Operator's Manual

Root[®] with noninvasive blood pressure and temperature





For Sale in the USA

These operating instructions provide the necessary information for proper operation of all models of the Root. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of Root are prerequisites for its proper use. 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.

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

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

Wireless Radio FCC ID:VKF-RDS7A IC:7362A-RDS7A IC Model: RDS7A

Masimo Corporation 52 Discovery Irvine, CA 92618, USA Tel.: 949-297-7000 Fax.: 949-297-7001 www.masimo.com



EU authorized representative for Masimo Corporation:

EC REP

MDSS GmbH Schiffgraben 41 D-30175 Hannover, Germany

MEDICAL ELECTRICAL EQUIPMENT



WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH

Conforms to ANSI/AAMI ES 60601-1, CAN/CSA C22.2 No. 60601-1, and applicable Particular (IEC 60601-2-49, IEC 80601-2-30, ISO 80601-2-56) and related Collateral (IEC 60601-1-8:2006) Standards for which the product has been found to comply by Intertek.

Patents: www.masimo.com/patents

Iris, Masimo, MOC-9, PVi, Radical-7, Radius-7, rainbow, Root, RRa, SedLine, SET, Signal Extraction Technology, SpCO, SpHb, and SpMet are federally registered trademarks of Masimo Corporation.

ISA, MyView, and SpOC are trademarks of Masimo Corporation.

The use of the trademark Patient SafetyNet is under license from University HealthSystem Consortium.

All other trademarks and registered trademarks are property of their respective owners.

© 2018 Masimo Corporation

Contents

| About This Manual | 7 |
|--|----|
| Product Description and Features, Intended Use and Indications for Use | 9 |
| Product Description and Features | 9 |
| Intended Use | |
| Indications for Use | |
| Contraindication | 11 |
| Safety Information, Warnings, and Cautions | 13 |
| Safety Warnings and Cautions | 13 |
| Performance Warnings and Cautions | 15 |
| Cleaning and Service Warnings and Cautions | 18 |
| Compliance Warnings and Cautions | 18 |
| Chapter 1: Description | 21 |
| Features | 21 |
| Chapter 2: Setting Up | 25 |
| Unpacking and Inspection | 25 |
| Guidelines for Setting Up | 25 |
| Power On | 26 |
| Initial Battery Charging | 27 |
| Radical-7 Connection | 28 |
| Radius-7 Connection | 28 |
| MOC-9 Connection | 29 |
| Nurse Call Connection | 30 |
| Attach the Probe Well | |
| Attach the Temperature Probe | 31 |
| Attach NIBP Cuff | 31 |
| Masimo Kite | 31 |
| Bluetooth Devices | 31 |
| Chapter 3: Operation | 33 |
| About the Main Screen | 33 |
| About the Status Bar | 34 |
| About the Action Bar | 36 |
| | |

| Using the Touchscreen Interface | 37 |
|---|---|
| Menu Navigation | 40 |
| Understanding Windows | 41 |
| Accessing Main Menu Options | 49 |
| Alarm Interface | 77 |
| Trend Download | 81 |
| Session Management | 82 |
| Screen Capture | 83 |
| Lights | 86 |
| Chapter 4: Temperature Measurement | 89 |
| Operation - Temperature | 89 |
| Temperature Probes | 91 |
| Chapter 5: NIBP Measurement | 93 |
| Patient Measurement Mode | 93 |
| Cuff Selection and Placement | 93 |
| Patient Conditions | 94 |
| Operation - NIBP | 95 |
| | |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 |
| Chapter 6: Admit and Discharge to Patient SafetyNet Not Admitted | 103 103 |
| Chapter 6: Admit and Discharge to Patient SafetyNet Not Admitted Admitting a Patient | 103 103 104 |
| Chapter 6: Admit and Discharge to Patient SafetyNet Not Admitted Admitting a Patient Discharging a Patient | 103 103 104 105 |
| Chapter 6: Admit and Discharge to Patient SafetyNet Not Admitted Admitting a Patient Discharging a Patient Not Monitoring Message | |
| Chapter 6: Admit and Discharge to Patient SafetyNet Not Admitted Admitting a Patient Discharging a Patient Not Monitoring Message Monitoring Resumed Message | 103 103 104 105 106 107 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 103 104 105 106 107 109 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 103 104 105 106 109 109 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 104 105 106 107 109 109 109 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 104 105 106 107 109 109 109 109 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 104 105 106 109 109 109 110 110 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 104 105 106 109 109 109 109 110 111 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 104 105 106 106 109 109 109 110 110 111 113 115 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 104 105 106 109 109 109 109 110 111 111 115 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 104 105 106 106 109 109 109 109 110 111 115 115 115 |
| Chapter 6: Admit and Discharge to Patient SafetyNet | 103 103 104 105 106 107 109 109 109 110 111 113 113 115 115 115 117 118 |

| Iris Icon | 119 |
|---|-----|
| Iris Screen | 120 |
| Chapter 12: Bluetooth Devices | 123 |
| Connect Device to Root | 123 |
| Chapter 13: Messages | 125 |
| Chapter 14: Troubleshooting | 129 |
| Troubleshooting Radical-7, Radius-7, and MOC-9 Modules | 129 |
| Troubleshooting Root | 129 |
| Chapter 15: Specifications | 133 |
| Measurement Accuracy | 133 |
| Alarms | 134 |
| Nurse Call Specifications | 134 |
| Connectors | 134 |
| Display Ranges | 135 |
| NIBP Pressurization Ranges | 136 |
| Electrical | 136 |
| Environmental | 136 |
| Touchscreen Display | 137 |
| Wireless Specifications | 137 |
| Compliance | 139 |
| Guidance and Manufacturer's Declaration-Electromagnetic Emissions | 141 |
| Guidance and Manufacturer's Declaration-Electromagnetic Immunity | 142 |
| Recommended Separation Distances | 144 |
| Symbols | 145 |
| Chapter 16: Service and Maintenance | 149 |
| Cleaning | 149 |
| Replacing the Fuses | 149 |
| Power-On Self Test | 150 |
| NIBP Module Calibration Test | 150 |
| Zero Point Calibration | 152 |
| Span Point Calibration | 153 |
| NIBP Air Leak Test | 154 |
| Overpressure Test | 156 |
| | |

| Nurse Call Setting Connections | 159 |
|--|-----|
| Battery Test | 160 |
| Repair Policy | 160 |
| Return Procedure | 160 |
| Masimo Technical Services | 160 |
| Contacting Masimo | 161 |
| Appendix: Concepts of Alarm Response Delay | 163 |
| Concepts of Alarm Response Delay | 163 |
| Index | 165 |
| | |

About This Manual

This manual explains how to set up and use Root® with noninvasive blood pressure and temperature. 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 device, or damage to other property.

CAUTION: This is an example of a caution statement.

A note is given when additional general information is applicable.

Note: This is an example of a note.

Product Description and Features, Intended Use and Indications for Use

Product Description and Features

Root[®] with noninvasive blood pressure and temperature is a patient monitoring and connectivity platform. 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.
- 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[®] Battery Module.
- Integrated noninvasive blood pressure (NIBP) technology.
- Optional integrated temperature technology.
- Ability to display data on a secondary display.
- Ability to display data from external devices using Bluetooth.

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.

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

The Masimo Root Monitoring System can be used with the optional Radical-7, ISA product family, Radius-7, and/or the SedLine module.

The Masimo Root Monitoring System 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 Root

www.masimo.com

🕈 Masimo

Root NIBPT

Monitoring System, when used with the optional ISA module, is not intended to be used in road ambulances.

The Masimo Root Monitoring System can communicate with network systems 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, 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 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 Masimo Radius-7 Wearable Pulse Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) , pulse rate, and/or respiratory rate (RRa). The Masimo Radius-7 Wearable Pulse 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.

The optional ISA product family consists of three types of side stream gas analyzers (ISA CO_2 , 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 CO_2 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 temperature module is indicated to measure temperature (oral, adult axillary, pediatric axillary, and rectal) of adult and pediatric patients. The device is intended to be used by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

The optional non-invasive blood pressure (NIBP) module is indicated for the noninvasive measurement of arterial blood pressure in healthcare environments. The NIBP module is designed to measure blood pressure for patient population described in the following table:

| Patient Population | Approximate Age Range |
|--------------------|---------------------------|
| Newborn (neonate) | Birth to 1 month of age |
| Infant | 1 month to 2 years of age |
| Child | 2 to 12 years of age |
| Adolescent | 12-21 years of age |
| Adult | 21 years of age and older |

Contraindication

There are no contraindications.

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 for ISA, Kite, Patient SafetyNet, Radical-7, Radius-7, TIR-1 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 Root. Injury to personnel or equipment damage could occur. Return Root for servicing.

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

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

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

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

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

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: To protect against fire hazard, replace only with recommended fuses of the same type, current rating, and voltage rating.

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: Do not plug in or remove the power cord with wet hands to avoid risk of electric shock. 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: As with all medical equipment, carefully route patient cables 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 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.

Note: It is recommended that Root is attached to an AC power source when it is not in use to ensure that the battery remains fully charged.

Note: For medical technologies that require AC power, the battery should be adequately charged to ensure backup power in case of AC power disruption.

Noninvasive Blood Pressure

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

WARNING: Only use Root in neonatal mode with a neonatal blood pressure cuff to measure blood pressure on neonates.

WARNING: Neonatal blood pressure measurements must always use a three (3) meter hose in order to avoid overpressure error caused by lack of air volume within the overall pneumatic system.

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

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

www.masimo.com



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

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

WARNING: Before applying the cuff on the patient, confirm the cuff size is appropriate.

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

CAUTION: Applying the blood pressure cuff over a wound can cause further injury.

CAUTION: A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.

CAUTION: If the blood pressure cuff is on the same limb as monitoring equipment (i.e., pulse oximeter probe), the pressurization within the cuff can cause temporary loss of function of the monitoring equipment.

Optional Integrated Temperature

WARNING: Always use single-use disposable probe covers to limit patient cross-contamination and/or patient discomfort.

WARNING: Before use, verify the color of the removable probe well to confirm the proper application site: Red (rectal), Blue (oral/axillary).

WARNING: The use of any other probe cover may produce temperature measurement errors or may result in inaccurate readings.

WARNING: Do not take axillary temperature through the patient's clothing, direct probe cover-to-skin contact is required.

CAUTION: Long-term continuous temperature monitoring, greater than 5 minutes, is not recommended.

CAUTION: Ensure probe well is properly in place.

CAUTION: Biting the probe tip while taking a temperature may result in damage to the probe.

CAUTION: Use of the incorrect probe at the measurement site will result in temperature errors.

Note: If a reliable spot check measurement cannot be made, the temperature module will automatically switch to continuous mode to make the measurement.

Note: Verify the compatibility of the temperature probe and probe cover before use with Root.

Performance Warnings and Cautions

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



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

WARNING: Root may be used during electrocautery. 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.

WARNING: Radical-7 may not fully charge in a high ambient temperature environment.

WARNING: Always ensure settings including alarms are appropriate for each patient prior to use.

WARNING: When using multiple devices in the same or similar environment, use of the same patient profile (including the same alarm presets) to avoid confusion that can lead to patient harm.

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 device, preventing it from working properly.

CAUTION: Failure to charge Root promptly after a Low Battery alarm may result in the device 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 ≤ 30 milliseconds, and
 b. No more than 2 % packets loss.
- Wireless Network Connection During Ping Test, passing result if:
 a. At least 98% of packets have latency ≤ 100 milliseconds,
 b. No more than 2 % packets loss, and
 - c. Primary access point signal strength at least -67 dBm.

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

www.masimo.com



potential signs of interference such as loss of communication or reduced Wi-Fi signal strength.

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: When the Root monitor is in synchronized waveform view, the EEG Chart Speed of the SedLine Window cannot be changed.

Noninvasive Blood Pressure

WARNING: Before applying the cuff on the patient, confirm the cuff size is appropriate.

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

CAUTION: If the blood pressure cuff is on the same limb as monitoring equipment (i.e., pulse oximeter probe), the pressurization within the cuff can cause temporary loss of function of the monitoring equipment.

Optional Integrated Temperature

WARNING: The use of any other probe cover may produce temperature measurement errors or may result in inaccurate readings.

WARNING: Do not take axillary temperature through the patient's clothing, direct probe-cover-to-skin contact is required.

CAUTION: Long-term continuous temperature monitoring, greater than 5 minutes, is not recommended.

CAUTION: Ensure probe well is properly in place.

CAUTION: Biting the probe tip while taking a temperature may result in damage to the probe.

CAUTION: Use of the incorrect probe at the measurement site will result in temperature errors.

Note: If a reliable spot check measurement cannot be made, the temperature module will automatically switch to continuous mode to make the measurement.

 $\ensuremath{\textbf{Note:}}$ Verify the compatibility of the temperature probe and probe cover before use with Root.

Kite

WARNING: When using Root the Kite accessory does not generate or manage alarms. The Root alarms, used in conjunction with clinical signs and symptoms, are the primary sources for determining that an alarm condition exists.

CAUTION: Kite is not a primary display. Medical decisions should be made using data from the primary display of a device in conjunction with clinical signs and symptoms.

www.masimo.com

🕈 Masimo

Patient SafetyNet System

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

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 device 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: To prevent damage to the temperature probe do not autoclave.

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 and could void the user's authority to operate the 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 60601-1-1 standard should be made when configuring Root as part of a Medical System.

www.masimo.com



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

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

Note: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. If this equipment does cause harmful interference to radio or television, 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 a hospital environment.

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 Battery Module.
- As a bedside monitoring display for parameters on Radical-7, Radius-7, and MOC-9 modules.
- As a bedside monitor for continuous or non-continuous NIBP and temperature. Note: Continuous Mode will take a measurement every one (1) second.
- 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 a frontal display and interface for user interactions. |
| 3 | Home Button | Provides access to the Main Screen. |
| 4 | Root Charging Indicator | Shows an indication of the battery charge for Root. |

| Ref. | Feature | Description |
|------|------------------------------------|---|
| 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



| Ref. | Feature | Description |
|------|-------------------------|---|
| 1 | Handle | Allows the user to transport Root. |
| 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. |
| www | .masimo.com | 22 S Masimo |

| Ref. | Feature | Description |
|------|-----------------------------------|--|
| 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





Left Side

Right Side

| Ref. | Feature | Description |
|------|--------------------------------|---|
| 1 | System Status Lights | Provides an indication of system messages and alarm priority. See System Status Lights on page 86. |
| 2 | Power Button | Places Root in Power On, Sleep, and Power Off modes. |
| 3 | MOC-9 Ports (3) | Provide connectivity for MOC-9 modules. |
| 4 | NIBP Nib | Connection port for NIBP Hose. |
| 5 | Temperature Probe Port* | Allows connection of temperature probe to Root. |
| 6 | Temperature Probe Well Holder* | Provides dock for temperature probe when not measuring. |
| 7 | Probe Covers Holder | Holds extra probe covers for quick access. |

*This feature is optional on Root

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. Confirm that you have all components for the Root by checking all materials against the packing list:
 - Root
 - AC power cord

Note: Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.

If anything is missing or damaged, contact Masimo's Technical Service Department. See *Return Procedure* on page 160.

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 on page 27.

Root should not be operated outside the environmental conditions listed in the specifications section. See **Environmental** on page 136.

Power On

The Power Button can be used for Power On, Sleep, 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 Sleep Mode and Power Off, see *Sleep and Power Off* on page 88. www.masimo.com 26 **3** Masimo

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.
- 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* on page 86 and *About the Status Bar* on page 34.
- The Root Charging Indicator remains orange while the battery is charging and will illuminate green when Root is fully charged. See *Root Battery* on page 68 and *About the Status Bar* on page 34.

See Safety Information, Warnings, and Cautions on page 13.



Radical-7 Connection

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

- 1. Snap the Radical-7 into the Docking Station.
- 2. If the Radical-7 is not yet turned on, press the power button on the Radical-7 to power it on.
- 3. When properly connected, the Radical-7 Charging Indicator light will illuminate. An illuminated Radical-7 Battery icon will also appear in the Status Bar. See **About the Status Bar** on page 34
- 4. Root display will show active measurements and parameters.



For Radical-7 charging conditions, see Radical-7 and Radius-7 Charging Indicator on page 87.

Radius-7 Connection

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

- 1. Ensure the Radius-7 Battery Charging Adapter is properly docked in the Docking Station area of Root.
- Activate the Bluetooth radio on Root. (for more information see Operator's Manual for Radius-7).
- 3. Place the Radius-7 Battery Module into the charging area of the Radius-7 Battery Charging Adapter.
- 4. Root will emit a tone when pairing has completed (see Operator's Manual for Radius-7 for more information).

5. When properly connected, an illuminated Radius-7 Battery icon will appear in the Status Bar, and the rainbow Window will appear on the Root display.



MOC-9 Connection

To connect a MOC-9 module to Root

1. Identify the Masimo Open Connect (MOC-9) end of the module.



2. Insert the MOC-9 end of the module securely into a MOC-9 port on Root.



For more information about MOC-9 modules, see *Chapter 10: MOC-9* on page 115.

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* on page 72.

Attach the Probe Well

For a list of compatible temperature probes and accessories, visit http://www.masimo.com/.

1. Align the probe well with the tabs facing up and down and insert the probe well into the temperature module.

Note: The probe well snaps into place when it is fully seated.

2. Insert the temperature probe into the probe well.



Attach the Temperature Probe

- 1. Hold the temperature probe cable connector with the spring tab on the right and insert it into the probe port of the temperature module.
- 2. Push the cable connector into place until it clicks.
- 3. Place probe cover onto the temperature probe and dock in the probe well.

Attach NIBP Cuff

For a list of compatible NIBP patient hoses and cuffs, visit *http://www.masimo.com/*.

- 1. Attach an adapter to the end of the cuff hose (if necessary).
- Connect blood pressure cuff to the NIBP Nib located on the side of Root. See Chapter 5: NIBP Measurement on page 93.

Masimo Kite

Masimo Kite Software Application is a passive monitoring interface to Point-of-Care (POC) Masimo medical devices (Root for example) that co-exist under the same Wi-Fi network. Kite remotely displays system and parameter status reported by the POC device on a separate monitor.

Root must be on the same network as Kite.

Note: If the device is not on the same network, it can be added, but Kite will not be able to connect it to view the parameters monitored by that device until both Kite and the device are connected to the same network.

To add Root to Kite to view parameter status, refer to the Masimo Kite Software Application Operator's Manual.

Bluetooth Devices

External devices can be connected to Root through Bluetooth. For more information about connecting an external device to Root through Bluetooth, see *Chapter 12: Bluetooth Devices* on page 123.

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 Main Screen

The Main Screen consists of several features. The following shows the Main Screen when two different devices are connected: Radical-7 (top) showing rainbow[®] parameters and measurements, SedLine module (middle) 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 on page 34. |
| 2 | Windows | Provides a dynamic, user-configurable display area for all the data from connected medical devices. |
| 3 | Action Bar | Provides icons for access to Root options for Patient Admit, EMR Push, Session Management, Manual Events and the Main Menu. See Accessing Main Menu Options on page 49. |

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.

| 1 2 | 3 | 4 | 56 | 7 | 8 | 9 10 | 11 | 12 | 13 | |
|-----|---|---|------|----|---|------|-----|----|----------|----|
| | C | | ₽ù ∦ | () | 윪 | | ÷ 🛍 | | 11:40 AM | 14 |

| Ref. | Feature | Description |
|------|---------------|---|
| 1 | Alarm Silence | Displays alarm status and temporarily mutes all audible alarms for Root, Radical-7, Radius-7, and MOC-9 modules. See Alarm Silence on page 79. |
| 2 | Audio Pause | Displays Audio Pause status and temporarily silences an alarm event. See Audio Pause on page 80. |
| 3 | Standby Mode | Allows for patient monitoring to be temporarily suspended. Available when using Root with Radical-7 or Radius-7. See Standby Mode on page 80. |
| 4 | Device Output | Provides access to the <i>Device Output</i> screen for activation or deactivation of nurse call functions, USB port output formats, and IntelliBridge connection. If this icon is visible, then USB port 1 and/or USB port 2 are activated. See <i>Device Output</i> on page 72. |
| Ref. | Feature | Description | |
|------|-------------------------------------|--|--|
| 5 | Kite | Provides access to the <i>Kite</i> screen for activation or deactivation of Kite connection. If this icon is visible, then Kite connectivity has been enabled. | |
| | | See <i>Kite</i> on page 66. | |
| 6 | Bluetooth | Provides access to the <i>Bluetooth</i> screen. If this icon is visible, then Bluetooth connectivity has been enabled. | |
| | | See Bluetooth on page 68. | |
| 7 | Wi-Fi | Provides access to the <i>Wi-Fi</i> screen. If this icon is visible, then wireless connectivity has been enabled. The icon also indicates signal strength and Patient SafetyNet connectivity. | |
| | | See Wi-Fi on page 66. | |
| 8 | Ethernet | Provides access to the <i>Ethernet</i> screen. If this icon is visible, then Ethernet connectivity has been enabled. | |
| | | See Ethernet on page 67. | |
| 9 | lris | Provides access to the <i>Iris</i> screen. The example shown above indicates that a standalone device is connected to Port 1 and the information is being sent to Patient SafetyNet or Connectivity Gateway. Ports 2, 3, and 4 are disconnected. | |
| | | The color of the Iris icon matches the status colors of connected standalone devices on the Iris screen. See Chapter 11: Iris on page 117. | |
| 10 | Radical-7 or Radius-7 Battery | Displays charging status for Radical-7 or Radius-7 and provides access to the <i>Battery Radical-</i> 7 screen. The example shows that the battery is currently charging. | |
| | | See Radical-7 and Radius-7 Charging Indicator on page 87. | |
| 11 | 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 on page 87. | |
| 12 | 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 <i>Sounds</i> on page 63. | |

| Ref. | Feature | Description | |
|------|--------------|---|--|
| 13 | 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 <i>Localization</i> on page 65. | |
| 14 | 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 on page 75. | |

About the Action Bar

At the bottom of the Main Screen is the Action Bar with interactive icons. Each icon provides a shortcut to a menu item or an action on Root.

| 1 | 1 2 3 4 5 ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ ▲ | | | | |
|------|---|---|--|--|--|
| Ref. | Feature | Description | | | |
| 1 | Patient Admit/Discharge* | Provides access to admit or discharge a patient. See Admit and Discharge to Patient SafetyNet. on page 103 | | | |
| 2 | EMR Push* | Provides access to send measured or manually entered patient parameter data. See <i>Electronic Medical Record (EMR) Push</i> on page 109. | | | |
| 3 | Session Management | Provides access to Session Management. See Session Management on page 82. | | | |
| 4 | Manual Events | Provides access for manual event markers. | | | |
| 5 | Main Menu | Provides access to device control options for Root and connected medical devices. See <i>Accessing Main Menu Options</i> on page 49. | | | |

*These icons will only appear when Root is connected to a Patient SafetyNet system v5.0.0.0 or higher or an Iris Gateway system.

Using the Touchscreen Interface

Use the gestures described below 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 | | OR APOD 12) Sec | Press and release. Action performed once finger is released. |
| Slide | | | Press, move (left, right, up or down), and release. Moves an object across the display. |
| Swipe | ł | | Press, move (left, right, up or down), and release quickly. |
| Pinch | • | | Press, move, and release two points. Moving points apart zooms in, and moving them together zooms out. |
| Drag and Drop | Ļ | See Customizing Windows on page 46. | Press, 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 |
| | Press left or right of toggle | Quickly moves knob left or right |

| Control | Applicable Actions | Description |
|----------------|-------------------------------------|--|
| 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) 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 |

| Control | Applicable Actions | Description |
|-----------------------|-----------------------------------|---|
| | 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 Waveform | Swipe down | Separates pleth and acoustic waveforms |
| | 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 |

| Control | Applicable Actions | Description |
|---------------------------|--------------------|----------------------------------|
| 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 directions for use or Operator's Manual of Radical-7, Radius-7, and MOC-9 modules.

Trend View



Analog View



| Ref. | Feature | Description | |
|------|------------------|--|--|
| 1 | Window | The area where all data from a docked Radical-7, Radius-7, or connected MOC-9 module are displayed. | |
| 2 | Action Menu | This menu allows the user to change between Trend View and Analog View. For NIBP and Temperature, the action menu allows access to additional settings. Sensitivity settings can also be selected through the action menu. | |
| 3 | Waveform | Shows a parameter or measurement over time (only for Radical-7, Radius-7, and MOC-9 modules). | |
| 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. See Using Trend View on page 43. | |
| 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 on page 44. | |
| 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.

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



| Ref. | 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. |
| 2 | Trend Graph | Displays parameter and measurement over a period of time. Zoom in and out of a Trend Graph 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 directions for use or operator's manuals for Radical-7, Radius-7, and the appropriate MOC-9 module(s).

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-orients 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. |
| 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. |

| 97 | | 1 |
|---------------------|-----------------------------|---|
| SpO2 % | RRa rpm | 2 |
| •3 8.0 Pi | 18 SpOC ml/dl | |
| 70 PR 5 PVi | 1.0 sph 0.5 spMet 2 spco | 3 |

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. |

Manual Sizing of Windows

Expanding and minimizing of windows can be performed from the Main Screen.



| Steps | Instruction |
|-------|--|
| 1 | Press and hold the header bar of the window to be resized to activate the feature. Window borders turn blue for all windows visible on the main screen. |
| 2 | Touch the up arrow to expand the selected window. |
| 3 | Touch the down arrow to minimize the selected window. |

Note: The selected window can also be resized by touching the bar with an up or down arrow and dragging to resize.

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:



Layout See Layout on page 50.



rainbow See *Rainbow* on page 54



Temperature See *Temperature* on page 54.



NIBP See NIBP on page 58.



Sounds See Sounds on page 63.



Device Settings See Device Settings on page 64.



About See *About* on page 74.



Trend Settings See Trend Settings on page 75.



Profiles See Profiles on page 75.



See Chapter 11: Iris on page 117.

Layout



The **Layout** menu allows the user to view and customize settings for the main screen layout by changing any of the following options:



Available Layouts

See Available Layouts on page 51.



Active Channels

See Active Channels on page 52.



Additional Settings

See Additional Settings on page 53.

Available Layouts



From the Layout screen, touch Available Layouts.

When a Radical-7 or Radius-7 is docked to Root and/or multiple MOC-9 modules are connected to Root, the user will have the option to select from several pre-configured layouts. The image below is an example of **Available Layouts** in Root with Radical-7 docked.

Note: The rainbow window can be viewed on a Radical-7, using software v1.5.3.5 or greater, in several of the pre-configured layouts.



Active Channels



From the Layout screen, press Active Channels.

In the $\mbox{Active Channels}$ screen, Temperature and NIBP can be enabled to display on the Root main screen.



| Ref | Option | Description | Factory Default Settings | User Configurable Settings |
|-----|-------------|--|--------------------------------|-------------------------------|
| 1 | Temperature | Enables/disables the temperature window on the Root main screen. | enabled | enabled or disabled |
| 2 | NIBP | Enables/disables the NIBP window on the Root main screen. | enabled | enabled or disabled |

Additional Settings for Layouts



From the Layout screen, press Additional Settings. Change any of the following options:

| Option | Description | Factory Default Settings | User Configurable Settings |
|-----------------|---|-----------------------------|-------------------------------|
| Trend Layout | Controls the sizing of Trend Displays. | Dynamic | Fixed or Dynamic |
| Analog Range | Controls Analog Range Setting. | 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 on page 46. |

| Ref. | Description |
|------|--------------------------------------|
| 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 <i>Customizing Windows</i> on page 46. |
| 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.

Rainbow



The rainbow icon is displayed only when a Radical-7 or Radius-7 is docked to Root. See Operator manuals for Radical-7 or Radius-7.

Temperature



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



Alarms

See Alarms for Temperature on page 55.





Trends See *Trends for Temperature* on page 56.



Additional Settings See Additional Settings for Temperature on page 57.

Alarms for Temperature



From the **Temperature** screen, touch **Alarms**, and then change any of the following options:

| Options | Description | Alarm Priority | Factory Default Settings | Configurable Options |
|---------------------|---|-------------------|--------------------------------|---|
| High Limit (°F) | The High Limit is upper threshold that triggers an alarm. | Medium | Off | 80.20-109.9 in steps of 0.1, or Off When set to Off, alarm is disabled |
| Low Limit (°F) | Low Limit is the lower threshold that triggers an alarm. | Medium | Off | 80.1-109.8 in steps of 0.1, or Off When set to Off, alarm is disabled |
| High Limit (℃) | The High Limit is upper threshold that triggers an alarm. | Medium | Off | 26.9-43.2 in steps of 0.1, or Off When set to Off, alarm is disabled |
| Low Limit (°C) | Low Limit is the lower threshold that triggers an alarm. | Medium | Off | 26.8-43.1 in steps of 0.1, or Off When set to Off, alarm is disabled |
| Silence Duration | Temporarily suspend audible alarms for a period of time. | None | 2 min | 30 sec, 1 min, 2 min, 5 min |

Trends for Temperature



From the **Temperature** screen, touch **Trends**, and then change any of the following options:

| Options | Description | Factory Default Settings | Configurable Options |
|--------------------|---|-----------------------------|-------------------------------|
| Y-Axis Max (°F) | The Temperature Trend Max. The upper limit a measurement will be shown. | 110.0 | 80.1-110.0 in steps of 0.1 |
| Y-Axis Min (°F) | The Temperature Trend Min. The lower limit a measurement will be shown. | 80.0 | 80.0-109.9 in steps of 0.1 |
| Y-Axis Max (°C) | The Temperature Trend Max. The upper limit a measurement will be shown. | 43.3 | 26.8-43.3 in steps of 0.1 |
| Y-Axis Min (°C) | The Temperature Trend Min. The lower limit a measurement will be shown. | 26.7 | 26.7-43.2 in steps of 0.1 |

Additional Settings for Temperature



From the **Temperature** screen, touch **Additional Settings**, and then change any of the following options:

| Options | Description | Factory Default Settings | User Configurable Settings |
|------------------------|--|--------------------------------|-------------------------------------|
| Unit of Measure | The unit of measure for temperature. | °F | °F, °C |
| Probe Mode | A patient-specific probe setting. | Oral | Oral, Adult Ax, Pediatric Ax |
| Continuous Mode | Provides continuous temperature readings through a direct measurement. Direct measurement is used to continuously read temperatures until it reaches the thermal steady state. (unchanging). | Start | None |
| Measurement Timeout | Spot Check timing customization. | 5 minutes | 5, 10, 15, 30, 60 and 90 minutes |

Note: No menu is given when rectal probe is used.

NIBP



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



Parameter Settings

See Parameter Settings for NIBP on page 58.



Intervals

See Intervals for NIBP on page 61.



Additional Settings

See Additional Settings for NIBP on page 62.



Calibration

See Calibration for NIBP on page 63.

Parameter Settings for NIBP

From the **NIBP** screen, touch **Parameter Settings**, and then change individual parameter settings/alarms by selecting one the following parameters:



Systolic/Diastolic

See Systolic/Diastolic (SYS/DIA) on page 59.



Pulse Rate

See **Pulse Rate (PR)** on page 60.



Mean Arterial Pressure

See Mean Arterial Pressure (MAP) on page 61.

Systolic/Diastolic (SYS/DIA)



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

| Options | Description | Alarm Priority | Factory Default Settings | Configurable Options |
|-------------------------|---|-------------------|--------------------------------|--|
| Systolic High Limit | The High Limit is upper threshold that triggers an alarm. | Medium | 220 | 42-259 in steps of 1, or Off When set to Off, alarm is disabled |
| Systolic Low Limit | Low Limit is the lower threshold that triggers an alarm. | Medium | 75 | 41-258 in steps of 1, or Off When set to Off, alarm is disabled |
| Diastolic High Limit | The High Limit is upper threshold that triggers an alarm. | Medium | 110 | 22-199 in steps of 1, or Off When set to Off, alarm is disabled |
| Diastolic Low Limit | Low Limit is the lower threshold that triggers an alarm. | Medium | 35 | 21-198 in steps of 1, or Off When set to Off, alarm is disabled |

Trends for NIBP



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

| Options | Description | Factory Default Settings | Configurable Options |
|---------------|--|-----------------------------|-------------------------|
| Y-Axis Max | The NIBP Trend Max. The upper limit a measurement will be shown. | 260 | 21-260 in steps of 1 |
| Y-Axis Min | The NIBP Trend Min. The lower limit a measurement will be shown. | 20 | 20-259 in steps of 1 |

Pulse Rate (PR)



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

| Options | Description | Alarm Priority | Factory Default Settings | Configurable Options |
|---------------|---|-------------------|--------------------------------|--|
| High Limit | The High Limit is upper threshold that triggers an alarm. | Medium | 120 | 40-215 in steps of 5, or Off When set to Off, alarm is disabled |
| Low Limit | Low Limit is the lower threshold that triggers an alarm. | Medium | 50 | 35-210 in steps of 5, or Off When set to Off, alarm is disabled |

Mean Arterial Pressure (MAP)



From the **Mean Arterial Pressure** screen, touch **Alarms**, and then change any of the following options:

| Options | Description | Alarm Priority | Factory Default Settings | Configurable Options |
|---------------|---|-------------------|--------------------------------|--|
| High Limit | The High Limit is upper threshold that triggers an alarm. | Medium | 120 | 28-219 in steps of 1, or Off When set to Off, alarm is disabled |
| Low Limit | Low Limit is the lower threshold that triggers an alarm. | Medium | 50 | 27-218 in steps of 1, or Off When set to Off, alarm is disabled |

Intervals for NIBP



From the **NIBP** screen, select **Intervals**, then select a **Set Mode**: Automatic, Stat, or Schedule. See the table below for factory default and user configurable settings:

| Set Mode | Description | Configuration | Factory Default Settings | User Configurable Settings |
|-----------|--|---------------|--------------------------------|--|
| Automatic | Automatic interval measurement mode will take blood pressure measurements once every defined interval. See Set Mode: Automatic on page 97. | Interval | 15 min | 2 min, 3 min, 4 min, 5 min, 10 min, 15 min, 30 min, 60 min, 90 min |

| Set Mode | Description | Configuration | Factory Default Settings | User Configurable Settings |
|----------|---|------------------------|--------------------------------|---|
| Stat | Stat interval measurement mode will take blood pressure measurements continuously for the defined duration. See Set Mode: Stat on page 99. | Stat Duration | 10 min | 5 min, 10 min |
| Schedule | Schedule measurement mode will take blood pressure measurements once every defined interval for the defined duration. See Set Mode: Schedule on page 101. | Interval : Duration | | Interval and Duration settings can be customized to accommodate a facilities protocol. |
| | | | NA | Note: Schedule mode is configured in Root by authorized personnel. Up to five (5) uniquely defined Interval : Duration pairs can be stored. |

Additional Settings for NIBP



From the **NIBP** screen, touch **Additional Settings**, and then change the following option:

| Options | Description | Factory Default Settings | User Configurable Settings |
|------------------------|---|--------------------------------|-------------------------------------|
| Measurement Timeout | Defines the value of when the last BP reading values will clear the window. | 15 min | 5, 10, 15, 30, 60 and 90 minutes |

Calibration for NIBP



The **Calibration** option on the **NIBP** menu allows a qualified service professional to access calibration settings and tools for the NIBP module. For more information, see **NIBP Module** *Calibration Test* on page 150.

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

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. | 3 | 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 on page 80. | 2 minutes | 1, 2, 3 minutes, Permanent*, Permanent with Reminder*. If <i>Permanent</i> is selected, there will be no audible alarms when Audio Pause is enabled, 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 when Audio Pause is enabled. |
| SmartTone | Allows the audible pulse to continue to beep when the pleth graph shows signs of motion. | Off | On or Off |

*Requires the **all mute enabled** option to be toggled to **ON** in the Access Control menu. See **Access Control** on page 70.

Device Settings



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



Localization See *Localization* on page 65.



Kite See Kite on page 66



Wi-Fi See Wi-Fi on page 66.



Ethernet See Ethernet on page 67.



Bluetooth See **Bluetooth** on page 68.



Root Battery See *Root Battery* on page 68.



Radical-7 Battery See Radical-7 and Radius-7 Battery on page 69.



Brightness See Brightness on page 69.



Access Control See Access Control on page 70.



Device Output See Device Output on page 72.

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** on page 34.

| 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 Format | 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 |

Kite



Use the Kite screen to enable or disable Kite connectivity.

| Option | Description | Factory Default Setting | Configurable Settings |
|---------------------------|---|-------------------------------|--|
| Enable Kite Connection | Activates or deactivates an active Kite connection. | Off | On or Off |
| Pairing Key | Four (4) digit code automatically assigned for active Kite session. | N/A | Automatic with active Kite connection |

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* on page 34.

| Option | Description | Factory Default Setting | Configurable Settings |
|--------|---|----------------------------|-----------------------|
| Wi-Fi | Enables or disables Wi-Fi connectivity. | Off | On or Off |

Additional fields in the *Wi-Fi* 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, see the Patient SafetyNet Operator's Manual.

CAUTION: Unanticipated failure or alteration of network components (including but not limited to: disconnection or malfunctioning of a networking device/switch/router/ethernet cable) may result in loss of connectivity of Kite to other hospital systems. Altering or making changes to the hospital network should be done with proper knowledge.

Connecting Root to Patient SafetyNet

Root can be configured to connect to Patient SafetyNet wirelessly by authorized and trained personnel only.

The wireless icon in the Status Bar on Root displays the current connection status. See **About the Main Screen** on page 33.

| lcon | Description |
|------|---|
| ((• | A gray icon indicates Root wireless radio is on, but it is not connected to a wireless network. |
| (: | A blue icon indicates Root is connected to a wireless network, but not communicating with Patient SafetyNet. |
| (: | A green icon indicates Root is connected to a wireless network and communicating directly with 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** on page 34.

| 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** on page 34.

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

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

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** on page 34.

| 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 and Radius-7 Battery



Use the Battery screen to view the specific percentage of charge on the Radical-7 or Radius-7's battery. For Radical-7, the user can also access the Battery screen by pressing the Battery icon on the Status Bar. See **About the Status Bar** on page 34.

| 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.



 When the numeric screen displays, enter the following numbers: 6 2 7 4 Asterisks (****) will be displayed.

To undo an entry, press **Backspace**.

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 |
|-----------------------------------|---|-------------------------------|--|
| Power On Profile | Sets the profile used when the device is powered on. | Previous Profile | Adult, Adult Modified, Neonatal, Pediatric, or Previous Profile |
| All Mute Enabled | Enables or disables parameter Alarm Silence menu option. See Sounds on page 63. | Off | On or Off |
| Lock Alarm Volume | Sets the lowest alarm volume level. | Off | 3, 4, or Off |
| Optical Sensor Off Alarm Delay | Enables or disables alarm delay when Optical Sensor is off. | O Sec. | 0, 5, 10, 15, 30, or 60 seconds |
| Option | Description | Factory Default Setting | Configurable Settings | |
|--------------------------------------|---|-------------------------------|--|--|
| Standby Enabled | Enables or disables option for Standby Mode. See Standby Mode on page 80. | Off | On or Off | |
| Standby Reminder Tone Interval | Allows for time interval of 30 sec, 1 min, 2 min, 3 min, 5 min, 10 min, or 15 min, as well as Off. | 30 sec | 30 sec, 1 min, 2 min, 3 min, 5 min, 10 min, 15 min, or Off | |
| Allow Unsigned Upgrade | Allows for Root software to be reverted back to older version | Off | On or Off | |
| Sessions Enabled | Enables or disables Session Management. See Session Management on page 82 | Off | On or Off | |
| USB Port 1* baud rate | Enables option to change baud rate of device | 921600 | 9600, 19200, 38400, 57600, 115200, 230400, ol 921600 | |
| USB Port 2* baud rate | Enables option to change baud rate of device | 921600 | 9600, 19200, 38400, 57600, 115200, 230400, or 921600 | |
| Data Collection Enabled | Enables or disables physical data collection mode. | Off | On or Off | |
| EDF Collection Enabled | Enables or disables EDF data collection from SedLine (See Operator's Manual for SedLine) | Off | On or Off | |
| Synchronized Waveforms Enabled | Enables or disables Synchronization Waveform view. | rm Off On or Off | | |
| Presence Monitoring | esence Enables or disables onitoring Presence Monitoring Off | | On or Off | |
| Save as Adult | Saves current profile parameter as the Adult Profile. | N/A | Press Save to update the profile. | |

| Option | Description | Factory Default Setting | Configurable Settings |
|----------------------|---|-------------------------------|--|
| Save as Pediatric | Saves current profile parameter as the Pediatric N/A Profile. | | Press Save to update the profile. |
| Save as Neo | Saves current profile parameter as the Neonatal Profile. | N/A | Press Save to update the profile. |
| Factory Defaults | Options are restored to factory value. | N/A | Press Restore . |

*Changes to USB Ports baud rate will take effect after Root is power cycled, turned off then on again.

Note: Restore Factory Defaults can only be performed during non-monitoring and no cable connections are present.

Device Output



The *Device Output* screen allows the user to configure additional data output options. 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 Trigger | Controls the source of monitoring which sets off the trigger. | Alarms | Alarms, Low SIQ, Alarms + SIQ |
| 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 |
| USB Port 1 | Controls the output type for USB Port 1. | None | None, SatShare, ASCII 1, IntelliBridge, or IAP |

| Option | Description | Factory Default Setting | Configurable Settings | |
|---------------------------------|---|-------------------------------|---|--|
| USB Port 2 | Controls the output type for USB Port 2. | IAP | None, SatShare, ASCII 1, IntelliBridge, or IAP | |
| IntelliBridge Output Options | Controls the data type output for IntelliBridge. | Radical | Radical * Sedline, O3 Sensor 1/2/L/R* O3 Sensor 1/2/L/R* SedLine Numerics only* Radical Module A* | |

*Options when IntelliBridge is selected.

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* on page 80.

IntelliBridge Connectivity

IntelliBridge connectivity allows Root to transmit parameters and waveforms to Philips multi-parameter patient monitors that support Philips IntelliBridge device interfacing modules. This option allows parameters and waveforms on Root to be displayed on a Philips monitor and, if applicable, transmitted to the electronic medical record system.

Masimo parameters from SET, rainbow SET, and SedLine, channels are supported.

Masimo waveforms from SET, rainbow SET, channels are supported.

Note: Root supports the transmission of data only. Validations of the retrieval and display of data transmitted is the responsibility of the IntelliBridge manufacturer.

Parameters Supported

IntelliBridge connectivity allows for up to six (6) parameters and two (2) waveforms or eight (8) parameters and no waveform to be displayed on Philips monitors.

| Channel | Supported Parameters | Waveforms |
|------------------|---|---|
| SET [®] | SpO ₂ , PR, Pi, PVi | Pleth |
| rainbow® | RRa, SpHb, SpCO, SpOC, SpMet | RRa |
| SedLine® | PSi [™] , SR, EMG, ARTF, SEFR, SEFL | N/A |
| Capnography | etCO₂, FiCO₂, RR, etN₂O, FiN₂O, EtO₂, FiO₂, EtENF, FiENF, EtDES, FiDES, EtHAL, FiHAL, EtISO, FiISO, EtSEV, FiSEV, MAC | CO ₂ , uom %, CO ₂ uom kPa, CO ₂ , uom mmHg, O ₂ , AA1 |

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. |
| MIB | Displays MOC-9 interface revision. |

Information about Radical-7, Radius-7, and MOC-9 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 Graph. | 2 hours | 15, 30, and 45 minutes 1, 2, 4, 8, 12, 24, 48, 72, and 96 hours |
| Clear Trends | Delete all stored trend data. | N/A | Press Clear to delete all stored trend data. |

To configure trend settings for specific parameters and measurements, see Directions 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 |
|----------------------|--|----------------------------|---------------------------------------|
| Profile Name | Identifies the Profiles setting in the device. | Adult | Adult, Pediatric, Neonatal, Custom |
| Configure Profile | Identifies the patient category type. | 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.

Root has the ability to support up to eight (8) custom profiles to accommodate usage in any hospital environment. 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 Screen* on page 120.

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 |
|----------|----------------|
| High | 10-pulse burst |
| Medium | 3-pulse burst |

| Alarm Source | Example | Explanation |
|--------------------|--|--|
| Parameter Level | ADULT & CO & & & & B = = (*) 1126AM REAL-63 97 sc. 6 6 6 14 14 15 0.7 subur 5 5 7 15 5 7 15 5 7 18 8 5 7 18 8 5 7 18 8 5 7 12 12 12 12 12 12 12 12 12 12 | The example shown here is a PR alarm as the reading (61) exceeds the lower alarm limit (65). Note: 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 (PR Low < 65). |

| Alarm Source | Example | Explanation |
|-----------------|---|---|
| Window Level | ADULT & D. # • & & & | The example shown here is a "High Impedance" alarm in the lower Window. Note: The border of the Window illuminates red, and the explanation of the alarm is shown at the top of the Window (High Impedance Detected). |
| System Level | Image: Section of the section of th | The example shown here is a "Low Battery" alarm. Note: The border of the entire Root display is illuminated yellow, and the explanation of the alarm is shown in the Status Bar (Low Battery). |

For more details about specific alarms on Radical-7, Radius-7, and MOC-9 modules, see Directions 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).

| lcon 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. See **About the Status Bar** on page 34.

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 15 seconds left until Audio Pause is inactive again.

To configure Audio Pause, see *Sounds* on page 63.



Audio Pause active. 15 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.

Standby Mode

Standby Mode allows for patient monitoring to be temporarily suspended. The Standby icon (see image below) is located in the top-left corner of the screen.

To enable Standby Mode (suspend monitoring)

- 1. On Root, open the Access Control menu.
- 2. Swipe the **standby enabled** button to **ON**. Return to the home screen on Root, and the Standby icon will appear on the screen in the top-left corner.
- 3. Press the Standby icon, and a notification message will appear on the screen indicating that monitoring is suspended (see image below).

To exit Standby Mode (resume monitoring)

• Tap anywhere on the screen.

WARNING: When Root is in Standby Mode, monitoring is suspended and no alarms will be active, with the exception of the low battery alarm.



Note: Standby Mode will not affect any devices using Root's Iris Connectivity to Masimo Patient SafetyNet.



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.

Session Management

Session Management, when enabled, allows clinicians to input a label (session name) which will output with data downloaded from Root.

Enabling Session Management

To enable session management go to Devices Settings. Choose Access Control then slide the Sessions Enabled button to the on position.

Starting Session Management

Press the session management icon on the Action Bar. Session Name window will open in which you can label the session. When data is downloaded from Root it can be identified by the label assigned to a particular session. See **About the Action Bar** on page 36.

Note: When Session Management is enabled multiple sessions can be recorded, not simultaneously but sequentially.

Ending Session Management

To end a session, go to the Action Bar, press the session management icon with the timer

overlay ²²². End Session window will open. Push the End button to end the session.

Note: The maximum time for a session is 96 hours.

Screen Capture

Up to 20 screen capture images can be stored in Root and transferred to a USB drive as PNG files. When the limit of 20 screen captures is reached in Root, every new screen capture will replace the oldest dated screen capture.

Note: There must be a folder titled "screen_shot" in the USB drive with a FAT or FAT32 system file to enable the download of the screenshots.

Capturing Screens

To capture a screen:

Swipe across the Root screen from right to left using three fingers simultaneously (see image below).



83

A confirmation flash will appear on the screen indicating a capture is in progress. A status message [1] will be displayed briefly at the top of the screen and the **patient label name will be masked with asterisks** [2].



| Reference | Example | Description | | |
|-----------|---|---|--|--|
| 1 | | The screen capture status message displays the following information: | | |
| | | • Date: Date of screen capture (YYYYMMDD) | | |
| | Date Time Root Serial Number 20180425_154604_1284567890.png 8/208 Capturing screen. | • Time: Time of screen capture (HHMMSS) | | |
| | | • Device Serial Number: 10 digit Root serial number | | |
| | Number of Screen Captures | • Number of Screen Captures: The number of screen captures saved on Root of 20 screen capture limit. When the limit of 20 screen captures is reached, every new screen capture will replace the oldest dated screen capture. | | |
| 2 | ***** | The patient label is masked with asterisks when capturing a screen. | | |

Downloading Screen Captures

To download screen captures:

1. Remove any sensors connected to the patient to stop monitoring, and acknowledge any alarms triggered on Root.

Note: Before connecting the USB drive in the next step, there must be a folder titled "screen_shot" in the USB drive with a FAT or FAT32 system file to enable the download of the screen captures.

- 2. Plug the USB drive into the USB port located on the rear panel of Root; the screen captures will automatically download. A status message will display briefly at the top of the Root screen to indicate the start of the download.
- 3. A confirmation status message will display briefly at the top of the Root screen when the file transfer is complete.
- 4. Unplug the USB drive from Root.

To import the screen captures from the USB drive onto a computer, plug the USB drive into the computers USB port, then open the folder titled "screen_shot" (from the USB drive) on the computer to access the .png files.

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* on page 24.

System Status Light

| Light Status | Alarm Priority | Indication |
|-----------------|----------------|--|
| None | None | Monitoring has not started. |
| Green | None | There is currently no active alarms. |
| Flashing Yellow | Medium | There is an active alarm of medium priority. |
| Flashing 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 | Medium |
| Service required | High |

AC Power Indicator



Whenever Root is connected to an AC power source, the AC power indicator illuminates.

| 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. |

Radical-7 and Radius-7 Charging Indicator



When Root is connected to an AC power source, it is able to charge a correctly docked Radical-7 or Radius-7. This is true whether the device is powered on, in Sleep Mode, or powered off. Conversely, when Root is not connected to AC power, it will not charge the device.

The light status provides a visual indication of the battery condition:

| Light Status | Battery Indication |
|--------------|--|
| Green | Battery is fully charged. |
| Orange | Battery is charging. |
| Red | Battery is unable to charge. |
| Off | Battery is fully charged, not being charged. |

Sleep and Power Off

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

| State | Description |
|-------------------|---|
| Sleep | Press and hold the Power Button for two (2) seconds until one (1) audible tone sounds. |
| Mode | Sleep Mode conserves power while enabling a quicker startup sequence. |
| Power Off Mode | 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. |
| | Power Off Mode completely shuts down Root and results in a longer startup sequence. |

Chapter 4: Temperature Measurement

Note: This feature is optional on Root.

For temperature measurements obtained with the TIR-1 bluetooth thermometer, refer to the TIR-1 manual. Root offers an optional integrated temperature module and takes a temperature measurement through the use of a temperature probe. The temperature probe is designed for use on adult and pediatric patients. Patient temperature can be measured via an oral/axillary or rectal probe.

Operation - Temperature

Spot Check Mode

Spot Check mode provides a one-time predictive measurement that takes a temperature in approximately 6 to 15 seconds, before a steady state temperature is achieved. Predictive measurements reduce the time required for measurement by using algorithms to predict what the temperature would be if the probe were left in place until steady state is achieved.

Continuous Mode

Continuous mode provides continuous temperature readings for up to 10 minutes through a direct measurement. Direct measurement is used to continuously read temperatures until it reaches the thermal steady state (unchanging). The thermal steady state is achieved through an oral or rectal measurement in approximately 3 minutes and through an axillary measurement in approximately 5 minutes.

Taking Temperature Measurement

1. Ensure that the correct measurement site is selected before measurement.



Note: If a rectal probe is attached, the **Site** button

will not appear.

Note: The site selection toggle is disabled once the probe has been placed on the site. The toggle will be re-enabled once the probe has been returned to the probe well holder.

2. To change the measurement site, touch the **Main Menu** icon **W**, then select

Temperature Settings 📟

Select Additional Settings 🔩, then select the desired measurement site through **Probe Mode**. The measurement site can also be changed using the action menu.

| addit | tional settings |
|-----------------|-----------------|
| unit of measure | °F 💽 °C |
| probe mode | Oral |

3. Remove the temperature probe from the probe well holder to initiate spot check.



Note: Ready status will display in the status bar and sound will play.

4. Apply a single-use disposable probe cover to the temperature probe before measurement.

WARNING: The use of any other probe cover may produce temperature measurement errors or may result in inaccurate readings.

5. Place the temperature probe on the site to begin spot check.

WARNING: Before use, verify the color of the probe cover eject button on the temperature probe to confirm the proper application site: Red (rectal), Blue (oral/axillary).

| Temperature | Measuring | | ORAL | $\overline{}$ |
|-----------------|-----------|---|--------|-----------------|
| 104 99 94 | | _ | | 101 94 °F |
| | | | 2:00 h | + |
| 7 | | | | • |

Note: Measuring status displayed in the status bar.

6. Wait for measurement to complete or return the probe to stop measurement.



Note: If a reliable spot check measurement cannot be made, the temperature module will automatically switch to continuous mode to make the measurement.

Note: Once measurement is successfully completed, value is displayed.

If continuous monitoring is not needed, dock the temperature probe in the probe well holder to reset measurement.

7. To continuously monitor temperature, touch the action menu



Note: Continuous mode can only be enabled if the probe has not been removed from the measurement site during spot check.

Note: Continuous mode provides continuous temperature readings for up to 10 minutes through a direct measurement.

Note: Another spot check cannot be performed until the probe is first returned to the probe well holder.

| Tempera | ature | | | ORAL | |
|-----------------|-------|--|----------|--------|----------------------------|
| 104 99 94 | | | CONTINUE | pus | ORAL ADULT AX PED AX |
| 08/21/201 | | | | 2:00 h | + |
| Y | | | | | • |

8. Dock the temperature probe in the probe well holder to end temperature monitoring.

Temperature Probes

Two types of probes are available for use with the Root: an oral/axillary probe and a rectal probe.

Root will automatically detect the probe type when connected: oral/axillary or rectal.

- Adult axillary Spot Check Mode (predictive) temperatures are measured using the oral/axillary probe in combination with the Root in Adult axillary mode. A temperature reading is provided in approximately 12-15 seconds.
- Pediatric axillary Spot Check Mode (predictive) temperatures are measured using oral/axillary probes in combination with the Root in Pediatric axillary mode. A temperature reading is provided in approximately 10-13 seconds.

• For oral temperatures, place the probe tip under the patient's tongue on either side of the mouth to reach the sublingual pocket and ask the patient to close his/her lips.

Sublingual Pocket Location



- For axillary temperatures, lift the patient's arm so that the entire axilla is
 easily seen and place the probe as high as possible in the axilla. Do not allow
 the probe tip to come into contact with the patient until the probe is placed
 in the measurement site. Any prior contact between the probe tip and the
 tissue with another material may cause inaccurate readings. Verify that
 axillary tissue completely surrounds the probe tip and place the arm snugly
 at the patient's side. Firmly hold the probe in place and keep the tip of the
 probe in contact with the tissue throughout the measurement process.
- Remove the probe after the temperature measurement is complete and firmly press the ejection button on the top of the probe to release the probe cover.
- Return the probe to the probe well.
- Rectal temperatures are measured using rectal probes which give a Spot Check Mode (predictive) temperature in approximately 10-13 seconds.
 - For rectal temperatures, separate the patient's buttocks with one hand. Use
 the other hand to gently insert the probe only 5/8 in. (1.5 cm) inside the
 rectum (less for infants and children). The use of a lubricant is optional. Tilt
 the probe so that the tip is in contact with tissue. Continue to separate the
 buttocks and hold the probe in place throughout the measurement process.
 - Remove the probe after the temperature measurement is complete and firmly press the ejection button on the top of the probe to release the probe cover.
 - Return the probe to the probe well and wash your hands.

Regularly wipe the probe with a cloth dampened with warm water and a mild detergent solution, a 70% isopropyl alcohol solution, or a 10% chlorine bleach solution.

Supported Masimo Probes and Probe Covers

For a list of compatible temperature probes and accessories, visit http://www.masimo.com/.

Chapter 5: NIBP Measurement

Root provides noninvasive blood pressure readings through an oscillometric method.

An oscillometric method of blood pressure measurement is a noninvasive method that monitors the amplitude of cuff pressure changes during cuff deflation to determine arterial blood pressure. The NIBP module is designed for use on adult, pediatric, and neonatal patients.

Patient Measurement Mode

Below is a table that provides a method for selecting the appropriate NIBP patient category. To change patient category see *Profiles* on page 75.

| Weight | Patient Category | Maximum Pressure |
|-----------------------------|------------------|------------------|
| Greater than 75lbs (34kg) | Adult | 280 mmHg |
| Between 15.4-75lbs (7-34kg) | Pediatric | 280 mmHg |
| Less than 15.4lbs (7kg) | Neonatal | 140 mmHg |

Cuff Selection and Placement

Root uses a bayonet hose with a blood pressure cuff to measure NIBP. For a list of compatible NIBP patient hoses and cuffs, visit *http://www.masimo.com/*.

To ensure the correct cuff size

Wrap the cuff around the arm.







If the index line does not fit within the range markings, select a larger or smaller cuff.

To place cuff on the measurement site

Wrap the cuff around the non-dominant arm, making sure that the Artery Marker is aligned over the brachial artery as shown in the image below. To locate the brachial artery, place the pads of your index and middle fingers halfway between the shoulder and elbow, in the middle of the inner arm, between the bicep and triceps muscles. If possible, do not wrap the cuff over the patient's clothing. The cuff should fit snugly around the patient's arm for maximum oscillometric signal quality. The lower edge of the cuff should be located 2 cm above the antecubital fossa (interior bend of the elbow).



Ensure that the air hose from the monitor to the cuff is not compressed, crimped, or damaged.

Patient Conditions

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

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

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

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

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

Note: It is recommended to notify the patient to relax and not talk during the measurement.

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

www.masimo.com

🛿 Masimo

Operation - NIBP

Root works by noninvasively monitoring the amplitude of cuff pressure changes during cuff deflation to determine arterial blood pressure. The cuff pressure is first elevated above the patient systolic blood pressure level. The cuff will then begin to deflate at a certain rate. The initial rise in the amplitude of pressure fluctuations during cuff deflation corresponds closely to the systolic blood pressure. As the cuff is further deflated, the pressure fluctuations increase in amplitude until a peak is reached which is usually referred to as the mean arterial pressure (MAP). As cuff deflation continues, the diastolic pressure can be determined based upon the rapidly diminishing amplitude of the pressure fluctuations.

Spot Check Measurement

To spot check measure NIBP

1. Ensure that the correct patient profile is selected before measurement.



WARNING: Only use Root in Neonatal mode with a neonatal blood pressure cuff to measure blood pressure on neonates.

Note: The **Patient Category** determines the initial inflation pressure of NIBP. Ensure that the proper patient profile and subsequent patient category are appropriate for the intended patient to be measured.

2. To change the patient profile, press the **Main Menu** icon **W**, then select **Profiles**

Press the **Profile Name** to select the desired patient profile.

| G | profiles |
|-------------------|----------|
| profile name | Adult |
| configure profile | Edit |
| | |

3. Properly place the blood pressure cuff on patient. See *Cuff Selection and Placement* on page 93.

4. Press the **Start** button to begin measurement.



5. Wait for measurement to complete or press the **Stop** button to stop measurement.



Note: Measuring status displayed in the status bar.

6. Wait for measurement values to appear to ensure that spot check is complete.



Set Mode: Automatic

Automatic interval measurement mode will take blood pressure measurements once every desired interval.

To measure blood pressure in Automatic interval mode

1. Ensure that the correct patient profile is selected before measurement.



WARNING: Only use Root in Neonatal mode with a neonatal blood pressure cuff to measure blood pressure on neonates.

2. To change the patient profile, press the Main Menu icon , then select Profiles

Press the **Profile Name** to select the desired patient profile.

| ¢ | profiles | |
|-------------------|----------|-------|
| profile name | | Adult |
| configure profile | Edit | |
| | | |

- 3. Properly place the blood pressure cuff on patient. See *Cuff Selection and Placement* on page 93.
- 4. To enable Automatic mode, press the Main Menu icon , then select NIBP Settings

On the **Intervals** screen, change **Set Mode** to **Automatic**, and then select the desired **Interval**. The set mode can also be changed using the action menu.

| | intervals |
|----------|------------------|
| set mode | automatic 🛃 stat |
| interval | 30m |
| | Start Auto |

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

- 5. To begin measurement, press the **Start Auto** button and then press the arrow at the top-left corner of the touchscreen to return to the **Main View**.
- 6. Wait for measurement to complete or press the **Stop** button to stop the measurement.



Note: Once finished measuring, values will appear and the next measurement will begin after the specified interval.



Set Mode: Stat

Stat interval measurement mode will take blood pressure measurements continuously for the desired duration. \\

To measure blood pressure in Stat interval mode

1. Ensure that the correct patient profile is selected before measurement.



WARNING: Only use Root in Neonatal mode with a neonatal blood pressure cuff to measure blood pressure on neonates.

2. To change the patient profile, press the Main Menu icon , then select Profiles

Press the **Profile Name** to select the desired patient profile.

| ¢ | profiles | |
|-------------------|----------|--|
| profile name | Adult | |
| configure profile | Edit | |
| | | |

- 3. Properly place the blood pressure cuff on patient. See *Cuff Selection and Placement* on page 93.
- 4. To enable **Stat** mode, press the **Main Menu** icon **t**, then select **NIBP Settings**

On the **Intervals** screen, change **Set Mode** to **Stat**, and then select the desired **Stat Duration**. The set mode can also be changed using the action menu.

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

| | intervals |
|---------------|------------------|
| set mode | automatic 💽 stat |
| stat duration | 5m 10m |
| | Start Stat |

- 5. To begin measurement, press the **Start Stat** button and then press the arrow at the top-left corner of the touchscreen to return to the **Main View**.
- 6. Wait for measurement to complete or press the **Stop** button to stop the measurement.



Note: Once measurement is completed and values appear, the next measurement will begin and repeat until duration time has elapsed.



Set Mode: Schedule

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

*Schedules are configured by authorized personnel.

To measure blood pressure in Schedule mode:

1. Ensure that the correct patient profile is selected before measurement.



WARNING: Only use Root in Neonatal mode with a neonatal blood pressure cuff to measure blood pressure on neonates.

- 2. To change the patient profile, press the Main Menu icon , then select Profiles
- 3. Press the **Profile Name** to select the desired patient profile.

| Θ | profiles |
|-------------------|----------|
| profile name | Adult |
| configure profile | Edit |
| | |

- 4. Properly place the blood pressure cuff on the patient. See *Cuff Selection and Placement* on page 93.
- 5. To enable **Schedule** mode, press the **Main Menu** icon **W**, then select **NIBP**

Settings

6. On the **Intervals** screen, change **Set Mode** to **Schedule**. The set mode can also be changed using the action menu.

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

7. Press the **Start Schedule** button.

| ⊖ intervals | | |
|---------------------|----------------|--------|
| set mode | Sci | hedule |
| interval : duration | 5m | 20m |
| interval : duration | 10m | 20m |
| interval : duration | 20m | 1h |
| interval : duration | 30m | 1h |
| interval : duration | 1h | 4h |
| | Start Schedule | |

- 8. Press the arrow at the top-left corner of the touchscreen to return to the $\ensuremath{\textbf{Main}}$ $\ensuremath{\textbf{View}}.$
- 9. Wait for the interval measurement to complete or press the **Stop** button to stop the interval measurement.



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



Chapter 6: Admit and Discharge to Patient SafetyNet

The Admit/Discharge icon is located at the bottom left of the Main Screen and allows for clinicians to admit or discharge patient's on Masimo Patient SafetyNet directly from Root.

Note: In order to use this feature Masimo Patient SafetyNet software version 5.0.1.0 or higher is required.

Not Admitted

A **Not Admitted** message will appear on the Root screen when the sensor is placed onto a patient and a patient has not yet been admitted on the Root. Press the **Admit** button on the screen to admit the patient or press skip and the patient data will not be transmitted to the Masimo Patient Safety Net.



Admitting a Patient

To admit a patient:

- 1. Press the admit icon **bottom**-left of the main screen.
- 2. Enter the authentication PIN.



- 3. Either press the **patient info** search button (1) to select existing patient information, or enter new patient information in the data fields (2).
- 4. Press the **assignments** search button (3) and select the primary and secondary pagers (4).
- 5. Press the **Admit** button (5).

| | Φ | | patient | |
|-----|----------|---------------|-----------|----------------|
| | | | | |
| | patient | info | | |
| | | label | Doe | P 1 |
| | | first name | John | |
| | | middle name | | |
| | | last name | Doe | |
| | n | oom number | 123 | |
| | | date of birth | 1/2/76 | 2 |
| | | mrn | 123456 | |
| | | account | 123456 | |
| | c | CustomField1 | | |
| | c | CustomField2 | | |
| | c | CustomField3 | | |
| | accignm | onto | | |
| | assignin | primary | 1 | P |
| 4 – | | secondary | 2 | م 3 |
| | | Clear A | All Admit | - 5 |



Discharging a Patient

To discharge a patient:

- 1. Press the discharge icon **L** on the bottom-left of the main screen.
- 2. Enter the authentication PIN.



3. Press the **Discharge** button. A confirmation message will appear.

| 5 | | 0 |
|--------------------------|------------|----|
| Ð | patient | |
| patient info | | |
| label | patient1 | |
| first name | One | |
| last name | Pateint 1 | |
| middle initial | 0 | |
| room | | |
| date of birth | 06-13-1969 | |
| medical record number | | |
| patient identifier | | |
| assignments | | |
| primary | | |
| Pager 1 | | \$ |
| secondary | | |
| | | 2 |
| | | |
| | | |
| | Discharge | |

- 4. Press the **Discharge** confirmation button.
- www.masimo.com

Note: Once patient is discharged from Root, or session is ended, the NIBP parameter display will be cleared.

| DISCHARGE | | |
|-----------|-----------|--|
| | | |
| pa | onfirm | |
| Cancel | Discharge | |
| | | |

Not Monitoring Message

When the sensor is off the patient for an extended period of time, a **Not Monitoring** message will appear on the screen. Acknowledge the message by pressing **Cancel** or **Discharge**. Press **Discharge** to discharge the patient that is currently admitted on the Root, or press **Cancel** to keep the same patient admitted.




Monitoring Resumed Message

When the sensor is taken off and placed back onto a patient, a **Monitoring Resumed** message will appear on the Root screen.

If this is a new patient, press **Discharge** on the screen to discharge the previous patient. If the same patient is being monitored, press **Confirm** to continue monitoring the same patient.



Chapter 7: Electronic Medical Record (EMR) Push

The Electronic Medical Record (EMR) Push feature allows clinicians to send validated patient vitals data from any of the Masimo devices, MOC-9 modules, or Iris devices connected to Root directly to a Patient Data Management System, such as an Electronic Medical Record (EMR).

Determining EMR Push is Active



The EMR Push icon is appears at the bottom of the Root main screen when the EMR Push feature is active. The EMR Push feature is active when a Root patient profile is connected to a Patient SafetyNet server. If the EMR Push icon does not appear, see Masimo Technical Services on page 160.

Note: The Patient SafetyNet server can be configured to require clinicians to provide access credentials to activate the EMR Push feature. To configure Patient SafetyNet to require access credentials, see *Masimo Technical Services* on page 160.

Manually Entering Patient Data

Follow the instructions below to manually enter patient data.

Note: Parameters with manual entry permissions can be pre-configured on Patient SafetyNet. See Masimo Technical Services on page 160.

In the EMR Push screen, press a parameter that has a pencil icon 1.



- 2. In the manual entry screen, move the slide knob or press the spinner to select the desired parameter value.
- 3. Press **OK** to accept the selected manual entry value, or press **Cancel** to delete the manual entry value and return to the EMR Push screen. After pressing **OK**, the selected manual entry value appears on the EMR Push screen.

Sending Patient Data to the EMR

Follow the instructions below to send patient data to a data management system using the *EMR Push* feature.

Note: Parameters that appear on the *EMR Push* screen can be pre-configured on Patient SafetyNet. For questions about pre-configuring *EMR Push* parameters, see *Masimo Technical Services* on page 160.

- 1. Select the *EMR Push* icon at the bottom of the Root Main Screen.
- 2. In the *Authentication* screen, enter a username and PIN.
- 3. Press OK.

Note: Username and PIN requirements are enabled through Patient SafetyNet. If unable to authenticate a username and PIN, see *Masimo Technical Services* on page 160.

| aut | hent | ication | |
|-----------------|------|---------|---|
| username PIN | | | 8 |
| Cancel | | ОК | |

- 4. In the *EMR Push* screen, review and manually enter patient data before submitting to the EMR. See *Manually Entering Patient Data* on page 109.
- 5. Press the **Submit** button to send patient data to the EMR or press the **Back** button to return to the Main Screen.
- 6. After pressing the **Submit** button, select Approve to send patient data to the EMR.
- 7. Press **OK** in the *Successfully Sent Data to EMR* confirmation screen.



Chapter 8: Radical-7

The Radical-7 is a detachable portable noninvasive monitor that measures arterial oxygen saturation (SpO_2) , pulse rate (PR), and perfusion index (Pi), along with optional measurements of hemoglobin (SpHb), carboxyhemoglobin (SpCO), total oxygen content (SpOC), methemoglobin (SpMet), pleth variability index (PVi), and/or acoustic respiration rate (RRa). It can be docked to Root to transfer parameter data to Root. When Radical-7 is docked to Root, the device automatically creates a Window that displays all the data from Radical-7.

Root also acts as a charging station for Radical-7. See Radical-7 Operator's Manual for more information.



Chapter 9: Radius-7

The Radius-7 is a patient wearable device for continuous monitoring when the patient is ambulatory. It measures arterial oxygen saturation (SpO_2) , pulse rate (PR), perfusion index (Pi), and pleth variability index (PVi) along with optional measurements of hemoglobin (SpHb), carboxyhemoglobin (SpCO), total oxygen content (SpOC), methemoglobin (SpMet), and/or acoustic respiration rate (RRa). It uses a Bluetooth connection to transfer parameter data to Root. When Radius-7 is connected to Root via Bluetooth, 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 10: MOC-9

Flexible measurement expansion is enabled through MOC-9. It can display parameters and measurements captured by SedLine, ISA Capnography, and 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 ISA capnography MOC-9 modules that are connected to Root. For any MOC-9 device connected to Root, refer to the MOC-9 device's Operator's Manual/Directions for Use for all information.



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 11: 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 | Standalone devices connected via Iris (e.g., monitor, pump, ventilator) |
| 2 | Root |
| 3 | Patient SafetyNet View Station |



| Ref. | Description |
|------|--|
| 4 | Patient SafetyNet or Masimo Connectivity Gateway |
| 5 | Notification devices |
| 6 | Electronic Health Records system |

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 Iris Adapter to the standalone device. Refer to the Iris Adapter Directions for Use.
- 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.

Iris Icon

The Iris icon located in the *Status Bar* indicates Iris port connectivity status. See **About the Status Bar** on page 34. The Iris ports are mapped to the Iris icon according to the diagram below:



Iris connectivity port status is indicated in the Iris icon by color and shape. See the table below for further description.

| Iris Port Connection Status | Iris Icon Description | Example | Description of Connection |
|---|--|---------|--|
| Connected | Green border with solid green square | | Standalone device is successfully connected to Root and Root is successfully connected to a Patient SafetyNet or Connectivity Gateway. |
| Attempting/Unable to Connect to Server | Yellow border with solid yellow square | | Standalone device is connected to Iris adapter in <prod_name_short, but="" root<br="">is attempting or unable to connect to a Patient SafetyNet or Connectivity Gateway.</prod_name_short,> |
| Disconnected | White border | | No standalone device is connected to Root and Root is not connected to a Patient SafetyNet or Connectivity Gateway. |

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

Iris Screen

The Iris Screen displays Iris port connectivity and standalone device information.

To view the Iris Screen:

Press the Iris icon in the Status Bar. See **About the Status Bar** on page 34. The Iris Screen displays 4 Iris port connectivity tiles.



Each Iris port connectivity tile displays the [1] Iris port connectivity indicator and [2] device type, model, and Iris port connectivity status.



The Iris port connectivity status is indicated by color and displayed message. See the table below for further description.

| Connectivity Status Message | Connection Status Color | Description of Connection |
|--------------------------------|--|---|
| Connected | Green tile border Green indicator | Standalone device is successfully connected to Root, and Root is successfully connected to Patient SafetyNet or Iris Gateway. |

| Connectivity Status Message | Connection Status Color | Description of Connection |
|--------------------------------|--|---|
| Connecting to Iris Server | Yellow tile border Yellow indicator | Standalone device is connected to Iris adapter in Root, but Root is attempting or unable to connect to Patient SafetyNet or Iris Gateway. |
| Disconnected | No color tile border Gray indicator | No standalone device is connected to Root, and Root is not connected to Patient SafetyNet or Iris Gateway. |

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

Chapter 12: Bluetooth Devices

Flexible measurement expansion is possible through the Root Bluetooth connection. Root displays measurements captured by external device technologies in an all-in-one view on Root.

When an external device is connected to Root via Bluetooth, Root automatically creates a window that displays all the data from that device on the *Main Screen*.

Connect Device to Root

Connect an external device to Root using Bluetooth

- 1. Ensure Bluetooth is enabled on Root. See *Bluetooth* on page 68.
- 2. Ensure Bluetooth is enabled on the external device; refer to the external device's *Operator's Manual* if needed.
- 3. On the Root main screen, touch the **Main Menu** icon.
- 4. Press the **Device Settings** icon.
- 5. Press the **Bluetooth** icon.
- 6. On the **Bluetooth** screen:
 - Press the *Pair* button for the desired external device.
 - Select the desired external device under the Devices Found list.

The external device is now paired with Root. Refer to the external device's *Operator's Manual* for proper operation.

Chapter 13: Messages

| The following measures are specific to noor. |
|--|
|--|

| 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. |
| Check Probe | Probe is not responsive. | Check probe tip condition. Re-insert probe into probe well or check for alignment problem. If problem persists, replace the probe. If problem still persists, contact Customer Service. |
| Retake Measurement | An error has occurred in the process of taking a patient temperature measurement with the optional integrated temperature module. | Try another measurement cycle. If problem persists, replace probe. |
| Check Ambient Temperature | Ambient temperature may be too high or too low. | Verify ambient temperature does not exceed operating specification. Check internal temperature at probe well. |
| Replace Probe | Probe is not responsive due to not being calibrated or damaged. | Replace probe. |

| Message | Explanation | Next Step |
|---------------------------------|--|---|
| | | Verify patient temperature is not outside of the measurement range. |
| Temperature Out | Patient or environmental temperature conditions may be | Verify ambient temperature does not exceed operating specification. |
| of Range | too low for a temperature measurement. | If conditions are valid and problem persists, replace probe. |
| | | lf problem still persists, contact Customer Service. |
| | | Power cycle the device. |
| Module Error | Module communication error. | lf problem still persists, contact Customer Service. |
| Connect Probe | The optional integrated Temperature Probe has been disconnected or is not responsive. | Reconnect Temperature Probe and try another measurement cycle. |
| Check Cuff (Weak Signal) | Weak or no signal measured during blood pressure measurement. | |
| Check Cuff (Artifact) | Motion may be affecting ability to take measurement. | |
| Check Cuff (Out of | Measurement is out of range | Check that the hose is connected. |
| Range) | | being applied. |
| Check Cuff (Measurement | Weak Signal when measurement is being taken. | Check that the cuff is in the correct position. |
| | | Check that there is no excessive clothing between arm and cuff. |
| Check Cuff (Pneumatic | May be a blockage in the air | Retake another measurement. |
| Blockage) | 1050. | Check that the cuff is not leaking air. |
| Check Cuff (Inflate Timeout) | May be a blockage in the air hose. | lf problem still persists, contact Customer Service. |
| Check Cuff (Safety Timeout) | Weak Signal when measurement is being taken. | |
| Check Cuff (Overpressure) | May be due to a faulty cuff. | |

| Message | Explanation | Next Step |
|-------------------------|--|---|
| Calibration Required | Blood pressure measurement transducer may be out of range or there has been a calibration data failure. | Perform calibration procedures per User Manual. If problem still persists, contact Customer Service. |

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

Chapter 14: 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 |
|---|---|--|
| | Power Button not pressed long enough. | Press Power Button for two (2) seconds. |
| Root does not turn on. | 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 <i>Replacing the Fuses</i> on page 149. |
| Root turns on, but Main Screen is dim or blank. | The brightness setting is not correct. | Adjust the brightness setting. See Brightness on page 69. If the condition persists, Root requires service. Contact Masimo Technical Services. See Return Procedure on page 160. |
| Touch functionality is not responsive. | Internal failure. | Root requires service. Contact Masimo Technical Services. See Return Procedure on page 160. |
| 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 Bluetooth. Refer to Operator's Manual of Radius-7 for more information. |
| Iris screen does not display connection status for standalone devices. | Connection error. | Unplug and replug the Iris Adapter. |

| Symptom | Possible Cause | Correction |
|---|---|--|
| 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 on page 160. |
| 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 Sleep Mode, press Power Button for two (2) seconds. To Power Off when turned on or in Sleep Mode, press the Power Button for eight (8) seconds. |
| | Internal failure. | Root requires service. See <i>Return Procedure</i> on page 160. |
| Home Button does not work when pressed. | Internal failure. | Root requires service. See Return Procedure on page 160. |
| 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 on page 160. |
| Nurse Call does not communicate. | Connection error. | Unplug and replug Nurse Call connector. See Nurse Call Setting Connections on page 159. |
| <i>EMR Push</i> icon does not appear in Action Bar. | Wi-Fi is not enabled. Root is not connected to Patient SafetyNet. | Ensure Wi-Fi is enable. See Wi-Fi on page 66. If <i>EMR Push</i> icon does not appear, see Masimo Technical Services on page 160. |
| Parameter does not appear in EMR Push screen. | Parameter is not configured for <i>EMR</i> <i>Push</i> on Patient SafetyNet. | See Masimo Technical Services on page 160. |

| Symptom | Possible Cause | Correction |
|--|---|---|
| Unable to manually enter parameter data in <i>EMR Push</i> screen. | Parameter is not configured for manual entry on Patient SafetyNet. | See Masimo Technical Services on page 160. |

Chapter 15: Specifications

This chapter contains specifications of Root.

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

Measurement Accuracy

NIBP

| Pressure Transducer | |
|-----------------------------|--------|
| Between 0 mmHg and 300 mmHg | ±3mmHg |

Optional Integrated Temperature*

| Temperature | | | | |
|---|-------------------------|-----------------------|------------------------|---------------------------|
| Between 80°F and 110°F (26.7°C and 43.3°C) | All patient populations | | | ±0.2°F (0.11°C)** |
| Temperature Measurement Site/Mode | Number of Subjects | Clinical Bias (°C) | Limits of Agreement | Clinical Repeatability |
| Oral | 106 | 0.01 | 0.63 | 0.14 |
| Rectal | 105 | -0.12 | 0.59 | 0.29 |
| Pediatric Axillary | 117 | -0.03 | 0.56 | 0.14 |
| Adult Axillary | 105 | 0.13 | 0.43 | 0.14 |

*Test Report #:2010036 Test Report of Clinical Investigation to demonstrate that the SureTemp® Plus thermometer meets the essential performance of clinical thermometers for body temperature measurement as described in ISO 80601-2-56:2009

**Applicable to Continuous Mode only. See Operation - Temperature on page 89.

Alarms

| Audio Alarm Type | System Status Light Color | Audio Description |
|---------------------|------------------------------|---|
| High Priority | Flashing Red | 10-pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time:10s |
| Medium Priority | Flashing Yellow | 3-pulse burst, pulse spacing: 0.375s, 0.375s, repeat time: 7s |
| Low Priority | Solid Yellow | No audio |

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 | Туре | 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 |
| NIBP Nib | Male Bayonet | 1 |
| Temperature | MOLEX 52271-0690 | 1 |

Display Ranges

NIBP

| Patient Population | Measurement | Display Range |
|--------------------|-------------|---------------|
| Adult | Systolic | 40-260 mmHg |
| | Diastolic | 20-200 mmHg |
| | MAP | 26-220 mmHg |
| Pediatric | Systolic | 40-230 mmHg |
| | Diastolic | 20-160 mmHg |
| | MAP | 26-183 mmHg |
| Neonatal | Systolic | 40-130 mmHg |
| | Diastolic | 20-100 mmHg |
| | MAP | 26-110 mmHg |

Optional Integrated Temperature

| Measurement | Display Range |
|-------------|------------------------|
| Temperature | 80-110°F (26.7-43.3°C) |

Pulse Rate

| Measurement | Display Range |
|-----------------|---------------|
| Pulse Rate (PR) | 30-220 bpm |

NIBP Pressurization Ranges

| Weight | Patient Category | Initial Pressurization | Maximum Pressure |
|--------------------------------------|---------------------|---------------------------|---------------------|
| Greater than 75 lbs (34 kg) | Adult | 160 mmHg | 280 mmHg |
| Between 15.4 - 75 lbs (7 - 34 kg) | Pediatric | 140 mmHg | 280 mmHg |
| Less than 15.4 lbs (7 kg) | Neonatal | 90 mmHg | 140 mmHg |

Electrical

| Root | |
|-----------------------|---|
| AC Power requirements | 100-240 VAC~, 47-63 Hz, 180 VA (Max) |
| Fuses (2) | 2 Amp, Time Delay High Breaking Capacity (5x20mm), 250V |
| Battery | |
| Туре | Lithium Ion |
| Voltage | 10.8V (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 | 50°F to 104°F (10°C to 40°C) |
| Transport/Storage Temperature | -4°F to 122°F (-20°C to 50°C) |
| Operating Humidity | 10% to 95%, non-condensing |

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

Touchscreen Display

| Characteristic | Description |
|------------------|-------------------------------|
| Туре | Backlit Active Matrix TFT LCD |
| Resolution | 1280 x 800 pixels |
| Size | 10.1 in (25.65 cm) Diagonal |
| Color | 24 bit RGB |
| Touchscreen Type | Multi-Touch P-Cap |

Wireless Specifications

| Communication (Wi-Fi) | | |
|---------------------------------------|---|--|
| Туре | 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 | |



r

| Communication (Wi-Fi) | | |
|-----------------------|---|--|
| 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) | | |
|---------------------------------------|----------------------|--|
| Туре | 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 | |
| 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 - RDS-7A | | |
| Canada | IC:7362A-RDS7A | | |
| | IC Model: RDS-7A | | |
| | RSS-210 | | |
| Europe | EN 300 328 | | |
| | EN 301 893 | | |
| | EN 301 489-1 | | |
| | EN 301 489-17 | | |
| | R & TTE Directive | | |

Compliance

Electrical Safety

ANSI/AAMI ES 60601-1:2005

CAN/CSA C22.2 No. 60601-1:2008

EN 60601-1:1990 + AI: 1993 + A2:1995

IEC 60601-1:2005

IEC 60601-1-8:2006

IEC 60601-2-49:2011

IEC 80601-2-30:2009

ISO 80601-2-56:2012

NIBP Module Standards

AAMI SP10:2002

ISO 81060-2:2009

EN 1060-1:1996 +A2:2009

EN 1060-3:1997 +A2:2009

EN 1060-4:2004

EMC Compliance

EN 60601-1-2, Class A

| Equipment Classification per IEC 60601-1 | | |
|---|--|--|
| Type of Protection | Class I (on AC power) | |
| | Internally powered (on battery power) | |
| Degree of Protection of Electrical Shock | Defibrillation proof BF-Applied Part ¹ | |
| Protection against harm from liquid ingress | IPX1 Protection against liquid drops falling vertically. | |
| Mode of Operation | Continuous Operation | |

¹Connected devices should be used in accordance with their respective degrees of electrical protection to maintain electrical safety.

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 | | 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 | | |
| Harmonic Emissions IEC 61000-3-2 | Class A | For hospital environment only. Not intended for use in a domestic environment. | |
| 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. |
| Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11 | 100% for 0.5 cycle 60% for 5 cycles 30% for 25 cycles 100% for 5 seconds | | 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. |
| Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment. |
Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Recommended Separation Distance |
|-------------------------------|--------------------------------|---------------------|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | 80 MHz to 800 MHz: $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ |
| | | | 800 MHz to 2.5 GHz: $d = \left[\frac{7}{E_1}\right] \sqrt{P}$ |
| | | | 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). |
| | | | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . |
| | | | Interference may occur in the vicinity of equipment marked with the following symbol: |
| | | | $((\bullet))$ |

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.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

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

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment

The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.

| Rated maximum output power of transmitter (W) | Separation Distance According to Frequency of Transmitter (m) | | | |
|---|---|---|---|--|
| | 150 K Hz to 80 MHz d = 1.17*Sqrt (P) | 80 MHz to 800 MHz d = 1.17*Sqrt (P) | 800 MHz to 2.5GHz d = 2.33*Sqrt (P) | |
| 0.01 | 0.12 | 0.12 | 0.23 | |
| 0.1 | 0.37 | 0.37 | 0.74 | |
| 1 | 1.17 | 1.17 | 2.33 | |
| 10 | 3.7 | 3.7 | 7.37 | |
| 100 | 11.7 | 11.7 | 23.3 | |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

Symbols

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

| Symbol | Description | Symbol | Description |
|--------------------|--|----------|--|
| E | Follow instructions for use | li | Consult instructions for use |
| C E 0123 | Mark of conformity to European medical device directive 93/42/EEC | CUSTED | ETL Intertek certification See Declarations on Page 1 for certifications |
| IPX1 | Protection against vertically falling water drops | | Fuse replacement- Only replace with time-delay fuses specified in this Instructions for Use |
| | Defibrillation-proof. Type BF applied part | † | Type BF applied part |
| | NIBP | Ø | Arm Circumference |
| | Artery symbol and arrow should be placed over brachial or femoral artery | | Cuff index line must fall within range markings for an accurate measurement |



| Symbol | Description | Symbol | Description |
|--------------|--|-----------|--|
| NDEX | Index Line | NON | Non-Sterile |
| EC REP | Authorized representative in the European community | ĬX I | Separate collection for electrical and electronic equipment (WEEE) |
| Rx ONLY | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician | C) | Recyclable |
| (((₊))) | Non-ionizing electromagnetic radiation | F© | Federal Communications Commission (FCC) Licensing |
| Â | Warning, electricity | FCC ID: | Identifies unit has been registered as a radio device |
| | Electrostatic | IC Model: | Industry Canada Identification |
| \bigotimes | No parameter alarms | A A | Biohazardous Waste |
| Â | Caution | SpO2 | Not for continuous monitoring (No alarm for SpO ₂) |
| REF | Catalog number (model number) | | Product contains no PVC (polyvinyl chloride) material |
| | Manufacturer | | Not made with natural rubber latex |

| Symbol | Description | Symbol | Description |
|----------|------------------------------------|---------------------------------|--|
| | Date of manufacture YYYY-MM-DD | ### | Masimo reference number |
| 1 | Storage temperature range | SN | Serial number |
| | Keep dry | | Fragile, handle with care |
| <u>%</u> | Storage humidity limitation | | Do not use if package is damaged |
| (| Atmospheric pressure limitation | \rightarrow | Equipotential Ground Terminal |
| \sim | AC current | ф | Fuse |
| Y | Wireless Symbol level | () | Wireless features can be used in member states with the restriction of indoor use in France -Class 2 wireless device |
| Ċ | Stand-By | | Iris Connection |
| ←→RS-232 | RS-232 Interface | <u> </u> | Ethernet |
| ≅ ←∕> | Analog Out Interface | $\hat{\mathbf{D}}_{\mathbf{A}}$ | Nurse Call Interface |
| > | Greater than | Ŷ | USB port |
| < | Less than | | China Restriction of Hazardous Substances |

| Symbol | Description | Symbol | Description |
|---------------|--|--------|---|
| | | | The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual |
| affu Indicato | Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs Note: eIFU is not available in all countries. | | |

Chapter 16: 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:

- Cidex Plus (3.4% glutaraldehyde)
- 10% bleach solution
- \leq 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 250V, 2 amp, metric 5x20 mm and with a time delay 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 Sleep Mode. See *Sleep and Power Off* on page 88.
- 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* on page 160.

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.

NIBP Module Calibration Test

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 \pm 3mmHg or 2% or 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
- 500mL bottle or regular-sized cuff wrapped around solid object
- Hand Bulb
- Connection Tubing

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

Procedure

1. Connect the manometer, 500mL bottle or cuff wrapped around solid object, and hand bulb to the NIBP module using "T" adapters 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 Root.
- 4. On the Root home screen, press the Main Menu icon
- 5. Press NIBP
- 6. Press CALIBRATION
 - For the password, enter 4258.
 - Press the Enter key.
- 7. Press CALIBRATION TEST
- 8. Press Test.



- Apply various pressures (OmmHg to 280mmHg) to the NIBP module with the hand bulb.
- 10. 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 11.
 - If the NIBP module pressure and manometer pressure differ BEYOND the ±3mmHg tolerance, (1) perform the Zero Point Calibration, (2) then perform the Span Point Calibration. See *Zero Point Calibration* on page 152 and *Span Point Calibration* on page 153. If the NIBP module pressure and manometer pressure still differ BEYOND the ±3mmHg tolerance, contact Masimo Technical Services. See *Masimo Technical Services* on page 160.
- 11. Disconnect the manometer, 500mL bottle or cuff wrapped around solid object, and hand bulb from the NIBP module.
- 12. Power OFF the manometer.

Zero Point Calibration

Zero Point Calibration is performed when an NIBP module does NOT PASS the NIBP Module Calibration Test. See the **NIBP Module Calibration Test** on page 150.

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

- 1. Press the back button in the upper-left corner of the CALIBRATION TEST screen to go back to the CALIBRATION menu screen.
- 2. Select ZERO POINT CALIBRATION 📼
- Apply O (zero) mmHg to the NIBP module.
 Note: The O (zero) mmHg can be verified on the manometer.
- 4. Press **Calibrate** to start the Zero Point Calibration:
 - A "Success" message will appear if the calibration was successful. Go to step 5.
 - If a "Result Failure" message appears, verify the O (zero) mmHg is applied to the NIBP module and press Calibrate again. If the "Result Failure" message is repetitive, contact Masimo Technical Services. See Masimo Technical Services on page 160.
- 5. After a successful Zero Point Calibration, complete the Span Point Calibration. See *Span Point Calibration* on page 153.

Span Point Calibration

Span Point Calibration is performed when an NIBP module does NOT PASS the NIBP Module Calibration Test, and after completing Zero Point Calibration. See the NIBP Module Calibration Test on page 150 and Zero Point Calibration on page 152 before completing the instructions below.

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

- 1 After successful completion of Zero Point Calibration, press the back button in the upper-left corner of the ZERO POINT CALIBRATION screen to go back to the CALIBRATION menu screen.
- Select SPAN POINT CALIBRATION 2



- 3. Press Close Valve
- 4. Use the hand bulb to apply exactly 250mmHg to the NIBP module, then press Calibrate.
 - A "Success" message will appear if the calibration was successful. Go to step 5.
 - If a "Result Failure" message appears, repeat the test by applying • 250mmHg to the NIBP module and pressing **Calibrate**. If the "Result Failure" message is repetitive, contact Masimo Technical Services. See Masimo Technical Services on page 160.
- 5. After successful Span Point Calibration, press the back button to go back to the CALIBRATION menu screen.
- Press CALIBRATION TEST 6.
- 7 Press Test
- Apply various pressures (OmmHg to 280mmHg) to the NIBP module with the 8. hand bulb.
- q 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 required. Go to step 10.

Note: For pass criteria, see the NIBP Module Calibration Test on page 150.

- If the NIBP module pressure and manometer pressure still differ BEYOND the • ±3mmHg tolerance, contact Masimo Technical Services. See Masimo Technical Services on page 160.
- 10. Disconnect the manometer, 500mL bottle or cuff wrapped around solid object, and hand bulb from the NIBP module.
- 11 Power OFF the manometer

NIBP Air Leak Test

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 air leakage within the pneumatic system must not exceed 6mmHg/minute.

Equipment

- Calibrated Manometer*
- Pneumatic "T" Adapters
- 500mL bottle
- Hand Bulb
- Connection Tubing

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

Procedure

1. Connect the manometer, 500mL bottle, and hand bulb to the NIBP module using "T" adapters and connection tubing.



- 2. Power ON the manometer.
 - Set the unit of measurement to mmHg.
 - Verify the manometer has been calibrated.
- 3. Power ON the Root.
- 4. On the Root home screen, press the Main Menu icon
- 5. Press NIBP



- For the password, enter 4258.
- Press the Enter key.
- 7. Press AIR LEAK TEST
- 8. To begin the air leak test, press **Test**.
 - Wait for the **countdown timer** to reach 0 second.



- At the bottom of the screen, in the **Result** section, verify the **leak rate** is less than 6mmHg. If the leak rate is greater than 6mmHg, verify there are no leaks in the calibration equipment (tubing, 500mL container, arm cuff, etc.). If there are no leaks detected from the calibration equipment and the leak rate is still greater than 6mmHg, contact Masimo Technical Services. See *Masimo Technical Services* on page 160.
- 9. Disconnect the manometer, 500mL bottle, and hand bulb from the NIBP module.
- 10. Power OFF the manometer.

Overpressure Test

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 pressure must not exceed 300mmHg on adults and pediatric patients and 150mmHg on neonatal patients with a tolerance of 10% for 15 seconds or greater than 10% for 3 seconds. The overpressure pass criteria for the Advantage module are:

| Adults, Pediatrics | 300 ±10mmHg |
|--------------------|-------------|
| Neonates | 150 ±5mmHg |

Equipment

- Calibrated Manometer*
- Pneumatic "T" Adapters
- 500mL bottle or regular-sized cuff wrapped around solid object
- Hand Bulb
- Connection Tubing

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

Test Method for Adults and Pediatrics

Connect the manometer, 500mL bottle or cuff wrapped around solid object, and hand bulb to the NIBP module using "T" adapters and connection tubing. 1 Note: If using a cuff, verify the cuff is Adult or Pediatric. Do not use a Neonate cuff for this test method.



- 2. Power ON the manometer.
 - Set the unit of measurement to mmHg. •
 - Verify the manometer has been calibrated. •
- 3. Power ON the Root.
- On the Root home screen, press the Main Menu icon 4.
- Press NIBP MBP 5.
- Press CALIBRATION 6.
 - For the password, enter 4258.
 - Press the Enter key.
- Press OVERPRESSURE TEST 7.

- 8. To begin the overpressure test, press the **Test** button, then increase the pressure to the overpressure point:
 - Increase pressure to approximately 280mmHg using the hand bulb.
 - Very slowly increase the pressure as you approach the overpressure point.
 - When the overpressure point is reached, the valves will open (a faint click can be heard when this occurs) and the pressure will rapidly reduce to O (zero) mmHg. Be sure to observe the pressure measurement on the manometer when the valves open.
- q Determine if the NIBP module passed the overpressure test:
 - If the valves opened WITHIN the overpressure pass criteria, then the NIBP module PASSED the overpressure test for adults and pediatrics. Go to step 10.
 - If the valves opened BEYOND the overpressure point pass criteria, then press the **Test** button again to confirm the overpressure point. If the valves open repetitively beyond the pass criteria, contact Masimo Technical Services. See Masimo Technical Services on page 160.
- 10. To stop testing, press Stop.
- Disconnect the manometer, 500mL bottle or cuff wrapped around solid object. 11 and hand bulb from the NIBP module.
- Power OFF the manometer 12

Test Method for Neonates

- 1 Follow steps 1 through 3 from Test Method for Adults and Pediatrics above. Note: If using a cuff, verify the cuff is Neonate. Do not use an Adult or Pediatric cuff for this test method.
- 2. On the Root Main Screen, touch the *Profiles* option in the Status Bar. See **About** the Status Bar on page 34.
- Select Neonates in the Profiles screen, then touch OK. 3
- 4 Start the NIBP measurement then immediately abort:
 - Touch the Start NIBP button. •
 - Touch the Start NIBP button again when then pump starts to inflate the • system.
- Press the Main Menu icon 5



- Press NIRP 6
- Press CALIBRATION 7.
 - For the password, enter 4258.
 - Press the Enter key.
- Press OVERPRESSURE TEST 8.
- q To begin the overpressure test, press the **Test** button, then increase the pressure to the overpressure point:



- Increase pressure to approximately 130mmHg using the hand bulb.
- Very slowly increase the pressure as you approach the overpressure point.
- When the overpressure point is reached, the valves will open (a faint click can be heard when this occurs) and the pressure will rapidly reduce to OmmHg. Be sure to observe the pressure measurement on the manometer when the valves open.
- 10. Determine if the NIBP module passed the overpressure test:
 - If the valves opened WITHIN the overpressure pass criteria, then the NIBP module PASSED the overpressure test for neonates. Go to step 11.
 - If the valves opened BEYOND the overpressure point pass criteria, then press the **Test** button again to confirm the overpressure point. If the valves open repetitively beyond the pass criteria, contact Masimo Technical Services. See *Masimo Technical Services* on page 160.
- 11. To stop testing, press **Stop**.
- 12. Disconnect the manometer, 500mL bottle or cuff wrapped around solid object, and hand bulb from the NIBP module.
- 13. Power OFF the manometer.

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. See **Device Output** on page 72.

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

| Cable Type | Nurse Call Event | Menu Setting |
|------------|---|--------------------------------|
| 2-Circuit | 2 contacts normally opened | Nurse Call Polarity Normal |
| Com O | 2 contacts normally closed | Nurse Call Polarity Inverse |
| 3-Circuit | 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 |

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* on page 149. Make sure the equipment is fully dry before packing.

To return the device for service, see *Return Procedure* on page 160.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in *Cleaning* on page 149. 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 Contacting Masimo.

Masimo Technical Services

To contact Masimo Technical Services, refer to the Masimo Technical Services web page:

http://www.masimo.co.uk/company/global-services/technical-services/



Contacting Masimo

Masimo Corporation 52 Discovery Irvine, California 92618

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

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product (Root® with noninvasive blood pressure and temperature) 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 12 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

www.masimo.com

Masimo

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

- 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: Concepts of Alarm Response Delay

Concepts of Alarm Response Delay

As with any patient monitors, 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 occurrence of the generation of its alarm signal. The graphic below is a simplified illustration of the concept of alarm response delay using a pulse oximeter that measures SpO_2 as an example. The graphic does not reflect actual lengths of delays.



| Reference | Definition |
|------------------|-------------------------|
| 1 | SaO ₂ |
| 2 | Alarm Limit |
| 3 | Displayed SpO $_2$ |
| 4 | Alarm Signal Generation |
| SpO ₂ | Saturation |
| t | Time |

The Alarm Condition Delay is graphically represented as $t_{z}-t_{1}$ 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 IEC 60601-1-8.

Index

A

About • 49.74 About the Action Bar • 36, 82 About the Main Screen • 33, 67 About the Status Bar • 27, 28, 34, 65, 66. 67, 68, 69, 80, 119, 120, 158 About This Manual • 7 AC Power Indicator • 27 86 Access Control • 63, 64, 70 Accessing Main Menu Options • 34, 36, **4**Q Active Channels • 50. 52 Additional Settings for Layouts • 50, 53 Additional Settings for NIBP • 58, 62 Additional Settings for Temperature • 55, 57 Admitting a Patient • 104 Alarm Interface • 77 Alarm Silence • 34, 79 Alarms • 134 Alarms for Temperature • 54, 55 Appendix Concepts of Alarm Response Delay • 163 Attach NIBP Cuff • 31 Attach the Probe Well • 30 Attach the Temperature Probe • 31 Audio Pause • 34, 63, 73, 80 Available Layouts • 50, 51

В

Back View • 22 Battery Test • 160 Bluetooth • 35, 64, 68, 123 Bluetooth Devices • 31 Brightness • 64, 69, 129

С

Calibration for NIBP • 58, 63 Capturing Screens • 83 Chapter 1 Description • 21 Chapter 10 MOC-9 • 30, 115 Chapter 11 Iris • 35, 50, 117 Chapter 12 Bluetooth Devices • 31, 123 Chapter 13 Messages • 125 Chapter 14 Troubleshooting • 129 Chapter 15 Specifications • 133 Chapter 16 Service and Maintenance • 149 Chapter 2 Setting Up • 25 Chapter 3 Operation • 33 Chapter 4 Temperature Measurement • 89 Chapter 5 NIBP Measurement • 31, 93 Chapter 6 Admit and Discharge to Patient SafetyNet 36, 103 Chapter 7 Electronic Medical Record (EMR) Push • 36.109 Chapter 8 Radical-7 • 111 Chapter 9 Radius-7 • 113 Cleaning • 149, 160 Cleaning and Service Warnings and Cautions • 18 Compliance • 139

www.masimo.com

S Masimo

Root NIBPT

Compliance Warnings and Cautions • 18 Concepts of Alarm Response Delay • 163 Connect Device to Root • 123 Connecting Root to Patient SafetyNet • 67 Connectors • 134 Contacting Masimo • 161 Contraindication • 11 Cuff Selection and Placement • 93, 95, 97, 99, 101 Customizing Windows • 37, 46, 53, 54

D

Determining EMR Push is Active • 109 Device Output • 30, 34, 65, 72, 159 Device Settings • 49, 64 Discharging a Patient • 105 Display Ranges • 135 Downloading Screen Captures • 85

E

Electrical • 136 Environmental • 25, 136 Ethernet • 35, 64, 67 Exclusions • 161

F

Features • 21 Front View • 21

G

Guidance and Manufacturer's Declaration-Electromagnetic Emissions • 141 Guidance and Manufacturer's Declaration-Electromagnetic Immunity • 142 Guidelines for Setting Up • 25

I

Indications for Use • 9 Initial Battery Charging • 25, 27 IntelliBridge Connectivity • 73 Intended Use • 9 Intervals for NIBP • 58, 61 Iris • 76 Iris Icon • 119 Iris Screen • 76, 120

K

Kite • 17, 35, 64, 66

L

Layout • 49, 50 Lights • 86 Limitation of Warranty • 161 Limited Warranty • 161 Localization • 36, 64, 65

Μ

Manual Sizing of Windows • 48 Manually Entering Patient Data • 109, 110 Masimo Kite • 31 Masimo Technical Services • 109, 110, 130, 131, 152, 153, 156, 158, 159, 160 Mean Arterial Pressure (MAP) • 58, 61 Measurement Accuracy • 133 Menu Navigation • 40 MOC-9 Connection • 29 Monitoring Resumed Message • 107

Ν

NIBP • 49, 58 NIBP Air Leak Test • 154 NIBP Module Calibration Test • 63, 150, 152, 153 NIBP Pressurization Ranges • 136 Noninvasive Blood Pressure • 14, 17 Not Admitted • 103 Not Monitoring Message • 106 Nurse Call Connection • 30 Nurse Call Setting Connections • 130, 159 Nurse Call Specifications • 134

0

Operation - NIBP • 95 Operation - Temperature • 89, 133 Overpressure Test • 156

Р

Parameter Settings for NIBP • 58 Parameters Supported • 74 Patient Conditions • 94 Patient Measurement Mode • 93 Patient SafetyNet System • 18 Performance Warnings and Cautions • 15 Power On • 26 Power-On Self Test • 150 Product Description and Features • 9 Product Description and Features, Intended Use and Indications for Use • 9 Profiles • 36, 49, 75, 93 Pulse Rate (PR) • 58, 60

R

Radical-7 and Radius-7 Battery • 64, 69 Radical-7 and Radius-7 Charging Indicator • 28, 35, 87 Radical-7 Connection • 28 Radius-7 Connection • 28 Rainbow • 49, 54 www.masimo.com Recommended Separation Distances • 144 Repair Policy • 149, 160 Replacing the Fuses • 129, 149 Restrictions • 162 Return Procedure • 25, 129, 130, 160 Root Battery • 27, 64, 68 Root Charging Indicator • 35, 87

S

Safety Information, Warnings, and Cautions • 13. 27 Safety Warnings and Cautions • 13 Sales & End-User License Agreement • 162 Screen Capture • 83 Sending Patient Data to the EMR • 110 Session Management • 36, 71, 82 Set Mode Automatic • 61.97 Schedule • 62.101 Stat • 62.99 Side Views • 24, 86 Sleep and Power Off • 26, 88, 149 Sounds • 35, 49, 63, 70, 80 Span Point Calibration • 152, 153 Spot Check Measurement • 95 Standby Mode • 34, 71, 80 Symbols • 145 System Status Lights • 24, 86 Systolic/Diastolic (SYS/DIA) • 58, 59

Т

167

Taking Temperature Measurement • 89 Temperature • 15, 17, 49, 54 Temperature Probes • 91 Touchscreen Display • 137 Trend Download • 81 Trend Settings • 49, 75

🕈 Masimo

Trends for NIBP • 60 Trends for Temperature • 55, 56 Troubleshooting Radical-7, Radius-7, and MOC-9 Modules • 129 Troubleshooting Root • 129

U

Understanding Windows • 41 Unpacking and Inspection • 25 Using Analog View • 42, 44 Using Iris Connectivity Ports • 118 Using MOC-9 Ports • 115 Using the Touchscreen Interface • 37 Using Trend View • 42, 43

W

Wi-Fi • 35, 64, 66, 130 Wireless Specifications • 137

Ζ

Zero Point Calibration • 152, 153



38280/LAB-9274H-1118