, touchscreen navigation for easy and adaptable use in any hospital environment.
- Flexible measurement expansion through Masimo Open Connect (MOC-9™).
- Designed for third-party measurement expansion to allow other companies to add to the platform measurements.
- Built-in network connectivity gateway through Iris™ for standalone devices such as IV pumps, ventilators, beds, and other patient monitors.
- Docking and charging station for Radical-7 and Radius-7 devices.

For all prescribing information and instructions for use of the compatible medical devices that are connected to Root, see Operator's Manual or Instructions for Use for the specific medical device.

Intended Use

The Masimo Root Monitoring System is indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments.

Root can transmit data for supplemental remote viewing and alarming (e.g., at a central station).

Root can be used with the optional Radical 7, ISA product family and/or the SEDLine module.

Root is intended to be used with connected measurement modules compatible with Root interfaces.

Indications for Use

The Masimo Root Monitoring System is indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments.

The Masimo Root Monitoring System can transmit data for supplemental remote viewing and alarming (e.g., at a central station).

The optional Masimo Radical 7 Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical 7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate to multi-parameter devices for the display of those devices.

The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO₂, ISA AX+ and ISA OR+), intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

ISA CO₂: CO₂

ISA AX+: CO₂, N₂O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+: CO₂, O₂, N₂O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA CO₂, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO₂ is also intended to be used in road ambulances. The intended patient population is adult, pediatric and infant patients.

The optional SEDLine Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

The optional Radius-7 Wearable Pulse CO-Oximeter and accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (PR) and/or respiratory rate (RRa). The Radius-7 Wearable Pulse CO-Oximeter and accessories are indicated for use with

adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

Safety Information, Warnings and Cautions

CAUTION: Root® is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use. Refer to Operator's Manuals of Patient Safety Net, Radical 7, Radius-7, ISA and SEDLine for additional safety information, warnings and cautions.

Safety Warnings and Cautions

WARNING: Do not use Root if it appears or is suspected to be damaged.

WARNING: Do not adjust, repair, open, disassemble, or modify the Root. Injury to personnel or equipment damage could occur.

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

WARNING: To ensure safety, only use Masimo authorized devices with Root.

WARNING: Explosion Hazard: Do not use the Root in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

WARNING: To reduce the risk of explosion, only replace battery with Masimo supplied parts.

WARNING: Fire Hazard: To protect against fire hazard, replace only with fuses of same type, current rating, and voltage rating.

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

WARNING: Do not remove the back panel of the device. This could cause injury to personnel or device damage.

WARNING: Electrical Shock Hazard: To protect against injury, follow the directions below:

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

WARNING: Electrical Shock Hazard: Injury to personnel could occur. Do not plug in or remove the power cord with wet hands. Ensure that your hands are clean and dry before touching the power cord.

WARNING: When positioned on a flat surface, the device should be secured with a mounting system recommended by Masimo.

WARNING: To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.

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

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

CAUTION: Do not place the Root where the controls can be changed by the patient.

CAUTION: To ensure patient isolation, connect only Masimo devices that have been designed for Root.

CAUTION: Equipment intended to be connected to signal input/signal output ports should comply with applicable electrical safety standards to further minimize the risk of electric shock. Only devices that have been configured to operate with Root may function properly when connected.

CAUTION: Only use the AC power cable provided by Masimo. Using a different AC power cable could cause damage to Root. Check the power cord and plug to ensure that it is intact and undamaged.

CAUTION: To avoid risk of electrical shock, this equipment must only be connected to a supply mains with a protective earth connection. Do not under any circumstances remove the grounding conductor from the power plug.

CAUTION: Use a grounded outlet for proper equipment grounding. A hospital-grade outlet is required.

CAUTION: Do not place Root where the appliance inlet or the AC power plug cannot be readily disconnected.

Note: Disconnect the device from AC mains by removing the AC power cord connector from the device inlet.

Note: If there is any doubt about the integrity of the protective earth conductor arrangement, operate the Root on internal battery power until the AC power supply protective conductor is fully functional.

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

Performance Warnings and Cautions

WARNING: Root may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: Root may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

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

WARNING: Do not place the Root against a surface that may cause the alarm to be muffled.

CAUTION: Ensure the speaker is not covered.

CAUTION: Before using Root under high intensity surgical lights, confirm that the display settings allow for clear display of measurements.

CAUTION: Do not connect to an electrical outlet controlled by a wall switch or dimmer.

CAUTION: Do not place the Root on electrical equipment that may affect the instrument, preventing it from working properly.

CAUTION: Failure to charge Root promptly after a Low Battery alarm may result in the instrument shutting down.

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

CAUTION: If the Radical-7 or Radius-7 stops communicating with Root, parameters and measurements will not show on the Root; however, this will not affect Radical-7's or Radius-7's ability to monitor the patient.

CAUTION: In order to establish and maintain Root'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 \leq 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 \leq 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.

Note: The wireless communication status between Root and Patient SafetyNet is displayed by Patient SafetyNet.

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

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

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

Cleaning and Service Warnings and Cautions

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

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

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

CAUTION: Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any AC power source.

CAUTION: An operator may only perform maintenance procedures specifically described in the manual. Refer servicing to qualified service personnel trained in the repair of this equipment.

CAUTION: Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

Note: Excessive cleaning solution can flow into the device and cause damage to internal components.

Compliance Warnings and Cautions

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

WARNING: Do not incinerate the battery.

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

CAUTION: Consideration to the compliance of the IEC 60601-1 standard should be made when configuring Root as part of a Medical System.

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

Note: Use Root in accordance with the *Environmental Specifications* section in the Operator's Manual.

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

Note: 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.

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 A 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: To satisfy RF exposure requirements, this device and its antenna must operate with a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Note: This equipment has been tested and found to comply with the Class A limits for medical devices according to the EN 60601-1-2: 2007, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

Note: This Class A digital apparatus complies with Canadian ICES-003.

Note: Root is not intended for use during patient transport outside the healthcare facility.

Chapter 1- Description

Root can be used in the following ways:

- As a docking station and charger for Radical-7 and Radius-7.
- As a bedside monitoring display for parameters on Radical-7, Radius-7 and MOC-9 modules.
- As a connectivity gateway for standalone devices.

Features

Front View

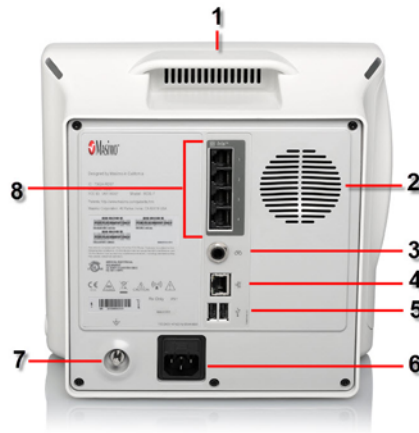


Ref.	Feature	Description
1	Docking Station	Provides a docking station for the Radical-7 and Radius-7 (Note: Battery Charging Adapter required for Radius-7). While docked, the Radical-7 can communicate monitored parameters and measurements.*
2	Root Display and Touchscreen	Provides an interface for user interactions.
3	Home Button	Provides access to the Main Screen.

Ref.	Feature	Description
4	Root Charging Indicator	Shows an indication of the battery charge for Root.
5	AC Power Indicator	Shows an indication of AC power connection Root.
6	Radical-7 Charging Indicator	Shows an indication of battery charge for the Radical-7 in the Docking Station.

**Only the touchscreen version of the Radical-7 is able to communicate monitored parameters and measurements. All other versions can only charge in the docking station but not communicate with Root.*

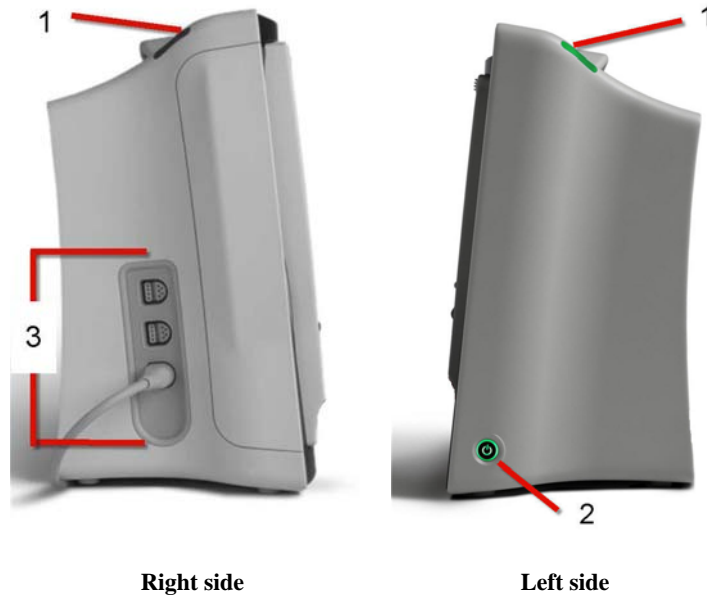
Back View



	Feature	Description
1	Handle	Allows the user to transport Root.

	Feature	Description
2	Speaker	Provides audible notification.
3	Nurse Call Connector	Provides a connection to a Nurse Call system.
4	Ethernet Port	Provides a network connection to Root using an RJ-45 cable.
5	USB Ports (2)	Provide USB 2.0 connectivity.
6	Power Entry Module	Contains the input connector for a hospital grade AC power cord and the fuse holder.
7	Equipotential Ground Connector	Provides optional functional earthing for Root to eliminate potential differences. The use of the Equipotential Ground Connector should be in accordance with IEC 60601-1.
8	Iris Connectivity Ports (4)	Provide connection for standalone devices.

Side Views



	Feature	Description
1	System Status Lights	Provides an indication of alarms and system messages. See System Status Lights.
2	Power Button	Places Root in Power On, Standby and Power Off modes.
3	MOC-9 Ports (3)	Provide connectivity for MOC-9 modules.

Chapter 2- Setting Up

Unpacking and Inspection

To unpack and inspect Root

1. Remove Root from the shipping carton and examine it for signs of shipping damage or exposed electronics.
2. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.
3. Confirm that you have all components for the Root:
 - Root
 - AC Power Cord

If anything is missing or damaged, contact Masimo's Technical Service Department. See Return Procedure.

Guidelines for Setting Up

Root has a built-in bracket interface that allows it to be mounted on a pole or roll stand.

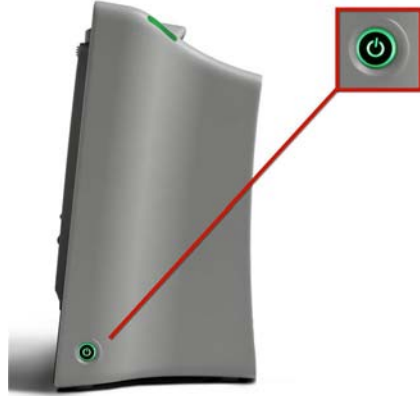
When setting up Root, follow these guidelines:

- Place on a stable, hard, flat and dry surface near the patient.
- Maintain a minimum of three (3) centimeters (one [1] inch) of free space around Root.
- Ensure that the back panel Speaker is not covered to avoid a muffled alarm sound.
- Charge Root's battery fully before use. See Initial Battery Charging.

Root should not be operated outside the environmental conditions listed in the specifications section. See Environmental Specifications.

Power On

The Power Button can be used for Power On, Standby, and Power Off. To Power On, press the Power Button for two (2) seconds until a single audible tone sounds.






Once Root turns on, if no Radical-7, Radius-7 or MOC-9 module is connected, the Root display shows the following message: *Please Connect a Device*. The user is now able to connect Radical-7, Radius-7 and MOC-9 module.



For information about Standby Mode and Power Off, See Standby and Power Off.

Initial Battery Charging

To charge the battery for the first time

1. Securely plug the AC power cord into power entry module.
2. Plug the hospital grade AC power cord into an AC power source.
3. Verify that Root's battery is charging by ensuring that the AC Power Indicator (1) is green and the Battery icon on the Status Bar (2) is solid green or has the charging symbol. See AC Power Indicator and About the Status Bar.

(1)

(2)
4. The Root Charging Indicator remains orange while the battery is charging and will illuminate green when Root is fully charged. See Root Battery and About the Status Bar.


See Safety Informations, Warnings and Cautions.

Radical-7 Connection

It is recommended that Root be powered on before performing the steps below.

- Snap the Radical-7 into the Docking Station.
- If the Radical-7 is not yet turned on, press the power button on the Radical-7 to power it on.
- When properly connected, the Radical-7 Charging Indicator light will illuminate. An illuminated Radical-7 Battery icon will also appear in the Status Bar.
- Root display will show active measurements and parameters.



For Radical-7 charging conditions, see Radical-7 Charging Indicator.

Nurse Call Connection

Use a Nurse Call connection cable to connect to a Nurse Call System.



To connect to a Nurse Call System

1. Identify the Nurse Call connection end (1/4 inch round female connector) of the cable.
2. Insert the Nurse Call connection cable securely into the compatible port on Root.
3. Depending on the connection type of the Nurse Call System, it may be necessary to orient the other end of the Nurse Call connection cable to fit correctly into the system connection.
4. For more information, see Device Output.

Chapter 3- Operation

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

About the Status Bar

At the top of the Main Screen is the Status Bar with interactive icons. Each icon provides a shortcut to a menu item or an action on Root. An example is shown below.

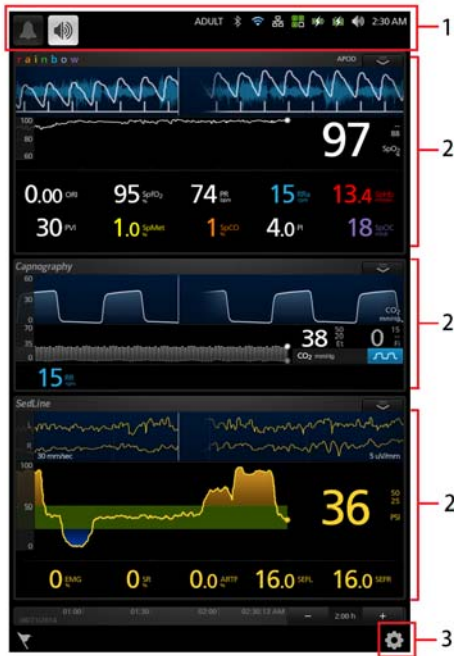


Ref.	Feature	Description
1	Alarm Silence	Displays alarm status and mutes all audible alarms for Root, Radical-7, Radius-7 and MOC-9 modules. See Alarm Silence.
2	Audio Pause	Displays Audio Pause status and temporarily silences an alarm event. See Audio Pause.
3	Profiles	Provides access to the <i>Profiles</i> screen. The example shown illustrates that Profiles is currently set to <i>Adult</i> for an adult patient. See Profiles.
4	Bluetooth	Provides access to the <i>Bluetooth</i> screen. If this icon is visible, then Bluetooth connectivity has been enabled. See Bluetooth.

Ref.	Feature	Description
5	Wi-Fi	Provides access to the <i>Wi-Fi</i> screen. If this icon is visible, then Wi-Fi connectivity has been enabled. The icon itself also indicates the strength of the wireless signal. See Wi-Fi.
6	Ethernet	Provides access to the <i>Ethernet</i> screen. If this icon is visible, then Ethernet connectivity has been enabled. See Ethernet
7	Iris	Provides access to the <i>Iris</i> screen. The example shown above indicates that standalone devices are connected to Ports 1, 2 and 3 and the information is being sent to Patient SafetyNet or Connectivity Gateway. The color of the icon matches the status colors of connected standalone devices on the Iris screen. See Iris.
8	Radical-7 Battery	Displays charging status for Radical-7 and provides access to the <i>Battery Radical</i> screen. The example shows that the battery is currently charging. See Radical-7 Charging Indicator.
9	Root Battery	Displays charging status for Root and provides access to the <i>Battery Root</i> screen. The example shows that the battery is currently charging. See Root Charging Indicator.
10	Sounds	Provides access to the <i>Sounds</i> screen to adjust alarm and pulse tone volume. This icon does not indicate the actual volume level of the alarm and pulse tone. See Sounds.
11	Current Time	Displays the current time and provides access to the <i>Localization</i> screen which contains settings related to local time, language and geography. See Localization.

About the Main Screen

The Main Screen consists of several features. The following shows the Main Screen when three different devices are connected, Radical-7 (top) showing rainbow® parameters and measurements, Phasein module (middle) showing capnography measurements and SedLine module (bottom) showing brain function measurements.


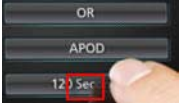









Ref.	Feature	Description
1	Status Bar	Displays system status as well as icons that provide shortcuts to menu items or actions. See About the Status Bar.
2	Windows	Provides a dynamic, user-configurable display area for all the data from connected medical devices.

Ref.	Feature	Description
3	Main Menu icon	Provides access to the configuration options for Root and connected medical devices. See Accessing Main Menu Options

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. The availability of navigation features is dependent on the connected medical devices.

Action	Illustration	Example	Description
Press			Touch and release. Action performed once finger is released.
Slide			Touch, move (left, right, up or down), and release. Moves an object across the display.
Swipe			Touch, move (left, right, up or down), and release quickly.
Pinch			Touch, move, and release via two touch points. Moving touch points apart zooms in, and moving them together zooms out.
Drag and Drop		See Customizing Windows.	Touch, hold, drag an object to desired position, and drop it by releasing.

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

Control	Applicable Actions	Description
Toggle	Slide knob	Switches between toggle states

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

Control	Applicable Actions	Description
		position
	Press anywhere outside spinner	When open, collapses spinner
Button	Press	Performs action (as defined by the button description)
Icon Menu	Press tile	Opens menu specified by tile
	Swipe left or right (anywhere)	Scrolls icons left or right
	Press bottom indicator icon	Quickly centers tile corresponding to indicator icon
Window	Press parameter or measurement	When no parameter or measurement alarm is present, opens parameter or measurement menu When parameter or measurement alarm is present, silences parameter or measurement alarm
	Press and hold	Enables parameter and measurement drag and drop
Well	Press parameter or measurement	When no parameter or measurement alarm is present, opens parameter or measurement menu When parameter or measurement alarm is present, silences parameter or measurement alarm
	Press and hold	Enables parameter and measurement drag and drop
Live	Swipe down	Separates pleth and acoustic waveforms

Control	Applicable Actions	Description
Waveform	Swipe up	Combines pleth and acoustic waveforms
Trend Line	Pinch in	Zooms in
	Pinch out	Zooms out
	Pan	Changes time range
	Press y-axis	Opens parameter or measurement trend menu
Trend Zoom	Press '+'	Increases time range
	Press '-'	Decreases time range
	Press time label	Resets time range to default
Alarm Silence icon	Press	Silences all alarms
Audio Pause icon	Press	Enables Audio Pause
Other Status Bar icons	Press	Opens relevant menu
Back Arrow	Press	Exits menu, abandons any changes

Menu Navigation

When navigating through menus and 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.



To navigate to the previous screen, press the arrow at the top left corner of the touchscreen.



To return to the *Main* Screen, at any time, press the **Home Button** at any time. The Home Button is always illuminated when Root is powered on.

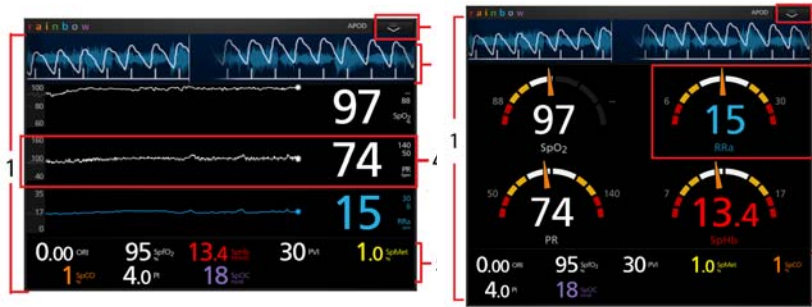


Understanding Windows

Root creates a Window for Radical-7, Radius-7 and compatible medical devices that are connected to Root. Parameters or measurements can be expanded or minimized within a Window to customize view. Radical-7 Windows are shown in the examples below.

Windows provide waveforms along with either a Trend View or an Analog View. Trend View displays each parameter or measurement alongside a graph of its values over time. Analog View displays values in relation to alarm ranges.

Details about the displayed information of parameters and measurements can be found in the instructions for use or Operator's Manual of Radical-7, Radius-7 and MOC-9 modules.




Trend View

Analog View

	Feature	Description
1	Window	The area where all data from a docked Radical-7, Radius-7 or connected MOC-9 module are displayed.
2	Drop Down Settings Menu	
3	Waveform	Shows a parameter or measurement over time (only for Radical-7, Radius-7 and MOC-9 modules).

	Feature	Description
4a	Trend Display	(Available only in Trend View) Parameters and measurements are shown as Trend Displays in Trend View. A parameter or measurement's Trend Display includes its Value Range, Numeric Value, Alarm Limits and Parameter label. Using Trend View.
4b	Analog Gauge	(Available only in Analog View) Parameters and measurements are shown as Analog Gauges in Analog View. A parameter's Analog Gauge includes its Alarm Limits, Numeric Value, Parameter Label, as well as Alarming, Caution and Normal Ranges. See Using Analog View.
5	Well	Displays parameters and measurements which are not shown as Trend Displays or Analog Gauges.

Using Trend View

In Trend View, a parameter or measurement is displayed as a graph of its values over time. If a Window supports Trend View, then  (Trend View icon) displays in the upper right corner. Press the icon to view parameter or measurement data in Trend View.

The following diagram and table describe key features of a parameter's Trend Display in Trend View.




	Feature	Description
1	Value Range	Indicates current viewing of the parameter or measurement. Press to access the Trend menu where the minimum and maximum of the range can be modified.

	Feature	Description
2	Trend Line	Displays parameter and measurement over a period of time. Zoom in and out of a Trend Line by pinching out and in.
3	Numeric Value	Indicates current reading of the parameter or measurement.
4	Alarm Limits	Indicate high and low alarm limits for the parameter or measurement, if supported.
5	Parameter or Measurement Label	Indicates the name of the parameter or measurement.

Using Analog View

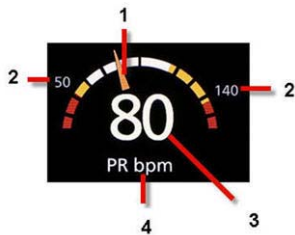
The Analog View shows parameter and measurement data as a needle pointing to graduations in a circular array around a dial. This view provides indications of change that can be interpreted at a quick glance.

Analog View displays alarming and normal ranges of a parameter or measurement. These indicators can be used to alert clinicians to a patient's condition. To understand specific parameters or measurements, refer to the instructions for use or operator's manuals for Radical-7, Radius-7 and the appropriate MOC-9 module(s).

If a Window supports Analog View, then  (Analog View icon) displays in the upper right corner. Press the icon to view parameter and measurement data in Analog View.

The following diagrams and tables describe key features of a parameter's Gauge in Analog View.

When alarm limits for a specific parameter or measurement are set, the corresponding Analog gauge re-orientes itself.



General features of the Analog View are:

Ref.	Feature	Description
1	Needle	Indicates current status of a parameter or measurement.
2	Alarm Limits	Indicate high and low alarm limits for the parameter or measurement.
3	Numeric Value	Indicates current reading of the parameter or measurement

Ref.	Feature	Description
4	Parameter or Measurement Label	Indicates the name of the parameter or measurement.

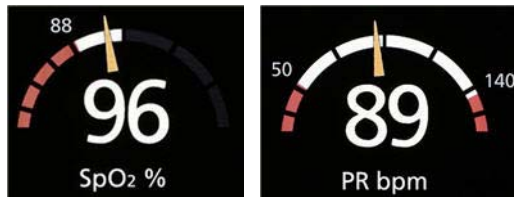


Specific ranges of the Analog View are:

Ref.	Feature	Color	Description
1	Normal Range	White	Area of the display range where an alarm will not be triggered.
2	Caution Range	Yellow	Area of the display range that provides a caution indicator.
3	Alarming Range	Red	Area of the display range where an alarm will be triggered.

Some ranges display as quarter circles, others display as half circles. A quarter circle displays when the value has a physiologic normal level at one end of the range. A half circle displays when the value has a physiologic normal level in the middle of the display range.

In the example below, the SpO₂ gauge is shown as a quarter circle, where values lower than 88% will trigger an alarm, and the PR gauge is shown as a half circle, where values below 50 bpm and above 140 bpm will trigger an alarm.



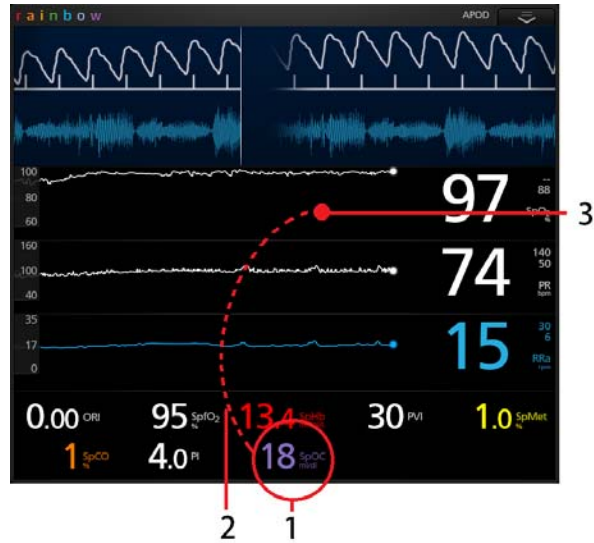
Quarter Circle

Half Circle

Customizing Windows

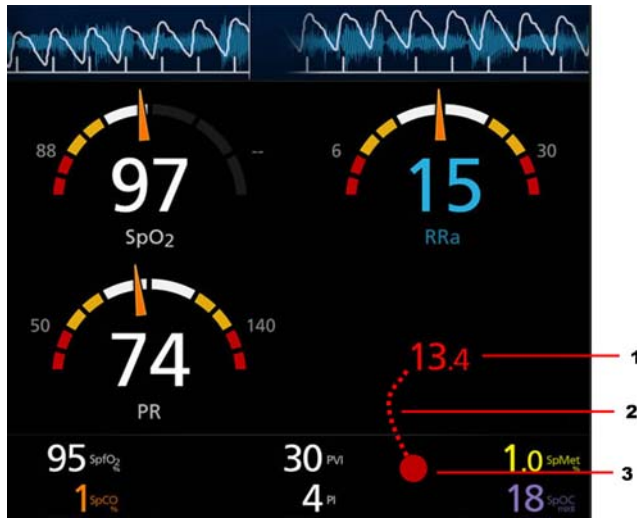
Windows can be customized by expanding and minimizing parameters and measurements in both Trend View and Analog View. When a parameter is minimized, it is only displayed in the Well with its Numeric Value and Parameter Label. When a parameter is expanded, it will be shown as either a Trend Display or Gauge.

To expand a parameter or measurement



Order	Instruction
Step 1	Press and hold the Numeric Value until it dims.
Step 2	Drag the Numeric Value over any Trend Display.
Step 3	Release the Numeric Value.

Minimizing a parameter or measurement



Order	Instruction
Step 1	Press and hold the Numeric Value until it shrinks.
Step 2	Drag the Numeric Value to the Well.
Step 3	Release the Numeric Value.

Accessing Main Menu Options

To access the Main Menu options

At the bottom right corner of the touchscreen, press the **Main Menu icon**.



The Main Menu options are:



Device Settings

See Device Settings.



About

See About.



Trend Settings

See Trend Settings.



Profiles

See Profiles.



Iris

See Iris.



Layout

See Layout.



Sounds

See Sounds.

Device Settings



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

The Device Settings options are:

**Localization**

See Localization.

**Wi-Fi**

See Wi-Fi

**Ethernet**

See Ethernet.

**Bluetooth**

See Bluetooth.

**Root Battery**

See Root Battery

**Radical-7 Battery**

See Radical-7 Battery.

**Brightness**

See Brightness.

**Access Control**

See Access Control.

**Device Output**

See Device Output

Localization



Use the Localization screen to view the current date and time and configure settings related to local time, language and geography. The user can also access the *Localization* screen by pressing the current time on the Status Bar. See About the Status Bar.

Option	Description	Factory Default Setting	Configurable Settings
Language	Selects the language display for Root.	English	Choose from available languages.
Date Format	Sets the display format for current date.	mm/dd/yy	mm/dd/yy or dd/mm/yy
Time	Sets the display format for current time.	12 hour	12 hour or 24 hour
Line Frequency	Sets to match regional power line frequency.	60 Hz	50 Hz or 60 Hz
Date	Sets the current date.	N/A	N/A
Time	Sets the current time.	N/A	N/A

Wi-Fi



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

transmission is an optional network data transmission to the wired network data transmission, using Root’s integral Ethernet Port.

Root uses only configured MAC addresses to establish wireless communications to prevent unauthorized connections to other wireless devices. As risk mitigation to the loss of the wireless communication, Root’s alarm capabilities have been designed to be independent of the Wi-Fi communication feature in order to preserve Root’s primary alarms.

Use the Wi-Fi screen to enable or disable Wi-Fi connectivity. When Root is connected to a Wi-Fi network, the Wi-Fi icon on the Status Bar conveys the strength of the connection. See About the Status Bar.

Option	Description	Factory Default Setting	Configurable Settings
Wi-Fi	Enables or disables Wi-Fi connectivity.	Off	On or Off
Additional fields in the <i>Wi-Fi</i> screen display read-only settings about the Wi-Fi connection that cannot be configured by the user.			

Your Masimo sales representative can provide necessary information regarding an initial Wi-Fi connection. For more information on Patient SafetyNet, see Operator's Manuals of Patient SafetyNet.

Ethernet



Use the Ethernet screen to enable or disable Ethernet connectivity. When Ethernet connectivity is enabled, the Ethernet icon will appear in the Status Bar. See About the Status Bar.

Option	Description	Factory Default Setting	Configurable Settings
Ethernet	Enables or disables Ethernet connectivity.	On	On or Off
Additional fields in the Ethernet screen display read-only settings about the Ethernet connectivity that cannot be configured by the user.			

Bluetooth



The Bluetooth radio allows for the detection of the close proximity of Masimo's MyView Presence Tag. Root's detection of Masimo's MyView Presence Tag is an optional feature that allows for the display of predetermined customized settings by a clinician. Root utilizes only configured MAC addresses to establish Bluetooth communication to prevent unauthorized connection to other Bluetooth enabled devices.

Use the Bluetooth screen to enable or disable Bluetooth connectivity. When Bluetooth connectivity is enabled, the Bluetooth icon will appear in the Status Bar. See About the Status Bar

Option	Description	Factory Default Setting	Configurable Settings
Bluetooth	Enables or disables Bluetooth connectivity.	Off	On or Off

For more information on how to configure Masimo MyView Presence Tag, see Operator's Manual of Patient SafetyNet.

Root Battery



Use the Root Battery screen to view the specific percentage of charge on the battery. The user can also access Root's Battery screen by pressing the Battery icon on the Status Bar. See About the Status Bar.

Option	Description
State of Charge	Provides a read-only display of battery level remaining.
Battery Diagnostics	Allows trained personnel to access battery diagnostic information.

Radical-7 Battery



Use the Battery screen to view the specific percentage of charge on the Radical-7's battery. The user can also access the Battery screen by pressing the Radical-7's Battery icon on the Status Bar. See About the Status Bar.

Option	Description
State of Charge	Provides a read-only display of battery level remaining.
Battery Diagnostics	Allows trained personnel to access battery diagnostic information

Brightness



Use the Brightness screen to adjust the brightness of the Root display.

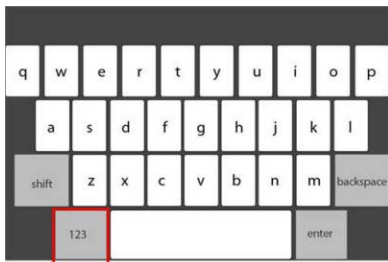
Option	Description	Factory Default Setting	Configurable Settings
Auto Brightness	Allows automatic adjustment of Root's display brightness based on ambient light.	Off	On or Off
Brightness	Adjust the brightness level of the Root display by sliding the button (4 is brightest).	4	1, 2, 3, 4

Access Control



Access Control contains configurable options and settings that require a password.

To enter Access Control



1. Press the 123 key.
2. When the numeric screen displays, enter the following numbers: **6 2 7 4**
Asterisks (****) will be displayed.
To undo an entry, press **Backspace**.
3. Press **Enter** to access the password protected screen.

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

Option	Description	Factory Default Setting	Configurable Settings
All Mute Enabled	Enable parameter Alarm Silence menu option. See Sounds.	Off	On or Off
Lock Alarm Volume	Sets the lowest alarm volume level.	Off	3, 4, or Off
Save as Adult	Saves current profile parameter as the Adult Profile.	N/A	Press Save to load.
Save as Pediatric	Saves current profile parameter as the Pediatric Profile.	N/A	Press Save to load.
Save as Neo	Saves current profile parameter as the Neonatal Profile.	N/A	Press Save to load.
Factory Defaults	Options are restored to factory values.	N/A	Press Restore .

Device Output



A Nurse Call can be triggered based on alarm, low Signal IQ events or both. In addition, Nurse Call Polarity can be inverted to accommodate local Nurse Call station requirements.

Option	Description	Factory Default Setting	Configurable Settings
Nurse Call Polarity	Controls the mechanism of action for triggering to occur. Should be changed to accommodate institutional Nurse Call settings.	Normal	Normal or Inverted
Nurse Call Trigger	Controls the source of monitoring which sets off the trigger.	Alarms	Alarms, Signal IQ Alarms, and Signal IQ
Port 0		None	None, IAP, IntelliBridge, and ASCII 1
Port 1		IAP	None, IAP, IntelliBridge, and ASCII 1
SpecTable		Radical	Radical, Radical Module A, Sedline, and Sedline Numerics Only

Note: The Nurse Call feature is disabled when Audio Pause is enabled and Nurse Call Trigger is set to *Alarms*. For more information about Audio Pause, see Audio Pause.

About



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

Option	Description
Serial Number	Displays the serial number for the device.
MCU 1	Displays software version number.
Processor	Displays processor version number.
MCU 2	Displays software version number.

Information about Radical-7, Radius-7 and MOC-7 modules will display in a separate list. These fields are read-only and cannot be configured by the user.

Trend Settings



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

Option	Description	Factory Default Setting	Configurable Settings
Default Duration	Duration captured by Trend Lines.	2 hours	15, 30, 45 minutes 1, 2, 4, 8, 12, 24 hours
Clear Trends	Delete all stored trend data.	N/A	Press Clear to delete all stored trend data.

To configure trend settings of specific parameters and measurements, see Instructions for Use or Operator's Manuals for Radical-7, Radius-7 and appropriate MOC-9 module(s).

Profiles



Use the Profiles screen to select patient type.

Option	Description	Factory Default Setting	Configurable Settings
Patient Type	Identifies the Profiles setting in the device.	Adult	Adult, Pediatric, Neonatal

Root can be configured for various patient types by using the Profiles feature. Profile selection controls the management of patient configuration settings on Root. The settings of the three default profiles (Adult, Pediatric, and Neonatal) configure parameter alarms, averaging time, and sensitivity modes.

Custom profiles can also be created to accommodate usage in any hospital care area. See the Masimo Instrument Configuration Tool Directions for Use for information on adding Profiles.

For more information regarding Profiles, see the Instructions for Use or Operator's Manuals for Radical-7, Radius-7 and appropriate MOC-9 module(s).

Iris



The status of the four (4) Iris Connectivity Ports as well as the connection type (for example, monitor, pump, ventilator) will be displayed on the Iris Status screen. See Iris Status Screen.

Layout



Use the Layout screen to select sizing options for Windows and Trend Displays.

Additional Settings

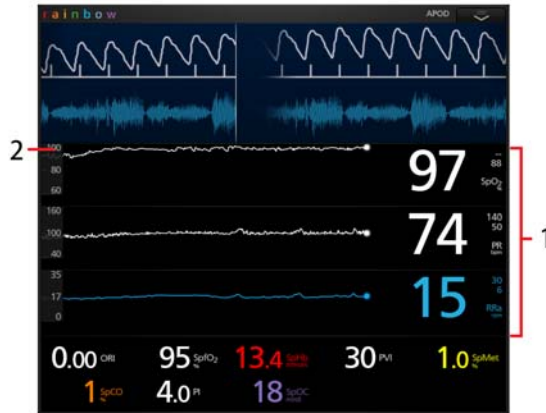


There are different ways to display the parameters and measurements by changing the Layout Style.

Note: This feature only applies to Trend View. See Using Trend View.

Option	Description	Factory Default Setting	Configurable Settings
Layout Style	Controls the sizing of Trend Displays.	Fixed	Fixed or Dynamic

The following diagram and tables explain the differences between Fixed and Dynamic modes for a Trend View.



Fixed

Ref.	Description
1	A set number of Trend Displays can be shown at the same time and all Trend Displays are fixed in size. Every additional parameter or measurement expanded will replace an existing Trend Display. For more information about expanding parameters, see Customizing Windows.
2	Size of each Trend Display is fixed.

Dynamic

Ref.	Description
1	Size of all Trend Displays decreases or increases to accommodate parameter(s) expanded or minimized. All Trend Displays are always evenly sized.* . For more information about expanding and minimizing parameters, see Customizing Windows.
2	*Size of each Trend Display is automatically adjusted.

**When the number of Trend Displays reaches maximum viewing capacity, additional parameters expanded will result in the replacement of existing Trend Displays.*

Available Layout



When only Radical-7, Radius-7 or a single MOC-9 module is connected to Root, the Available Layout will be 100%. When Radical-7 and/or multiple devices are connected, the user will have the option to select from several pre-configured layouts.

Sounds



Use the Sounds screen to control the volume level of sounds and duration of audio pause for Root.

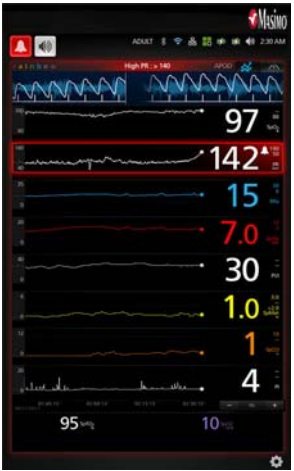
Option	Description	Factory Default Setting	Configurable Settings
Alarm Volume	Sets the alarm volume level.	Highest volume	Slide towards the left to decrease volume to silence.
Pulse Tone Volume	Sets the pulse tone volume level.	Highest volume	Slide towards the left to decrease volume to silence.
Audio Pause Duration	Sets the length of time that the audible alarm remains silenced, when Audio Pause is enabled. See Audio Pause.	2 minutes	1, 2, 3 minutes, Permanent*, Permanent with Reminder*. If <i>Permanent</i> is selected, there will be no audible alarms, but visual alarms will still display. If <i>Permanent with Reminder</i> is selected, a tone will sound every three (3) minutes as a reminder that <i>Permanent</i> is active.



*Requires user to have All Mute Enabled (Permanent Silence Duration) in the Access Control menu. See Access Control.

Alarm Interface

Alarms can have different priority levels and come from different sources. The following tables describe alarm behaviors in more detail.

Priority	Alarm Sound
1	Five (5) beeps: beep-beep-beep, <i>brief pause</i> , beep-beep
2	Three (3) beeps: beep-beep-beep

Alarm Source	Example	Explanation
Parameter Level		<p>The example shown here is a PR alarm as the reading (142) exceeds the upper alarm limit (140). Note that the borders of both the PR Trend Display as well as the Window are illuminated red, and the explanation of the alarm is shown at the top of the Window (High PR > 140).</p>





Alarm Source	Example	Explanation
Window Level		<p>The example shown here is a "High Impedance" alarm in the lower Window.</p> <p>Note that the border of the Window illuminates red, and the explanation of the alarm is shown at the top of the Window (High Impedance Detected).</p>
System Level		<p>The example shown here is a "Low Battery" alarm. Note that the border of the entire Root display is illuminated red, and the explanation of the alarm is shown in the Status Bar (Low Battery).</p>

For more details about specific alarms on Radical-7, Radius-7 and MOC-9 modules, see Instructions for Use or Operator’s Manuals for Radical-7, Radius-7 and MOC-9 modules.

Alarm Silence

The Alarm Silence icon is an indicator as well as a functional button. It always indicates the presence of alarms, and it can be used to temporarily suspend audible alarms for a pre-configured amount of time, known as Silence Duration.

Silence Duration configurations vary across different parameters and measurements. For more information about Silence Duration, refer to the instructions for use or Operator’s Manuals for Radical-7, Radius-7 and appropriate MOC-9 module(s).

Icon Appearance	Description	Visual Alarms
	There are currently no active alarms, and no alarms have been silenced.	No
	There are currently no active alarms, but at least one alarm has been and is still silenced.	No
	There is currently at least one active alarm that has not been silenced.	Yes
	There is currently at least one active alarm, but all active alarms are silenced.	Yes

Audio Pause

Audio Pause temporarily suspends all audible alarms on Root. When it is active, visual alarms are not impacted and will still display. The Audio Pause icon is located on the left side of the Status Bar – do not confuse with the Sounds icon on the right side of the Status Bar.

By default, Audio Pause is inactive, and the icon appears in the following way:



Audio Pause inactive

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 117 seconds left until Audio Pause is inactivated again.

To configure Audio Pause, see Sounds.



Audio Pause active. 117 seconds until Audio Pause is inactive.

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

Trend Download

Root can store up to 96 hours of trend data captured at 2-second intervals from Radical-7, Radius-7 and MOC-9 modules. Trend data from Root can be transferred to a computer via USB for evaluation.

Trend data is stored in non-volatile memory, so it is not erased when Root is shut off. Trend data download is initiated using the Masimo Instrument Configuration Tool, which converts the data to a .TXT or .CSV file.

Lights

System Status Lights

The System Status Lights provide visual indications of alarms and system messages. The lights will illuminate in different colors depending on the state of the device.

To locate the System Status Lights, see Side Views

System Status Light

Light Status	Alarm Priority	Indication
None	None	Monitoring has not begun.
Green	None	There is currently no active alarms.
Yellow	Low	There is an active alarm of low priority.
Red	High	There is an active alarm of high priority.

The alarm priority is determined by the Radical-7, Radius-7 and MOC-9 module(s) that are connected to Root. The following are system level alarm messages that accompany System Status Lights when Radical-7, Radius-7 and MOC-9 modules are not connected:

Status Light Message	Alarm Priority
Low battery	Low
Service required	High

AC Power Indicator



Whenever Root is connected to an AC power source, this light will illuminate:

Light Status	Indication
Green	Root is connected to an AC power source.
Off	Root is not connected to an AC power source.

Root Charging Indicator



Whenever Root is connected to an AC power source, if not fully charged, its battery will charge.

Light Status	Battery Indication
Green	Battery is fully charged.
Orange	Battery is charging.
Red	Battery charging error.
Off	Battery is not being charged. Root is not connected to AC power source.

Standby and Power Off

To put Root in the Standby Mode or Power Off Mode, follow these steps:

State	Description
Standby Mode	<p>Press and hold the Power Button for two (2) seconds until one (1) audible tone sounds.</p> <p>Standby Mode conserves power while enabling a quicker startup sequence.</p>
Power Off Mode	<p>Press and hold the Power Button for eight (8) seconds, until two (2) audible tones sound. The Home Button will flash, and the Power Button will flash orange.</p> <p>Power Off Mode completely shuts down Root and results in a longer startup sequence.</p>

Chapter 4- Radius-7

The Radius-7 is a patient wearable device for continuous monitoring when the patient is ambulatory. It measures arterial oxygen saturation (SpO₂), pulse rate (PR), perfusion index (PI), and Pleth Variability Index (PVI®) along with Acoustic Respiration Rate (RRa®). It uses a Bluetooth or Wi-Fi connection to transfer parameter data to Root. When Radius-7 is connected to Root via Bluetooth or Wi-Fi, the device automatically creates a Window that displays all the data from Radius-7.

Root also acts as a charging station for Radius-7. Radius-7 is docked onto Root via a Battery Charging Adapter. See Radius-7 Operator's Manual for more information.

Chapter 5- O3 Regional Oximetry

The O3 system is a patient-connected, noninvasive oximeter designed to continuously measure and monitor regional hemoglobin oxygen saturation in the tissue (rSO₂), including cerebral tissue. It can be used in any hospital and hospital-type facility where rSO₂ measurements might improve patient outcomes.

The Masimo O3 Regional Oximeter and Sensors are indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood (rSO₂) in the tissue below the sensor in hospital and hospital-type facilities. See the O3 Operator's Manual for more information.

Chapter 5- MOC-9

Flexible measurement expansion is enabled through MOC-9. It can display parameters and measurements captured by third-party technologies in an all-in-one view on Root.

When any MOC-9 module is connected, Root automatically creates a Window that displays all the data from that module. The example below shows the “SedLine” and “Capnography” Windows which display data from the SedLine brain function monitoring and Phasein capnography MOC-9 modules that are connected to Root.



Using MOC-9 Ports

Use a MOC-9 cable to connect other MOC-9 modules to Root.



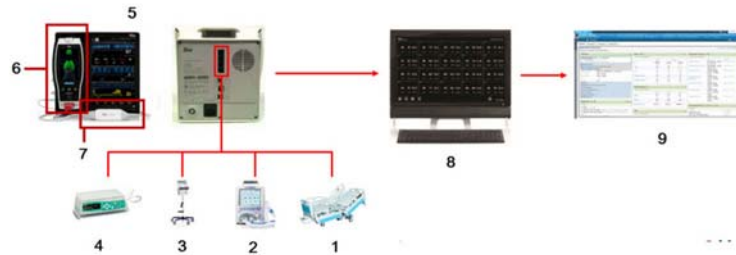
To use an MOC-9 Port

1. Identify the MOC-9 end of the cable.
2. Orient the cable to fit correctly into an MOC-9 Port.
3. Insert the MOC-9 cable securely into any of the three (3) compatible ports on Root.

Chapter 7- Iris

Iris allows a variety of standalone devices to connect to Root. Patient data can be passed through Root to Patient SafetyNet or Connectivity Gateway, which can send the data to electronic health records.

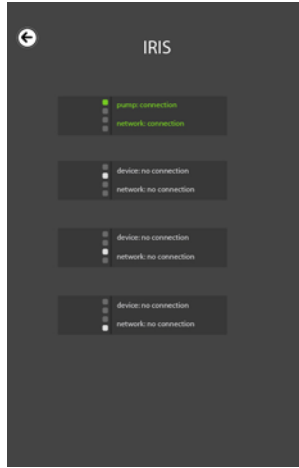
Below is an example of one way Root can be used in a network setting using Patient SafetyNet. Root receives and may display information from Radical-7, MOC-9 modules, as well as standalone devices.



Ref.	Description
1 - 4	Standalone devices connected via Iris (e.g., monitor, pump, ventilator)
5	Root
6	Radical-7
7	MOC-9 modules
8	Patient SafetyNet or Masimo Connectivity Gateway
9	Electronic Health Records system


Iris Status Screen

Information about Iris Connectivity Ports are displayed on this screen, which is accessible by selecting the Iris option on the Main Menu.



Connection Status Color	Description of Connection
Green	Standalone device is successfully connected to Root, and Root is successfully connected to a Patient SafetyNet or Connectivity Gateway.
Yellow	Standalone device is successfully connected to Root; however, Root is not successfully connected to a Patient SafetyNet or Connectivity Gateway.
Gray	No standalone device is connected to the Iris Connectivity Port.

Additionally, the Ports are also mapped to the Iris icon on the Status Bar. When a standalone device is connected to Root via one of the Ports, the corresponding part of the icon will be lit green or yellow. In the example below, a standalone device is connected to Iris Connectivity Port 1.

Port 1 (connected)  Port 2

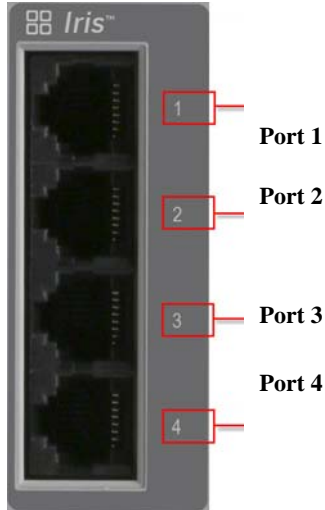
Port 3

Port 4

Status and connection type are read-only and not configurable by the user. For more information on Iris connectivity, see Instructions for Use or Operator's Manual for the appropriate version of Masimo Patient SafetyNet.

Using Iris Connectivity Ports

Use Iris Adapters and RJ-45 cables to connect standalone devices to Root.



To connect a standalone device via an Iris Connectivity Port:

1. Connect the RS-232 end of the Iris Adapter to the standalone device.
2. Connect the RJ-45 end of the Iris Adapter to any of the four (4) compatible Iris Connectivity Ports on Root using a RJ-45 cable.

Chapter 8- Messages

Messages

The following messages are specific to Root:

Message	Explanation	Next Step
Battery Charge is Low.	The internal battery needs to be charged. System Status Lights flash yellow.	Charge Root's battery using AC power.
MOC-9 module disconnected (e.g. SedLine Disconnected)	A MOC-9 module is disconnected from Root.	Reconnect module or acknowledge message by pressing the Alarm Silence icon.
Radical-7 Disconnected	Radical-7 is disconnected from Root.	Reconnect Radical-7 or acknowledge message by pressing the Alarm Silence icon.
Radius-7 Disconnected	Radius-7 is disconnected from Root	Reconnect Radius-7 or acknowledge message by pressing the Alarm Silence icon.

For additional messages, see Instructions for Use or Operator's Manuals for Radical-7, Radius-7 and MOC-9 modules.

Chapter 9- Troubleshooting

Troubleshooting Radical-7, Radius-7 and MOC-9 Modules

For information on troubleshooting values that are provided from Radical-7, Radius-7 and MOC-9 modules refer to their respective Instructions for Use or Operator's Manuals.

Troubleshooting Root

Symptom	Possible Cause	Correction
Root does not turn on.	Power Button not pressed long enough.	Press Power Button for two (2) seconds.
	The battery may be depleted.	Connect Root to AC power to charge battery.
	One of the fuses is not operating properly.	Replace the fuse. See Replacing the Fuses.
Root turns on, but Main Screen is dim or blank.	The brightness setting is not correct.	Adjust the brightness setting. See Brightness. If the condition persists, Root requires service. Contact Masimo Technical Support. See Return Procedure.
Touch functionality is not responsive	Internal Failure	Root requires service. Contact Masimo Technical Support. See Return Procedure.
Not displaying data from Radical-7, Radius-7 or MOC-9 modules.	Connection error.	Ensure that the connections are securely in place and properly plugged in, or that the cable is not defective. For Radius-7, ensure that the device is paired with Root via Wi-Fi or Bluetooth. Refer to Operator's Manual of Radius-7 for more information.

Symptom	Possible Cause	Correction
Iris screen does not display connection status for standalone devices.	Connection error	Unplug and replug the Iris Adapter.
Iris screen does not display connection status for standalone devices.	Connection error.	If the problem persists, refer to instructions for use or operator's manual for the connected standalone devices or Iris section of the instructions for use or operator's manual for the appropriate version of Patient SafetyNet.
Root has a continuous speaker tone.	Internal failure.	To silence an alarm, press the Power Button for eight (8) seconds. If alarm continues to sound, Power Off Root. Root requires service. See Return Procedure.
Power Button does not respond when pressed.	Power Button may need to be pressed for a longer time.	To Power On when turned off or in Standby Mode, press Power Button for two (2) seconds. To Power Off when turned on or in Standby Mode, press the Power Button for eight (8) seconds.
	Internal failure.	Root requires service. See Return Procedure.
Home Button does not work when pressed.	Internal failure.	Root requires service. See Return Procedure.
Battery does not charge.	AC power cable may be disconnected.	Unplug and replug AC power cable.
Root Charging Indicator illuminates red.	Internal failure.	Root requires service. See Return Procedure.

Symptom	Possible Cause	Correction
Nurse Call does not communicate.	Connection error	Unplug and replug Nurse Call connector. See Nurse Call Setting Connections

Chapter 10- Specifications

This chapter contains specifications of Root.

For information on the specifications of Radical-7, Radius-7, MOC-9 modules, and standalone devices, see Instructions for Use or Operator's Manuals for these devices.

Electrical

Root	
AC Power requirements	100-240 VAC~, 47-63 Hz, 65 W (Max)
Fuses (2)	2 Amp, Fast Acting, Metric, (5x20mm), 250V, 1500A Breaking Capacity
Battery	
Type	10.8V Lithium Ion (Nominal)
Capacity	4 hours*
Maximum Charging Time	4 hours

*This represents approximate run time at the lowest brightness, using a fully charged battery.

Environmental

Root	
Operating Temperature	32°F to 122°F (0°C to 50°C)
Transport/Storage Temperature	-40°F to 158°F (-40°C to 70°C)
Operating Humidity	10% to 95%, non-condensing

Root	
Storage Humidity	10% to 95%, non-condensing
Operating Altitude	500 mbar to 1060 mbar -1000 ft to 18,000 ft (-304 m to 5,486 m)

Display

Characteristic	Description
Type	Backlit Active Matrix TFT LCD
Resolution	1280 x 800 pixels
Size	10.1 in (25.65 cm) Diagonal
Color	24 bit RGB

Touchscreen

Characteristic	Description
Type	Multi-Touch P-Cap

Alarms

Visual Alarm Priority	System Status Light Color
High	Red
Low	Yellow

Nurse Call Specifications

The Nurse Call relays have the following electrical specifications per switch:

Parameter	Specification
Max Voltage	36 VDC or 24 VAC peak

Connectors

Connector	Type	Number of Ports
Ethernet	10/100 MBps	1
Nurse Call	1/4 inch round female	1
MOC-9	Masimo Connector	3
USB	USB 2.0	2
Iris	RS-232/RJ-45	4

Wireless Specifications

Communication (Wi-Fi)	
Type	WLAN Radio: IEEE 802.11 a/b/g
Frequency	802.11a: 5180-5240 MHz, 5745-5825 MHz 802.11b/g: 2412-2462 MHz
Max Peak Output Power	WLAN 17 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	OFDM, BPSK, CCK
Modulation Signals	Analog and Digital
Available Data Rates	802.11a - 6, 9, 12, 18, 24, 36, 48, 54 Mbps. 802.11b - 1, 2, 5.5, 11 Mbps. 802.11g - 6, 9, 12, 18, 24, 36, 48, 54 Mbps.
Communication (Bluetooth)	
Type	Bluetooth
Frequency	2402-2480 MHz
Max Peak Output Power	Bluetooth 1.3 dBm
Classification of Output Power Rating	Conducted
Output Power Type	Fixed at the Factory
Modulation Types	DH5

Communication (Wi-Fi)	
Modulation Signals	Analog and Digital
Available Data Rates	Bluetooth 1 Mbps
Security and Authentication	
Encryption	64/128-bit WEP, Dynamic WEP, WPA-TKIP, WPA2-AES
Authentication	Open System, Shared Key, Pre-Shared Key (PSK), 802.1X: LEAP, PEAP< TTLS, TLS, EAP-FAST
Radio Compliance	
USA	FCC ID: VKF-RDS7A Model - RDS7A
Canada	IC:7362A-RDS7 IC Model: RDS7A RSS-210
Europe	EN 300 328 EN 301 489-17 R & TTE Directive

EMC Compliance

EMC Compliance
EN 60601-1-2, Class A device

Software Compliance

Software Compliance
EN 60601-1-4:1996 + A1: 1999

Safety Standards Compliance

Protection from Ingress of Liquids
IPX1 per IEC 60529
Electrical and Mechanical Safety
UL 60601-1:2003
CAN/CSA 22.2 No. 601.1:2005
IEC 60601-1 / UL 60601-1: 1988 + A1: 1991 + A2:1995
EN 60601-1: 1990 + AI: 1993 + A2:1995
ISO 9919:2005
IEC-60601-2 - 49:2001
Type of Protection
Class I (on AC power)
Internally powered (on battery power)


Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	For hospital environment only. Not intended for use in a domestic environment.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+2 kV for power supply lines. +1 kV for input/output lines.	--	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+1 kV - differential mode +2 kV - common mode	--	Mains power quality should be that of a typical hospital environment.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11</p>	<p>100% for 0.5 cycle 60% for 5 cycles 30% for 25 cycles 100% for 5 seconds</p>	<p>--</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. Root provides a battery for continued operation during power mains interruption for a maximum of 4 hours.</p>
<p>Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.</p>
<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz</p>	<p>3 Vrms</p>	

<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p>800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment.













b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.








Recommended Separation Distances

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

Symbols

The following symbols are found on Root or its packaging and are defined below. Some of the interfaces and symbols are not available on all versions.

Symbols	Definition	Symbols	Definition
	Follow Instructions for Use		Separate Collection for Electronic Waste
	Manufacturer		Storage Temperature Limitation Storage Altitude Limitation
	Date of Manufacture		Storage Humidity Limitation
	Non-ionizing Electromagnetic Radiation		Keep Dry
IPX1	IPX1 Protection Against Liquid Drops Falling Vertically		Fragile/Breakable, Handle with Care
Rx ONLY	Federal (USA) Law Restricts this Device to Sale by Or on the Order of a Physician		Fuse Replacement. See <i>Replacing the Fuses</i> section of the Operator's Manual.
	UL, LLC, Certification		Equipotential Ground Terminal
FC	Federal Communications Commission (FCC) licensing		Iris Connection

Symbols	Definition	Symbols	Definition
FCC ID, IC, IC Model	Identifies Unit has been Registered as a Radio Device		USB port
	Mark of Conformity to European Medical Device Directive 93/42/EEC		AC Current
	Authorized representative in the European community		Nurse Call Interface
	Wireless Features Can be Used in Member States with the restriction of indoor use in France		Defibrillation Proof Type BF

Chapter 11- Service and Maintenance

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

Cleaning

Root is a non-sterile and reusable device. The surface of the Root should be cleaned when the device is visibly dirty, before and after each procedure, and/or according to hospital practice.

To surface clean, wipe down the outer surface of Root using any of the following solvents:

- Cidex Plus (3.4% glutaraldehyde)
- 10% bleach solution
- 70% isopropyl alcohol solution

Do not allow liquids to enter the interior of Root. Using the recommended cleaning solutions on the touchscreen will not affect the performance of Root.

Replacing the Fuses

If a power-related problem causes one or both of the fuses to fail, the fuse(s) will need to be replaced. Replace fuse(s) with UL Listed fuses rated fast-acting, 250V, 2 amp, metric, 5x20 mm and with a breaking capacity of minimum 1500A.

WARNING: To ensure safety, only replace with appropriately rated fuses.

The fuses can be removed by hand or with a 5-millimeter or 3/16-inch screwdriver.

To replace the fuse(s)

1. Power Off Root completely. Do not put in Standby Mode. See Standby and Power Off.
2. Remove the AC power cord from the Power Entry Module in the back panel.
3. Remove the fuse holder by pulling it forward from the Power Entry Module.
4. Remove a fuse by gently pulling the top of the fuse away from the center and then pulling up. The fuse should easily be removed. Do not force.
5. Place a new fuse in the fuse holder.
6. If replacing both fuses, repeat steps 4 and 5 for the second fuse.
7. Slide the fuse holder back into the Power Entry Module and press firmly to make sure it is secure.

Root is ready to be reconnected to AC power. If the fuses fail shortly after replacement, Root requires service. See Repair Policy.

Power-On Self Test

To conduct a Power-On Self Test


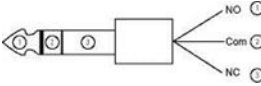
1. Connect Root to AC power, and verify that the AC Power Indicator is illuminated.
2. Power On Root. Within five (5) seconds, all available indicators will illuminate, the device will emit a tone, and the Masimo logo will display.

Nurse Call Setting Connections

For maximum flexibility, either normally open or normally closed signals are available. During an alarm condition or a low Signal IQ event, depending on the configuration of the device output, the normally open pin will be connected to the common pin and the normally closed pin will be disconnected. In addition, the

Nurse Call Polarity can be inverted to accommodate various nurse call station requirements.

Only qualified personnel should connect one of these two signals to a hospital's Nurse Call system.

Cable Description	Nurse Call Event	Menu Setting
	2 contacts normally opened	Nurse Call Polarity Normal
	2 contacts normally closed	Nurse Call Polarity Inverse
	1 and 2 contacts normally opened 2 and 3 contacts normally closed	Nurse Call Polarity Normal
	1 and 2 contacts normally closed 2 and 3 contacts normally opened	Nurse Call Polarity Inverse
	1 and 2 contacts normally closed 2 and 3 contacts normally opened	Nurse Call Polarity Inverse

Battery Test

To conduct a Battery Test

1. Fully charge Root by connecting it to AC power.
2. Verify that the Root Charging Indicator is illuminated.
3. When Root is fully charged, the Root Charging Indicator turns off.
4. Power On Root and verify that the Root Battery Indicator icon on the Status Bar shows a full charge.

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, see Return Procedure.

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 Root. 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 Root 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 Root has been decontaminated for bloodborne pathogens.
- Return the Root to the shipping address listed in the Contacting Masimo section below.

Contacting Masimo

Masimo Corporation
40 Parker
Irvine, California 92618
Tel:+1 949 297 7000
Fax:+1 949 297 7001

Warranty with Battery

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

Batteries are warranted for six (6) months.

To request a replacement under warranty, Purchaser must contact Masimo for a returned goods authorization. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs shall be the responsibility of Purchaser.

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

Exclusions

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

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

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