Radical-7

Radical-7

Operator's Manual

This Operator's Manual presents Masimo features and/or products that are marketed outside of the United States (OUS). It is not intended for use in the United States.

These operating instructions provide the necessary information for proper operation of all models of the Radical-7® Pulse CO-Oximeter®. 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 Radical-7 are prerequisites for its proper use. Do not operate Radical-7 without completely reading and understanding these instructions.

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

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

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

Wireless Radio
FCC ID: VKF-RAD7CA or VKF-RAD7A or VKF-RAD7B | IC ID: 7362A-RAD7CA or 7362A-RAD7A or 7362A-RAD7B

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

CE 0123

EU authorized representative for Masimo Corporation:
EC REP

MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

Authorized Brazil Company Representative:
MEDSTAR IMPORT AND EXPORT EIRELI
R VALENCIO SOARES RODRIGUES, 89- ROOM 1
CEP: 06.730-000
NEIGHBORHOOD: CENTER
MUNICIPALITY: VARGEM GRANDE PAULISTA
UF: SP

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

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

, Adaptive Probe Off Detection, APOD, 3D Alarm, Discrete Saturation Transform, DST, FastSat, FST, Masimo, Pulse CO-Oximeter, PVI, Radical-7, Root, rainbow, rainbow Acoustic Monitoring, RAM, rainbow Resposable, RDS, RRa, RRp, SatShare, SedLine, SET, Signal Extraction Technology, Signal IQ, SpCO, SpHb, and SpMet are federally registered trademarks of Masimo Corporation.

3D Desat Index Alarm, In Vivo Adjustment, ORI, SpfO2, SpOC and SST are trademarks of Masimo Corporation. All other trademarks and registered trademarks are property of their respective owners.

The use of the trademarks PATIENT SAFETYNET and PSN is under license from University HealthSystem Consortium.

Contents

About this Manual

This manual explains how to set up and use the Radical-7® Pulse CO-Oximeter®. Important safety information relating to general use of the Radical-7 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. The following is an example of a warning:

Warning: This is a sample 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. The following is an example of a caution:

Caution: This is a sample of a caution statement.

A *note* is given when additional general information is applicable. The following is an example of a note:

Note: This is a sample of a note.

Product Description

The Radical-7 is a 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®), Oxygen Reserve Index (ORI™), Acoustic Respiration Rate (RRa®), and Pleth Respiration Rate (RRp).

The Radical-7 can be used as either a Handheld or a Standalone monitor. The Radical-7 features a touchscreen that continuously displays numeric values for all parameters.

The Radical-7 provides graphical displays for plethysmographic waveform, respiratory waveform, Signal Identification and Quality Indicator (Signal IQ®).

The Radical-7 can also be used to interface with a multi-parameter patient monitor to send Masimo SET® pulse oximetry information to that monitor for display.

The Radical-7 has an embedded 802.11 wireless radio that can be used for connectivity.

Key Features

The following features are available for the Radical-7. Some features are optional:

- Masimo SET® technology is clinically proven to satisfy all sensitivity and specificity requirements for pulse oximetry.
- Masimo rainbow® technology uses 7+ wavelengths of light to continuously and noninvasively measure carboxyhemoglobin (SpCO), methemoglobin (SpMet), and total hemoglobin (SpHb®), as well as providing a more reliable probe-off detection.
- Total oxygen content (SpOC) provides a calculated measurement of the amount of oxygen in arterial blood, which may provide useful information about oxygen both dissolved in plasma and combined with hemoglobin.
- Perfusion Index (PI) with trending capability indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion.

- Pleth Variability Index (PVI) may show changes that reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions. [The utility of PVI is unknown at this time and requires further clinical studies. Technical factors that may affect PVI include probe malposition and patient motion.]
- Oxygen Reserve Index (ORI) is an index to measure changes in oxygen states under hyperoxic conditions.
- Respiration rate can be determined by the acoustic (RRa) or plethysmographic waveform (RRp).
- Signal IQ waveform for signal identification and quality indication during excessive motion and low signal to noise situations.
- FastSat® tracks rapid changes in arterial O_2.
- Variable pitch provides tonal variance for every 1% change in saturation.
- SatShare® interface allows transfer of SpO_2 and pulse rate to an existing multi-parameter monitor and allows for the reading of SpCO, SpMet, SpHb, and SpOC on adjacent Radical-7® monitor.
- Automatic screen rotation provides upright display for vertical or horizontal monitor positioning.
- Multi-gesture touchscreen interface.
- Detachable portable Handheld for patient transport.
- Remote alarm interface.

Indications for Use

The Masimo Radical-7 and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial

hemoglobin (SpO_2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet®), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa).

The Masimo Radical-7 and accessories have been validated and 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 and accessories are indicated to provide the continuous noninvasive monitoring data obtained from the Masimo rainbow SET® Radical 7 Pulse CO-Oximeter® and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) to multi-parameter devices for the display of those devices.

Contraindications

Radical-7 is not intended for use as an apnea monitor.

Warnings and Cautions

Caution: Radical-7 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.

Safety Warnings and Cautions

Warning: Do not use the Radical-7 if it appears or is suspected to be damaged.

Warning: Do not start or operate Radical-7 unless the setup was verified to be correct.

Warning: Do not use Radical-7 during magnetic resonance imaging (MRI) or in an MRI environment.

Warning: Explosion hazard: Do not use the Radical-7 in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

Warning: Do not place the Radical-7 or accessories in any position that might cause it to fall on the patient.

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

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

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

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

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.

- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this operator's manual.
- Do not attempt to clean Radical-7 while monitoring patient.

Warning: To protect from electric shock, always remove the sensor and completely disconnect Radical-7 before bathing the patient.

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

Caution: Do not place the Radical-7 where the controls can be changed by the patient.

Caution: When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

Caution: Electric shock hazard: Do not open the Radical-7 cover except to replace the battery or batteries.

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

Caution: To ensure patient electrical isolation, only dock to Masimo devices that have been designed for Radical-7.

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

Caution: Do not place Radical-7 where the appliance inlet or the AC power plug cannot be readily disconnected.

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

Caution: To ensure patient electrical isolation, all external device connections to the Analog Output/Nurse Call connector must be IEC-60950 compliant.

Caution: To ensure patient electrical isolation, all external device connections to the RS-232 serial port must be IEC-60950 compliant.

Note: If there is any doubt about the integrity of the protective earth conductor arrangement, operate the Radical-7 on internal battery power until the AC power supply protective conductor is fully functional.

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

Performance Warnings and Cautions

Warning: Radical-7 is not an apnea monitor.

Warning: Radical-7 should not be used for arrhythmia analysis.

Warning: Radical-7 may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

Warning: Radical-7 may be used during defibrillation; however, the display may require up to 15 seconds to return to normal operation.

Warning: Radical-7 may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

Warning: Do not place containers with liquids on or near Radical-7. Liquids spilled on Radical-7 may cause it to perform inaccurately or fail.

Warning: Radical-7 is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.

Warning: A functional tester cannot be used to assess the accuracy of the Radical-7.

Warning: Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.

Warning: SpO2, SpCO, SpMet, and SpHb are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

Warning: Inaccurate SpO2 readings may be caused by:

- Improper sensor application.
- Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Intravascular dyes, such as indocyanine green or methylene blue.
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin
- Severe anemia
- Low arterial perfusion
- Motion artifact

Warning: Inaccurate SpHb and SpOC readings may be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated PaO2 levels
- Elevated levels of bilirubin
- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation levels
- Elevated carboxyhemoglobin levels
- Elevated methemoglobin levels
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Vasospastic disease such as Raynaud's
- Elevated altitude
- Peripheral vascular disease
- Liver disease
- EMI radiation interference

Warning: Inaccurate SpCO and SpMet readings can be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Abnormal hemoglobin levels
- Low arterial perfusion

- Low arterial oxygen saturation levels including altitude induced hypoxemia
- Elevated total bilirubin levels
- Motion artifact
- SpCO readings may not be provided if SpO2 readings are less than 90%
- SpCO readings may not be provided if SpMet readings are greater than 2%

Warning: SpCO readings may not be provided if there are low arterial saturation levels or elevated methemoglobin levels.

Warning: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check Radical-7 for proper functioning.

Warning: Inaccurate respiration rate measurements may be caused by:

- Improper sensor application
- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation
- Excessive ambient or environmental noise

Warning: Inaccurate ORI readings may be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin

- Low arterial perfusion
- Motion artifact
- Patient attached to blood pressure cuff
- Elevated carboxyhemoglobin levels
- Elevated methemoglobin levels
- Vasospastic disease such as Raynaud's
- Peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc
- Elevated levels of Dyshemoglobin
- Patient is under Hypocapnic and Hypercapnic Conditions
- EMI radiation interference
- Birthmark(s) or skin discolorations in sensor path
- Moisture on the skin
- Deformed Fingers
- Foreign objects in the light path
- Excessive ambient light or direct sunlight
- Use of incorrect sensor type(size)
- Extreme anemia or extremely low total hemoglobin concentrations
- Severe vasoconstriction, or hypothermia
- Low ORI SIQ episodes

Warning: ORI is not intended as a replacement for SpO2 monitoring, PaO2 monitoring, or as a sole indicator of the patient condition.

Caution: ORI measurements are only displayed on Root® when Radical-7 has been configured for ORI and is communicating to Root.

Caution: ORI may not indicate additional changes in oxygen states above 200 mmHg of PaO2

Caution: Do not place the Radical-7 on electrical equipment that may affect the device, preventing it from working properly.

Caution: The device must be configured to match your local power line frequency to allow for the cancelation of noise introduced by fluorescent lights and other sources.

Caution: Do not place the Radical-7 against a surface that may cause the alarm to be muffled.

Caution: Ensure the speaker is not covered.

Caution: To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the Radical-7 is used.

Caution: For home use, ensure that the Radical-7 alarm can be heard from other rooms in the house, especially when noisy appliances such as vacuum cleaners, dishwashers, clothes dryers, televisions, or radios are operating.

Caution: When Silence Duration is set to All Mute or All Mute with Reminder on Radical-7, there will be no audible alarms on Radical-7 or Patient SafetyNet; however, there will be visual alarms displayed on Radical-7 and Patient SafetyNet view.

Caution: When All Mute or All Mute with Reminder is selected, there will be no audible alarms.

Caution: Failure to charge Radical-7 promptly after a Low Battery alarm may result in the device shutting down.

Caution: If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

Caution: If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.

Caution: Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

Caution: If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

Caution: When using In Vivo Adjustment™, confirm offset values(s) periodically as the difference between the displayed parameter value and the laboratory reference value may vary over time.

Caution: Do not use In Vivo Adjustment if the monitor displays a Low SpHb SIQ message.

Note: Use the Radical-7 in accordance with Environmental Specifications section in this manual.

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

Note: It is recommended that Radical-7 battery is fully charged prior to use.

Note: Always charge Radical-7 when it is not in use to ensure that the Radical-7 battery remains fully charged.

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

Note: Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.

Note: Additional information specific to the Masimo sensors compatible with Radical-7, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).

Note: When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the Radical-7 is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.

Note: The 3D Desat Index™ alarm is intended as an adjunct alarm rather than in place of the Low SpO2 alarm.

Note: When monitoring acoustic respiration, Masimo recommends minimally monitoring both oxygenation (SpO2) and respiration (RRa).

Note: High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse CO-Oximeter® to obtain vital sign readings.

Warning: Plethysmographic waveforms displayed on multi-parameter monitors using SatShare should only be used for reference. Only

plethysmographic waveforms displayed on the Radical-7 should be used for monitoring purposes.

Warning: Simultaneous use of SatShare and serial port is not supported.

Caution: To minimize electromagnetic interference, only use a SatShare cable that has a ferrite bead installed.

Caution: During SatShare operation, alarms may be muted on the Radical-7. Use the multi-parameter monitor for audible alarms during SatShare operation.

Caution: Ensure Radical Docking Station is connected to AC power source when charging Radical-7.

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

Note: SatShare signals are ideal simulated waveforms corresponding to the calculated saturation and pulse rate values and do contain all of the information contained in physiological waveforms. The multi-parameter patient monitor decodes these signals into saturation and pulse rate values.

Cleaning and Service Warnings and Cautions

Warning: Do not adjust, repair, open, disassemble, or modify Radical-7. Injury to personnel or equipment damage could occur. Return Radical-7 for servicing.

Warning: Electrical Shock Hazard: The battery should be installed and/or removed from the Radical-7 by qualified personnel only.

Warning: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the Radical-7. These substances affect the device's materials and device failure can result.

Warning: 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: 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: Do not submerge Radical-7 in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage Radical-7.

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

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

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

Warning: Electrical Shock Hazard: The Docking Station battery should be installed and/or removed from the Docking Station only by qualified personnel.

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.

Compliance Warnings and Cautions

Warning: Do not incinerate battery.

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

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

Caution: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to Radical-7.

Note: Cleared Use Only: The device and related accessories have obtained CE Mark for noninvasive patient monitoring and may not be used for any processes, procedures, experiments or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the instructions for use or labeling.

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

Note: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause

harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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

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

Note: Users are advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5.25-5.35 GHz and 5.65-5.85 GHz

and that these radars could cause interference and/or damage to LE-LAN devices.

Note: In accordance with FCC requirements, radio accessories on Radical-7 cannot be attached directly to the patient using any accessory containing metal components.

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.

Caution: External device connections to the SatShare port must be IEC-60601-1 compliant.

Note: Change or modifications that are not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Chapter 1: Technology Overview

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

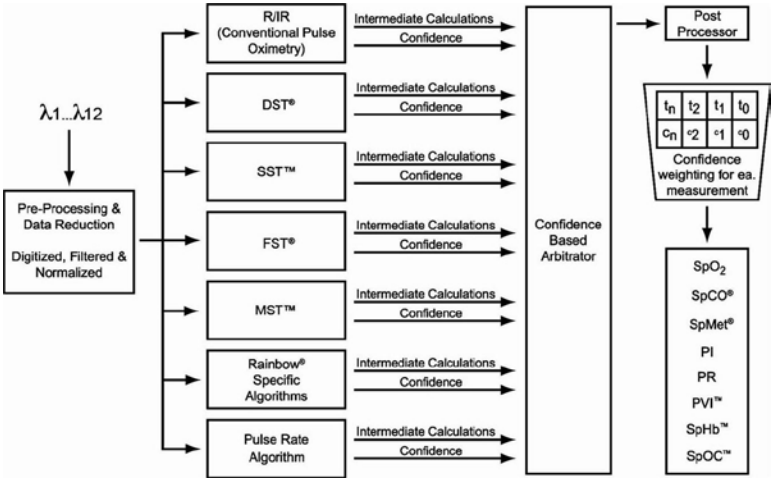
Signal Extraction Technology (SET)

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

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

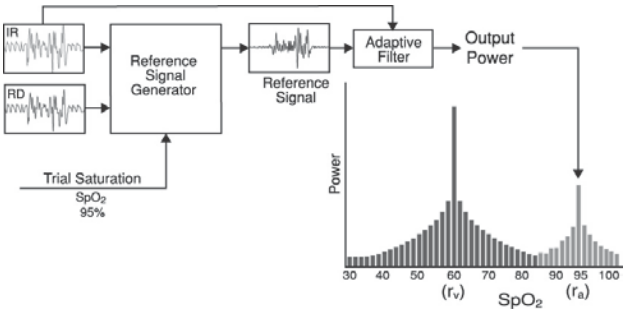
Masimo rainbow SET® Parallel Engines

This figure is for conceptual purposes only.



Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (SpO2)

Pulse oximetry is governed by the following principles:

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

Successful Monitoring for SpO2, PR, and PI

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

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

Functional Oxygen Saturation (SpO2)

The Radical-7 is calibrated to measure and display functional oxygen saturation (SpO2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.

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

General Description for Pulse Rate (PR)

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

General Description for Perfusion Index (PI)

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

General Description for Pleth Variability Index (PVI)

The pleth variability index (PVI) is a measure of the dynamic changes in the perfusion index (PI) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI is displayed as a percentage (0-100%).

The utility of PVI is unknown at this time and requires further clinical studies. Technical factors that may affect PVI include probe malposition and patient motion.

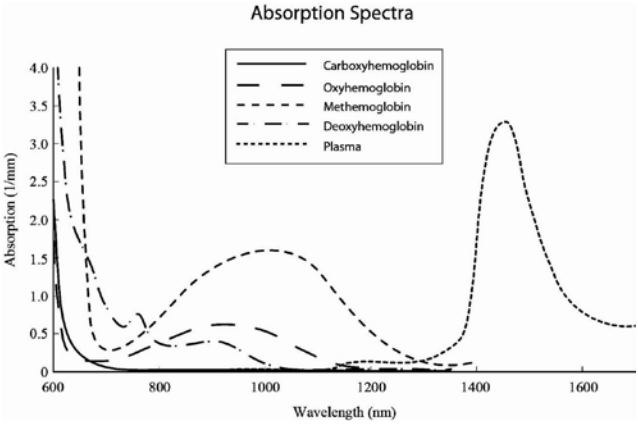
rainbow Pulse CO-Oximetry Technology®

rainbow Pulse CO-Oximetry technology is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized

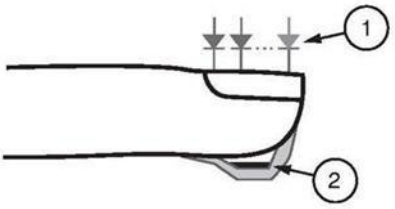
hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).

2. The amount of arterial blood in tissue changes with pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.



The Radical-7 uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma.

The Radical-7 utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to a diode (detector). Signal data is obtained by passing various visible and infrared lights (LEDs, 500 to 1400nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the Radical-7 for calculation.



1. Light Emitting Diodes (LEDs)
   (7 + wavelengths)
2. Detector

Once the Radical-7 receives the signal from the sensor, it utilizes proprietary algorithms to calculate the patient's functional oxygen saturation (SpO_2 [%]), blood levels of carboxyhemoglobin (SpCO [%]), methemoglobin (SpMet [%]), total hemoglobin concentration (SpHb [g/dL]) and pulse rate (PR). The SpCO, SpMet and SpHb measurements rely on a multi-wavelength calibration equation to quantify the percentage of carbon monoxide and methemoglobin and the concentration of total hemoglobin in arterial blood. Maximum skin-sensor interface temperature was tested to be less than 41° C (106° F) in a minimum ambient temperature of 35° C (95° F). The tests were conducted with sensors operating at reasonable worst case power.

Pulse CO-Oximetry vs. Drawn Whole Blood Measurements

When SpO_2, SpCO, SpMet, and SpHb measurements obtained from the Radical-7 (noninvasive) are compared to drawn whole blood (invasive) measurements by blood gas and/or laboratory CO-Oximetry methods, caution should be taken when evaluating and interpreting the results.

The blood gas and/or laboratory CO-Oximetry measurements may differ from the SpO_2, SpCO, SpMet, SpHb, and SpOC measurements of the Radical-7. Any comparisons should be simultaneous, meaning the measurement on the device should be noted at the exact time that blood is drawn.

In the case of SpO_2, different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen (pO_2) and saturation, such as: pH,temperature, the partial pressure of carbon dioxide (pCO_2), 2,3-DPG, and fetal hemoglobin.

In the case of SpCO, different results are also expected if concentration of methemoglobin in the blood gas sample is abnormal (greater than 2% for methemoglobin concentration).

In the case of SpHb, variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. As with most hemoglobin tests, a laboratory blood sample should be analyzed prior to clinical decision making.

High levels of bilirubin may cause erroneous SpO_2, SpMet, SpCO, and SpHb readings. As blood samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation, carboxyhemoglobin, and methemoglobin concentration of the patient are stable and not changing over the period of time that the blood gas sample is taken. Subsequently, blood gas and laboratory CO-Oximetry measurements of SpO_2, SpCO, SpMet, SpHb, and SpOC may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn whole blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

Measurements with Low Signal IQ should not be compared to laboratory measurements.

General Description for Total Hemoglobin (SpHb)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of total hemoglobin (SpHb) in arterial blood. It relies on the same principles of pulse oximetry to make its SpHb measurement. The measurement is taken by a sensor capable of measuring SpHb, usually on the fingertip for adults and pediatric patients.

The sensor connects directly to the Pulse CO-Oximeter or with a patient cable. The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data as measurement of total hemoglobin concentration.

Successful Monitoring for SpHb

A stable SpHb reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. See ***Warnings and Cautions*** on page 15 and ***Troubleshooting Measurements*** on page 171.

General Description for Total Arterial Oxygen Content (CaO_2)

Oxygen (O_2) is carried in the blood in two forms, either dissolved in plasma or combined with hemoglobin. The amount of oxygen in the arterial blood is termed the oxygen content (CaO_2) and is measured in units of ml O_2/dL blood. One gram of hemoglobin (Hb) can carry 1.34 ml of oxygen, whereas 100 ml of blood plasma may carry approximately 0.3 ml of oxygen*. The oxygen content is determined mathematically as:

$$CaO_2 = 1.34 \text{ (ml } O_2\text{/g)} \times Hb \text{ (g/dL)} \times HbO_2 + PaO_2 \text{ (mmHg)} \times 0.003 \text{ (ml } O_2\text{/dL/mmHg)}$$

Where HbO_2 is the fractional arterial oxygen saturation and PaO_2 is the partial pressure of arterial oxygen.

For typical PaO_2 values, the second part of the above equation is approximately 0.3 ml O_2/dL based on PaO_2 being approximately 100 mmHg. Furthermore, for typical carboxyhemoglobin and methemoglobin levels, the functional saturation (SpO_2) as measured by a pulse oximeter is given by:

$$SpO_2 = 1.02 \times HbO_2$$

When calculating oxygen content (SpOC), the Radical-7 will use $SpfO_2$™ if available instead of SpO_2. $SpfO_2$ is the measured fractional arterial oxygen saturation.

**Martin, Laurence. All You Really Need to Know to Interpret Arterial Blood Gases, Second Edition. New York: Lippincott Williams & Wilkins, 1999.*

General Description for SpOC

The above approximations result in the following reduced equation for oxygen content via the Pulse CO-Oximeter:

$$SpOC \text{ (ml/dL*)} = 1.31 \text{ (ml } O_2\text{/g)} \times SpHb \text{ (g/dL)} \times SpO_2 + 0.3 \text{ (ml } O_2\text{/dL)}$$

*When ml O_2/g Hb is multiplied by g/dL of SpHb, the gram unit in the denominator of ml/g cancels the gram unit in the numerator of g/dL resulting in ml/dL (ml of oxygen in one dL of blood) as the unit of measure for SpOC. See ***Warnings and Cautions*** on page 15.

General Description for Carboxyhemoglobin (SpCO)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of carboxyhemoglobin concentration (SpCO) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpCO measurement.

The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry device or through an device patient cable.

The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data as percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

Successful Monitoring for SpCO

A stable SpCO reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site). Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

General Description for Methemoglobin (SpMet)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of methemoglobin concentration (SpMet) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpMet measurement.

The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry device or through a patient cable.

The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data as percentage value for the SpMet.

Successful Monitoring for SpMet

A stable SpMet reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site).

Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. See *Warnings and Cautions* on page 15.

General Description for Oxygen Reserve Index (ORI)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring changes in oxygen states in hyperoxic conditions. It relies on the same principles of pulse oximetry to make its ORi* measurement.

The measurement is taken by a sensor capable of measuring ORi, usually on the fingertip for adult or pediatric patients. The sensor connects directly to the Pulse CO-Oximeter or with a patient cable. The sensor collects signal data from the patient and sends it to the device. The device displays the processed data as an indicator of changes in oxygen states in hyperoxic conditions.

*Available only on Root display

Successful Monitoring for ORI

A stable ORi* reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. See ***Warnings and Cautions*** on page 15 and ***Troubleshooting Measurements*** on page 171.

*Available only on Root display

SpCO, SpMet, and SpHb Measurements During Patient Motion

The Radical-7 displays measurements of SpCO, SpMet, and SpHb during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be reliable during excessive motion. In this case, the measurement value for SpCO, SpMet, or SpHb displays as dashes (---) and a message (*Low SpCO SIQ*, *Low SpMet SIQ*, or *Low SpHb SIQ*) displays to alert the clinician that the device does not have confidence in the value due to poor signal quality caused by excessive motion or other signal interference.

rainbow Acoustic Monitoring (RAM) Technology

rainbow Acoustic Monitoring™ (RAM) continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Sensor, which is applied on the patient's neck, translates airflow sounds generated in the upper airway to an electrical signal that

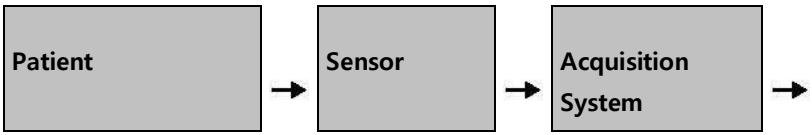
can be processed to produce a respiration rate, measured as breaths per minute.

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

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

rainbow Acoustic Monitoring Architecture

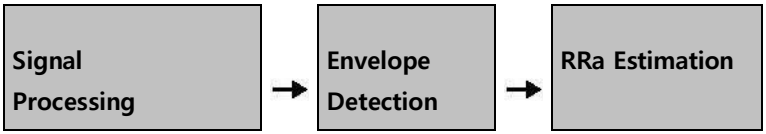
The following figure illustrates how a respiratory sound produced by a patient can be turned into a numerical measurement that corresponds to a respiratory parameter.



Respiratory airflow to sound

Sound to electrical signal

Electrical signal to digital signal



Digital signal to respiratory measurement

Patient

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

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

Sensor

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

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

Acquisition System

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

Signal Processing

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

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

[1] A.R.A. Sovijärvi, F. Dalmasso, J. Vanderschool, L.P. Malmberg, G. Righini, S.A.T. Stoneman. Definition of terms for applications of respiratory sounds. Eur Respir Rev 2000; 10:77, 597-610.

[2] Z. Moussavi. Fundamentals of respiratory sounds analysis. Synthesis lectures on biomedical engineering #8. Morgan & Claypool Publishers, 2006.

[3] Olsen, et al. Mechanisms of lung sound generation. Semin Respir Med 1985; 6: 171-179.

[4] Pastercamp H, Kraman SS, Wodicka GR. Respiratory sounds – Advances beyond the stethoscope. Am J Respir Crit Care Med 1977; 156: 974-987.

[5] Gavriely N, Cugell DW. Airflow effects on amplitude and spectral content of normal breath sounds. J Appl Physiol 1996; 80: 5-13.

[6] Gavrieli N, Palti Y, Alroy G. Spectral characteristics of normal breath sounds. J Appl Physiol 1981; 50: 307-314.

Chapter 2: Radical-7 Descriptions

The following chapter contains the Radical-7 descriptions, including descriptions of the Handheld monitor , the Standalone monitor, and the optional SatShare monitor interface.

General System Description

The Radical-7 system includes the following:

1. Device
2. Patient Cable
3. Sensor

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

Functionality of the Radical-7

The Radical-7 provides the functionality of three devices in one:

Handheld Pulse CO-Oximeter

The Radical-7 is a fully featured Handheld.

The Handheld contains the majority of the device features. All measurements and device status datum are displayed on the touchscreen. All user input is performed through the touchscreen and control buttons. The sensor cable connector is located on the Handheld.

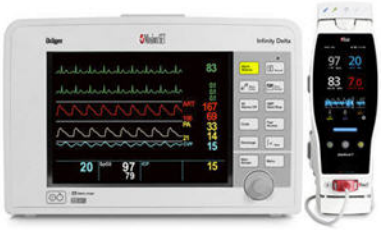
Standalone Pulse Oximeter

The Radical-7 is a fully featured Standalone Pulse-Oximeter, and Acoustic Monitor.

The Handheld snaps into the Docking Station to provide a fully featured standalone monitor. The Docking Station connects to AC power for standalone operation or charging of the Handheld. An optional Docking Station battery is available. The Standalone features Nurse Call, analog output, and serial output.

Monitor Interface

The Radical-7 interfaces to the SpO_2 input module of multi-parameter patient monitors to upgrade conventional pulse oximetry technology on the multi-parameter monitor to Masimo SET® technology.



Utilizing a SatShare cable, the standalone Radical-7 also interfaces with the SpO_2 input of a validated multi-parameter patient monitor, instantly upgrading the conventional pulse oximetry to Masimo SET® pulse oximetry. The SatShare cable attaches to the back of the Radical Docking Station, and SatShare cables are available to interface with most multi-parameter patient monitors.

Handheld

All user input and displays are controlled by this component. The patient cable connects into the connector on the Handheld device. The Handheld is battery powered and can be used either as a transport monitor or as a Handheld Pulse CO-Oximeter for spot checks.

Handheld Front Panel

The following figure numbers and corresponding table describes the hardware features of the Radical-7.

1. Handheld Release button

Press down the Handheld Release Button to pull the Handheld off the Docking Station.

2. Touchscreen Display

The Touchscreen Display refers to the interactive area on the Handheld. There are different Display Views that can appear in this area. For more about using the Touchscreen and Display Views, see *Changing the Size of Parameter Values* on page 73.

3. Profile button

The Profile button provides instant access to the Profile Screen. See *Chapter 5: Profiles* on page 145.

4. Power button

To turn on the Radical-7, press the Power button. To place Radical-7 in standby, press and hold the Power button for two (2) seconds. To turn off, press and hold the button for eight (8) seconds.

5. Home button

The Home button provides instant access to the Display View screen.

6. Alarm Silence Button

The Alarm Silence button temporarily

silences alarms. See *Silencing the Alarms* on page 153.

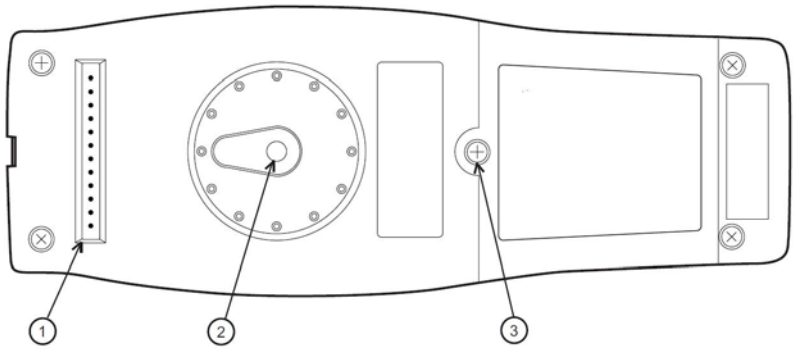
7. Speaker
The speaker indicates audio alarms. Care should be taken not to cover the speaker and muffle the audible alarm volume.

8. Patient Cable Connector
Connect a patient cable or a direct cable sensor into the Radical-7.

Caution: Refer to the Directions for Use for the sensor before applying it on patients.

Handheld Back Panel

The Handheld back panel features the connection to the Docking Station, an accessory mount for the pole clamp accessory, and access to the Handheld battery pack.



Item and Description
1. Connector The Handheld interfaces with the Docking Station through this connector.
2. Pole Clamp The optional Pole Clamp accessory attaches to this holder. See the directions for use of the Pole Clamp accessory for attachment instructions.
3. Battery Compartment The Handheld is powered by a lithium ion battery located in this compartment. For battery care and replacement, see *Battery Operation and Maintenance* on page 196.

Standalone

When the Handheld is placed into the Docking Station, they become a full-featured standalone system. In this manual, when the Handheld and the Docking Station are connected, they are referred to *Standalone*. The Standalone acts as a battery charger for the Handheld and has AC power connection capabilities. If the AC power from the wall outlet is temporarily interrupted, then the battery in the Handheld allows for continuous operation. The Standalone can also interface with serial devices, Nurse Call or analog output devices, and multi-parameter patient monitors through a SatShare cable.

There are several models of compatible Docking Stations available: RDS-1, RDS-2, and RDS-3. The RDS-1 and RDS-3 are optionally available with SafetyNet capability. The following table lists which features are available for each model of Docking Station.

Docking Station Features	RDS-1	RDS-2	RDS-3
AC Power Input	■	■	■
SatShare Interface	■		
Serial RS-232 interface	■		■
Nurse Call/Analog Output interface	■		■
10-Hour Extended Battery			

Docking Station Features	RDS-1	RDS-2	RDS-3
Automatic Display Rotation Support (Gravity Detector)	■		■
Docking Station Battery Charging indicator			■
Handheld Battery Charging indicator	■	■	■
Visual Alarm indicator	■		■
AC Power indicator	■	■	■
Docking indicator	■		■

Standalone Front Panel

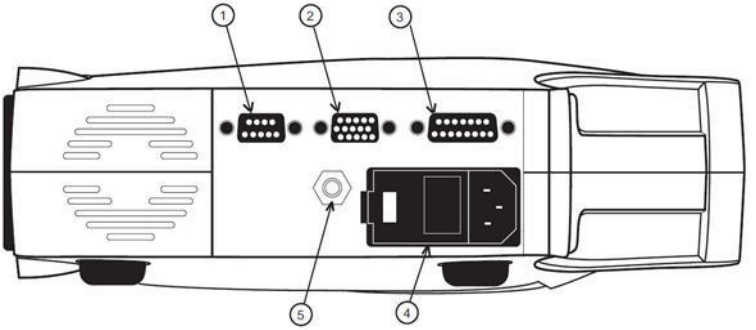
The following figure and corresponding text review the features of the Radical-7 Standalone. Note that when the Standalone is turned on, all indicator LEDs initially turn on and off at start up.

Item and Description	
1. Docking Station Battery Charging Indicator	
	The Docking Station Battery Charging indicator is illuminated when the Docking Station battery is charging. The indicator blinks just prior to charging. The Charging Indicator does not illuminate when the battery is fully charged or when the battery is not present.
2. Handheld Battery Charging indicator	
	The Handheld Battery Charging indicator is illuminated when the Handheld battery is charging. The indicator blinks just prior to charging. The Charging Indicator does not illuminate when the battery is fully charged or when the battery is not present.
3. Visual Alarm Indicator	
	The Visual Alarm indicator is illuminated when an alarm condition is active and the Alarm Status Indicator is shown.
4. AC Power Indicator	
	The AC Power indicator is illuminated when the Radical-7 Docking Station is plugged into AC line power.
5. Docking Indicator	

Item and Description	
	The Docking indicator is illuminated when the Handheld device is turned on and is properly interfaced to a Docking Station.

Standalone Back Panel

The following figure and corresponding text review the features of the Radical-7 Standalone.



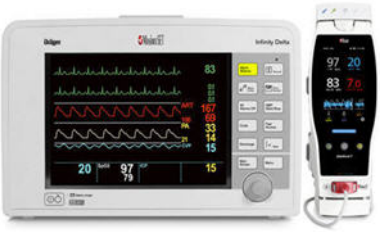
Item and Description
1. Serial Output connector
Use the Serial Output connector with a ferrite bead installed to connect a serial device, including a serial printer, a monitoring system or PC to the Radical-7. The data is provided in standard RS-232C format. All external device connections to the Serial Output connector must be IEC-60950 compliant.

Item and Description
2. Analog Output/Nurse Call connector
Use the Analog Output connector with a ferrite bead installed to interface with an analog output device, such as a chart recorder or Nurse Call system. All external device connections to the Analog Output/Nurse Call connector must be IEC-60950 compliant. See *Serial Interface Specifications* on page 186.
3. SatShare Cable connector
Use the SatShare Cable connector to connect a SatShare cable to the SpO_2 input connector of a multi-parameter patient monitor. All external device connections to the SatShare Cable Connector must be IEC-60601-1-1 compliant. SatShare cables are available to interface with most major multi-parameter patient monitors. Check the label on the SatShare cable and the SatShare Directions for Use to ensure that the correct cable is used for each type of patient monitor. Visit *www.masimo.com* for the latest SatShare cables and validated devices.
4. Power Entry module
The Power Entry module contains the input connector for AC power and two fuses. The AC input provides power to the system from the AC line. Always connect the Radical-7 to the mains power for continuous operation and/ or battery recharging. Note: Use the power cord as the means to disconnect the device from the mains power supply.

Item and Description
5. Equipotential Ground connector
Use the Equipotential Ground connector for grounding.

Monitor Interface With SatShare

The Radical-7 has a unique SatShare interface that links to most existing multi-parameter patient monitors through a SatShare cable.



- Upgrades any approved and validated monitor to Masimo SET® performance by using the calculated SpO_2 and pulse rate determined by Radical-7 to simulate an ideal plethysmograph waveform, which is sent to the validated multi-parameter patient monitor.
- Connects into the SpO_2 patient cable or SpO_2 input connector of the multi-parameter patient monitor.

See ***Setting Up and Using SatShare*** on page 62.

Chapter 3: Setup

The following chapter contains information about setting up the Radical-7 before use.

Unpacking and Inspection

To unpack and inspect the device

1. Remove the device from the shipping carton and examine it for signs of shipping damage.
2. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.
3. If anything is missing or damaged, contact the Technical Service Department. See ***Return Procedure*** on page 204.

Docking Station Power Requirements

- Always use a hospital-grade, AC power cable to connect the Docking Station to an AC power source.
- Do not connect the Docking Station to an AC outlet that is controlled by a switch because the power to the Docking Station may be inadvertently switched off.
- Verify the AC power voltage and line frequency before use.
- Verify that the power source can provide an adequate power rating as indicated on the rear panel of the Docking Station.
- The Radical-7 is designed to operate on 100 to 240VAC, 47-63 Hz.
- The Radical-7 is rated at 55 VA max.

- Connect a hospital-grade power cable (IEC-320 connector type at the device) to the Power Entry module on the Docking Station.
- Connect the power cable to an AC power source.
- Ensure that the device is adequately powered by verifying that the AC power indicator on the Docking Station is illuminated.

See *Warnings and Cautions* on page 15.

Setting Up the Docking Station

Place the Docking Station on a stable hard flat surface near the patient. Always place the Radical-7 on a dry surface. Maintain a minimum of 3 cm (1 inch) free space around the Radical-7. Make sure that the Radical-7 speaker is not covered to avoid a muffled alarm sound.

The Radical-7 Handheld, Docking Station or Standalone should not be operated outside the environmental conditions listed in the specifications section *Environmental* on page 181.

Initial Battery Charging

Before use, the Radical-7 Handheld battery and the Docking Station battery must be charged completely.

To charge the Handheld and Docking Station for the first time

1. Attach the Handheld to the Docking Station.
2. Plug in the AC power cord to power entry module. Make sure it is securely plugged in.
3. Plug the AC power cord into an AC power source.
4. Verify that the batteries are charging.

- The Battery Charging indicators on the Docking Station flash prior to charging and remain illuminated while the batteries are charging.

See *Standalone Front Panel* on page 54 and *Battery Operation and Maintenance* on page 196.

Setting Up for Philips, Agilent, or HP VueLink

To set up for use with VueLink compatible monitors (Philips, Agilent, or HP)

1. On the Radical-7, on the *device output* screen, for the *serial* option, select **Hp VueLink**.
2. Connect one end of the VueLink cable to the Serial Output connector on the Docking Station.
3. Connect the other end of the VueLink cable to the VueLink module and insert the module into the VueLink compatible monitor rack.

   The SpO_2 and pulse rate values appear on the VueLink compatible monitor.
4. In order for the plethysmographic waveform to be displayed on the VueLink compatible monitor, and for the VueLink monitor to convey alarm conditions measured by the Radical-7, the VueLink compatible monitor must be properly configured.
5. See instructions for use provided with the VueLink compatible monitor and the VueLink module. See *Compliance* on page 183 and *Serial Interface Specifications* on page 186.

Setting Up for SpaceLabs Flexport

To set up for use with SpaceLabs Flexport

1. On the Radical-7, on the *device output* screen, for the *serial* option, select **SpaceLabs Flexport**.
2. Connect one end of the Spacelabs Flexport cable to the Serial Output connector on the Docking Station.
3. Connect the other end of the Spacelabs Flexport cable to the Spacelabs Universal Flexport connector.

   The SpO_2 and pulse rate values appear on the Spacelabs screen.
4. In order for the plethysmographic waveform to be displayed on the Spacelabs screen, and for the Spacelabs monitor to convey alarm conditions measured by the Radical-7, the Spacelabs monitor must be properly configured.
5. See instructions for use provided with the Spacelabs monitor. See ***Compliance*** on page 183 and ***Serial Interface Specifications*** on page 186.

Setting Up and Using SatShare

Parameter values from the Radical-7 can be displayed on a multi-parameter monitor through the SatShare feature. The SatShare feature provides an ideal, simulated plethysmographic waveform that corresponds to the parameter values determined the by Radical-7. This waveform may be used to display these values on multi-parameter monitors through the multi-parameter oximetry sensor or input connector.

It is recommended that the Radical-7 be positioned near the multi-parameter monitor, with the Radical-7 screen displaying the

plethysmographic waveform and the parameter values. Refer to the instructions for use provided with the multi-parameter monitor. See *Compliance* on page 183.

To set up for use with SatShare interface

1. Select the SatShare cable that is appropriate for the multi-parameter monitor. For the latest list of available SatShare cables and validated devices, see ***www.masimo.com***.
2. Connect the labeled end of the SatShare cable to the SatShare Cable connector on the Docking Station. See *Standalone Back Panel* on page 56. For a secure connection, tighten the cable connector screws.
3. Connect the other end of the SatShare cable to one of the following:
   - Sensor connector of the multi-parameter monitor cable
   - Directly to the multi-parameter monitor
4. Verify that the multi-parameter monitor recognizes the SatShare cable.
5. As appropriate, configure alarm limits on the multi-parameter monitor.
6. Set the averaging time for the multi-parameter monitor to its lowest setting (or fastest response). The ideal waveform for the Radical-7 requires additional averaging by the monitor. If the averaging time of the multi-parameter monitor is not changed, the time to display physiological changes in saturation on the monitor is increased with SatShare. However, the delay can be minimized by reducing the averaging time on the multi-parameter monitor.

7. While in the SatShare mode, if there are any significant discrepancies between the readings from Radical-7 and those on the monitor displaying the values obtained from SatShare, the values reported by the Radical-7 are to be considered the correct values.
8. It is possible to use the Radical-7 with SatShare while the Radical-7 is not connected to AC power. However, in this configuration, battery run time is reduced. See ***Battery Operation and Maintenance*** on page 196.
9. On the Radical-7, turn on the *Satshare Numbers* option. See ***Device Output*** on page 126.
10. If displaying the simulated waveform is not desirable, it is recommended to turn off the plethysmographic waveform display of the multi-parameter patient monitor. See ***Serial Interface Specifications*** on page 186.

Chapter 4: Operation

The following chapter contains information about using the Radical-7.

Using the Touchscreen and Buttons

1. Display View

To access other screens, touch a value on the Display View. See ***About the Display View*** on page 70.

2. Profiles button

To the access the *Profiles* screen, press Profiles. See ***Chapter 5: Profiles*** on page 145.

3. Alarm Silence button

To temporarily silence audible alarms, press Alarm Silence. See ***Silencing the Alarms*** on page 153.

4. Home button

To return to the *Display View*, press Home.

5. Power button

To turn on the Radical-7, press the Power button. To turn off, press and hold the button for more than 2 seconds

Using Screen Lock

When turned on, the *Screen Lock* feature may prevent unintentional interaction with *Display View*.

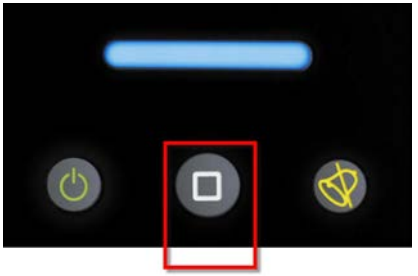
Using the Screen Lock feature

1. When turned on, any interaction with the *Display View* triggers the Screen Lock feature.
2. To bypass *Screen Lock* when it appears, press and hold the Lock icon until it unlocks.

3. To turn on or turn off *Screen Lock*, see ***Access Control*** on page 117.

Using the Home Button

One option to return to *Display View* is by using the Home button.



To return to Display View using the Home button

- From any screen, press **Home**.

Standby and Power Off

To put Radical-7 in Standby Mode or to Power Off, follow these steps:

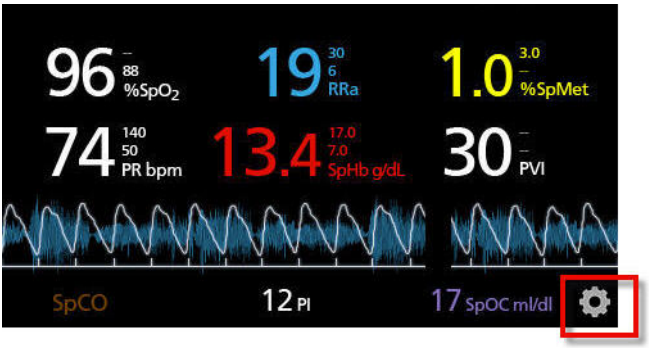
State	Description
Standby Mode	Press and hold the Power Button for two (2) seconds until a single audible tone sounds. Standby Mode conserves power while enabling a quicker startup sequence.
Power Off	Press and hold the Power Button for eight (8) seconds, until two (2) audible tones sound. The Home Button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

Navigating the Radical-7

Navigate the Radical-7 screens via the *Display View* or the *Main Menu*.

Display View

The following is the primary interactive screen that the user views.



To access the *Main Menu* screen

- Touch the gear icon at the lower right corner of the display.

Main Menu

The following is the *Main Menu* screen where users can access additional screens and information. Users can swipe the screen left or right to pan the Menu Icons. Users can touch the arrow icon to return to the *Display View*. See ***Accessing the Main Menu*** on page 84.

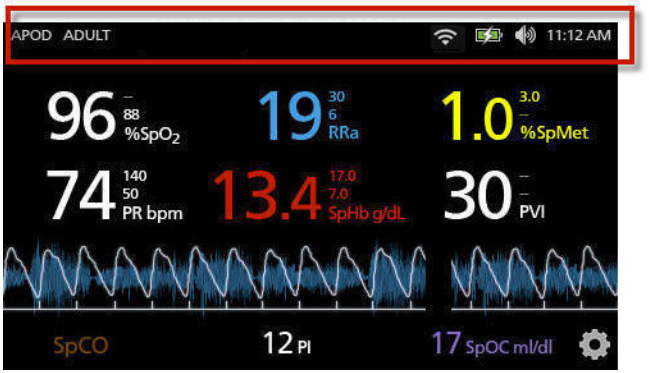
Display Timeout

When no user interaction occurs within one minute, the display times out and returns to the *Display View*.

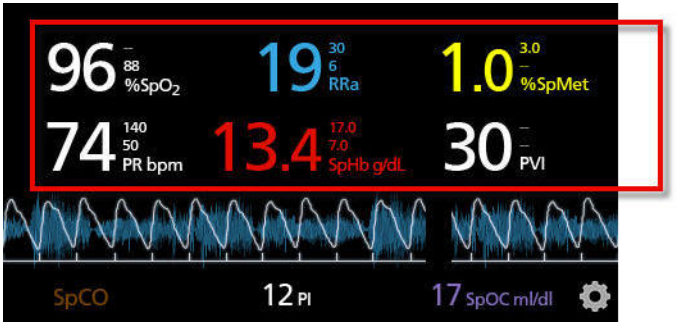
About the Display View

The *Display View* consists of different areas:

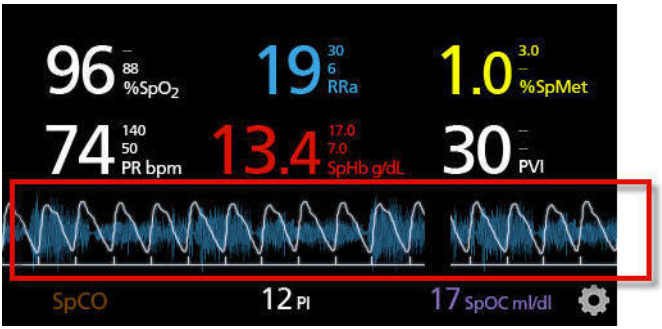
Status Bar. See ***About the Status Bar*** on page 72.



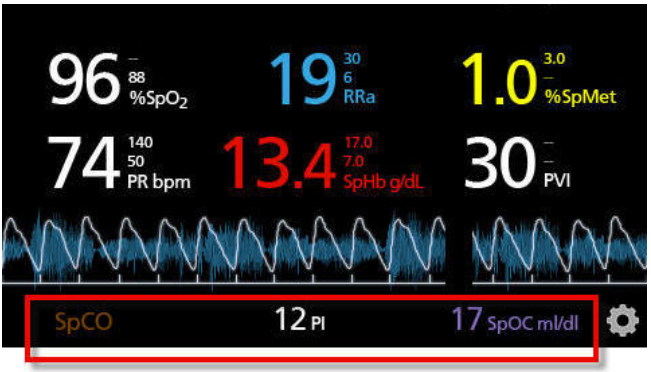
Parameter Display. See ***Changing the Size of Parameter Values*** on page 73.



Trend Field. See *Waveform and Trend Views* on page 76.



Small Parameter View. See *Accessing the Main Menu* on page 84.



About the Status Bar

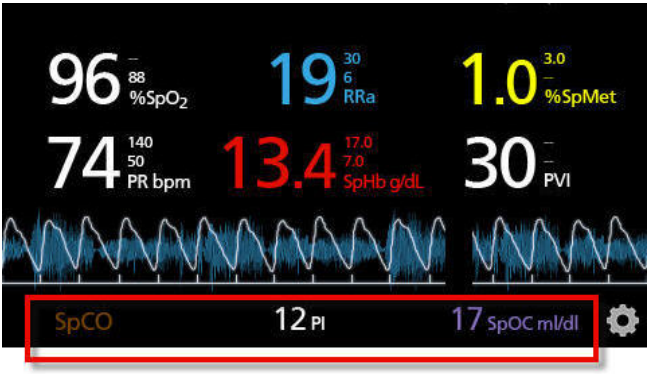
The Status Bar is visible on the top portion of the *Display View*.

Status Bar

Access additional screens, more information, or toggle features by touching directly on any of the following indicators in the Status Bar.

- Sensitivity Modes. See ***Sensitivity Modes Overview*** on page 81.
- Profiles. See ***Profiles Overview*** on page 145.
- ***Messages*** on page 161.
- ***WiFi*** on page 124.
- ***Battery*** on page 125.
- ***Sounds*** on page 113.
- Time settings. See ***Localization*** on page 121.

Changing the Size of Parameter Values



To change the size of parameter values on the Display View

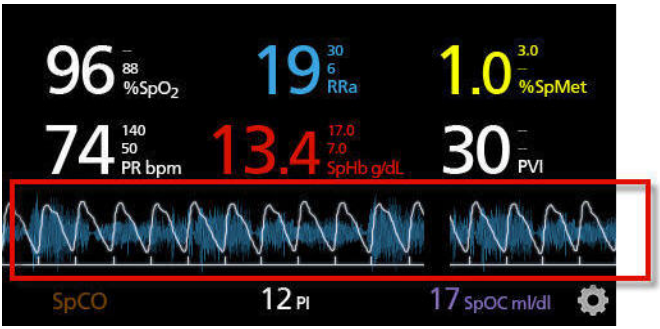
1. On the *Small Parameter* view, touch and hold any one of the parameters, as shown above.
2. When the parameter value dims, shakes, and grows in size, drag and drop that parameter above the *Trend Field*.
3. The parameter value appears on the screen in a larger font. The device automatically configures the screen for optimal display of the parameter values.
4. To remove parameter values from the larger font display, press and hold the larger parameter value. Then drag and drop the parameter value back to the *Small Parameter* view.

Trend Field

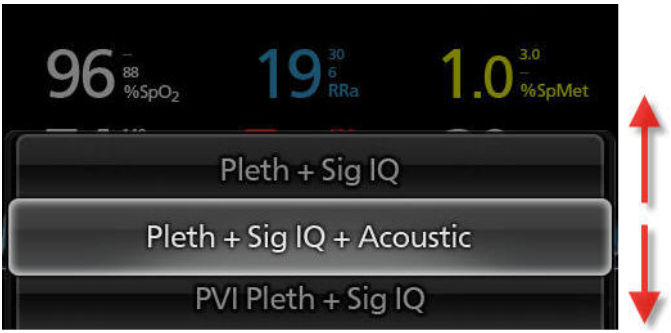
The *Trend Field* allows users to access various customizable views. See ***Trends*** on page 127.

To access trend, waveform, or customize the views on the Display View screen

1. Touch the **Trend Field**, as shown below.

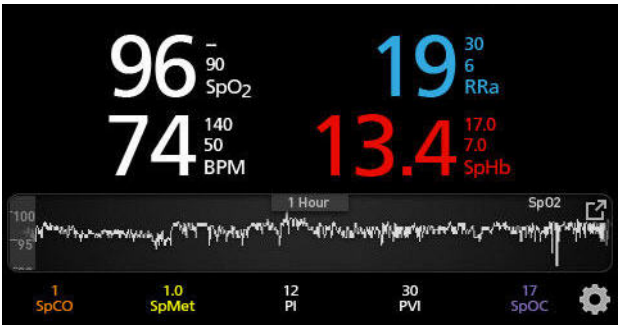


2. The following screen appears.



3. Swipe up or swipe down the available options.
4. Touch on the desired option.

5. The *Trend Field* displays trend data specific to the option that was selected.



Pulse Bar

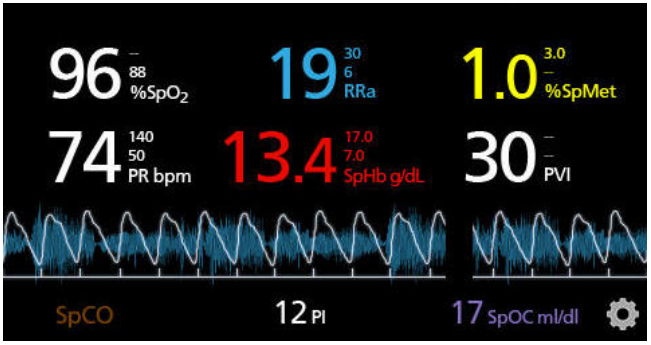
The *Pulse Bar* is a visual indicator that conveys the detection of pulse and the Signal IQ (SIQ) displayed on each individual pulsation. The height of the bars provides an assessment of the confidence in the measurement displayed. See ***Signal IQ Indicators*** on page 77.

Waveform and Trend Views

The following section contain information about trends and waveforms available from the *Trend Field* on the *Display View* screen. The following are examples of some of the views that are available.

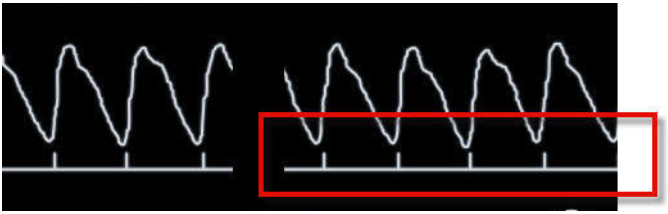
Pleth + Sig IQ + Acoustic View

Shows the parameter values on the top of the screen. The waveform is located below the parameter values. The *Small Parameter* view is located along the bottom of the screen. This view contains the Pleth waveform, signal quality indications, and acoustic waveform.



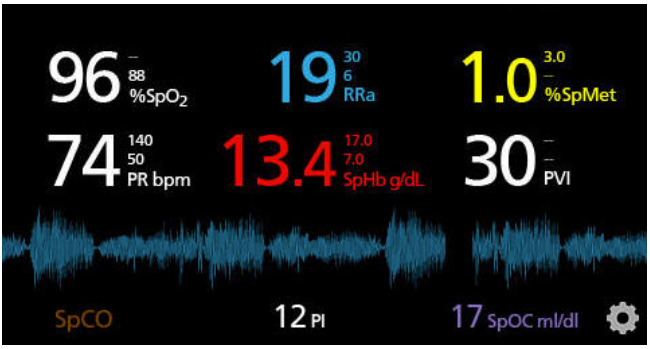
Signal IQ Indicators

The Signal IQ (SIQ), displayed on each individual pulsation, is conveyed by vertical bars, as shown below. The height of the bar provides an assessment of the confidence in the measurement displayed.



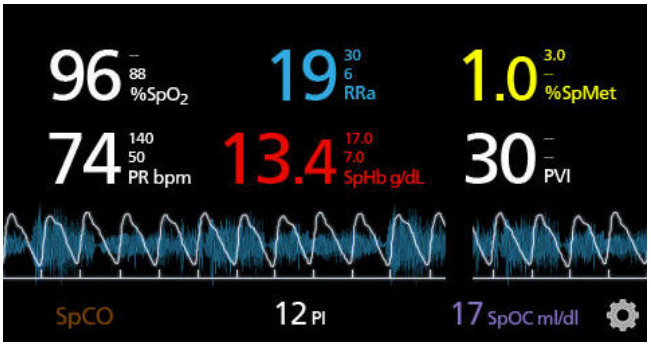
Acoustic Waveform View

Shows the parameter values on the top of the screen. The RRa waveform is located below the parameter values. The *Small Parameter* view is located along the bottom of the screen. Acoustic Respiratory Rate (RRa) must be available for this feature to be shown. This view contains acoustic respiratory rate waveform only.



Pleth + Sig IQ + Acoustic View

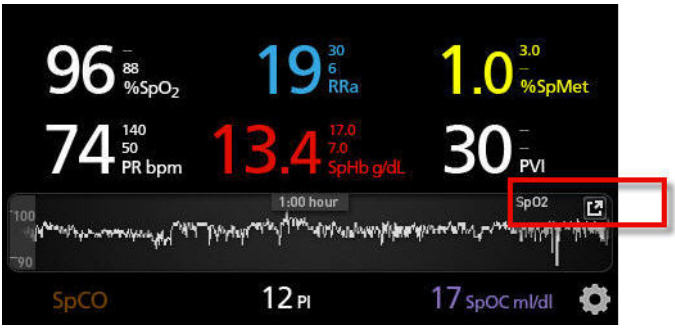
Shows the parameter values on the top of the screen. The waveform is located below the parameter values. The *Small Parameter* view is located along the bottom of the screen. This view contains the Pleth waveform, signal quality indications, and acoustic waveform.



Parameter Quick Trend View

This view displays the quick trend of the selected parameter over an adjustable period of time. The default is 1 hour. Enlarge the quick trend to the full trend view by touching the expand icon of the waveform display.

With a pinch gesture, using two fingers, the user can zoom in and out of the quick trend data within the *Trend Field*.



About Events Feature

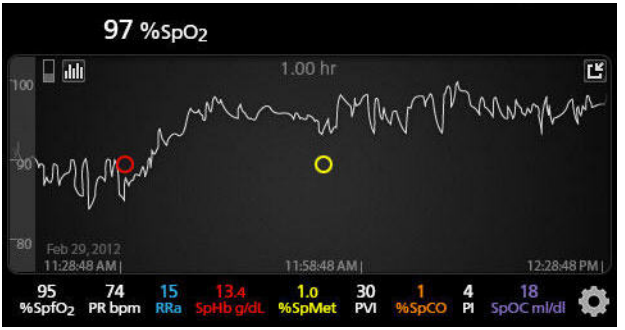
The Events feature provides graphical display of parameter or measurement alarms and non-clinical exception messages. This feature is only viewable in the Full Trend screen; however, it is available at all times for all parameters and measurements. For more information about these alarms and exceptions, see **Chapter 6: Alarms and Messages**.

Events appear as color-coded circles along the trend of a parameter or measurement.

Color of Event Circle	Visibility	Description	Example Messages
Red		Parameter or measurement alarm.	• *SpO_2 low* • *SpCO high* • *PR low*

	Specific to parameters and measurements shown in Full Trend screen.	Change in In Vivo offset.	• *SpO_2 In Vivo offset changed: -1.9*
Yellow	Whenever in Full Trend screen.	Non-clinical exception.	• *Replace sensor* • *Low battery* • *No cable connected*

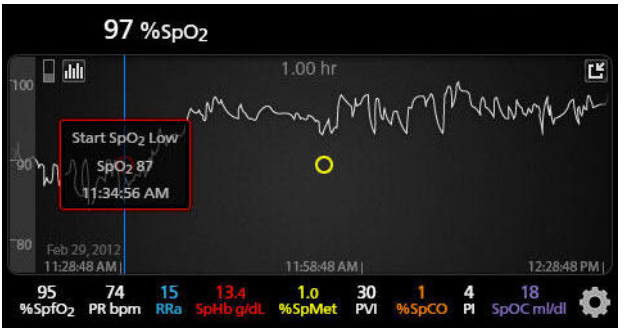
In the example below showing two (2) Events, the yellow circle represents a system exception and the red circle represents a parameter alarm related to the patient's SpO_2 level.



If there are two (2) parameters and/or measurements displayed in the Full Trend screen, then only Events related to those parameters and/or measurements will be visible.

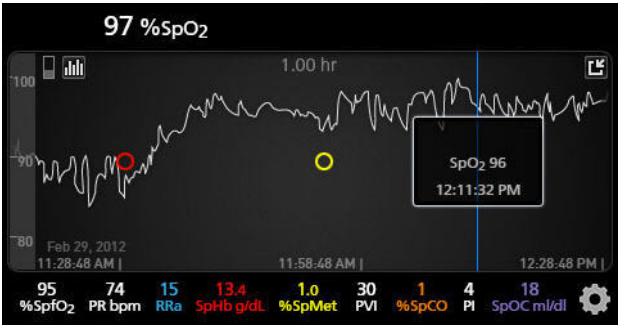
Using the same example, tapping on the red circle reveals a message box displaying the alarm (*Start SpO_2 Low*), the reading (*SpO_2 87*), as well as

its timestamp (*11:34:56 AM*), which correlates with the position of the vertical blue line.



To view time and reading information about a specific parameter or measurement, tap anywhere along the trend.

Using the same example, tapping on the trend somewhere towards the right reveals a message box displaying the parameter reading (*SpO_2 96*) and its timestamp (*12:11:32 PM*).



Sensitivity Modes Overview

Three sensitivity levels enable a clinician to tailor the response of the Radical-7 to the needs of the particular patient situation. Access the

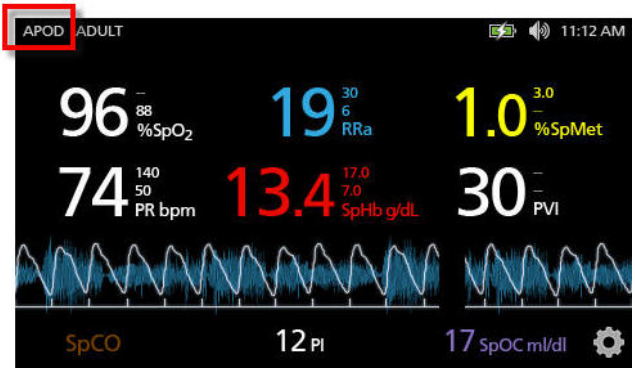
menu by touching on the indicator in the upper left corner of the *Display View*. The sensitivity levels are as follows:

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

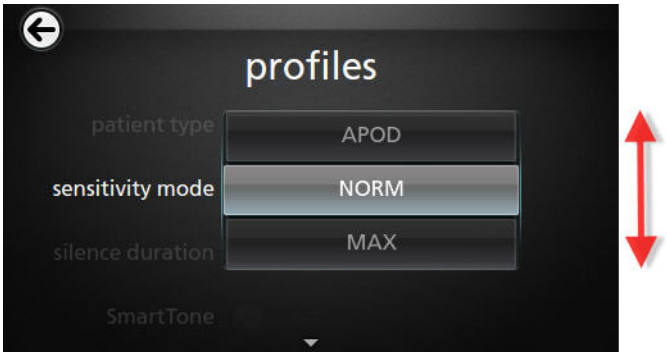
Changing Sensitivity Modes

There are two ways to change the sensitivity modes.

1. Press the indication on the top left of the *Display View*.



2. Alternatively, from the *Main Menu*, touch the *Profiles* icon. From the *Profiles* screen, select the desired mode by scrolling up or down. Then select **OK**.

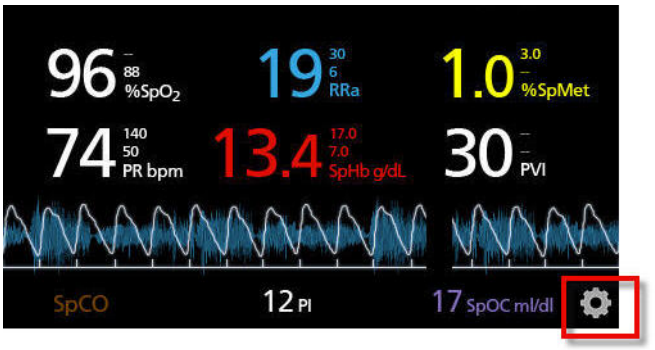


Note that the device will revert to APOD mode after a power cycle.

See *Changing Profiles* on page 146.

Accessing the Main Menu

To access *Main Menu* from the *Display View*, touch the gear icon on the bottom right corner of the *Small Parameter View*.



Navigating the Main Menu

- From the *Main Menu* screen, touch the icons for any of the following screens:

Device Settings

See ***Device Settings*** on page 116.

Parameter Settings

See ***Parameter Settings*** on page 87.

Profiles

See ***Changing Profiles*** on page 146.

3D Alarms

See ***3D Alarms*** on page 157.

Trends

See ***Trends*** on page 127 and ***Trend Field*** on page 73.

Sound

See ***Sounds*** on page 113.

About

See ***About*** on page 141.

Parameter Settings

The following is an example of the *Parameter Settings* screen. Only parameters that have been loaded onto the system will be visible.

To access any of the available parameter setting screens

1. From the *Parameter Settings* screen, to access the desired parameter, flick the on-screen icons left or right.
2. Touch the icon of the desired parameter. For details, see any of the following sections.

SpO2 Settings on page 91.

SpHb Settings on page 94.

PVI Settings on page 106.

PR Settings on page 98.

Perfusion Index (PI) Settings on page 99.

SpCO Settings on page 108.

SpMet Settings on page 109.

SpOC Settings on page 111.

Respiration Rate (RR) on page 101

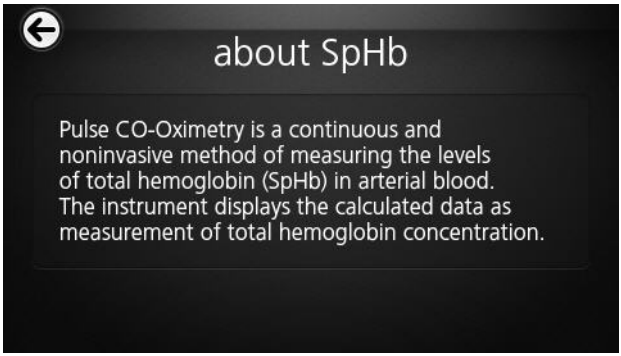
About Parameter Information

Additional information about each parameter is available.

To access additional information about parameters

1. From the parameter settings screen, touch the **About** icon. The following is an example for SpHb.

2. An *About* screen appears for the selected parameter.



In Vivo Adjustment Overview

The In Vivo Adjustment feature lets clinicians manually adjust one or more clinical parameters to match that of a corresponding laboratory reference for continuous trending. To remind clinicians that the feature is active, an offset value displays alongside the adjusted parameter value.

The In Vivo Adjustment feature for a parameter can be turned on by accessing the In Vivo screen in the settings menu of that parameter. After enabling the feature, set an offset value. Once the feature is enabled, a positive or a negative offset value appears, as shown in the following illustration.

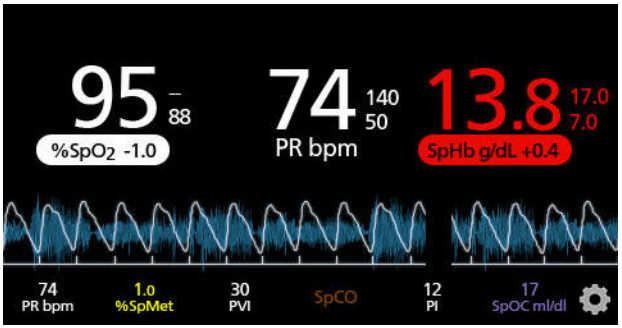
The In Vivo offset is set to zero for any of the following:

- Cable or sensor is disconnected from device.
- Sensor goes off patient causing a sensor initialization to occur.
- Eight hours has elapsed since the In Vivo value was activated.
- Restore of factory defaults.
- The user turns off In Vivo.

Offset Value

When In Vivo Adjustment is activated for a specific parameter, the offset value appears beneath that specific parameter. A positive value means that the displayed parameter value has been increased (according to a laboratory reference value as entered by a clinician) and a negative value means the displayed parameter value has been decreased (according to a laboratory reference value as entered by a clinician).

In the example below, the displayed SpO_2 value of 95 takes into account an offset of -1.0, and the displayed SpHb value of 13.8 takes into account an offset of +0.4.



The In Vivo Adjustment feature can be set to *On* or *Off*. the factory default setting is *Off*. If set to *On*, the parameter value is adjusted and an offset value appears. The offset value is set by the user.

The feature applies to any of the following parameters:

In Vivo for SpO2 on page 94.

In Vivo for SpHb on page 98.

In Vivo for SpCO on page 108.

In Vivo for SpMet on page 110.

SpO2 Settings

Access any of the following options:

Alarms for SpO2 on page 91.

Additional Settings for SpO2 on page 92.

About Parameter Information on page 88.

Alarms for SpO2

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

Options	Description	Factory Default Settings	Configurable Options
High Limit	The High Limit is upper threshold that triggers an alarm.	Off	2% to 99% in steps of 1%, or Off When set to Off, alarm is disabled
Low Limit	Low Limit is the lower threshold that triggers an alarm.	88%	1% to 98% in steps of 1%

Options	Description	Factory Default Settings	Configurable Options
Rapid Desat	Sets the Rapid Desat limit threshold to the selected amount below the Low Alarm Limit. When SpO_2 value falls below rapid desat limit the audio and visual alarm are immediately triggered without respect to the alarm delay.	-10%	Off, -5%, or -10%
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	5 seconds	0, 5, 10, or 15 seconds
Adaptive Threshold Alarm (ATA)	ATA establishes patient-specific limit thresholds based upon the baseline value of the parameter. See ***Adaptive Threshold alarm (ATA) Feature*** on page 156.	Off	Off or On

Additional Settings for SpO2

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

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time	The length of time over which the system calculates the average of all data points.	8 seconds	2-4, 4-6, 8, 10, 12, 14, or 16 seconds
FastSat	See ***FastSat Overview*** on page 93.	Off	On or Off

FastSat Overview

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

When the Radical-7 is set to FastSat *On*, the averaging algorithm evaluates all the saturation values providing an averaged saturation value that is a better representation of the patient's current oxygenation status. With FastSat, the averaging time is dependent on the input signal.

In Vivo for SpO2

From the *In Vivo* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Enabled	See ***In Vivo Adjustment Overview*** on page 89.	Off	On or Off
Offset Amount	See ***In Vivo Adjustment Overview*** on page 89.	0 when turned on	Adjust difference of ± 6%, in steps of 0.1%

SpHb Settings

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

SpHb Alarms on page 94.

Additional Settings for SpHb on page 96.

About Parameter Information on page 88.

SpHb Alarms

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

Options	Description	Factory Default Settings	User Configurable Settings
High Limit	The High Limit is upper threshold that triggers an alarm.	17.0 g/dL (170 g/L) (11.0 mmol/L)	2.0 g/dL to 24.5 g/dL in steps of 0.1 g/dL, or Off (2 g/L to 249 g/L in steps of 1 g/L, or Off) (2.0 mmol/L to 15.0 mmol/L in steps of 0.1 mmol/L, or Off) When SpHb Precision is set to 1.0, the values are rounded down. When set to Off, alarm is disabled.

Options	Description	Factory Default Settings	User Configurable Settings
Low Limit	The Low Limit is lower threshold that triggers an alarm.	7.0 g/dL (70 g/L) (4.0 mmol/L)	Off, or 1.0 g/dL to 23.5 g/dL in steps of 0.1 g/dL (Off, or 1 g/L to 248 g/L in steps of 1 g/L) (Off, or 1.0 mmol/L to 14.5 mmol/L, in steps of 0.1 mmol/L) When SpHb Precision is set to 1.0, values are rounded down. When set to Off, alarm is disabled.

Additional Settings for SpHb

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

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time	The length of time over which the system calculates the average of all data points.	Medium	Short, Medium, or Long
Calibration	Provides an arterial or venous value that displays on the main screen.	Venous	Arterial or Venous
Precision	Allows the user to set the decimal for SpHb.	0.1	0.1, 0.5, or 1.0 (whole numbers)
Unit of Measure*	Displays total hemoglobin (SpHb) as g/dL (grams per deciliter), g/L (grams per liter), or mmol/L (milimoles per liter). Unit of Measure can not be changed during active monitoring.	g/dL	g/dL, g/L, or mmol/L,

*Changing Unit of Measure will delete all prior trend data for all parameters.

In Vivo for SpHb

From the *In Vivo* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
In Vivo Calibration	See ***In Vivo Adjustment Overview*** on page 89.	Off	On or Off
In Vivo Calibration Offset	See ***In Vivo Adjustment Overview*** on page 89.	0	± 3 g/dL in steps of ± 0.1 g/dL

PR Settings

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

PR Alarms on page 98.

About Parameter Information on page 88.

PR Alarms

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

Options	Description	Factory Default Settings	Options
High Limit	The High Limit is upper threshold that triggers an alarm.	140 bpm	35 bpm to 235 bpm, in steps of 5 bpm
Low Limit	The Low Limit is lower threshold that triggers an alarm.	50 bpm	30 bpm to 230 bpm, in steps of 5 bpm

Perfusion Index (PI) Settings

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

PI Alarms on page 99.

Additional Settings for PI on page 100.

About Parameter Information on page 88.

PI Alarms

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

Options	Description	Factory Default Settings	User Configurable Settings
High Limit	The High Limit is upper threshold that triggers an alarm.	Off	Step size: 0.04 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 19 in steps of 1, or Off
Low Limit	The Low Limit is lower threshold that triggers an alarm.	Off	Step size: Off, or 0.03 to 0.09 in steps of 0.01 0.10 to 0.90 in steps of 0.10 1 to 18 in steps of 1

Additional Settings for PI

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

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

Respiration Rate (RR)

The Radical-7 can determine respiration rate (RR) either by the acoustic signal (RRa) or by the plethysmographic waveform (RRp).

RRp Settings

When using a pulse oximetry or pulse CO-Oximetry sensor with the Radical-7, respiration rate can be determined by the plethysmographic waveform (RRp). This method measures a patient's respiratory rate based on plethysmographic amplitude changes that correspond to the respiratory cycle. When using a pulse oximetry or pulse CO-Oximetry sensor, RRp alarms and RRp settings are active and the *Display View* conveys respiratory rate as *RRp*, as shown below.

Note that the Radical-7 can monitor RRa or RRp but not both simultaneously. RRp is active under the following conditions:

- RRp is installed on the Radical-7.
- Dual Rainbow cable is disconnected.
- Pulse oximetry or pulse CO-Oximetry sensor is connected.
- Acoustic sensor is not connected.

When using an acoustic sensor, respiration rate (RR) is determined by the acoustic (RRa) signal. See ***rainbow Acoustic Monitoring (RAM) Technology*** on page 42. When the respiratory rate is determined by the acoustic signal, the *Display View* conveys respiratory rate as *RRa*, as shown below.

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

RRp Alarms on page 102.

Additional Settings for RRp on page 103.

RRp Alarms

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

Options	Description	Factory Default	Configurable Options
High Limit	The High Limit is upper threshold that triggers an alarm.	30 breaths per minute	6 breaths per minute to 69 breaths per minute, or Off
Low Limit	The Low Limit is lower threshold that triggers an alarm.	6 breaths per minute	5 breaths per minute to 68 breaths per minute, or Off
Alarm Delay	When an alarm condition is met, this feature delays the audible part of an alarm.	30 second	0, 10, 15, 30, 60 seconds

Additional Settings for RRp

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

Options	Description	Factory Default Settings	User Configurable Settings
Averaging Time	The length of time over which the system calculates the average of all data points.	Slow	No, Fast, Medium, Slow, Trending

Options	Description	Factory Default Settings	User Configurable Settings
Freshness	The duration of time that, during interference, the system displays the last valid reading.	5 minutes	0, 1, 5, 10, 15 minutes

RRa Settings

RRa is active under the following conditions:

- RRa is installed on the Radical-7.
- Dual rainbow cable is connected.
- Acoustic sensor is connected.

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

RRa Alarms on page 104.

Additional Settings for RRa on page 105.

About Parameter Information on page 88.

RRa Alarms

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

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

Additional Settings for RRa

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

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

PVI Settings

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

PVI Alarms on page 106.

Additional Settings for PVI on page 107.

About Parameter Information on page 88

PVI Alarms

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

Options	Description	Factory Default Settings	User Configurable Settings
High Limit	The High Limit is upper threshold that triggers an alarm.	Off	2 to 99, in steps of 1, or Off When set to Off, alarms are disabled.
Low Limit	The Low Limit is lower threshold that triggers an alarm.	Off	Off, 1 to 98 in steps of 1 When set to Off, alarms are disabled.

Additional Settings for PVI

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

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

SpCO Settings

From the *SpCO Setting*s screen, access the following screens:

SpCO Alarms on page 108.

About Parameter Information on page 88.

SpCO Alarms

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

Options	Description	Factory Default Settings	User Configurable Settings
High Limit	The High Limit is the upper threshold that triggers an alarm.	10	2% to 98%, in steps of 1%, or Off When set to Off, alarm is disabled
Low Limit	The Low Limit is the lower threshold that triggers an alarm.	Off	Off, 1% to 97%, in steps of 1% When set to Off, alarm is disabled

In Vivo for SpCO

From the *In Vivo* screen, access the following screens:

Options	Description	Factory Default Settings	User Configurable Settings
Enabled	See *In Vivo Adjustment Overview* on page 89.	Off	On or Off
Offset Amount	See *In Vivo Adjustment Overview* on page 89.	0	± 9% in steps of 0.1%

SpMet Settings

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

SpMet Alarms on page 109.

About Parameter Information on page 88.

SpMet Alarms

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

Options	Description	Factory Default Settings	User Configurable Settings
High Limit	The High Alarm Limit is upper threshold that triggers an alarm.	3.0	1% to 2% in steps of 0.1% 2.5% to 99.5% in steps of 0.5%, or Off
Low Limit	The Low Alarm Limit is lower threshold that triggers an alarm.	Off	Off, 0.1% to 2.0% in steps of 0.1% 2.5% to 99%, in steps of 0.5%

In Vivo for SpMet

From the *In Vivo* screen, access the following screens:

Options	Description	Factory Default Settings	User Configurable Settings
Enabled	Match the corresponding laboratory reference for continuous trending.	Off	On or Off

Options	Description	Factory Default Settings	User Configurable Settings
Offset Amount	Helps offset individual patient bias that is expected when comparing a noninvasive measurement to a laboratory reference.	0	±3% in steps of 0.1%

SpOC Settings

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

SpOC Settings on page 111.

About Parameter Information on page 88.

SpOC Alarms

From the *SpOC Alarms* screen, access the following screens:

Options	Description	Factory Default Settings	User Configurable Settings
High Limit	The High Limit is the upper threshold that triggers an alarm.	Off	2% to 34% in steps of 1%, or Off

Options	Description	Factory Default Settings	User Configurable Settings
Low Limit	The Low Limit is the lower threshold that triggers an alarm.	Off	Off, or 1% to 33% in steps of 1%

ORI Settings

The *ORI Settings* screen can only be accessed on Root. From the *ORI Settings* screen, access the following screens:

ORI Alarms on page 112.

About Parameter Information on page 88.

ORI Alarms

From the *ORI Alarms* screen, access the following screens:

Options	Description	Factory Default Settings	User Configurable Settings
Low Limit	The Low Limit is the lower threshold that triggers an alarm.	Off	Off or 0.01-0.99

Options	Description	Factory Default Settings	User Configurable Settings
Trending Down Alarm	The Trending Down Alarm is displayed when a rapid decrease in ORI is measured.	Off	On/Off

Sounds

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

Options	Description	Factory Default Settings	User Configurable Settings
Alarm Volume	Sets the alarm volume and provides a sample of the alarm volume.	Level 4	Level 1 to 4

Options	Description	Factory Default Settings	User Configurable Settings
Pulse Tone Volume	Sets the volume of the tone that conveys the pulse rate.	Level 3	Off, Level 1 to 4

Options	Description	Factory Default Settings	User Configurable Settings
Silence Duration	Length of time that the audible alarm remains muted.	120 seconds	30, 60, 90, or 120 seconds If *All Mute* is set to *On* (see ***Access Control*** on page 117), then the following additional settings become available: *All Mute* If selected, then no alarms will sound. Only visual elements are enabled. The following icon appears on the *Display View.*  *All Mute with Reminder* If selected, then no alarms will sound. Only visual elements are enabled A tone sounds every 3 minutes as a reminder. The following icon appears on the *Display View.* 

Device Settings

The following is an example of the *Device Settings* screen.

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

Screen Orientation on page 123.

Localization on page 121.

WiFi on page 124.

Battery on page 125.

Brightness on page 125.

Access Control on page 117.

Device Output on page 126.

Access Control

Password Screen

The *Access Control* screen is password-protected.

Using the Password screen

1. On the *Password* screen, enter the following numbers: **6 2 7 4**
   No numbers will be displayed, only asterisks (****).
2. Touch **Enter.**

3. To undo numbers, touch **Backspace**.

Settings

From the *Access Control* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Power On Profile	Allows user to select a specific Profile to be loaded the next time that the unit is powered on. This Profile can be one of the presets (ie. Adult, Pediatric, Neo), a customized Profile, or the last configuration used before the unit is powered off.	Previous Profile	Previous Profile, Adult, Pediatric, Neonatal, Custom, Custom1, Custom2, Custom3, Custom4, Custom5
All Mute Enabled	All patient alarm conditions are silenced. Only system alarms will be indicated by an audible alarm.	Disabled	Enabled or disabled If enabled, *All Mute* and *All Mute with Reminder* become available settings from the *Silence Duration* option on the *Sounds* screen. See ***Sounds*** on page 113.

Options	Description	Factory Default Settings	User Configurable Settings
Lock Alarm Volume	When set to 3 or 4, 3 or 4 shows dimly lit in the Alarm Volume section of the Alarms Menu screen and cannot be changed.	Off	3, 4, or Off
SpO_2 Low % Limit	Threshold at which SpO_2 Low Alarm Limit cannot be reduced.	Off	1% to 98% in steps of 1, or Off
Lock Layout	Prevents the user from making changes to the parameter layout.	N/A	On or Off
Screen Lock	Prevents unintentional interaction with *Display View*.	Off	On or Off
Legacy Mode	Changes the Display View from color to monochrome.	Color	Mono or Color
Save as Adult	Saves pre-configured profiles for adult patients.	N/A	Press **Save** to load all device configuration settings to adult profile.

Options	Description	Factory Default Settings	User Configurable Settings
Save as Neo	Saves pre-configured profiles for neonatal patients	N/A	Press **Save** to load all device configuration settings to neonatal profile.
Factory Defaults	Options are restored to factory values.	N/A	Press **Restore** to return to factory default values.

Localization

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

Options	Description	Factory Default Settings	User Configurable Settings
Current Date	Date	N/A	N/A
Current Time	Time	N/A	N/A
Language	Language in which the screens display.	English	Choose from available languages.

Options	Description	Factory Default Settings	User Configurable Settings
Time Zone	Setting based on Coordinated Universal Time (UTC).	A (UTC+1hr)	Choose local time zone settings.
Date Format	Set the format of the date display on the Display View.	MM/DD/YYYY	MM/DD/YYYY DD/MM/YYYY
Time Format	Set the format of the time display as it will be shown on the Display View.	12 hour	24 hour or 12 hour
Line Frequency	Set to match regional power line frequency to allow for cancelation of noise introduced by fluorescent lights and other sources.	60 Hz	50 Hz or 60 Hz
Date	Manually set the numerical date if Auto Set Date/Time is Off.	MM/DD/YYYY	Choose month, date, and year.

Options	Description	Factory Default Settings	User Configurable Settings
Time	Manually set the hour and minute, AM or PM, if Auto Set Date/Time is Off.	12-hour format	Choose hour and minute.

Screen Orientation

From the *Screen Orientation* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Auto Orientation	Allows the device to automatically adjust the *Display* screens depending on orientation.	On	Off or On

Options	Description	Factory Default Settings	User Configurable Settings
Orientation	Rotates the viewing screens depending on device orientation.	Landscape	*Landscape*: rotates the screen to horizontal viewing position *Inverted Landscape*: rotates the screen to (180 degree) viewing position *Portrait*: rotates the screen to vertical viewing position *Inverted Portrait*: rotates the screen to vertical (180 degree) viewing position

WiFi

When the Radical-7 is connected to a WiFi network, the Wifi icon located on the Status Bar conveys the strength of the Wifi connection. See ***About the Status Bar*** on page 72.

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

Options	Description	Factory Default Settings	User Configurable Settings
WiFi	Enables or disables the wireless connection	Off	On or Off
Additional fields in the Wifi screen provide information about WiFi connection. These additional fields are read only and not configurable.			

Battery

From the *Battery* screen, view the following information:

- Battery icon that conveys remaining battery charge as a green color.
- Battery icon that conveys that battery charging status. See ***About the Status Bar*** on page 72.

See ***Battery Operation and Maintenance*** on page 196.

Brightness

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

Options	Description	Factory Default Settings	User Configurable Settings
Brightness	The slider option adjusts the brightness level of the display and provides a sample of the brightness level.	4	Level 1 to 4

Device Output

From the *Device Output* screen, change any of the following options:

Options	Description	Factory Default Settings	User Configurable Settings
Serial	Output to serial devices from the Serial Output connector is RS-232 based. See ***Standalone Back Panel*** on page 56.	ASCII 1	ASCII 1, IAP, HP Vuelink, SpaceLabs Flexport, or Data Collection
Analog 1	An interface with various analog recording devices and/or strip chart recorders through connector located on Docking Station.	N/A	SpO_2 50% to 100%, Pulse rate, Pleth, SIG, 0V Output, 1V Output, SpO_2 0% to 100%

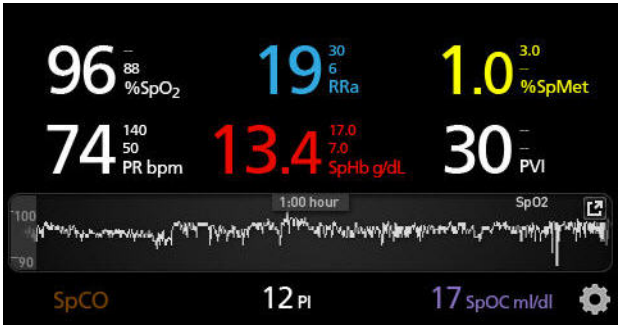
Options	Description	Factory Default Settings	User Configurable Settings
Analog 2	Depending on the configuration, the following parameters are output continuously on the Analog 1 and Analog 2.	N/A	Pleth, SIQ, 0V Output, 1V Output, SpO_2 0% to 100%, SpO_2 50% to 100%, or Pulse rate
Nurse Call Trigger	The nurse call output will be activated based on the alarm events. The nurse call with be activated based on Low Signal or Alarm and Low Signal IQ events.	N/A	Alarms + SIQ, SIQ, Alarms
Nurse Call Polarity	Can be inverted to accommodate various nurse call station requirements.	N/A	Normal or Inverted

Trends

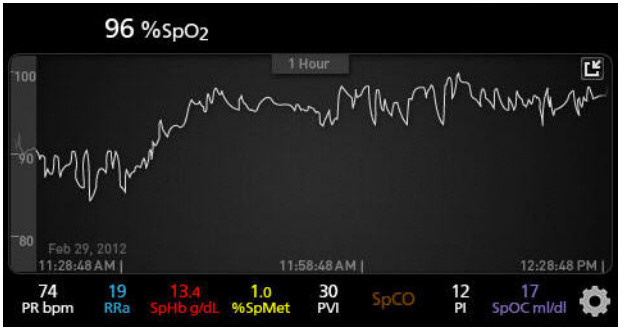
The following sections describe Trend Views and how to adjust trend settings.

About Trend Views

There are different ways to view trend information. The following is an example of trend information for SpO_2 as it appears within the *Display View* screen.



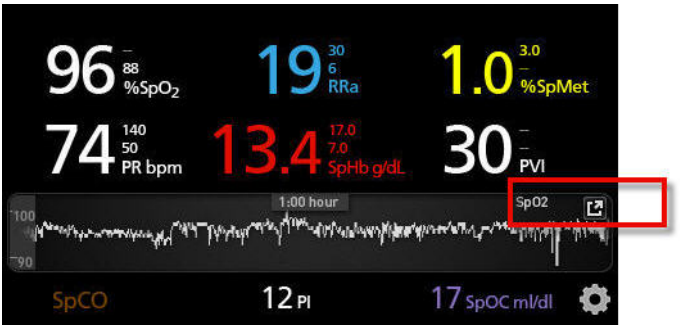
The following is an example of trend information for SpO_2 as it appears in the *Full Trend* screen.



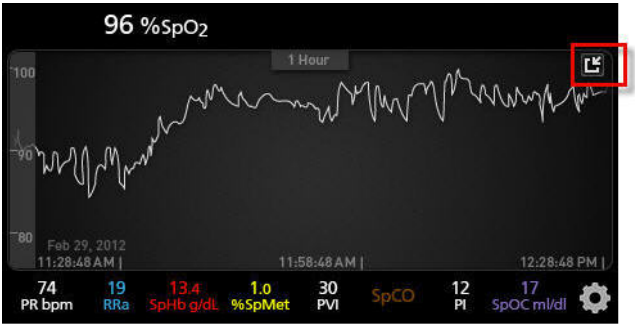
Changing Between Trend Views

To toggle between Display View and Full Trend

1. From the *Display View*, in the *Trend Field*, touch the icon as shown below.



2. From the *Full Trend screen*, touch the icon as shown below.



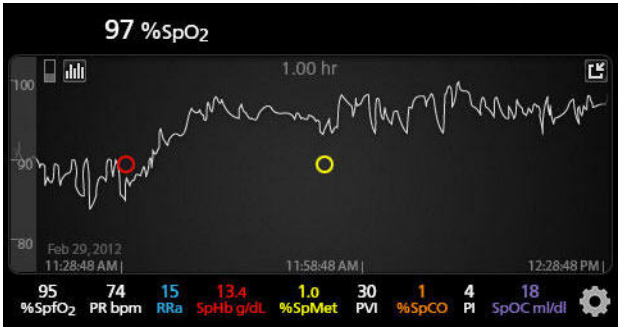
Using the Events Feature

The Events feature provides graphical display of parameter or measurement alarms and non-clinical exception messages. This feature is only viewable in the Full Trend screen; however, it is available at all times for all parameters and measurements. For more information about these alarms and exceptions, see **Chapter 6: Alarms and Messages**.

Events appear as color-coded circles along the trend of a parameter or measurement.

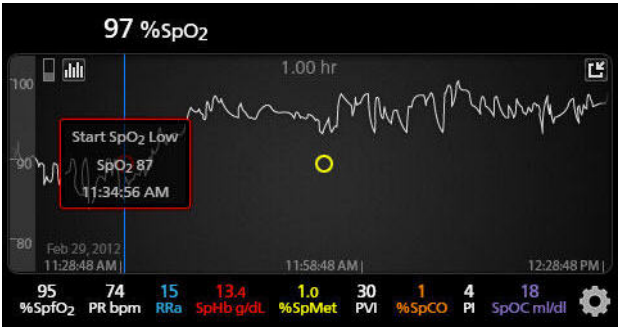
Color of Event Circle	Visibility	Description	Example Messages
Red	Specific to parameters and measurements shown in Full Trend screen.	Parameter or measurement alarm.	• *SpO_2 low* • *SpCO high* • *PR low*
		Change in In Vivo offset.	• *SpO_2 In Vivo offset changed: -1.9*
Yellow	Whenever in Full Trend screen.	Non-clinical exception.	• *Replace sensor* • *Low battery* • *No cable connected*

In the example below showing two (2) Events, the yellow circle represents a system exception and the red circle represents a parameter alarm related to the patient's SpO_2 level.



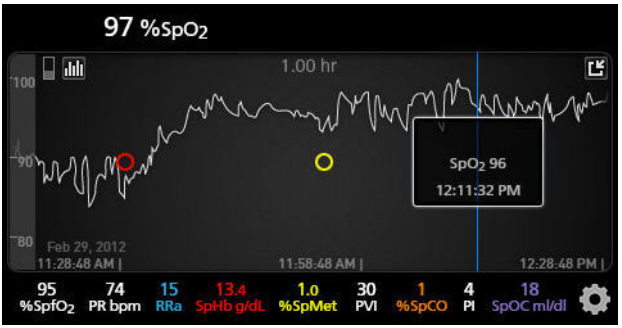
If there are two (2) parameters and/or measurements displayed in the Full Trend screen, then only Events related to those parameters and/or measurements will be visible.

Using the same example, tapping on the red circle reveals a message box displaying the alarm (*Start SpO_2 Low*), the reading (*SpO_2 87*), as well as its timestamp (*11:34:56 AM*), which correlates with the position of the vertical blue line.



To view time and reading information about a specific parameter or measurement, tap anywhere along the trend.

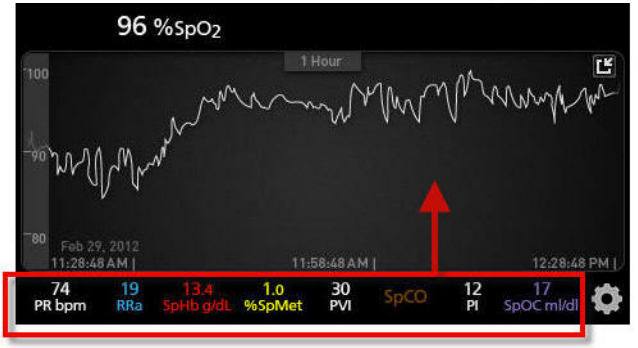
Using the same example, tapping on the trend somewhere towards the right reveals a message box displaying the parameter reading (*SpO_2 96*) and its timestamp (*12:11:32 PM*).



Manipulating View of Trend Data

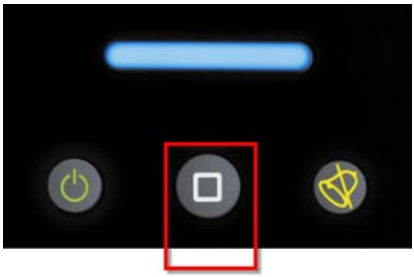
On the *Full Trend* screen, with a pinch gesture, using two fingers, the user can zoom in and out of the trend time scale.

The user can add parameters to the *Trend* view by dragging and dropping parameters from the *Small Parameter* view. To add a parameter to the *Trend* view, press and hold any of the parameters inside the *Small Parameter* view, as shown below. When the parameter dims, shakes, and grows in size, drag and drop the parameter into the *Trend* view.



To view past patient trend data, swipe the trend display to the left or to the right.

To exit a *Trend* view, press the **Home** button.



Changing the Time Interval of Trend Data

Users can change the time interval of trend data. The time options that can be selected are 10 minutes, 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, or 24 hours.

To change the time interval of trend data

1. From the *Display View*, in the *Trend Field*, or from the *Full Trend* screen, touch the *Time Interval* icon.

2. Scroll up or down to select a time interval.

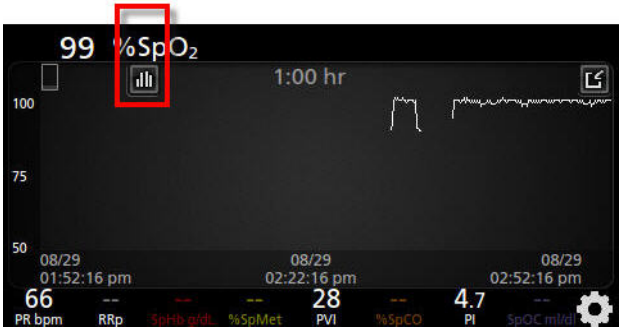
Using the Histogram Feature

Users can view trend data using the Histogram feature. When turned on, the Histogram feature displays trend data as a histogram.

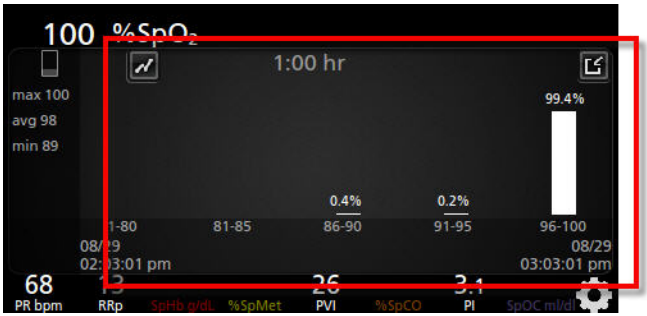
To turn on the Histogram feature

1. Navigate to a *Full Trend* screen. See ***Changing Between Trend Views*** on page 128.

2. The Histogram icon appears along the top of the *Trend Field*, as shown in the following example for SpO_2.

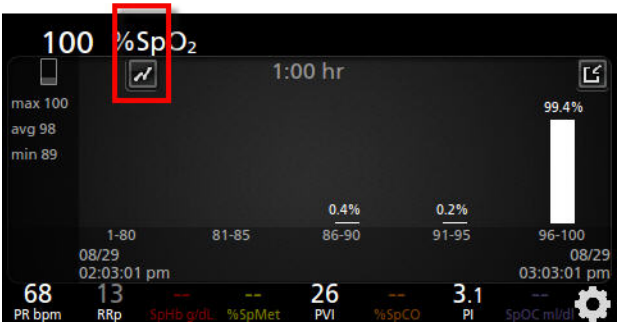


3. Touch the *Histogram* icon.
4. Trend data displays as a histogram.



To turn off the Histogram feature

- Touch the *Trends* icon, as shown.



Changing Histogram Settings

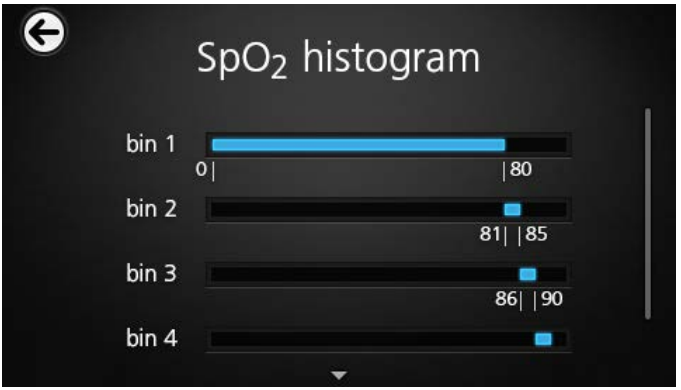
Users can change the ranges of bins in the histogram view for each individual parameter displayed.

To access the histogram settings for any of the available parameters:

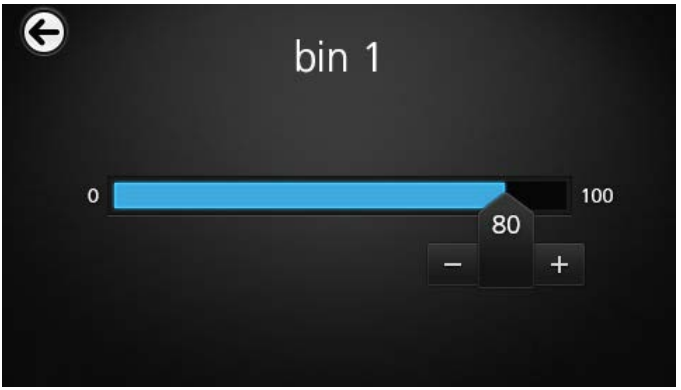
1. From the *Main Menu* screen, touch the *Parameter Settings* icon.
2. From any *Parameter Settings* screen, touch the *Histogram* icon.

To change the histogram settings for any of the available parameters:

1. Touch any *bin* to change the range values.



2. Touch and drag the markers to adjust the range values.



3. When finished, touch the back arrow and select **OK.**

Changing Trend Settings

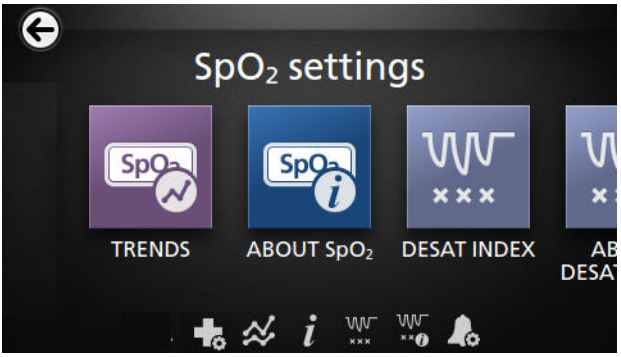
There are several ways to access and then change the maximum value and the minimum value of the Y axis for any of the available parameters.

To access the trend settings for any of the available parameters

1. From the *Main Menu* screen, touch the *Trends* icon.

2. From the *Trends* screen, touch any of the available parameters.

Alternatively, from any *Parameter Settings* screen, touch the *Trends* icon.



Alternatively, from the *Display View* or from the *Full Trend* view, touch the Y axis range on the left side of the screen as shown.

When viewing trends for an additional parameter, the Y axis range appears on the right side of the screen.

To change the trend settings for any of the available parameters

1. Touch the slider for the Y-axis maximum or the Y-axis minimum. The following is an example of the *SpO_2 Trend* screen.

2. Select the desired setting by scrolling up or down.

3. When finished, select **OK**.

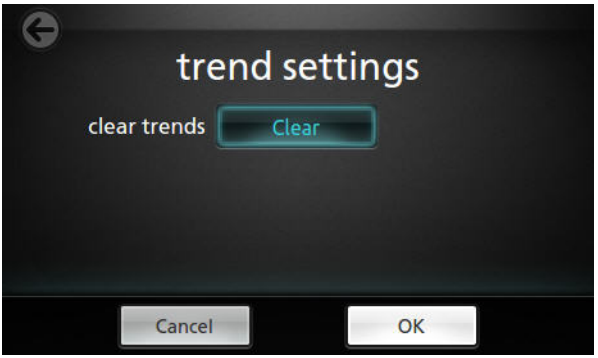
Deleting Trend Data

The user can delete patient trend data that has been stored on the Radical-7.

To delete patient trend data

1. From the *Trends* screen, touch the *Trend Settings* icon.

2. From the *Trend Settings* screen, touch **Clear**, and then touch **OK**. This deletes all stored trend data.



About

For information about parameters, see ***About Parameter Information*** on page 88.

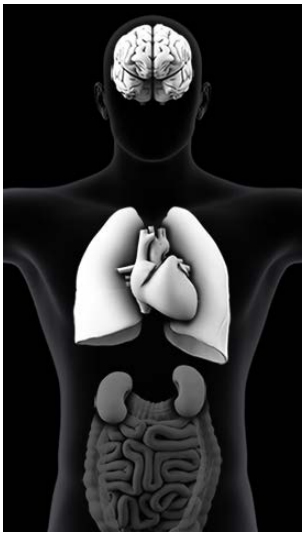
From the *About* screen, view any of the following options:

Options	Description
Serial Number	Displays the serial number of the Handheld.
MCU	Displays the version number of the device board software.

Options	Description
MX Board	Displays the version number of the technology level software.
Processor	Displays the version number of the system level software.
Docking Station	If docked, displays the current software version of the Docking Station.

Visualization

When the Radical-7 is connected to Root, the Radical-7 provides a supplemental visualization of the alarm status for the connected Masimo medical technologies.



Color Description Table

This visualization displays a human body on the Radical-7 device when it is connected to Root. Colors are used to represent the status of monitoring and the alarms:

Color	Description
Gray	No monitoring
Green	Monitoring, normal range
Yellow	Monitoring, caution range
Red	Monitoring, alarm range

Parameter Visualization Table

Alarms for various parameters and/or measurements are displayed as follows:

Parameter or Measurement	Area Displayed on Visualization Screen
SpO_2	Lung
PR	Heart
PI	N/A

Parameter or Measurement	Area Displayed on Visualization Screen
PVI	Vascular
SpHb	Vascular
SpMet	Vascular
SpCO	Lung
RRa	Lung
$SpfO_2$*	Lung
RRp*	Lung
SpOC	N/A
PSI**	Brain

*CE marked only. Not available in the USA.

**For use with SedLine® Sedation Monitor, upon availability

Chapter 5: Profiles

The Radical-7 can be configured for various patient types.

Profiles Overview

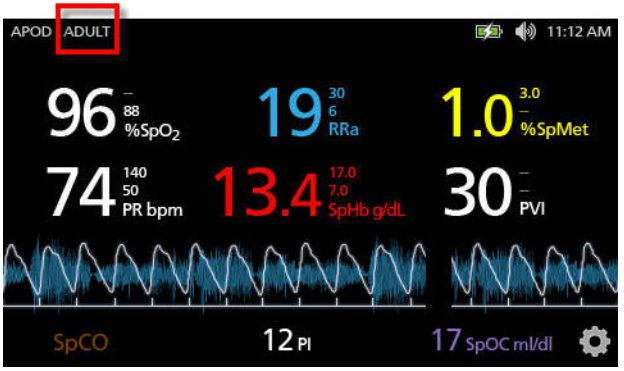
The Radical-7 contains a *Profiles* screen, which lets the user customize different settings for different patient populations:

- **Adult**
  Adult profile is the factory default profile. Displays in the Status bar as *ADULT* and the color of the Profile button turns blue.
- **Pediatric**
  Displays in the Status bar as *PEDIATRIC* and the color of the Profile button turns pink.
- **Neonatal**
  Displays in the Status bar as *NEO* and the color of the Profile button turns pink.
- **Custom**
  Displays in the Status bar as *CUSTOM* and the Profile button is not illuminated and appears gray.

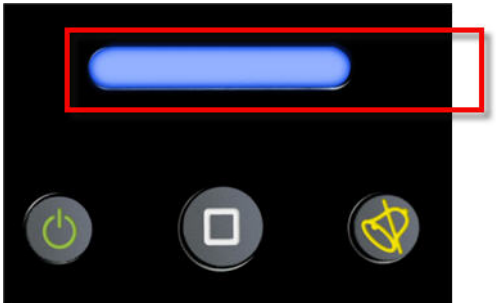
If no changes are made to settings, then after a power cycle, the Radical-7 automatically resets to the *Adult* profile because *Adult* is the factory default profile.

If the Profile setting is changed to *NEO* or *CUSTOM*, then after a power cycle, the Radical-7 remembers the previously selected Profile setting.

The active profile displays in the Status Bar. In the following example, the *Adult* profile is active.



The Radical-7 conveys the active profile by changing the color of the *Profiles* button.

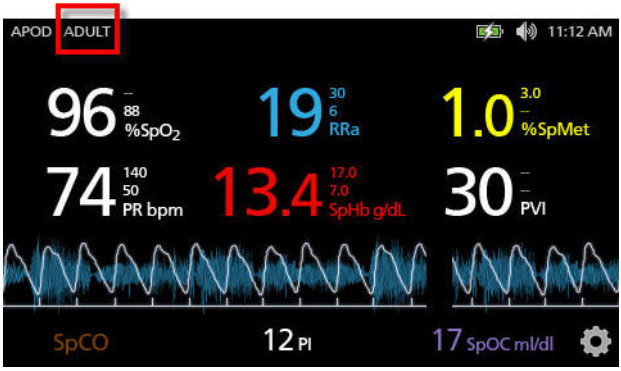


To restore all Radical-7 settings to factory default settings, see ***Access Control*** on page 117.

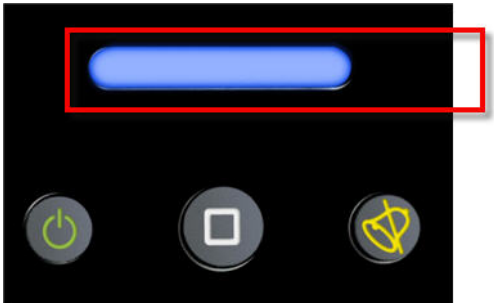
Changing Profiles

Changing Profiles is done in the *Profiles Settings* screen. There are different ways to access the *Profiles Settings* screen.

- The first way is by the touching the *Profiles* shortcut in the Status Bar, as show below.



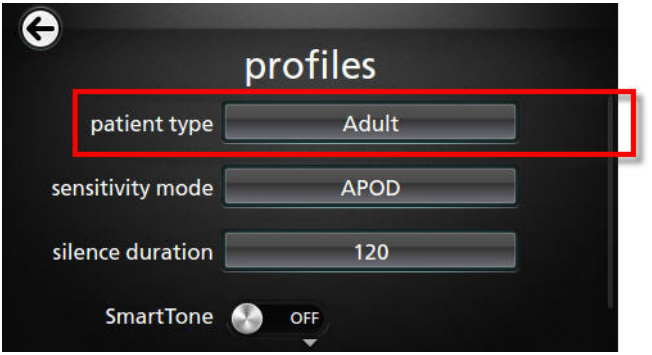
- Another way to access the *Profiles Settings* screen is by pressing the *Profile* button, as shown below.



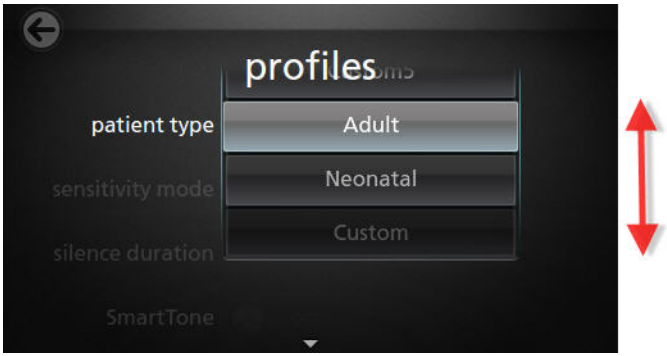
- Alternatively, from the *Main Menu* screen, touch the *Profiles* icon.

To change Patient Type

1. From the Profile screen, touch the *Patient Type* field.



2. Select the desired Patient Type by scrolling up or down.



3. When finished, touch **OK**. To confirm selection, check the Status Bar.

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

Options	Description	Factory Default Settings	User Configurable Settings
Patient Type	Defines the patient population for which the device will operate.	Adult	Neonatal, Adult, Custom, or Custom 1 to 5
Sensitivity Modes	Defines the sensitivity level for which the device will operate. See ***Sensitivity Modes Overview*** on page 81.	APOD	MAX, APOD, or NORM

Silence Duration	The amount of time for which the audible part of an alarm will be silenced. See ***Silencing the Alarms*** on page 153.	2 min	1 min, 2 min, or 3 min
Smart Tone	Allows the audible pulse to continue to beep when the pleth graph shows signs of motion.	Off	On or Off

Replacing Factory Default Settings for Adult and Neo Profiles

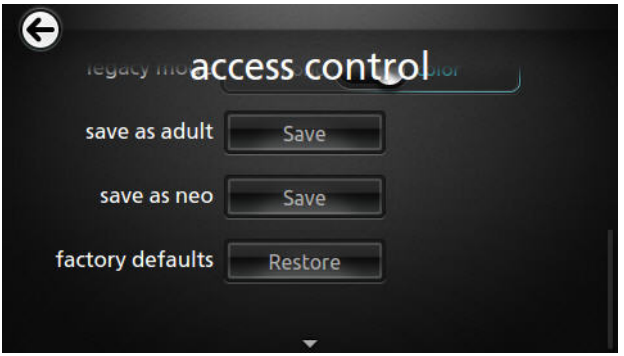
The *Adult* profile and the *Neonatal* profile can be modified to meet specific requirements and then they can replace the factory default settings for *Adult* and *Neonatal* profiles. As such, after a power cycle, the Radical-7 remembers the preferred settings for *Adult* and *Neonatal* profiles instead of the factory default settings. When preferred settings for *Adult* and *Neonatal* are saved instead of the factory default settings, the Profile button changes to the same blue or pink color respectively. See ***Profiles Overview*** on page 145.

A user can also load preferred profile configurations into the Radical-7 using a separate tool.

To change the factory default settings for Adult or Neonatal profile settings

1. Make the preferred changes to any of the Radical-7 settings.
2. Navigate to the *Access Control* screen. See ***Access Control*** on page 117.

3. For either Adult or Neonatal, touch **Save**.



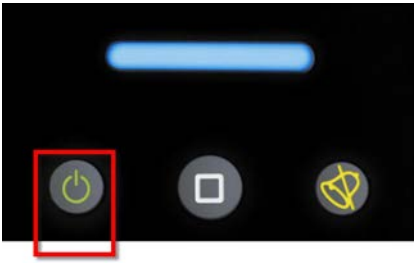
4. Touch **Ok**.
5. Alternatively, the user can restore all *Profile* settings to their factory default values by touching **Restore**, and then touching **Ok**.
6. Confirm the changes by powering off and powering on the Radical-7 and then verifying settings.

Powering Off the Radical-7

When turning off the Radical-7, the device remembers the preferred settings.

To turn off the Radical-7

1. Press and hold the button for more than 2 seconds.



2. To confirm the shutdown process, the following screen appears.

Chapter 6: Alarms and Messages

The following chapter contains information about alarms and messages.

For more information, see *Chapter 7: Troubleshooting* on page 171.

About Alarms

The Radical-7 visually and audibly indicates alarm conditions that the system detects. Audible alarms may be silenced, without affecting the operation of visual alarms. See *Warnings and Cautions* on page 15.

There are three priorities for alarms:

- High
- Medium
- Low

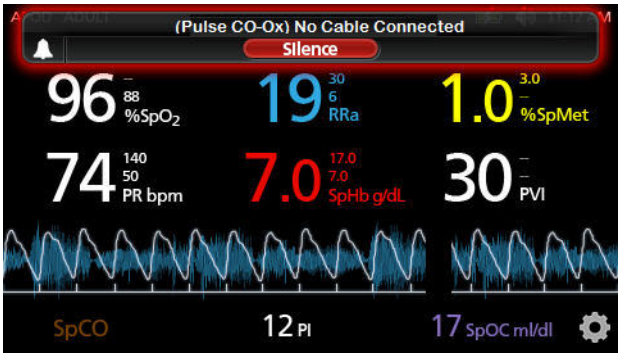
Alarm Delay

When an alarm condition is met, this feature delays the audible part of an alarm.

Silencing the Alarms

Alarms are conveyed in ways: audible, visual, or both.

The following is an example of a visual alarm for an exception message:



The following is an example of a typical alarm due to parameter limit violation.

To silence or dismiss alarms:

- Touch **Silence** (the highlighted area of the Status Bar).

Audible alarms can be temporarily suspended by pressing the *Alarm Silence* button. When alarms are in the s*uspend state,* pressing the *Alarm Silence* button cancels the alarm suspend.

To silence audible alarms

1. When an audible is active, push **Alarm Silence** one time.

2. The audible alarm is silenced for up to 120 seconds and a countdown timer displays.

3. The length of time for which an audible alarm remains silenced (suspended) can be changed using the Silence Duration feature located *on the Sounds sc*reen. See ***Sounds*** on page 113.

Adaptive Threshold alarm (ATA) Feature

The Adaptive Threshold Alarm (ATA) feature is an optional feature that provides continuous SpO_2 surveillance while allowing the clinician a useful tool to help reduce the frequency of audible alarms.

ATA establishes the alarm limit threshold based upon the patient-specific *baseline value* of the SpO_2 parameter which is determined from the recent history of SpO_2 values. An *Adaptive Threshold Limit* is continuously determined for the patient and SpO_2 values outside the Adaptive Threshold Limit trigger an audible alarm. The Adaptive Threshold Limit is bound by the standard SpO_2 low alarm limit and the Rapid Desat low alarm limit. SpO_2 values that exceed the Rapid Desat limit, whether it occurs rapidly or not, will activate an audible alarm.

Prior to activating ATA, review and select the appropriate standard low alarm limit and other alarm settings. Once ATA is selected, the Rapid Desat Alarm protection is always active. If the ATA low alarm limit is violated, ATA generates an audible alarm.

It is important to note that once activated, ATA has the following automatic safety features:

Reminder Tones

If an SpO_2 value from a patient drops below the standard low alarm limit set by the user, a visual alert will display and a reminder tone will repeat every 15 minutes as long as the condition persists. If the SpO_2 value drops below the ATA low alarm limit, an audible alarm will be activated.

Rapid Desat Alarm Protection

The Rapid Desat feature is always active when ATA is turned on. This means that deep desaturations (5% or 10%) from the standard SpO_2 low alarm limit immediately generate an audible alarm. When used with ATA,

it also serves as absolute low alarm limit protection. SpO_2 values exceeding the Rapid Desat low alarm limit, whether rapid or not, will activate an audible alarm. The user can change the Rapid Desat default setting from 5% to 10%. ATA does not allow a Rapid Desat default setting of 0%.

When ATA is turned *Off*, the device uses the standard alarm limits and standard alarm delays.

About Alarms on page 153.

Alarms for SpO2 on page 91.

3D Alarms

3D Alarms include the Desat Index Alarm and the PI Delta Alarm.

Desat Index Alarm Overview on page 157.

Perfusion Index (PI) Delta Alarm Overview on page 159.

Desat Index Alarm Overview

The 3D Desat Index Alarm is a user-selectable feature which allows a clinician to request an audible and visual alarm if a patient experiences a specified number of desaturations over a specific period of time.

Traditional high and low SpO_2 alarm limits alert clinicians to saturation levels that exceed user selected thresholds, and these thresholds are

typically established at a considerable change from the patients' baseline saturation level. However, in select patient populations, substantial desaturation events that exceed a typical low alarm limit threshold may be preceded by a cycle of transient desaturations over a limited timeframe, and the ability to alert clinicians to a cycle of these smaller desaturations may provide an earlier indication of a potential significant decline in the patient's status and the need for more focused monitoring and/or a change in treatment.

To address patient populations at risk for cyclic, moderate desaturations, the option includes a user-selectable 3D Desat Index Alarm which allows the clinician to request an audible and visual alarm in the event the patient experiences a specified number of desaturations beyond a defined level from the patient's baseline saturation over a specific window of time, with each of these variables selectable by the user within established ranges as noted in ***Desat Index Settings*** on page 158.

Desat Index Settings

From the *Desat Index Settings* screen, access the following screens:

Desat Index Alarms on page 158.

About Parameter Information on page 88.

Desat Index Alarms

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

Options	Description	Factory Default Settings	User Configurable Settings
Delta	See ***Desat Index Alarm Overview*** on page 157.	4%	2% to 10% in steps of 1%.
Time	See ***Desat Index Alarm Overview*** on page 157.	1 hour	1 to 4 hours, in steps of 1.
# of Events	See ***Desat Index Alarm Overview*** on page 157.	Off	Off, 1 to 24 desaturations in steps of 1.

Perfusion Index (PI) Delta Alarm Overview

The Perfusion Index (PI) Delta Alarm is a user-selectable feature which allows a clinician to request an audible and visual alarm if perfusion at the monitored site decreases by a specified level (delta) over a specific period of time.

Perfusion Index gives an indication of the level of perfusion at the monitored site. The Radical-7 measures perfusion at the SpO_2 site by comparing the pulsatile signal to the non-pulsatile signal, and expressing that ratio as a percentage. PI has been clinically proven to be useful as a predictor of the level of illness in neonates and adults and that PI may change dramatically in response to sympathetic changes caused by inhalational agents and pain stimulation.* If PI decreases over time, there may be underlying physiological reasons that may need to be addressed.

The PI Delta provides an audible and visual alert to important changes in perfusion compared to the patient's baseline PI rate. The baseline is set by the Radical-7 once the user has enabled the alarm. The baseline is 30 seconds of currently averaged PI. The feature includes a user-selectable PI Delta Alarm. This allows the clinician to request an audible and visual alarm if perfusion at the monitored site decreases by a specified level (delta) over a specified window of time. Three of the variables are selectable by the user within established ranges as noted in ***PI Delta Settings*** on page 160.

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

PI Delta Settings

From the *PI Delta Settings* screen, access the following screens:

Perfusion Index (PI) Delta Alarm Overview on page 159.

About Parameter Information on page 88.

PI Delta Alarms

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

Options	Description	Factory Default Settings	User Configurable Settings
Set Baseline	See ***Perfusion Index (PI) Delta Alarm Overview*** on page 159.	Off	On or Off
Baseline	See ***Perfusion Index (PI) Delta Alarm Overview*** on page 159.	Off, or PI baseline	N/A
Percent Change	See ***Perfusion Index (PI) Delta Alarm Overview*** on page 159.	50%	10% to 99% in steps of 1%
Timeout	See ***Perfusion Index (PI) Delta Alarm Overview*** on page 159.	None	1 min, 5 min, 30 min, 1 hr, 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr, or None.

Messages

The following section lists common messages, their potential causes, and next steps.

Replace Sensor Message

Message:

- *(Pulse CO-Ox) Replace Sensor*, or
- *(RAM) Replace Sensor*

Reusable sensor has used all its available monitoring time, sensor is non-functional, or defective sensor.
Next steps: Replace sensor.

Replace Cable Message

Message:

- *(Pulse CO-Ox) Replace Cable*, or
- *(RAM) Replace Cable*

The patient cable is non-functional or the life of the cable has expired.
Next steps: Replace the patient cable.

Replace Adhesive Sensor Message

Message:

- *(Pulse CO-Ox) Replace Adhesive Sensor*, or
- *(RAM) Replace Adhesive Sensor*

When a single-patient-use sensor is used, the adhesive portion of the sensor is non-functional, or the life of the adhesive portion of the sensor has expired.
Next steps: Replace the adhesive portion of the sensor.

Incompatible Sensor Message

Message:

- *(Pulse CO-Ox) Incompatible Sensor*, or
- *(RAM) Incompatible Sensor*

Not a proper Masimo sensor.
Next steps: Replace with a proper Masimo sensor.

Sensor is attached to a device without an appropriate parameter installed.
Next steps: Use a compatible sensor. Contact your local Masimo Representative to learn more about optional parameter upgrades.

Incompatible Adhesive Sensor Message

Message:

- *(Pulse CO-Ox) Incompatible Adhesive Sensor*, or
- *(RAM) Incompatible Adhesive Sensor*

Not a proper Masimo sensor.
Next steps: Replace with a proper Masimo sensor.

Sensor is attached to a device without an appropriate parameter installed.
Next steps: Use a compatible sensor. Contact your local Masimo Representative to learn more about optional parameter upgrades.

No Adhesive Sensor Connected Message

Message:

- *(Pulse CO-Ox) No Adhesive Sensor Connected*, or
- *(RAM) No Adhesive Sensor Connected*

When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.
Next steps: Ensure the adhesive portion is firmly connected to the sensor.

Interference Detected Message

Message:

- *(Pulse CO-Ox) Interference Detected*, or
- *(RAM) Interference Detected*

High intensity light such as pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight, or other monitor displays.
Next steps: Place a Masimo Optical Light Shield over the sensor.

Incorrect monitor line frequency setting (Hz).
Next steps: Adjust the Line Frequency to the correct Hz setting. See ***Device Settings*** on page 116.

SpO2 Only Mode Message

Message: *(Pulse CO-Ox) SpO_2 Only Mode*

Occurs during an unsuccessful sensor initialization/pulse search routine or during monitoring.
Next steps: See the directions for use provided with your sensor. Use a Masimo light shield to cover the sensor and adjust the sensor.

RAM Check Sensor Message

Message: (RAM) *RAM Check Sensor*

RAM unable to collect pulsing through RAM Sensor.
Next steps: Ensure proper sensor application. Check that no object is pulling on the sensor cable causing the sensor to peel off.

RAM Sensor Initializing Message

Message: *(RAM) Sensor Initializing*

Device is checking the sensor for proper functioning and performance.
Next steps: If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.

Low Battery Message

Battery charge is low.
Next steps: Charge battery by placing the Handheld into the Docking Station and powering the device with AC line power. Replace battery if necessary.

Low Perfusion Index Message

Message: *(Pulse CO-Ox) Low Perfusion Index*

Signal too small.
Next steps: Move sensor to better perfused site. See ***Low Perfusion*** on page 173.

Low Signal IQ Message

Message: *(Pulse CO-Ox) Low Signal IQ*

Low signal quality.
Next steps: Ensure proper sensor application. Move sensor to a better perfused site. See *Signal IQ (SIQ)*.

Low SpCO SIQ Message

SpCO measurement reading is obscured.
Next steps: Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. See *Successful Monitoring for SpCO* on page 40.

Low SpMet SIQ Message

SpMet measurement reading is obscured.
Next steps: Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. See *Successful Monitoring for SpMet.*

Low SpHb SIQ Message

SpHb measurement reading is obscured.
Next steps: Ensure proper sensor application. Check sensor to see if it is working properly. If not, replace the sensor. See *Successful Monitoring for SpHb* on page 38.

Speaker Failure Message

Device requires service. **Next steps:** Contact Masimo Tech Support. *Chapter 9: Service and Maintenance* on page 195.

Invalid Parameter Alarm Message

Denoted by dashes shown as parameter value.

Unable to provide a SpO2 or PR parameter value.
Next steps: Check patient's vital condition.

No Cable Connected Message

Message:

- *(Pulse CO-Ox) No Cable Connected*, or
- *(RAM) No Cable Connected*

Cable not attached or not fully inserted into the connector.
Next steps: Disconnect and reconnect cable into connector.

No Sensor Connected Message

Message:

- *(Pulse CO-Ox) No Sensor Connected*, or
- *(RAM) No Sensor Connected*

Sensor not fully inserted into the connector. May be an incorrect sensor or a defective sensor or cable.
Next steps: Disconnect and reconnect sensor. See the instructions for use provided with your sensor.

Device is searching for patient's pulse.
Next steps: Disconnect and reconnect the sensor into the Patient Cable connector.

Sensor is disconnected from patient cable. Sensor connected upside down into patient cable.
Next steps: Check to see if the sensor LED is flashing. Disconnect and reconnect the sensor. If the LED fails to operate, replace the sensor.

Pulse Search Message

Message: (*Pulse CO-Ox*) *Pulse Search*

Device is searching for pulse.
Next steps: If device fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.

Sensor Initializing Message

Message: *(Pulse CO-Ox) Sensor Initializing*

Device is checking the sensor for proper functioning and performance.
Next steps: If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.

Sensor Off Patient Message

Message:

- *(Pulse CO-Ox) Sensor Off Patient*, or
- *(RAM) Sensor Off Patient*

Sensor off patient.
Next steps: Disconnect and reconnect sensor. Reattach sensor.

Sensor not connected to patient properly. Sensor is damaged.
Next steps: Properly reapply the sensor on the patient and reconnect the sensor to the device or patient cable. If the sensor is damaged, replace the sensor.

Incompatible Cable Message

Message: *(Pulse CO-Ox) Incompatible Cable*

Not a proper cable.
Next steps: Replace with a proper cable.

Near Expiration Message

Messages:

- *(Pulse CO-Ox) Cable Near Expiration*
- *(RAM) Cable Near Expiration*

Patient cable has less than 10% of active monitoring life remaining.

Next steps: Replace with new patient cable.

Messages:

- *(Pulse CO-Ox) Sensor Near Expiration*
- *(RAM) Sensor Near Expiration*

Reusable sensor has less than 10% active monitoring life remaining.

Next steps: Replace with new reusable sensor.

Messages:

- *(Pulse CO-Ox) Adhesive Near Expiration*

- *(RAM) Adhesive Near Expiration*

Disposable sensor has less than 10% active monitoring life remaining.

Next steps: Replace with new disposable sensor.

Chapter 7: Troubleshooting

The following chapter contains information about troubleshooting the Radical-7 system.

Troubleshooting Measurements

See ***Safety Warnings and Cautions*** on page 15.

Signal IQ (SIQ)

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

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

The height of the vertical line of the SpO_2 SIQ provides an assessment of the confidence in the measurement displayed. A high vertical bar indicates higher confidence in the measurement. A small vertical bar indicates lower confidence in the displayed measurement. When the Signal IQ is very low, this suggests that the accuracy of the displayed measurement may be compromised. See ***About the Status Bar*** on page 72.

When parameters are dimly lit, proceed with caution and do the following:

- Assess the patient.

- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site for the Radical-7® Pulse CO-Oximeter® to maintain accurate readings. Misalignment of the sensor's emitter and detector can result in smaller signals and cause erroneous readings.
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or an episode of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site is not interrupted. Interruption, for example, may occur while lifting or crossing their legs during a diaper change.
- After performing the above, if the parameter remains dimly lit frequently or continuously, obtaining an arterial blood specimen for CO-Oximetry analysis may be considered to verify the oxygen saturation value.

See *Safety Warnings and Cautions* on page 15.

Dimly Lit Parameters

When the signal quality is very low, the accuracy of measurements may be compromised, the parameter may be dimly lit, and the parameter may display dashes instead of a numeric value.

Low Perfusion

It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation This "localized hypoxemia" may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. This may occur even with a pulse rate that correlates with the ECG heart rate.

Low Signal Quality

Improper sensor type or application.
Next steps: Excessive motion relative to perfusion. Sensor is damaged or not functioning. Check and see if blood flow to the site is restricted. Check the placement of the sensor. Reapply sensor or move to a different site. See *Appendix* on page 209.

SpO2 Values Do Not Correlate With Clinical Assessment or Arterial Blood Gas Measurements

Low perfusion or sensor displacement.
Next steps: Check for error messages. See *Chapter 6: Alarms and Messages* on page 153. Check placement of sensor or if it is too tight. Reapply sensor or select a new site. Set to MAX sensitivity and confirm that the sensor is securely on the patient. See the directions for use provided with your sensor.

Unexpected SpO2, SpCO, SpMet, or SpHb Reading

- Low SIQ or PI values.
  Next steps: Reposition sensor to site with strong SIQ and PI. Average readings taken from three different sites to improve accuracy. Submit blood sample for laboratory CO-Oximetry test for comparison.
- Inappropriate sensor size or sensor measurement location.
  Next steps: Verify proper sensor for patient size. Verify proper sensor site. See *Appendix* on page 209.

Unexpectedly High SpCO Reading

Possible elevated methemoglobin level.
Next steps: Submit blood sample for laboratory CO-Oximetry test. See *Appendix* on page 209.

Difficulty Obtaining a Reading

- Low battery/ not plugged into AC power supply.
  Next steps: Insert Handheld into Docking Station, verify Docking Station power cord plugged in and Docking Station power indicator light is illuminated.
- Interference from line frequency induced noise.
  Next steps: Verify/set 50/60hz menu setting. See *Localization* on page 121.
- Inappropriate sensor or sensor size.
  Next steps: Verify proper sensor and sensor size for the patient.

- Excessive ambient or strobing light.
  Next steps: Shield the sensor from excessive or strobing light. Minimize or eliminate motion at the monitoring site.

SpCO Reading Displays as Dashes

- SpO_2 value below 90% **Next steps:** Assess/address patient condition.
- SpMet value greater than 2% **Next steps:** Laboratory analysis of a blood sample should be performed.
- SpCO parameter has not yet stabilized during initial startup
  Next steps: Verify proper sensor and sensor size for the patient. Allow time for parameter reading to stabilize.

Troubleshooting the Radical-7

For more information, see ***Chapter 6: Alarms and Messages*** on page 153.

Device Does Not Turn On

One or both of the fuses are not operating properly.
Next steps: Replace the fuses. For details, see ***Replacing the Fuses*** on page 199.

Device Turns On But Screen is Blank

The viewing contrast is not correct.
Next steps: Adjust the brightness setting. See ***Brightness*** on page 125. If

the condition persists, requires service. See. ***Contacting Masimo*** on page 204.

Continuous Speaker Tone

Internal failure.
Next steps: To silence an alarm, press the *Alarm Silence* button. If alarm continues to sound, turn off the Radical-7. If necessary, remove Handheld battery. Requires service. See ***Contacting Masimo*** on page 204.

Buttons Do Not Work When Pressed

Internal failure.
Next steps: Requires service. See ***Contacting Masimo*** on page 204.

Handheld Battery Does Not Charge

AC power cable may be disconnected.
Next steps: Restore power to the device.

Battery Run Time Significantly Reduced

Battery memory effects. **Next steps:** See **Battery Operation and Maintenance on page 196.**

Indicators on Docking Station Continuously Flash

Incompatible version of software on Handheld and Docking Station.
Next steps: Upgrade to current software versions. Match Handheld to Docking Station with compatible software versions.

Chapter 8: Specifications

The following chapter contains specifications for the Radical-7 Handheld, compatible Docking Stations, and the Standalone system.

Measurement Range

Measurement	Display Range
SpO_2 (Oxygen Saturation)	0% to 100%
SpMet (Methemoglobin)	0% to 99.9%
SpCO (Carboxyhemoglobin)	0% to 99%
SpHb (Hemoglobin)	0 g/dL to 25.0 g/dL
SpOC (Oxygen Content)	0 ml of O_2/dL to 35 ml of O_2/dL of blood
PR (Pulse Rate)	25 bpm to 240 bpm
PI (Perfusion Index)	0.02% to 20%
PVI (Pleth Variability Index)	0% to 100%
ORI (Oxygen Reserve Index)	0.01 to 0.99
RRa (Respiration Rate)	0 breaths per minute to 70 breaths per minute

Measurement	Display Range
RRp (Respiration Rate)	0 breaths per minute to 70 breaths per minute

Accuracy (ARMS)

Oxygen Saturation (SpO_2)		
No Motion [1] (SpO_2 from 60% to 80%)	Adults, Pediatrics, Infants	3%
No Motion [2] (SpO_2 from 70% to 100%)	Adults, Pediatrics, Infants	2%
	Neonates	3%
Motion [3] (SpO_2 from 70% to 100%)	All patient populations	3%
Low perfusion [4] (SpO_2 from 70% to 100%)	All patient populations	2%
Pulse Rate (PR)		
Range	25 to 240 bpm	
No motion	All patient populations	3 bpm
Motion [5]	All patient populations	5 bpm

Low Perfusion	All patient populations	3 bpm
Carboxyhemoglobin Level (SpCO) [1]		
Range of 1% to 40%	Adults, Pediatrics, Infants	3%
Methemoglobin Level (SpMet) [1]		
Range 1% to 15%	All patient populations	1%
Total Hemoglobin SpHb [6]		
Range of 8 g/dL to 17 g/dL	Adults, Pediatrics	1 g/dL
Respiratory Rate (RRa, RRp) [11]		
Range of 4 to 70 bpm	Adults, Pediatrics	1 bpm

Resolution

Parameter	Resolution
%SpO2	1%
%SpCO	1%
%SpMet	0.1%
SpHb g/dL	0.1 g/dL

Parameter	Resolution
Pulse Rate	1 beats per minute
Respiration Rate	1 breath per minute

Electrical

Standalone	
AC Power requirements	100 to 240 VAC, 47 to 63 Hz
Power consumption	55 VA
Fuses	UL Listed, Metric (5x20mm), rated 250 VAC, 1 Amp, Fast Acting, 1500A breaking capacity

Handheld Battery	
Type	Lithium ion
Capacity	4 hours [7]
Time	3 hours

Environmental

Environmental Conditions	
Operating Temperature	32°F to 122°F (0°C to 50°C)
Transport/Storage Temperature	-40°F to 158°F (-40°C to 70°C) [8]
Operating Humidity	10% to 95%, non-condensing
Operating Altitude	500 mbar to 1060 mbar -1000 ft to 18,000 ft (-304 m to 5,486 m)

Physical Characteristics

Dimensions	
Handheld	8.9″ x 3.5″ x 2.1″ (22.6 cm x 8.9cm x 5.3 cm)
Standalone	3.5″ x 10.5″ x 7.7″ (8.9 cm x 26.7 cm x 19.6 cm)

Weight	
Handheld	1.2 lbs. (0.54 kg)
Docking Station (RDS-1, RDS-2, RDS-3)	2.5 lbs. (1.14 kg)
Standalone (RDS-1, RDS-2, RDS-3)	3.8 lbs. (1.73 kg)

Alarms

Technical Alarm Type	Description
High Priority	571 Hz tone, 5-pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time:10s
Medium Priority	550 Hz tone, 3-pulse burst, pulse spacing: 0.375s, 0.375s, repeat time: 7s
Low Priority	500 Hz tone, 1-pulse burst, repeat time: 5s

Alarm Characteristic	Description
Alarm Volume	High Priority: 70 dB (min) Medium Priority: 70 dB (min) Low Priority: 45 dB (min)
Sensitivity	NORM, MAX, APOD [10]

Display Indicators

Item	Description
Trend Memory	Max of 96 hours at 2-second resolution
Display Update Rate	1 second
Type	Backlit Active Matrix TFT LCD
Pixels	480 dots x 272 dots
Dot Pitch	0.25 mm

Compliance

EMC Compliance
IEC 60601-1-2:2007, Class B

Safety Standards Compliance
UL 60601-1
IEC 60601-1:1988 +A1:1991 +A2:1995
IEC 60601-1:2012
EN 60601-1:2013

EN/ISO 80601-2-61:2011
CAN/CSA C22.2 No. 601-1

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

Wireless Radio (If Installed)	
Radio Modes	802.11 a/b/g
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

Wireless Radio (If Installed)	
Duty Cycle	6% (maximum) *(Note: The software sends 120 bytes at 62.5 Hz for 7,500 bytes per second, or 60 Kbps. Worst duty cycle will be at the minimum transmission bit rate of 1.1 Mbps. Therefore, the calculated duty cycle is 0.06 Mbps / 1.1 Mbps, which results in a duty cycle of approximately 6%.)*
Compliance	
USA	FCC ID: VKF-RAD7CA or VKF-RAD7A or VKF-RAD7B. FCC parts 15.207, 15.209, 15.247, and 15.407
Canada	IC ID: 7362A-RAD7CA or 7362A-RAD7A or 7362A-RAD7B RSS-247
Europe	EU Radio Equipment Directive (RED 2014/53/EU): EN 300 328 V2.1.1:2016 EN 301 893 V2.1.1:2017 EN 301 489-17 V3.1.1:2012 EN 62311:2000

Output Interface

SatShare (RDS-1). See ***Serial Interface Specifications*** on page 186.

Serial RS-232 (RDS-1, RDS-3)
Nurse Call/Analog Output (RDS-1, RDS-3)
VueLink, (Philips, Agilent, HP, Spacelabs Flexport, RadNet, SafetyNet (RDS-1, RDS-3)

Serial Interface Specifications

The digital interface for serial communication is based on the standard RS-232 protocol. The Radical-7 by default always outputs ASCII 1 text data through the serial port, unless the user selects a different output mode. To interface with the Radical-7 and receive serial text data, connect a serial interface cable with a ferrite bead installed to the serial output connector located on the back of the Radical-7 Docking Station. The Radical-7 serial interface is only available when the Radical-7 Handheld is properly attached to the Docking Station. Once serial communication is established, packets of data are communicated at 1 second intervals. See *Device Settings* on page 116.

Serial Interface Setup

To interface with the Radical-7 serial port, set the following communication parameters on the interfacing serial device:

Parameter	Setting
Baud rate	9600 baud bi-directional
Number of bits per character	8

Parameter	Setting
Parity	None
Bits	1 start, 1 stop
Handshaking	None
Connector type	Female DB-9

The pin-outs for the RS-232 connector are shown in the following table:

Pin	Signal name
1	No Connection
2	Receive data – RS-232 ±9 V (±5 Vmin)
3	Transmit data – RS-232 ±9 V (±5 Vmin)
4	No Connection
5	Signal Ground Reference for COM signals
6	No Connection
7	No Connection
8	No Connection
9	No Connection

Analog Output and Nurse Call Specifications

Analog Out and Nurse Call are accessible on the same female high-density DB-15 connector. Analog Output and Nurse Call interface are only available when the Handheld is attached to the Docking Station. Only use an Analog and Nurse Call cable that has a ferrite bead installed. Analog Output and Nurse Call interface is not available in all versions of the Docking Station. See ***Nurse Call Test*** on page 201 and ***Handheld Front Panel*** on page 49.

The following table shows the pin out of the Analog Output and Nurse Call.

Pin	Signal Name
1	+5V (60mA max.)
2	Ground
3	Ground
4	Ground
5	Ground
6	Nurse Call (Normally Open)
7	Nurse Call (Normally Closed)
8	Ground
9	Analog 1

Pin	Signal Name
10	Ground
11	Ground
12	Nurse Call -Common
13	Ground
14	Ground
15	Analog 2

Analog Output

The Radical-7® Pulse CO-Oximeter® can interface with various analog recording devices or strip chart recorders through its Analog Output connector located on the back of the Docking Station. The output signals vary from approximately 0 to 1 volt in a linear fashion. The actual analog output voltage generated may not exactly range between 0.0V to 1.0V. A variance of ± 40 mV is acceptable.

Calibration

For device calibration purposes, the analog output signals can be set to either 0 Volts or 1 Volt. Calibrate the analog recording system to those levels before use.

Nurse Call

The Nurse Call feature is available when the Radical-7 is operating as a standalone. Nurse Call is based on the relay closing or opening depending on alarm, Low Signal IQ events, or both. For maximum

flexibility, either normally open (pin 6) or normally closed (pin 7) signals are available. Only qualified personnel should connect one of these two signals and common (pin 12) to a hospital's Nurse Call system. During an alarm condition or a Low Signal IQ event, depending on the configuration, the normally open pin will be connected to the common pin and the normally closed will be disconnected. The Nurse Call polarity can be inverted to accommodate various Nurse Call station requirements.

Parameter	Specification
Max voltage	100V DC or AC peak
Max Current	100mA

Symbols

The following symbols are found on the Radical-7, Docking Station, or packaging and are defined below. Some of the interfaces and symbols are not available on all versions of the Docking Station.

Symbols	Definition
	RS-232 interface
	SatShare interface
	Equipotential ground terminal

Symbols	Definition
	Relative humidity storage range
	Storage temperature range
	Keep dry

Symbols	Definition
	Follow Instructions for Use
	Fuse replacement
	Analog Out interface
	Nurse Call interface
	Separate collection for electronic waste
	Mark of conformity to European Medical Device Directive 93/42/EEC
R_x Only	Federal law restricts this device to sale by or on the order of a physician (USA FDA)

Symbols	Definition
	Fragile/breakable, handle with care
	Date of Manufacture
IPX1	IPX1 Protection against liquid drops falling vertically
	Defibrillation proof type BF
EC REP	Authorized Representative in the European Community
 CAUTION	Caution
	Name of Manufacturer

Symbols	Definition
	UL, LLC. Certification
	Non-ionizing electromagnetic radiation
IC Model	Industry Canada Registered Model

Symbols	Definition
	Wireless features can be used in member states with the restriction of indoor use in France
	Federal Communications Commission (FCC) licensing

Citations

[1] SpO_2, SpCO, and SpMet accuracy was determined by testing on healthy adult volunteers in the range 60% to 100% SpO_2, 0% to 40% SpCO, and 0% to 15% SpMet against a laboratory CO-Oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7 days to 135 days old and weighing between 0.5 kg and 4.25 kg. Seventy-nine (79) data samples were collected over a range of 70% to 100% SaO_2 and 0.5% to 2.5% HbMet with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet. Contact Masimo for testing specifications.

[2] The Masimo rainbow SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70%-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population weight.

[3] The Masimo rainbow SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and touching motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70%-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[4] The Radical-7 has been validated for low perfusion accuracy in bench-top testing against a Biotek Index 2TM simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70%-100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.*

[5] Masimo rainbow SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

[6] SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8 g/dL to 17 g/dL SpHb against a Coulter Counter. The variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

[7] This represents approximate run time at the lowest indicator brightness and pulse tone turned off using a fully charged battery.

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

[9] With FastSat the averaging time is dependent on the input signal. For the 2 and 4 second settings the averaging time may range from 2-4 and 4-6 seconds, respectively.

[10] Maximum sensitivity mode fixes perfusion limit to 0.02%.

[11] Respiration rate accuracy for the Masimo Acoustic Respiration Sensor and Instrument has been validated for the range of 4 to 70 breaths per minute in bench top testing. Clinical validation for up to 30 breaths per minute was also performed with the Masimo Acoustic Respiration Sensor and Instrument.

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

Chapter 9: Service and Maintenance

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

Cleaning

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations. *Warnings and Cautions* on page 15.

The Radical-7 is a reusable device. The device is supplied and used non-sterile.

To surface clean the Radical-7

- The outer surface of the device can be cleaned with a soft cloth dampened with a mild detergent and warm water solution.
- Do not allow liquids to enter the interior of the device.
- The outer surface of the device can also be wiped down using any of the following solvents:
  - Cidex Plus (3.4% glutaraldehyde)
  - 10% bleach solution
  - 70% isopropyl alcohol solution

Using the recommended cleaning solutions on the touchscreen panel will not affect the performance of the Handheld.

Battery Operation and Maintenance

The Radical-7 Handheld includes a lithium ion rechargeable battery. The Radical-7 Docking Station may include the optional 6.5 amp-hour nickel metal hydride rechargeable battery.

Before using the Radical-7 as a Handheld or as a transport monitor, the Handheld rechargeable battery and the optional Docking Station rechargeable battery must be fully charged.

To charge the Handheld rechargeable battery and the Docking Station rechargeable battery

1. Attach the Handheld to the Docking Station.
2. Connect the Docking Station to AC power.
3. Verify that the batteries are charging.
    - The Docking Station Battery Charging indicator momentarily flashes and then remains illuminated while the batteries are actively charging.
    - If the internal battery temperature exceeds recommended operating conditions for proper battery charging, the Handheld Battery Charging indicator continuously flashes. When the temperature returns to recommended operating conditions, proper battery charging proceeds.
    - The Handheld battery requires approximately 4 hours for charging. The Docking Station battery requires approximately 6 hours for charging.
    - When both the Handheld Battery Charging indicator and the Docking Station Battery Charging indicator turn off, additional trickle charging may occur to complete charging.

- Memory effects of the battery may shorten run-time. When battery run time is significantly reduced, it is advisable to completely discharge and fully recharge the battery. Charging can occur while the Handheld is docked and turned on, the most efficient charge times are achieved when the Handheld is turned off.

During battery operation of the Radical-7, note that the following operating conditions affect the estimated run time of the included rechargeable batteries:

Estimated Run Times of Battery Power

The following tables outline the estimated run times of the battery-powered Radical-7. The time estimates are based on a Radical-7 with fully charged batteries. The time estimates are also based on a Radical-7 with and without the back-light illuminated.

The Radical-7 is always configured to include the Handheld battery. It may optionally be configured to include the Docking Station battery. Determine the configuration of the system before referencing the following tables.

Run Time for Handheld Only

In this configuration, the Radical-7 is configured to only include the Handheld battery (standard configuration). When running on battery power, it is advisable to operate only the Handheld. On battery power, it is possible to operate the Standalone (Handheld attached to the Docking Station with the Handheld battery providing power to the Docking

Station). However, the capacity of the Handheld battery pack is not sufficient to support this mode for long periods of time.

For optimal battery run time, configure the device to automatically adjust the brightness. See ***Brightness*** on page 125.

Configuration	Operation Mode	Minimum run time
Handheld only	Handheld, undocked, not connected to AC power	4 hours
Handheld only	Handheld docked, not connected to AC power	1 hour

Replacing the Batteries

Before installing or removing the battery, make sure the AC power cord is removed and power to the Radical-7 is turned off.

To replace the rechargeable Handheld battery

1. Turn off the Radical-7 Handheld off and remove the patient cable connection. If docked, detach the Handheld from the Docking Station.
2. Loosen the closure screw on the battery compartment door and lift out the battery.
3. Take a new battery and place it in the compartment.
4. Tighten the closure screw.
5. Place the Handheld into Docking Station, turn on line power and charge battery.

See *Battery Operation and Maintenance* on page 196.

Replacing the Fuses

Should a power problem blow one or both of the fuses in the power entry module on the rear panel, the fuse(s) will need to be replaced. Before starting, the user will need a 5-mm or 3/16-in screwdriver.

To replace the fuse(s)

1. Disconnect device from AC power.
2. Remove AC power cord from the power entry module at the rear of the Docking Station.
3. Using the screwdriver, gently pry loose the fuse cover in the left portion of the power entry module, exposing the fuse holder.
4. Using the screwdriver, gently remove the fuse holder.
5. Note how the fuse(s) are placed in the fuse holder for installation of the new fuse(s).
6. To remove the fuses from the fuse holder, use the edge of the screwdriver blade to pry against the bottom of the metal portion of the fuse where it is secured to the glass portion of the fuse.
7. Place the fuse(s) in the fuse holder, properly orienting the fuse(s). For fuse specifications, see *Electrical*.

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

1. Slide the fuse holder back into the power entry module and press firmly to make sure it is completely seated.
2. Close the fuse cover and press gently until it seats completely, flush with the back of the Docking Station.

The device is ready to be reconnected to AC power. If the fuses blow shortly after replacement, the device requires service.

Performance Verification

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

To test the performance of the Radical-7 following repairs or during routine maintenance, follow the procedure outlined in this chapter. If the Radical-7 fails any of the described tests, discontinue its use and correct the problem before returning the device back to the user.

Before performing the following tests, do the following:

- Place the Handheld into the Docking Station.
- Connect the Docking Station to AC power and fully charge the Handheld battery.
- Disconnect any patient cables or pulse oximetry probes.
- Disconnect any SatShare, serial or analog output cables from the device.
- Set the Radical-7 to Normal operating mode by going to the Main menu and the Home Use feature to *No*.

Power-On Self Test

To conduct a Power-On Self Test

1. Connect the Battery Module to the Device Module. Refer to Setup for instructions on how to connect the Battery Module to the Device Module.

2. Upon connection, the device emits a tone and the Masimo logo displays.

Alarm Limit Test

To conduct an Alarm Limit Test

1. Change the High SpO_2 Alarm parameter to a value two points below the currently selected value. See *Alarms for SpO2* on page 91.
2. Verify that the newly set parameter is shown on the *Display* screen.
3. Return the parameter to its original setting.
4. Repeat steps 1 to 3 for all active parameters.
5. Reset the alarm limits again to the original settings.

Testing with the optional Masimo SET Tester

To conduct a test with the optional Masimo SET® Tester

1. Turn off and then turn on the Radical-7.
2. Use the Patient Cable connector on the Radical-7 to connect the Masimo SET® Tester to the Radical-7.
3. See the directions for use that were provided with the Masimo SET® Tester.

Nurse Call Test

To conduct a Nurse Call test

1. Disconnect any patient cables, sensors, or accessories from the Radical-7. Turn off the Radical-7 and then turn on again.

2. Ensure that there are no audible alarms and that the Audible Alarm feature is not set to silenced.
3. Verify the Nurse Call polarity is set to normal.
4. Connect the common lead of a digital multi-meter to the pin 12 (Nurse Call Common) of the Analog Output connector on the Radical-7. Connect the positive lead of the multi-meter to pin 6 (Nurse Call - Normally Open) of the Analog Output connector and measure that the resistance is greater than 1 MW (open circuit).
5. Trigger an alarm on the monitor (for example, by disconnecting a sensor after it was measuring data). Verify that the resistance is less than 35 ohms.

Analog Output Test

To conduct an Analog Output test

1. Disconnect any patient cables, sensors, or accessories from the Radical-7. Turn off the Radical-7 and then turn on again.
2. Connect the common lead of a digital voltmeter to the pin 2 (Ground) of the analog output connector on the Radical-7. Connect the positive lead of the voltmeter to pin 9 (Analog 1) of the analog output connector.
3. On the *device output* screen, on the *analog 1* option, select **0V Output**. See *Device Output* on page 126.
4. Verify that the voltmeter measures a voltage of approximately 0V.
5. Change the *analog 1* option to **1V Output**.
6. Verify that the voltmeter measures a voltage of approximately 1.0V.

7. Repeat steps 5 and 6, with the positive lead of the voltmeter connected to pin 15 (*analog 2*). See ***Serial Interface Specifications*** on page 186.
8. Connect a patient cable and sensor and verify that the voltage on pins 9 and 15 are between 0V and 1.0V while measuring a saturation and pulse rate.

Battery Test

To conduct a Battery test

1. Fully charge the Radical-7 by placing the Handheld into the Docking Station and then connect the AC power.
2. Verify that the Handheld Battery Charging indicator is illuminated.
3. When the Radical-7 is fully charged, the Handheld Battery Charging indicator turns off.
4. Turn on the Radical-7 on and verify that the Battery indicator shows a full charge.

Repair Policy

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

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

To return the device for service, refer to ***Return Procedure*** on page 204.

Return Procedure

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

- A letter describing in detail any difficulties experienced with the Radical-7. 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 Radical-7 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 Radical-7 has been decontaminated for bloodborne pathogens.
- Return the Radical-7 to the shipping address listed in ***Contacting Masimo*** on page 204 below.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

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

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product (Radical-7® Pulse CO-Oximeter®) 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 loss of use of any Products or Software. In no event shall Masimo's liability arising from any Product or Software (under contract, warranty, tort, strict liability, or otherwise) exceed the amount paid by purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

Sales & End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire

agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Restrictions

1. Copyright Restrictions: The Software and the accompanying written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged, or included with other software, or the written materials is expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of this Agreement. Nothing in this License provides any rights beyond those provided by 17 U.S.C. §117.
2. Use Restrictions: Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other instrument. 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

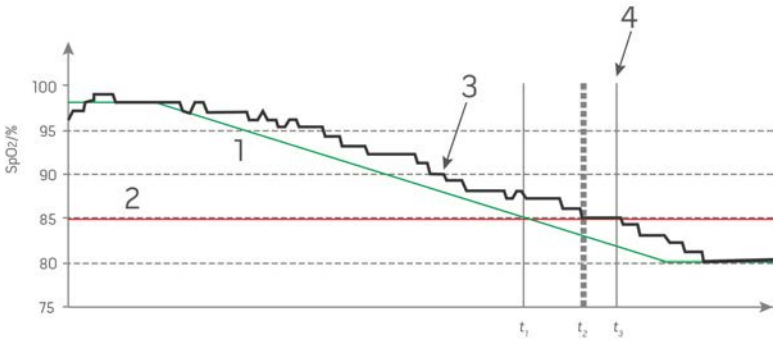
automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.

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

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



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

Reference	Definition
SpO_2	Saturation
t	Time

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

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

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

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

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**

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
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 B	Suitable for use in all establishments, including domestic environments.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

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 lines +/- 1 kV for input/ output lines		Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Surge IEC 61000-4-5	+/-1 kV line(s) to line(s) +/- 2 kV line(s) to earth		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	100% dip in mains voltage for 0.5 cycle 60% dip in mains voltage for 5 cycle 30% dip in mains voltage for 25 cycle		Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
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.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 20 V/m 80 MHz to 2.5 GHz	3V 20 V/m	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. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
			$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz 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, 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: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment. **b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment			
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 K Hz to 80 MHz d = 1.17*Sqrt (P)	80 MHz to 800 MHz d = 0.18*Sqrt (P)	800 MHz to 2.5GHz d = 0.35*Sqrt (P)
0.01	0.12	0.018	0.035
0.1	0.37	0.057	0.11
1	1.17	0.18	0.35
10	3.7	0.57	1.1
100	11.7	1.8	3.5

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.

Index

3

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

R

S

T

U

V

W

www.masimo.com

LAB-10107B-0319