Radical-7™

signal extraction pulse co-oximeter

OPERATOR'S MANUAL

Contains:

Oxyhemoglobin, Carboxyhemoglobin and Methemoglobin parameters

Masimo SET® rainbow

Radical-7™

Signal Extraction Pulse CO-Oximeter

OPERATOR'S MANUAL

The Radical-7 Pulse CO-Oximeter Operating Instructions provide the necessary information for proper operation of all models of the Radical-7 Pulse CO-Oximetry system. 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 the Radical-7 Pulse CO-Oximeter are a prerequisite for its proper use.

Do not operate the Radical-7 Pulse CO-Oximeter without completely reading and understanding the instructions in this manual.

If a Radical-7 unit has been upgraded to include the latest available parameters by utilizing the upgrade tool (sold separately), please discontinue using the previous Radical-7 manual and use the new manual provided.

NOTICE:

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

CAUTION:

Federal law (U.S.) restricts this device to sale by or on the order of a physician.

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MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1/CAN/CSA C22.2 No. 601.1

Covered by one or more of the following U.S. Patents: RE38,492, RE38,476, 6,850,787, 6,826,419, 6,816,741, 6,699,194, 6,684,090, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,584,336, 6,580,086, 6,501,975, 6,463,311, 6,430,525, 6,397,091, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,206,830, 6,157,850, 6,067,462, 6,011,986, 6,002,952, 5,919,134, 5,823,950, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036, international equivalents, or one or more of the patents referenced at www.masimo.com/patents. Products containing Satshare® feature are also covered by U.S. Patent 6,770,028. Other patents pending.

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Radical-7, RadNet, RadicalScreen, LNOPv and APOD are trademarks of Masimo Corporation.

SpMet and Signal Extraction Pulse CO-Oximeter are trademarks of Masimo Laboratories.

The Radical-7 Signal Extraction Pulse CO-Oximeter is designed to minimize the possibility of hazards from errors in the software program by following sound engineering design processes, Risk Analysis and Software Validation.

- Explosion hazard. Do not use the Pulse CO-Oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- 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.
- The Pulse CO-Oximeter is NOT intended for use as an apnea monitor.
- The Pulse CO-Oximeter should be considered an early warning device. As a trend towards patient hypoxemia is indicated, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.
- The Pulse CO-Oximeter is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
- Electric shock hazard. Do not open the Pulse CO-Oximeter cover except to replace the battery of the Handheld unit. Only a qualified operator may perform maintenance procedures specifically described in this manual. Refer servicing to Masimo for repair of this equipment.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the Pulse CO-Oximeter or accessories in any position that might cause it to fall on the patient. Do not lift the Pulse CO-Oximeter by the power cord or any other cable.
- Interfering Substances: SpO_2 is a functional calculation of arterial oxygen saturation. Carboxyhemoglobin and Methemoglobin may erroneously increase SpO_2 readings. The level of increase is approximately equal to the amount of carboxyhemoglobin and/or methemoglobin that is present. Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 and SpCO measurements.
- Elevated levels of Carboxyhemoglobin (COHb) will lead to inaccurate SpO_2 measurements.
- Severe anemia may cause erroneous SpO_2 readings.
- Do not use the Pulse CO-Oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Pulse CO-Oximeter may affect the MRI image and the MRI unit may affect the accuracy of the oximetry measurements.
- If using Pulse CO-Oximetry during full body irradiation, keep the sensor out of the irradiation field. If the sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.

- For home use, ensure that the Pulse CO-Oximeter's 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.
- Always remove the sensor from the patient and completely disconnect the patient from the Pulse CO-Oximeter before bathing the patient.
- Do not place the Pulse CO-Oximeter where the controls can be changed by the patient.
- Do not place the Pulse CO-Oximeter face against a surface. This will cause the alarm to be muffled.
- Do not place the Pulse CO-Oximeter on electrical equipment that may affect the Pulse CO-Oximeter, preventing it from working properly.
- Do not expose the Pulse CO-Oximeter to excessive moisture such as direct exposure to rain. Excessive moisture can cause the Pulse CO-Oximeter to perform inaccurately or fail.
- Do not place containers with liquids on or near the Pulse CO-Oximeter. Liquids spilled on the Pulse CO-Oximeter may cause it to perform inaccurately or fail.
- Failure of Operation - If the Pulse CO-Oximeter fails any part of the setup procedures or leakage tests, remove the Pulse CO-Oximeter from operation until qualified service personnel have corrected the situation.
- Patient Safety - If a sensor is damaged in any way, discontinue use immediately.
- Disposal of product - Comply with local laws in the disposal of the unit and/or its accessories.
- The Pulse CO-Oximeter can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.
- This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical 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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 device.
  - Increase the separation between the equipment.
  - Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
  - Consult the manufacturer for help.
- A functional tester cannot be utilized to assess the accuracy of the Pulse CO-Oximeter or any sensors.

About This Manual

This manual explains how to set up and use the Radical-7 Pulse CO-Oximeter containing Masimo Rainbow SET technology. Important safety information relating to general use of the Pulse CO-Oximeter appears before this introduction. Other important safety information is located throughout the manual where appropriate.
Read the entire safety information section before you operate the monitor.

In addition to the safety section, this manual includes the following sections:

SECTION 1 **OVERVIEW** gives a general description of Radical-7 Pulse CO-Oximeter.

SECTION 2 **SYSTEM DESCRIPTION** describes the Radical-7 Pulse CO-Oximeter system and its functions and features.

SECTION 3 **SETUP** describes how to setup the Radical-7 Pulse CO-Oximeter for use.

SECTION 4 **OPERATION** describes the operation of the Radical-7 Pulse CO-Oximetry system.

SECTION 5 **ALARMS AND MESSAGES** describes the alarm system messages.

SECTION 6 **TROUBLESHOOTING** describes troubleshooting information.

SECTION 7 **SPECIFICATIONS** gives the detailed specifications of the Radical-7 Pulse CO-Oximeter.

SECTION 8 **SENSORS AND PATIENT CABLES** outlines how to use and care for Masimo Rainbow SET technology sensors, Masimo Rainbow SET technology patient cables, Masimo Red sensors and Masimo Red PC cables.

SECTION 9 **SERVICE AND MAINTENANCE** describes how to maintain, service and obtain repair for the Radical-7 Pulse CO-Oximeter.

SECTION 10 **ACCESSORIES** lists the available Radical-7 Pulse CO-Oximeter accessories.

Warnings, cautions and notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels are as follows:

A **WARNING** is provided when actions may result in a serious outcome (i.e., injury, serious adverse affect, death) to the patient or user. Look for text in a gray shaded box.

Sample of 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.

Sample of Caution:

CAUTION: THIS IS A SAMPLE OF A CAUTION STATEMENT.

A ***NOTE*** is provided when extra general information is applicable.

Sample of Note:

NOTE: *This is a sample of a Note.*

Product Description

The Radical-7 Pulse CO-Oximeter is a noninvasive, arterial oxygen saturation and pulse rate monitor. The Radical-7 Pulse CO-Oximeter can be used as either a Handheld or a Standalone monitor. The Radical-7 Pulse CO-Oximeter features a backlit Liquid Crystal Display (LCD) that continuously displays numeric values for SpO_2, SpCO®*, SpMet™*, pulse rate, Perfusion Index (PI) and Pleth Variability Index (PVI). It also provides graphical displays for plethysmographic waveform and Signal Identification and Quality Indicator (Signal IQ®). The Radical-7 Pulse CO-Oximeter can be used to interface with a multiparameter patient monitor to provide only Masimo SET SpO_2 information to that monitor for display.

FEATURES

These features are common to the Radical-7 family:

- Masimo SET is clinically proven to be the highest sensitivity and specificity pulse oximeter in the world.
- Rainbow technology uses 7+ wavelengths of light to continuously and noninvasively measure carboxyhemoglobin (*SpCO®) and methemoglobin (*SpMet™), as well as providing a more reliable probe-off detection.
- 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): captures vital thoracic pressure changes that may compromise normal cardiac function affecting systemic circulation.
- Accurate on cyanotic patients when used with an LNOP® Blue Sensor.
- Signal IQ® waveform provides signal identification and quality indication during excessive motion and low signal to noise situations.
- FastSat® tracks rapid changes in arterial O_2 with high fidelity unlike any other pulse oximeter.
- Variable pitch provides tonal variance for every 1% change in saturation.
- SatShare ® interface allows transfer of SpO_2 and pulse rate to existing multiparameter monitor and allows for the reading of SpCO and SpMet on adjacent Radical-7 monitor.
- Automatic screen rotation provides upright display for vertical or horizontal monitor positioning.
- Remote alarming interface.
- Up to eighteen days of trending.
- Detachable portable hand-held unit for patient transport.
- 3D Alarm System Option:
  - Desat Index Alarm™ enables clinicians to detect an increasing quantity of smaller desaturations that may precede declining respiratory status.
  - PI Delta Alarm™ alerts clinicians to specified changes in perfusion, often a reliable indicator of illness severity.

INDICATIONS FOR USE

The Radical-7 Pulse CO-Oximeter and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), carboxyhemoglobin percentage and methemoglobin percentage (measured by a SpCO/SpMet sensor). The Radical-7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile and home environments.

* Optional parameters

Pulse CO-Oximetry

SpO_2 GENERAL DESCRIPTION

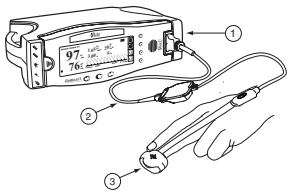
Pulse CO-Oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for neonates. The sensor is connected to the Pulse CO-Oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in three ways:

1. As a percent value for arterial oxygen saturation (SpO_2)

2. As a pulse rate (BPM)

3. As a plethysmographic waveform

The following figure shows the general monitoring setup.



1. Instrument
2. Patient Cable
3. Sensor

SpCO GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and non-invasive method of measuring the levels of carbon monoxide 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 instrument or through an instrument patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

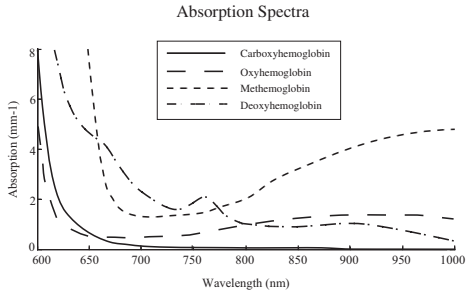
SpMet GENERAL DESCRIPTION

Pulse CO-Oximetry is a continuous and non-invasive 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 instrument or through an instrument patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpMet.

PRINCIPLE OF OPERATION

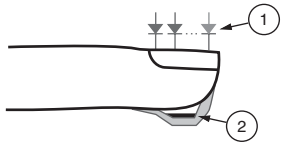
Pulse CO-Oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood) carboxyhemoglobin (blood with carbon monoxide content) and methemoglobin species differ in their absorption of visible and infrared light (using spectrophotometry, see figure below).



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

The Radical-7 Pulse CO-Oximeter uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide content and blood with oxidized hemoglobin. The Radical-7 utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to a photodiode (photodetector). See figure below. Signal data is obtained by passing various visible and infrared lights (LED's, 500 to 1000nm) 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 22mW. The photodetector 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. Recessed Photo Detector

Once the Radical-7 receives the signal from the sensor, it utilizes Masimo Rainbow SET signal extraction technology to calculate the patient's functional oxygen saturation, blood levels of carboxyhemoglobin (SpCO), methemoglobin (SpMet) and pulse rate. The SpCO and SpMet measurements rely on a multiwavelength calibration equation to quantify the percentage of carbon monoxide and methemoglobin in arterial blood. The maximum of the skin surface temperature is measured at an ambient temperature of less than 106° F (41° C). This is verified by Masimo sensor skin temperature test procedures

FUNCTIONAL SATURATION

The Radical-7 is calibrated to measure and display functional saturation (SpO_2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen. Note that carboxyhemoglobin and methemoglobin are not capable of transporting oxygen, but is recognized as oxygenated hemoglobin by conventional pulse oximetry.

MEASURED VS. CALCULATED SATURATION

SpO_2, SpMet and SpCO measurements that can be obtained from the Radical-7 are commonly compared to invasive measurements obtained from blood gas samples. When comparing invasive and noninvasive measurements and interpreting values, caution should be used, as the calculated values obtained from the blood gas sample may differ from the SpO_2, SpMet and SpCO measurements of the Pulse CO-Oximeter. 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 (PO2) and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO2), 2,3-DPG, and fetal hemoglobin. In the case of SpMet and SpCO, in addition to the effects of temperature and pH, different results are also expected if concentration of methemoglobin in the blood gas sample are abnormal (less than 90% for arterial oxygen saturation, and greater than 2% for methemoglobin concentration). As blood gas 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.

MASIMO SET SIGNAL EXTRACTION TECHNOLOGY FOR SpO_2 MEASUREMENTS

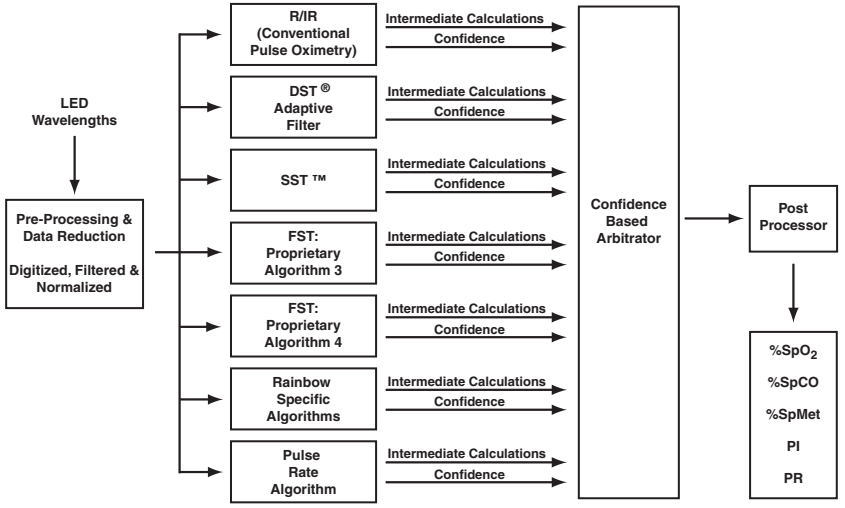
Masimo Signal Extraction Technology's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the non-arterial blood also moves, causing conventional 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 digital 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®) 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.

SpMet AND SpCO MEASUREMENTS DURING PATIENT MOTION

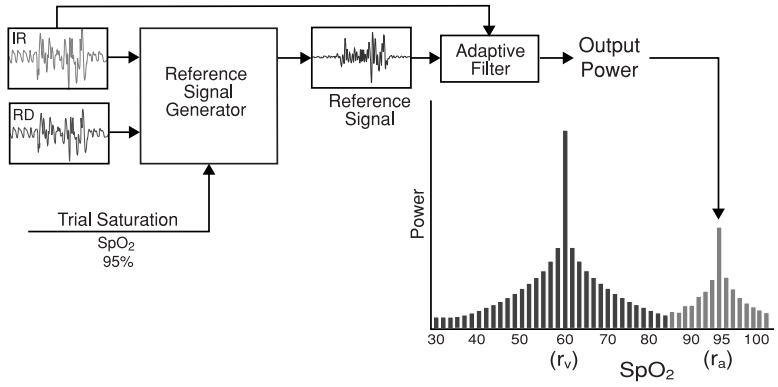
The Radical-7 displays measurements of SpMet and SpCO during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be readable during excessive motion.

MASIMO RAINBOW SET PARALLEL ENGINES

This figure is for conceptual purposes only.



MASIMO SET DST®

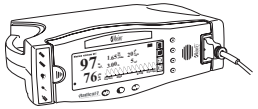


Introduction

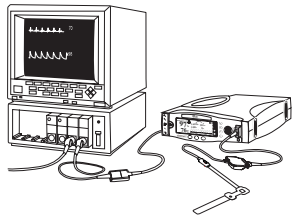
The Radical-7 provides the functionality of three instruments in one:

- The Radical-7 is a fully featured Handheld Pulse CO-Oximeter.
- The Radical-7 is a fully featured Standalone Pulse CO-Oximeter.
- The Radical-7 interfaces to the SpO_2 input module of multiparameter patient monitors* to upgrade conventional pulse oximetry technology to Masimo SET technology.

The Handheld portion of the Radical-7 contains the majority of the Pulse CO-Oximeter features. All pulse oximetry measurement information, as well as device status data is displayed on the Handheld LCD screen. All user input is performed through the control buttons on the front panel. The sensor cable connector is located on the Radical-7 Handheld Pulse CO-Oximeter.



The Handheld Pulse CO-Oximeter snaps into the Radical-7 Docking Station to provide a fully featured standalone Pulse CO-Oximeter. The Docking Station connects to AC power for standalone operation or charging of the Handheld. An optional Docking Station battery is available. The standalone Radical-7 features nurse call, analog output and interfaces to serial printers.



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

CAUTION:

- THE WAVEFORM DISPLAYED ON THE MULTIPARAMETER PATIENT MONITOR IS A SIMULATED SIGNAL (NON-NORMALIZED). REFER TO THE RADICAL-7 PULSE CO-OXIMETER DISPLAY FOR PATIENT WAVEFORM.
- IF DISPLAYING THE SIMULATED WAVEFORM IS NOT DESIRABLE, IT IS RECOMMENDED TO TURN OFF THE PLETH WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR.
- ONLY USE A SATSHARE CABLE THAT HAS A FERRITE BEAD INSTALLED.
- SpMet AND SpCO CANNOT BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH SATSHARE.

Refer to Section 3, *SatShare Setup* and Section 4, *SatShare Operation* for additional details.

*Contact Masimo for the latest list of SatShare validated multiparameter monitors.

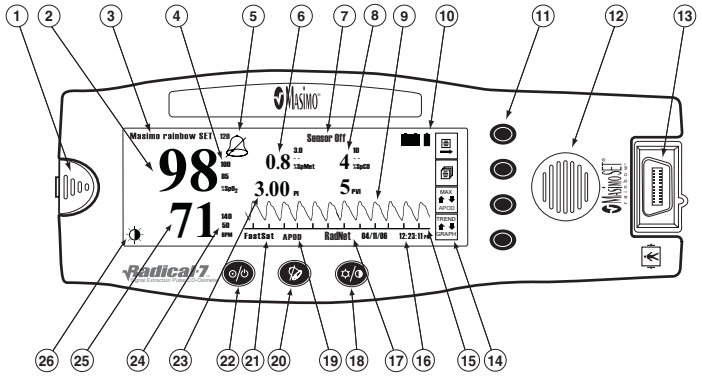
Radical-7 Pulse CO-Oximeter Handheld

The Handheld Radical-7 Pulse CO-Oximeter provides most of the functionality of the Pulse CO-Oximeter. All user input and displays are controlled by this part of the Radical-7 Pulse CO-Oximeter system. The sensor cable connects into the connector on the Handheld unit. The Handheld is battery powered and can be used either as a transport monitor or as a Handheld Pulse CO-Oximeter for spot checks.

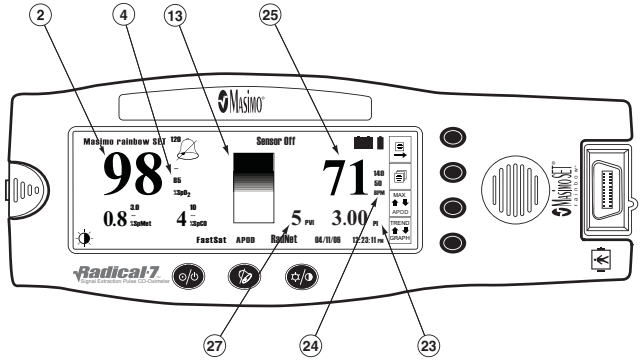
HANDHELD FRONT PANEL

The following figure and corresponding text outline all the features of the Handheld Radical-7 Pulse CO-Oximeter:

Pleth + Signal IQ Display View



Numbers Display View



1		**HANDHELD RELEASE BUTTON**	Press down the Handheld Release Button and pull the Handheld device off the Docking Station.
2	98	**SpO_2 MEASUREMENT DISPLAY**	The functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO_2. The upper and lower SpO_2 alarm limits are also displayed next to the SpO_2 measurement. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines and the message **SENSOR OFF** will appear at the top of the display screen. When the measured value is outside of the alarm limits, the SpO_2 Measurement Display flashes and an alarm will sound. The oxygen saturation is calculated and the display is updated at a frequency of once per second.
3	Masimo rainbow SET	**MASIMO SET OR MASIMO RAINBOW SET**	The Masimo SET or Masimo rainbow SET label is shown on the Radical-7 display when either SET processing is active. ***NOTE:*** *Patient information, not SET activity will be displayed when using a RadNet compatible unit connected to a RadNet central station.*
4	100 85	**SATURATION ALARM LIMITS DISPLAY**	The Saturation Alarm Limits Display shows the upper and lower saturation alarm limits. When an alarm limit is exceeded, the SpO_2 value and the violated limit flashes.
5		**ALARM STATUS INDICATOR**	The alarm status indicator (a bell) can be shown with or without a slash. It flashes when an alarm condition is present. When the alarm is silenced using the Alarm Silence Button, an alarm status indicator with a slash and a timer is shown to indicate that the alarm is temporarily silenced. When the alarm is silenced through the All Mute menu selection (which is permanent until power is cycled or deselected using the menu) an alarm status indicator with a slash is shown to indicate that alarm has been silenced.
6	0.8	**SpMet* MEASUREMENT DISPLAY**	The measurement of methemoglobin concentration levels is displayed in units of percentage SpMet. The upper and lower SpMet alarm limits are also displayed next to the SpMet measurement. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines and the message **SENSOR OFF** will appear at the top of the display screen. When the measured value is outside of the alarm limits, the SpMet measurement display flashes and an alarm will sound. The methemoglobin is calculated and the display is updated at a frequency of once per second.
7	Low Signal IQ	**SYSTEM MESSAGE AREA**	The system messages generated by the instrument are displayed in the System Message Area. See Section 5, *System Messages*.
8	4	**SpCO* MEASUREMENT DISPLAY**	The measurement of carbon monoxide concentration levels is displayed in units of percentage SpCO. The upper and lower SpCO alarm limits are also displayed next to the SpCO measurement. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines and the message **SENSOR OFF** will appear at the top of the display screen. When the measured value is outside of the alarm limits, the SpCO measurement display flashes and an alarm will sound. The carboxyhemoglobin is calculated and the display is updated at a frequency of once per second.

⑨		**PULSE WAVEFORM DISPLAY**	The Pulse Waveform Display shows the acquired plethysmograph waveform. The pleth waveform is scaled with signal strength. Signal strength is defined as the relation of arterial pulsatile signal to the non-pulsatile signal component.
⑩		**BATTERY STATUS INDICATORS**	The Battery Status Indicators show the capacity of the Radical-7 Handheld and optional Docking Station batteries. The indicator flashes when less than 15 minutes of battery life is left and the battery needs to be recharged. The Docking Station Battery Status indicator is not shown when the optional Docking Station battery is not present.
⑪		**TOUCH KEY CONTROL BUTTONS**	Press a Touch Key Control Button to select the corresponding touch key icon. See Section 4, *Touch Key Control Buttons and Icons* for more details.
⑫		**SPEAKER**	The speaker indicates audio alarms. Care should be taken not to cover the speaker and muffle the audible alarm volume.
⑬		**PATIENT CABLE CONNECTOR**	Connect the patient cable to the Handheld Radical-7 by plugging the cable into the Patient Cable Connector. Use only Masimo compatible sensors and cables with this oximeter. See Section 8, **Sensors and Patient Cables** for more details.
⑭		**TOUCH KEY ICONS**	The Touch Key Icons indicate the software menu items that can be selected through the Touch Key Control Buttons. Pressing a Touch Key Control Button next to an icon selects the option.
⑮		**SIGNAL IQ**	The Signal IQ shows the acquired signal quality and the timing of the pulse. A tall vertical line indicates a high quality signal, while a small vertical line indicates a low quality signal. The Signal IQ will be displayed as a single, pulsating bar in the Numbers mode.
	08:10:23pm 03/27/01	**TIME AND DATE INDICATOR**	The Time and Date Indicator displays the current time and date. The time is displayed in 12 or 24 hour format. The date is displayed in dd/mm/yy or mm/dd/yy format. Select the date and time display formats in the Clock menu.
⑯	Philips Vuelink HP01	**OUTPUT MODE INDICATOR**	The Output Mode Indicator displays the output mode selected by the user (Philips Vuelink or Spacelabs Flexport). The Output Mode Indicator also displays the type of SatShare® cable. The Output Mode Indicator is only displayed when the Radical-7 device actively outputs data other than ASCII text, or interfaces with a monitor through the SatShare cable. The Output Mode Indicator will take place of the Time and Date indicator when utilized.
⑰	RadNet	**SERIAL OUTPUT MODE**	The Serial Output Mode displays the selected output interface when interfaced with the Docking Station. and connected to the serial port with the selected serial cable.
⑱		**BACKLIGHT/ CONTRAST BUTTON**	Press the Backlight Button to change the illumination level of the backlight. With the AC line power connected, four levels of illumination are available (in addition to the no illumination level). In the Handheld mode, three levels of illumination are available (again in addition to the no illumination level). Use the lowest illumination for most efficient battery usage. The backlight Button is also used to change the contrast of the LCD display. Press and hold the Backlight Button for longer than six seconds to change the contrast. Release the Backlight Button at the desired contrast setting.

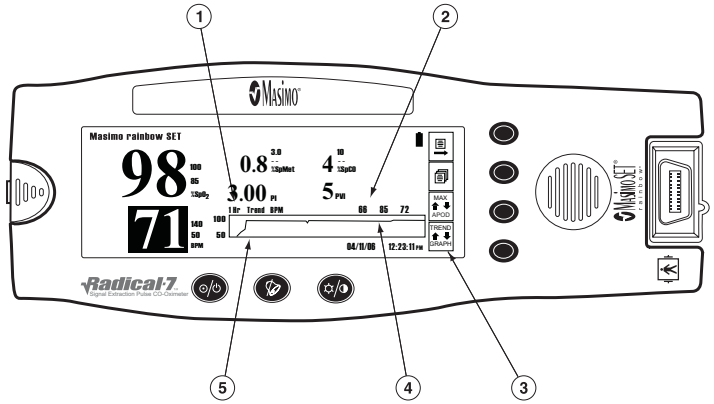
⑲	MAX APOD	**SENSITIVITY**	The MAX or APOD™ sensitivity icon is shown on the Radical-7 display to indicate if the Radical-7 is set to operate in Normal sensitivity, Maximum sensitivity or Adaptive Probe Off Detection mode. When in Normal mode, this area will appear blank.
⑳		**ALARM SILENCE BUTTON**	Press the Alarm Silence Button to temporarily silence patient and low battery alarms. Press the Alarm Silence Button when the **SENSOR OFF** message is flashing (i.e. the sensor is removed from the patient) to acknowledge the end of monitoring. In this state, all further alarms are suspended until the Pulse CO-Oximeter starts measuring SpO_2, SpMet, SpCO, PI and pulse rate again. ***NOTE:*** *System failure alarms can be silenced by pressing the Power/Standby or Alarm Silence Button. If the Power/Standby Button does not silence the system fault alarm, press the Alarm Silence Button.*
㉑	FastSat	**FASTSAT**	The FastSat® label is shown on the Radical-7 display whenever the Radical-7 is set to operate in the FastSat mode.
㉒		**POWER/ STANDBY BUTTON**	Press the Power/Standby Button to turn the instrument on. Press, hold the button for more than 2 seconds and then release the button to turn the instrument off.
㉓	PI	**PERFUSION INDEX**	The Perfusion Index indicates numerically the percentage of pulsatile signal to non-pulsatile signal (pulse strength)
㉔	140 50	**PULSE RATE ALARM LIMITS DISPLAY**	The Pulse Rate Alarm Limits Display shows the upper and lower pulse rate alarm limits. When an alarm limit is reached or exceeded, the pulse rate value and the violated limit flashes. (may change)
㉕	89	**PULSE RATE**	The Pulse Rate Measurement Display shows the patient's pulse rate in beats per minute. The upper and lower pulse rate alarm limits are also displayed next to the pulse rate measurement. The pulse rate is calculated and the display is updated at a frequency of once per second.
㉖		**BRIGHTNESS LEVEL**	The Brightness level icon displays when utilizing the Backlight/Contrast button.
㉗	5	**PLETH VARIABILITY INDEX**	The Pleth Variability Index indicates numerically the percentage of variation in the pleth waveform as a result of a inhalation and exhalation cycle.

* For instruments that include SpMet and SpCO parameters: the SpMet and SpCO parameters will be grayed out in the display screen if a non-Rainbow sensor is being used.

NOTE: *The Pulse CO-Oximeter display view will be different without the SpMet and SpCO options.*

MAIN SCREEN TREND GRAPH DISPLAY

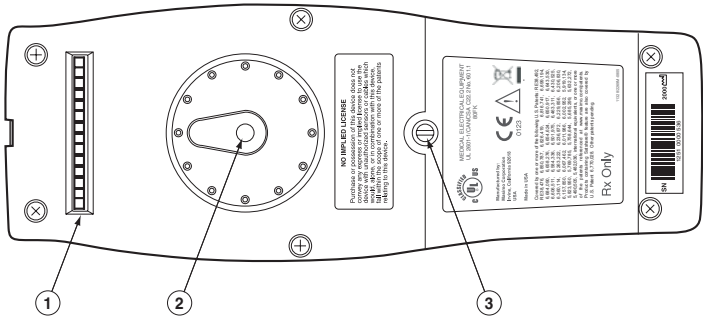
The Radical-7 Pulse CO-Oximeter provides a Trend Graph display function which allows the user to quickly check the trend of each parameter by allowing to step through and selecting the desired parameter. This is done by repeatedly pressing down on the Trend Graph control button. Once the parameter is selected, the numeric value is highlighted and the selected parameter is displayed above the trend graph.



1	The first top line of the trend graph display shows the time scale of the trend graph followed by the selected parameter. The parameter's numeric value is highlighted.
2	The second top line of trend graph display shows the minimum, maximum and average measurement of the selected parameter contained in the displayed data set (excluding zero measurements).
3	The Trend Graph control button initates the trend graph display. Repeatedly pressing down on the button will step through each parameter, highlighting the numeric value and displaying the parameter above the trend graph.
4	The lines on the trend graph indicate the minimum and maximum values of the parameter.
5	The trend graph shows the desired parameter measurements displayed versus time and the scale range

HANDHELD BACK PANEL

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



1		**DOCKING STATION CONNECTOR**	The Radical-7 Handheld interfaces with the Docking Station through this connector.
2		**POLE CLAMP ACCESSORY HOLDER**	The optional Pole Clamp accessory attaches to this holder. See the Directions for Use of the Pole Clamp accessories for attachment instructions.
3		**BATTERY PACK**	The Radical-7 Handheld is powered by a NiMH battery located in this compartment. For battery care and replacement please see Section 9, Replacing the Batteries.

Radical-7 Pulse CO-Oximeter Standalone

When the Radical-7 Pulse CO-Oximeter Handheld is placed into the Docking Station, the Radical-7 Pulse CO-Oximeter becomes a full-featured standalone device. The Radical-7 Pulse CO-Oximeter Standalone acts as a battery charger for the Handheld device and has AC power connection capabilities. If the mains supply is temporarily interrupted, then the battery in the Handheld device will allow continuous operation. The Standalone can also interface to serial devices, nurse call or analog output devices, and multiparameter patient monitors through a SatShare cable.

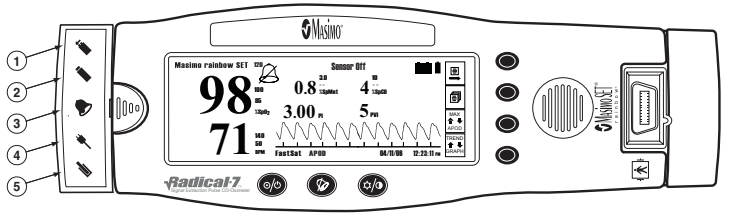
There are several models of Docking Stations available. The following table outlines which features are available for each model of Docking Station.

DOCKING STATION FEATURES	RDS-1	RDS-1B	RDS-2	RDS-3
AC Power Input	■	■	■	■
SatShare Interface	■	■		
Serial RS-232 Interface	■	■		■
Nurse Call/Analog Output Interface	■	■		■
10-hour Extended Battery		■		
Automatic Display Rotation Support (Gravity Detector)	■	■		■
Docking Station Battery Charging Indicator		■		
Handheld Battery Charging Indicator	■	■	■	■
Red Alarm Indicator	■	■		■
AC Power Indicator	■	■	■	■
Docking Indicator	■	■		■
Handheld Battery Deep Discharge Support	■	■		■
Docking Station Battery Deep Discharge Support	■	■		■

The RDS-1 and RDS-3 are optionally available with RadNet capability. (Refer to Section 3 *RadNet Setup* for details).

STANDALONE FRONT PANEL

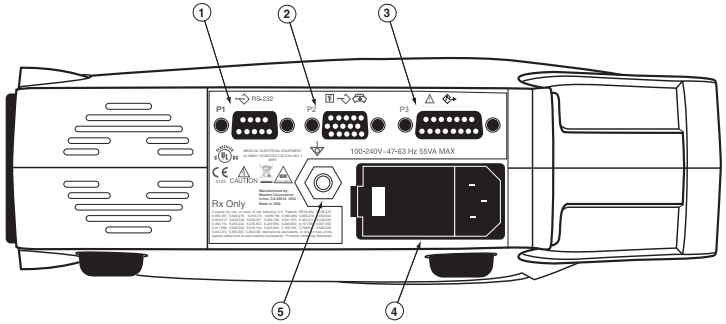
The following figure and corresponding text review the features of the Radical-7 Standalone device.



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**	The Docking Indicator is illuminated when the Handheld unit is turned on and is properly interfaced to a Docking Station.

NOTE: *When the Radical-7 Pulse CO-Oximeter Standalone is turned on, all indicator LEDs initially turn on and off at start up.*

STANDALONE BACK PANEL



1	**SERIAL OUTPUT CONNECTOR**	Use the Serial Output Connector with a ferrite bead installed to connect a serial device, including a serial printer, RadNet Interface Module or PC, to the Radical-7 Pulse CO-Oximeter. The data is provided in standard RS-232C format. See Section 7, *Serial Interface Specifications*. All external device connections to the Serial Output Connector must be IEC-60950 compliant.
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.
3	**SATSHARE CABLE CONNECTOR**	Use the SatShare Cable Connector to connect a SatShare cable to the SpO_2 input connector of a multiparameter 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 multiparameter 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. Refer to Section 10 - **Accessories** of this manual or the Masimo web site at www.masimo.com for the latest SatShare cables and validated instruments.
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 Pulse CO-Oximeter 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.*
5	**EQUIPOTENTIAL GROUND CONNECTOR**	Use the Equipotential Ground Connector for grounding.

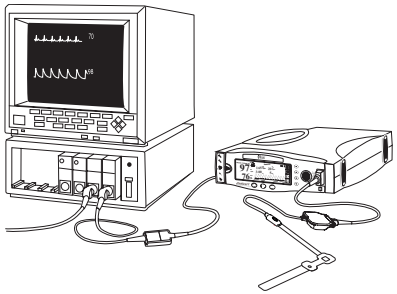
SYMBOLS

The following symbols are found on the Radical-7 Pulse CO-Oximeter Docking Station or packaging and are defined below:

NOTE: *Some of the interfaces and symbols are not available in all versions of the Docking Station.*

SYMBOLS	
RS-232	RS-232
	SatShare Interface
	Equipotential Ground Terminal
	Caution, consult accompanying documents
T1A 250V	Fuse Replacement
	Analog Out Interface
	Nurse Call Interface
	WEEE Compliant
	Defibrillation Proof (see front panel)
CE 0123	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 audiences only)
IPX1	Protection against liquid drops falling vertically.
	Year of manufacture
C UL US	Underwriter's Laboratories Inc. approved
5%-95% RH	Storage humidity range: 5% to 95%
+70 C -40 C +1060 hPa - +500 hPa 795 mmHg - 375 mmHg	Storage temperature range: +70˚C to -40˚C Storage altitude range: +1600hPa to +500hPa
	Keep dry
	Fragile/breakable, handle with care

Radical-7 Monitor Interface



In addition to being a full-featured Handheld and Standalone Pulse CO-Oximeter, the Radical-7 Pulse CO-Oximeter's unique SatShare interface links the Radical-7 Pulse CO-Oximeter to most existing multiparameter patient monitors through the pulse oximetry patient cable or SpO_2 input connector.

- 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 waveform, which is sent to the validated multiparameter patient monitor.
- Connects into the SpO_2 patient cable or SpO_2 input connector of the multiparameter patient monitor.

Refer to Section 3, *SatShare Setup* and Section 4, *SatShare Operation* for additional details.

CAUTIONS:

- THE WAVEFORM DISPLAYED ON THE MULTIPARAMETER PATIENT MONITOR IS A SIMULATED SIGNAL (NON-NORMALIZED). REFER TO THE RADICAL-7 PULSE CO-OXIMETER DISPLAY FOR PATIENT WAVEFORM.
- IF DISPLAYING THE SIMULATED WAVEFORM IS NOT DESIRABLE, IT IS RECOMMENDED TO TURN OFF THE PLETH WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR
- ONLY USE A SATSHARE CABLE THAT HAS A FERRITE BEAD INSTALLED.
- SpMet AND SpCO CANNOT BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH SATSHARE.

Introduction

Before the Radical-7 Pulse CO-Oximeter can be used in a clinical setting, it needs to be inspected, properly setup and the batteries need to be fully charged.

Unpacking and inspection

Remove the instrument from the shipping carton and examine it for signs of shipping damage. 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.

If anything is missing or damaged, contact the Technical Service Department. The contact address and phone numbers are listed in Section 9, *Service and Repair.*

Preparation for monitoring

The following sections of the manual describe the preparation, set-up and initial installation of the Radical-7 Pulse CO-Oximeter.

RADICAL-7 DOCKING STATION POWER REQUIREMENTS

Always use a hospital grade, AC power cable to connect the Radical-7 Pulse CO-Oximeter to an AC power source. Do not connect the Radical-7 Docking Station to an AC outlet controlled by a switch because the power to the instrument may be inadvertently be switched off.

Verify the AC power voltage and line frequency before use. Verify that the power source can provide adequate power rating as indicated on the rear panel of the Radical-7 Docking Station.

The Radical-7 Pulse CO-Oximeter is designed to operate on 100 to 240VAC, 47-63 Hz. The device is rated at 55 VA max.

Connect a hospital grade power cable to the power entry module of the Radical-7 unit (IEC-320 connector type at the unit). Connect the power cable to an AC power source. Ensure that the unit is adequately powered by verifying that the AC power indicator on the Docking Station is illuminated.

CAUTION:

- DO NOT UNDER ANY CIRCUMSTANCES REMOVE THE GROUNDING CONDUCTOR FROM THE POWER PLUG.
- DO NOT USE EXTENSION CORDS OR ADAPTERS OF ANY TYPE. THE POWER CORD AND PLUG MUST BE INTACT AND UNDAMAGED.
- USE THE POWER CORD AS THE MEANS TO DISCONNECT THE DEVICE FROM THE MAINS POWER SUPPLY.
- IF THERE IS ANY DOUBT ABOUT THE INTEGRITY OF THE PROTECTIVE EARTH CONDUCTOR ARRANGEMENT, OPERATE THE OXIMETER ON INTERNAL BATTERY POWER UNTIL THE AC POWER SUPPLY PROTECTIVE CONDUCTOR IS FULLY FUNCTIONAL.
- TO ENSURE PATIENT ELECTRICAL ISOLATION, CONNECT ONLY TO OTHER EQUIPMENT WITH ELECTRICALLY ISOLATED CIRCUITS.
- DO NOT CONNECT TO AN ELECTRICAL OUTLET CONTROLLED BY A WALL SWITCH OR DIMMER.

INITIAL BATTERY CHARGING

Before use, the Radical-7 Pulse CO-Oximeter Handheld battery and the optional Docking Station battery needs to be fully charged.

To charge the batteries:

1. Attach the Handheld unit 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 LED indicators on the Docking Station flash prior to charging and remain illuminated while the batteries are charging.

Refer to Section 9, *Battery Operation and Maintenance*, for proper battery charging.

INITIAL INSTALLATION

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

The Radical-7 Pulse CO-Oximeter Handheld, Docking Station or Standalone should not be operated outside the following environmental conditions:

OPERATING ENVIRONMENTAL CONDITIONS	
TEMPERATURE	+5°C to +40°C, +41°F to +104°F
HUMIDITY	5% to 95%, non-condensing
OPERATING ALTITUDE	1060 mbar to 500 mbar pressure -1000 ft to 18,000 ft (-304 m to 5,486 m)

Configure the unit for your regional power line frequency (50 or 60 hz) if needed. Default is 60 hz (standard for the United States). See Section 4, *Operation, Config.*

CAUTION: THE UNIT MUST BE CONFIGURED TO MATCH YOUR LOCAL POWER LINE FREQUENCY TO ALLOW FOR THE CANCELLATION OF NOISE INTRODUCED BY FLUORESCENT LIGHTS AND OTHER SOURCES.

Monitor Setup

The Radical-7 Pulse CO-Oximeter maintains three types of default values which will automatically revert to after a power cycle:

- Factory – these options are restored to factory set values
- Custom – these settings can be changed by the user and retained through the power cycle.
- Adult / Neo – these settings can be selected to revert to factory or hospital-defined values (for Adult or Neonatal) after a power cycle.

FACTORY SET DEFAULTS

The following outlines the Radical-7 Pulse CO-Oximeter option settings that can be changed by the user but will revert back to after a power cycle.

OPTION	DEFAULT SETTING
LCD SCREEN ILLUMINATION	
AC Power	Set to maximum, level 4
Battery Power	Set to minimum, level 1
SENSITIVITY	Set to APOD mode

CUSTOM (USER) DEFINED SETTINGS

This mode is indicated by "Mode Custom" on the Alarms menu.

The following table outlines the options that may be changed by the user and the Radical-7 Pulse CO-Oximeter will remember after a power cycle. The default settings listed below are those set at the factory and will revert back to if the user chooses to recall the factory settings. (see Section 4, *Display*).

OPTION	FACTORY DEFAULT SETTING	CONFIGURABLE SETTING
DISPLAY VIEW	Set to Pleth + SigIQ	Pleth + SigIQ, Pleth Only, Numbers
CONTRAST	Set to 32	0 to 63
AVERAGING TIME	Set to 8	2, 4, 8, 10, 12, 14, or 16 seconds
FASTSAT	Set to No	Yes/No
HOME USE	Set to No	Yes/No
INTERFACE ALARMS	Set to Yes	Yes/No
SATSHARE NUMBERS	Set to Yes	Yes/No
POWER SAVE	Set to No	Yes/No
DATE FORMAT	Set to mm/dd/yy	mm/dd/yy and dd/mm/yy
TIME FORMAT	Set to 12 hr.	12 and 24 hour
LANGUAGE	Set to English	See Section 4, *Display* for all settings
ANALOG OUTPUT	Set to Analog 1: SpO_2 0-100% Set to Analog 2: Pulse Rate	See Section 4, *Display* for all settings
SERIAL OUTPUT PORT MODE	Set to Binary	ASCII 1, ASCII 2, Binary, Philips Vuelink, Spacelabs Flexport
ALARM VOLUME	Set to Level 3	Level 1 to 4

OPTION	FACTORY DEFAULT SETTING	CONFIGURABLE SETTING
PULSE BEEP VOLUME	Set to Level 4	Level 1 to 7
TREND DISPLAY PARAMETERS	Set to %SpO_2 + BPM	See Section 4, *Display* for all settings.
TREND PERIOD	Set to 1 Hr.	See Section 4, *Trend Setup* for all settings.
LOW SpO_2 ALARM LIMIT	Set to 0	(Refer Section 4, *Display* for details on this user adjustable feature)
SpMet HIGH/LOW ALARM LIMIT	Set to High: 3.0/Low: ---	See Section 4, *Alarms* for all settings.
SpCO HIGH/LOW ALARM LIMIT	Set to High: 10/Low: ---	
SMART TONE	Set to No	Yes/No

ADULT/NEO (HOSPITAL DEFINED) SETTINGS

The following table outlines settings that may be defined by the hospital. If enabled (via a password protected screen, see Section 4 *Password Operation*), these settings will return to pre defined values after a power cycle. This mode is indicated by "Mode Adult" or "Mode Neo" on the Alarms menu. See Section 4, **Operation** for details on enabling and setting these parameters.

OPTION	CUSTOM SETTING	ADULT / NEO SETTING (PRE DEFINED)
SpO_2 HIGH/LOW ALARM LIMIT	Set to High: ---/Low: 90	Same settings
PULSE RATE HIGH/LOW ALARM LIMIT	Set to High: 140/Low: 50 BPM	
SpMet HIGH/LOW ALARM LIMIT	Set to High: 3.0/Low: ---	
SpCO HIGH/LOW ALARM LIMIT	Set to High: 10/Low: ---	
ALARM SILENCE	Set to 120 seconds	
ALARM VOLUME	Set to 3	
ALARM DELAY	Set to 5	

Satshare Setup

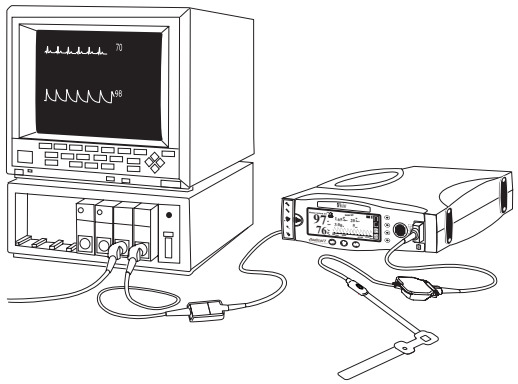
The Radical-7 Pulse CO-Oximeter has been proven to be accurate during patient motion and low perfusion conditions. Saturation and pulse rate values from the Radical-7 Pulse CO-Oximeter may be displayed on a multiparameter monitor through the SatShare feature.

The SatShare feature provides an ideal, simulated waveform corresponding to the measured saturation and pulse rate values determined by the Masimo SET technology. This waveform may be used to display these values on multiparameter monitors through the multiparameter monitor's oximetry sensor or input connector.

It is recommended that the Radical-7 Pulse CO-Oximeter is positioned close to the multiparameter monitor with the Radical-7 Pulse CO-Oximeter screen visibly displaying the plethysmographic waveform and the saturation and pulse rate measurements.

CAUTION: SIMULTANEOUS USE OF SATHSARE AND SERIAL PORT IS NOT SUPPORTED.

SATSHARE SETUP



1. Select the SatShare cable that is appropriate for the multiparameter monitor that is being connected. Check the Masimo web site at **www.masimo.com** for the latest list of available SatShare cables and validated instruments.
2. Connect the labeled end of the cable to the SatShare Cable Connector port on the back of the Docking Station. Tighten the connector screws for a secure connection.
3. Connect the other end of the SatShare cable either to the sensor connector of the multiparameter monitor's SpO_2 cable or directly to the SpO_2 connector on the monitor.
4. Verify that the Radical-7 Pulse CO-Oximeter recognizes the correct cable. The name of the SatShare cable will be displayed on the LCD screen when the SatShare mode is functional.
5. Set the multiparameter monitor's high and low saturation and pulse rate alarm limits as appropriate.
6. Set the multiparameter monitor's averaging time to the lowest setting (i.e. fastest

response). The Radical-7 Pulse CO-Oximeter's ideal waveform necessitates the need for additional averaging by the monitor. If the multiparameter monitor's averaging time is not changed, the time to display physiological changes in saturation on the monitor will be increased with SatShare. However, the delay can be minimized by reducing the multiparameter monitor's averaging time.

7. While in the SatShare mode, if there are any significant discrepancies between the readings from the Radical-7 Pulse CO-Oximeter and those on the monitor displaying the values obtained from SatShare, the values reported by the Radical-7 Pulse CO-Oximeter are to be considered the correct values.
8. To use the Radical-7 Pulse CO-Oximeter with SatShare while it is not connected to AC power, set the Power Save parameter in the General menu to "No" and refer to Section 4, **Operation**. Please note that if the Radical-7 Pulse CO-Oximeter is used in this mode, the length of time the Radical-7 Pulse CO-Oximeter can operate on battery power will be significantly diminished.
9. Set the SatShare Numbers and the Interface Alarms parameters in the General menu according to Customer preference. The Interface Alarms cannot be disabled if the SpCO and/or SpMet parameters are present in the Radical-7.
10. If displaying the simulated waveform is not desirable, it is recommended to turn off the pleth waveform display of the multiparameter patient monitor.

- SATSHARE SIGNALS ARE IDEAL SIMULATED WAVEFORMS CORRESPONDING TO THE CALCULATED SATURATION AND PULSE RATE VALUES AND DO NOT CONTAIN ALL OF THE INFORMATION CONTAINED IN PHYSIOLOGICAL WAVEFORMS. THE MULTIPARAMETER PATIENT MONITOR DECODES THESE SIGNALS INTO SATURATION AND PULSE RATE VALUES.
- DURING SATSHARE OPERATION, THE AUDIBLE ALARMS MAY BE MUTED ON THE RADICAL-7 PULSE CO-OXIMETER. WHEN THE AUDIBLE ALARM IS MUTED (INDICATED BY THE BELL WITH A SLASH THROUGH IT) ON THE RADICAL-7 PULSE CO-OXIMETER, USE THE MULTIPARAMETER MONITOR FOR AUDIBLE ALARM INDICATION.
- THE AUDIBLE ALARMS CANNOT BE MUTED IF THE SpCO AND/OR SpMet PARAMETERS ARE PRESENT IN THE RADICAL-7.
- DURING SATSHARE OPERATION DO NOT USE THE PLETH WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR FOR DIAGNOSTIC PURPOSES. INSTEAD, USE THE PLETH WAVEFORM DISPLAYED ON THE RADICAL-7 PULSE CO-OXIMETER SCREEN.
- TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SATSHARE CONNECTOR UNLESS THE RADICAL-7 PULSE CO-OXIMETER IS CONNECTED TO THE AC MAINS POWER SUPPLY.
- ONLY USE A SATSHARE CABLE THAT HAS A FERRITE BEAD INSTALLED.
- SpMet AND SpCO CANNOT BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH SATSHARE.

WARNING: EXTERNAL DEVICE CONNECTIONS TO THE SATSHARE PORT MUST BE IEC-60601-1-1 COMPLIANT.

Philips VueLink Setup

CAUTIONS:

- AFTER CONNECTING THE VUELINK CABLE TO THE SERIAL PORT, SATSHARE MONITORING WILL NOT BE SUPPORTED.
- A RADICAL DOCKING STATION THAT IS VUELINK COMPATIBLE MUST BE UTILIZED.
- SpMet AND SpCO CANNOT BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH VUELINK.

1. Select the Philips VueLink selection from the Output menu on the Radical-7 Pulse CO-Oximeter. Refer to Section 4, *Output*.
2. Connect one end of the VueLink cable to the Serial Output connector on the back of the Docking Station.
3. Connect the other end of the VueLink cable to the VueLink module and insert the module into the Philips monitor rack.
4. The SpO_2 and pulse rate values will automatically appear on the Philips monitor.
5. In order for the pleth waveform to be displayed on the Philips monitor and for the Philips monitor to indicate the alarm conditions measured by the Pulse CO-Oximeter, the user must configure the Philips monitor. Refer to the Philips Operator's Manual for complete instructions.
6. The Radical-7 can be set up to audibly indicate all patient alarms while communicating with the Philips VueLink module. Use the Interface Alarms setting in the General menu to enable and disable audible alarms on the Radical-7.

Spacelabs Universal Flexport Setup

CAUTIONS:

- AFTER CONNECTING THE SPACELABS FLEXPORT CABLE TO THE SERIAL PORT, SATSHARE MONITORING WILL NOT BE SUPPORTED.
- SpMet AND SpCO CANNOT BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH FLEXPORT.

1. Select the Spacelabs Flexport selection from the Output menu on the Radical-7.
2. Connect one end of the Spacelabs Flexport cable to the Serial Output connector on the back of the Docking Station.
3. Connect the other end of the Spacelabs Flexport cable to the Spacelabs Universal Flexport connector.
4. The SpO_2 and pulse rate values will automatically appear on the Spacelabs screen.
5. In order for the pleth waveform to be displayed on the Spacelabs screen and for the Spacelabs monitor to indicate the alarm conditions measured by the Pulse CO-Oximeter, the user must configure the Spacelabs monitor. Refer to the Spacelabs monitor Operator's Manual for complete instructions.
6. The Radical-7 Pulse CO-Oximeter can be set up to audibly indicate all patient alarms while communicating with the Spacelabs Flexport module. Use the Interface Alarms setting in the General menu to enable and disable audible alarms on the Radical-7 Pulse CO-Oximeter.

RadNet Setup

CAUTIONS:

- AFTER CONNECTING THE SERIAL CABLE TO THE SERIAL PORT, SATSHARE MONITORING WILL NOT BE SUPPORTED.
- SpMet AND SpCO CANNOT BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH RADNET.

NOTE: *Confirm that the Radical Docking Station is RadNet Ready before preceeding. This is done by pressing the* ***Menu*** *button then selecting* ***Output****. Confirm that the "D-Station" software is version R4.5.0.1 or higher.*

1. Select the ASCII 2 selection from the Serial options on the Output Menu on the Radical-7 Pulse CO-Oximeter.
2. Connect one end of the serial cable to the Serial Output connector on the back of the Docking Station.
3. Connect the other end of the serial cable to the RadNet Interface Module connector.
4. Turn the RadNet Interface Module on.
5. With a properly configured RadNet Interface Module, the Radical-7 will automatically display the pleth and SIQ waveforms as well as the SpO_2 and Pulse Rate parameters on the screen at the RadNet Central Station.
6. The Radical-7 Pulse CO-Oximeter can be set up to audibly indicate all patient alarms while communicating with the RadNet Interface module. Use the Interface Alarms setting in the General menu to enable and disable audible alarms on the Radical-7 Pulse CO-Oximeter.

CAUTION: ENSURE THAT THE RADICAL-7 PULSE CO-OXIMETER HANDHELD REMAINS IN THE RADNET READY DOCKING STATION WHEN CONNECTED TO THE RADNET CENTRAL MONITORING SYSTEM. REMOVING THE RADICAL-7 PULSE CO-OXIMETER HANDHELD FROM THE RADNET READY DOCKING STATION WILL CAUSE LOSS OF COMMUNICATION TO THE RADNET CENTRAL MONITORING STATION.

CAUTION: WHEN THE RADICAL-7 IS PLACED IN **ALL MUTE**, THE PATIENT ALARMS WILL NOT AUDIBLY SOUND ON THE RADICAL-7 OR THE RADNET CENTRAL STATION. THE RADNET CENTRAL STATION WILL DISPLAY A VISUAL ALARM.

Introduction

To operate the Radical-7 Pulse CO-Oximeter effectively, the device must be set up properly and the operator must:

- Know how the Pulse CO-Oximeter derives its readings (see Section 1, *Pulse CO-Oximetry*).
- Be familiar with its controls, components and operation.
- Understand its status and alarm messages (see Section 5, **Alarm and Messages** and Section 6, **Troubleshooting**).

Basic operation

GENERAL SETUP AND USE

1. Inspect the Pulse CO-Oximeter case for damage.
2. Connect a patient cable or a direct connect sensor to the Patient Cable Connector of the Radical-7 Pulse CO-Oximeter. Make sure it is a firm connection and the cable is not twisted, sliced or frayed.
3. If utilizing the Standalone setup, ensure that the power cord is plugged into the Power Cable Connector of the Docking Station and into the AC power.
4. If utilizing a patient cable, select a sensor that is compatible with the oximeter and the patient before connecting it to the patient cable. See section 8, **Sensors and Patient Cables**. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the photodetector are properly aligned. Remove any substances that may interfere with the transmission of light between the sensor's light source and photodetector.
5. Refer to the Directions for Use of the sensor before attaching the sensor to the patient.
6. With a single patient adhesive or disposable sensor, connect the sensor to the patient cable with the logos lining up; make sure it is a firm connection.
7. Press the Power/Standby button to turn the Pulse CO-Oximeter on.
8. Make sure the display window is free of alarm and system failure messages (see Section 5, *Alarm Identification*).
9. On the display, verify:
   - The high and low alarm limits for SpO_2, SpMet*, SpCO* and pulse rate.
   - The readings for SpO_2, SpMet*, SpCO*, pulse rate, perfusion index and PVI.

NOTE: *"- - - " will remain lit on the numeric display until the SpO_2, SpMet*, SpCO*, pulse rate and PI readings have stabilized (less than 15 seconds for SpO_2 and up to 25 seconds for SpMet* and SpCO*).*

* If these parameters are installed in the unit.

10. Verify that the patient alarms are functional by setting the high and low SpO_2, SpMet, SpCO and pulse rate alarm limits beyond the patient readings.
    - An alarm tone sounds.
    - The violated alarm limit and reading flash on the display.
    - The red alarm indicator flashes on the Docking Station (standalone operation).
11. Verify the sensor alarms are functional by removing the sensor from the sensor site.
    - **SENSOR OFF** appears in the message area of the graphic display.
    - The alarm tone sounds.
    - The alarm indicator flashes.
    - Disconnect the sensor from the patient cable or oximeter.
    - Confirm that **SENSOR OFF** appears in the message area of the graphic display.
12. Verify alarm silence operation.
    - Create an alarm condition by lowering the SpO_2 or pulse rate high alarm limits beyond the patient readings.
    - Press the Alarm Silence button.
    - The alarm tone ceases for the displayed amount of time.
    - Perform the above steps for the SpMet and SpCO alarm limits.
13. To begin patient monitoring:
    - Adjust the alarm limits.
    - Adjust the alarm volumes.
    - Adjust the pulse beep volume.
14. Verify the sensor is on correctly and that the measured data is appropriate, see Section 4, *Successful Monitoring*.
15. Monitor the patient .
16. After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to governing rules. See the sensor's Directions for Use.
17. Press and hold the Power/Standby Button for 2 seconds to turn the oximeter off.

Successful Monitoring

The following general points will aid in ensuring Pulse CO-Oximetry monitoring success.

- Place the sensor on a site that has sufficient perfusion and provides proper alignment of the LED's and photodetector.
- Place the sensor on a site that has unrestricted blood flow.
- Do not secure a sensor with tape.
- Do not select a site near potential electrical interference (electrosurgical unit, for example).
- Read the sensor Directions for Use for proper sensor application.

MASIMO SENSORS

Before use, carefully read the Masimo sensor Directions for Use.

Use only Masimo sensors for oximetry measurements.

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor Directions for Use to ensure skin integrity and correct positioning and adhesion of the sensor.

CAUTIONS

- DO NOT USE DAMAGED SENSORS. DO NOT USE A SENSOR WITH EXPOSED OPTICAL OR ELECTRICAL COMPONENTS. DO NOT IMMERSE THE SENSOR IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE SENSORS AND CONNECTORS ARE NOT WATERPROOF). DO NOT STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE UNLESS OTHERWISE INDICATED IN THE SENSOR DIRECTIONS FOR USE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR ALL MASIMO REUSABLE SENSORS.
- DO NOT USE DAMAGED PATIENT CABLES. DO NOT IMMERSE THE PATIENT CABLES IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE PATIENT CABLE CONNECTORS ARE NOT WATERPROOF). DO NOT STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE.
- DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE MASIMO SENSORS OR PATIENT CABLES AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.

NUMERIC DISPLAY - SpO_2

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.

NUMERIC DISPLAY - PULSE RATE

The Pulse Rate displayed on the Radical-7 Pulse CO-Oximeter may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor or patient

cable. The pulsations from intra-aortic balloon support can cause the pulse rate displayed on the Pulse CO-Oximeter to be significantly different than the ECG heart rate.

NUMERIC DISPLAY - 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.

Inaccurate measurements may be caused by:

- Significant levels of methemoglobin.
- Intravascular dyes such as indocyanine green or methylene blue.
- Abnormal hemoglobin levels.
- Abnormally low arterial perfusion.

NUMERIC DISPLAY - 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.

Inaccurate measurements may be caused by:

- Intravascular dyes such as indocyanine green or methylene blue.
- Abnormal arterial perfusion

NUMERIC DISPLAY - PI

The Perfusion Index (PI) display provides a relative numeric indication of the pulse strength at the monitoring site. It is a calculated percentage between the pulsatile signal and non-pulsatile signal of arterial blood moving through the site. PI may be used to find the best perfused site and to monitor physiological changes in the patient. It displays an operating range of 0.02 percent to 20.00 percent. A percentage greater than 1.00 percent is desired. Extreme changes in the display number are due to changes in physiology and blood flow.

SIGNAL IQ

The Radical-7 Pulse CO-Oximeter display provides a visual indicator of the plethysmogram signal quality and an alert when the displayed SpO_2 values are not based on adequate signal quality. The signal quality indicator displayed on the Radical-7 Pulse CO-Oximeter is called the Signal IQ. The Signal IQ can be used to identify the occurrence of a patient's pulse and the associated signal quality of the measurement.

With motion, the plethysmographic waveform is often distorted and may be obscured by artifact. The Signal IQ, shown as a vertical line, coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Radical-7 Pulse CO-Oximeter locates the arterial pulsation. The pulse tone (when enabled) coincides with the vertical line of the Signal IQ.

The height of the vertical line of the Signal IQ indicates the quality of the measured signal. A high vertical bar indicates that the SpO_2 measurement is based on a good quality signal. A small vertical bar indicates that the SpO_2 measurement is based on data with low signal quality. When the signal quality is very low the accuracy of the SpO_2 measurement may be compromised, and a Low Signal IQ message is displayed in the message area on the

Radical-7 Pulse CO-Oximeter display. When the Low Signal IQ message appears 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. Also, misalignment of the sensor's emitter and detector can result in smaller signals.
- 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 a spell 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 Low Signal IQ message is displayed frequently or continuously obtaining an arterial blood specimen for CO-Oximetry analysis may be considered to verify the oxygen saturation value.

LOW PERFUSION

The Radical-7 Pulse CO-Oximeter displays a "Low Perfusion" message when there are very low amplitude arterial pulsations.

It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation[1]. 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.)

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.

[1] Severinghaus JW, Spellman MJ. Pulse Oximeter Failure Thresholds in Hypotension and Vasoconstriction. Anesthesiology 1990; 73:532-537

ACTIONS TO BE TAKEN

If the SpO_2 readings show significant differences, do the following:

- Make sure the emitter and photodetector are aligned directly opposite each other.
- Select a site where the distance between the emitter and photodetector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) for 20-30 seconds to increase perfusion. However, strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electrosurgical units or other electrical/electronic equipment. If these solutions are not possible, operate the Pulse CO-Oximeter on battery power, or try plugging the Pulse CO-Oximeter into a different electrical outlet.

- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- If possible, ensure that the sensor is placed in a location with low ambient light. Although the Radical-7 with integrated Masimo Rainbow SET technology has significant immunity to ambient light, excessive ambient light may cause readings to be incorrect.

CAUTION: IF ANY MEASUREMENT SEEMS QUESTIONABLE, FIRST CHECK THE PATIENT'S VITAL SIGNS BY ALTERNATE MEANS AND THEN CHECK THE PULSE CO-OXIMETER FOR PROPER FUNCTIONING.

SENSITIVITY

The Radical-7 Pulse CO-Oximeter is equipped with 3 different sensitivity modes. Each mode allows the clinician to change the sensitivity settings of the device to meet the increased demands of the patient's physiological condition or enable it to work during periods of low perfusion and/or motion. They are as follows:

- **Normal Sensitivity** – This is the recommended mode for patients that are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as ICU's.
- **Adaptive Probe Off Detection (APOD)** – This is the recommended start-up monitoring mode for most patients with acceptable perfusion or where a more robust sensor off detection is desired. It is 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.
- **Maximum Sensitivity (MAX)** - This mode is recommended for patients with low perfusion or when the low perfusion or low signal quality message is displayed on the screen in APOD or normal sensitivity mode. This 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.

CAUTION: WHEN USING THE MAXIMUM SENSITIVITY SETTING, THE PERFORMANCE OF THE SENSOR OFF DETECTION MAY BE COMPROMISED. IF THE UNIT 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.

Touch Key Control Button and Icons

The touch key control buttons are the four dark grey control buttons to the right of the Handheld display. To select a touch key icon, press and release the dark gray control button to the right of the icon.

On the Radical-7 Pulse CO-Oximeter display, four icons are shown on the right side or bottom of the LCD display.

Traditional User Interface

FIRST PAGE

	**NEXT MENU PAGE**	Press the Next Menu Page button to access the second page of selections. Press and hold the button for 8 seconds to toggle between Traditional User Interface and the Simplified User Interface. Enter password when prompted. The Radical-7 will retain this setting after a power cycle.
	**MENU ACCESS**	Press the Menu Access button to enter the main menu.
	**SENSITIVITY**	Press the Sensitivity button to toggle between the Normal, APOD and Maximum Sensitivity modes. Use the Normal Sensitivity setting for typical monitoring purposes. Use the APOD setting where there is a high probability of the sensor becoming detached. Use the Maximum Sensitivity setting for patients with low perfusion or when the low perfusion message is displayed on the screen in APOD or normal sensitivity mode. The default is APOD. **CAUTION:** WHEN USING THE MAXIMUM SENSITIVITY SETTING, THE PERFORMANCE OF THE SENSOR OFF DETECTION MAY BE COMPROMISED. ***NOTE:*** *In "Custom" mode the unit will remain in Normal or APOD setting after a power cycle. Maximum Sensitivity will automatically reset to Normal Sensitivity after a power cycle.* In "Neo" or "Adult" mode the unit will reset the sensitivity to the hospital specified setting (Normal or APOD) after a power cycle.
	**TREND GRAPH**	Press the Trend Toggle button to alternate between SpO_2, BPM, SpMet, SpCO, PI and PVI Quick Trend displays.

SECOND PAGE

	**NEXT MENU PAGE**	Press the Next Menu Page button to access the first page of selections. Press and hold the button for 8 seconds to toggle between Traditional User Interface and the Simplified User Interface. Enter password when prompted. The Radical-7 will retain this setting after a power cycle.
	**TREND DISPLAY**	Press the Trend Display button to show the trend data on the display.
	**INCREASE LOUDNESS**	Press the Increase Loudness button to increase the volume of the pulse beep. Seven levels of volume exist
	**DECREASE LOUDNESS**	Press the Decrease Loudness button to decrease the volume of the pulse beep.

Simplified User Interface

By enabling the Simplified User Interface, users are exposed to only the most common oximeter features, while the all the remaining settings remain available behind password protection.

FIRST PAGE

	**NEXT MENU PAGE**	Press the Next Menu Page button to access the second page of selections. Press and hold the button for 8 seconds to toggle between Traditional User Interface and the Simplified User Interface. Enter password when prompted. The Radical-7 will retain this setting after a power cycle.
	**ALARM MENU**	Press the Alarm Menu Access button to enter the alarm settings menu.
 MAX APOD	**SENSITIVITY**	Press the Sensitivity button to toggle between the Normal, APOD and Maximum Sensitivity modes. Use the Normal Sensitivity setting for typical monitoring purposes. Use the APOD setting where there is a high probability of the sensor becoming detached. Use the Maximum Sensitivity setting for patients with low perfusion or when the low perfusion message is displayed on the screen in APOD or normal sensitivity mode. The default is APOD. **CAUTION:** WHEN USING THE MAXIMUM SENSITIVITY SETTING, THE PERFORMANCE OF THE SENSOR OFF DETECTION MAY BE COMPROMISED. ***NOTE:*** *In "Custom" mode the unit will remain in Normal or APOD setting after a power cycle. Maximum Sensitivity will automatically reset to Normal Sensitivity after a power cycle.* In "Neo" or "Adult" mode the unit will reset the sensitivity to the hospital specified setting (Normal or APOD) after a power cycle.
 TREND GRAPH	**TREND GRAPH**	Press the Trend Toggle button to alternate between SpO_2, BPM, SpMet, SpCO, PI and PVI Quick Trend displays

SECOND PAGE

	**NEXT MENU PAGE**	Press the Next Menu Page button to access the first page of selections. Press and hold the button for 8 seconds to toggle between Traditional User Interface and the Simplified User Interface. Enter password when prompted. The Radical-7 will retain this setting after a power cycle.
	**ALARM MENU**	Press the Alarm Menu Access button to enter the alarm settings menu.
	**INCREASE LOUDNESS**	Press the Increase Loudness button to increase the volume of the pulse beep. Seven levels of volume exist
	**DECREASE LOUDNESS**	Press the Decrease Loudness button to decrease the volume of the pulse beep.

Navigating the Main Menu

When the main menu is accessed, the plethysmograph and Signal IQ waveform displays are replaced with the main menu items. The touch key icons, displayed along the right edge of the LCD display, are also replaced by the menu access icons. When the main menu is accessed the monitor remains functional and the saturation and pulse rate numbers will continue to be displayed.

MAIN MENU SELECTION

The top menu category uses the following four menu selections and touch key control buttons and icons.

	**EXIT**	Select the Exit icon to exit the main menu.
	**SELECT CATEGORY**	Select the Select Category icon to select the highlighted menu item and enter the next level menu.
	**PREVIOUS**	Select the Previous icon to scroll through the menu items without selecting them. Once a menu item is highlighted, enter the menu by pressing the Select Category icon.
	**NEXT**	Select the Next icon to scroll through the parameters. Once a parameter is highlighted, edit the parameter by pressing the Edit Parameter icon.

MENU CATEGORIES

Once a menu category has been selected, a new set of menu selections and icons are displayed.

	**EXIT**	Select the Exit icon to exit the menu category and return to the previous menu.
	**EDIT PARAMETER**	Select the Edit Parameter icon to select the highlighted parameter for editing.
	**PREVIOUS**	Select the Previous icon to scroll through the parameters. Once a parameter is highlighted, edit the parameter by pressing the Edit Parameter icon.
	**NEXT**	Select the Next icon to scroll through the parameters. Once a parameter is highlighted, edit the parameter by pressing the Edit Parameter icon.

EDITING A PARAMETER

Once a parameter has been selected for editing, a new set of menu selections and icons are displayed.

	**EXIT**	Select the Exit icon to exit the parameter without making the new selections permanent.
	**ACCEPT**	Select the Accept icon to save the changes
	**PREVIOUS**	Select the Previous icon to increase or toggle the parameter settings.
	**NEXT**	Select the Next icon to decrease or toggle the parameter settings.

MENU TREE

ALARMS	SpO_2 High/Low limit
	Pulse Rate High/Low limit (bpm)
	SpMet High/Low limit
	SpCO High/Low limit
	Silence
	Volume
	Delay (volume delay)
	Mode

ROTATE SCREEN	Landscape 1
	Vertical 1
	Landscape 2
	Vertical 2

DISPLAY	View
	Trend
	Contrast
	Language
	Vertical Layout
	Default

GENERAL	Averaging Time
	FastSat
	Home Use
	Interface Alarms
	SatShare Numbers
	Power Save
	SmartTone

CLOCK	Time (hour/minute/seconds)
	Time display format
	Day
	Month
	Year
	Format (mm/dd/yy)
	Display Clock

ABOUT	Software Version

CONFIG	Enter password to change line frequency. (refer to Section 4 *Password Operation*)
	Enter password to change Rapid Desat Limit (refer to Section 4 *Password Operation*)

OUTPUT	Serial
	Analog 1
	Analog 2
	Nurse Call
	Polarity

SERVICE	Handheld Battery Deep Discharge
	DS Battery Deep Discharge

3D ALARM SYSTEM (OPTIONAL)	Desat Index
	PI Delta

Alarms

Check alarm limits each time the Pulse CO-Oximeter is used to ensure that they are appropriate for the patient being monitored. An audible alarm and a flashing alarm icon (and indicator light) will occur when an alarm limit is exceeded. It is best that the operator be within a minimum of 10 feet from the unit.

MENU ITEMS	DESCRIPTION
SpO_2 HIGH LIMIT	The SpO_2 high alarm limit can be set anywhere between 2% and 99%, with a 1% step size. In the "----" (off) setting, the alarm can be turned off completely.
SpO_2 LOW LIMIT	The SpO_2 low alarm limit can be set anywhere between 1% and 99%, with a 1% step size. ***NOTE:*** *The low alarm limit always has to be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.* ***NOTE:*** *The SpO_2 low limit can not be set below the password protected minimum low SpO_2 alarm limit. See Section 4, Operation, Display for details.*
PULSE RATE HIGH LIMIT (BPM)	The pulse rate high alarm limit can be set anywhere between 30 BPM and 240 BPM, with a 5 BPM step size.
PULSE RATE LOW LIMIT (BPM)	The pulse rate low alarm limit can be set anywhere between 25 BPM and 235 BPM, with a 5 BPM step size. ***NOTE:*** *The low alarm limit always has to be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.*
SpMet HIGH LIMIT	The SpMet high alarm limit can be set anywhere between 1% to 100%. Between 1% and 2%, the step increment is 0.1%. Between 2% and 100%, the step increment is 0.5%.
SpMet LOW LIMIT	The SpMet low alarm limit can be set anywhere between 0.1% to 99.5%. Between 0.1% and 2%, the step increment is 0.1%. Between 2% and 99.5%, the step increment is 0.5%. In the "----" (off) setting, the alarm can be turned off completely. ***NOTE:*** *The low alarm limit must always be below the high alarm limit. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit.*
SpCO HIGH LIMIT	The SpCO high alarm limit can be set anywhere between 1% and 100%, with a 1% step size.
SpCO LOW LIMIT	The SpCO low alarm limit can be set anywhere between 1% and 99%, with a 1% step size. In the "----" (off) setting, the alarm can be turned off completely. ***NOTE:*** *The low alarm limit must always be below the high alarm limit. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit.*

Alarms continued

MENU ITEMS	DESCRIPTION
SILENCE	This menu allows the user to set the alarm silence period. An alarm is silenced by pressing the Alarm Silence button on the front panel. **30, 60, 90,120 SECONDS** The alarm silence can be set for these durations. As an indicator that the alarm system is silenced, the Alarm Status Indicator is shown as a bell with a slash through it. A timer is shown next to the bell indicating the remaining alarm silence duration. ***NOTE:*** *The alarm silence period is reset to 120 seconds (or 90 seconds in neonatal mode) upon power cycle, except for when the Radical-7 is set to operate in the Home mode.* **ALL MUTE** All patient alarm conditions are silenced. Only system alarms will be indicated by an audible alarm. As an indicator that the system is set to All Mute, the Alarm Status Indicator is shown as a bell with a slash through it. **ALL MUTE WITH AUDIBLE REMINDER** All patient alarm conditions are silenced. Only system alarms will be indicated by an audible alarm. As a reminder, a single audible alarm will occur every three minutes. As an indicator that the system is set to All Mute the Alarm Status Indicator is shown as a bell with a slash through it.

WARNING: IF AN ALARM CONDITION OCCURS WHILE THE ALARM SILENCE PERIOD IS SET TO ALL MUTE, THE ONLY ALARM INDICATIONS WILL BE VISUAL DISPLAYS AND SYMBOLS RELATED TO THE ALARM CONDITION. NO ALARM TONE WILL SOUND.

NOTE: *With the Handheld unit, if there is a loss of power for any length of time, check the alarm settings. Generally, the Alarm limit settings will be set back to the User set defaults if the user previously selected YES in the Save Last option under the Display menu. If the user has not utilized this option, then they will be set back to the factory defaults.*

Alarms continued

<table>
<tr><th>MENU ITEMS</th><th>DESCRIPTION</th></tr>
<tr><td>VOLUME</td><td>This menu allows the user to set the alarm volume. Four levels are available: level 1 being the softest and level 4 being the loudest. The device retains the Alarm Volume setting upon a power cycle.
NOTE: For home use, set the alarm level to level 4.</td></tr>
<tr><td>DELAY</td><td>This menu allows the users to set an audible saturation delay. The delay can be set to either 0, 5, 10 or 15 seconds. The delay setting only affects saturation alarm indications.
NOTE: In “Custom” mode (see Section 4-Operation) the unit will retain the Alarm Delay setting after a power cycle. In “Neo” or “Adult” mode (see Section 4-Operation) the unit will reset the Alarm Delay to the hospital specified setting after a power cycle.</td></tr>
<tr><td>MODE</td><td>The Radical-7 stores three types of modes: Adult, Neonatal or Custom limits. Adult and Neonatal must be initially set and enabled (via password protected screen) before they can be selected.
CUSTOM
Any changes to settings on the Alarm menu will be retained after a power cycle.*
ADULT
Any changes to settings on the Alarm menu will be reset to pre-defined Adult defaults after a power cycle.†
NEO
Any changes to settings on the Alarm menu will be reset to pre-defined Neonatal defaults after a power cycle.†
<table>
<tr><th>TYPES</th><th>SpO_2 (HIGH)</th><th>SpO_2 (LOW)</th><th>PULSE RATE (HIGH)</th><th>PULSE RATE (LOW)</th></tr>
<tr><td>ADULT LIMITS†</td><td>Off</td><td>90%</td><td>140 BPM</td><td>50 BPM</td></tr>
<tr><td>NEONATAL LIMITS†</td><td>100%</td><td>90%</td><td>180 BPM</td><td>100 BPM</td></tr>
<tr><td>CUSTOM LIMITS*</td><td>Off*</td><td>90%*</td><td>140 BPM*</td><td>50 BPM*</td></tr>
</table>
</td></tr>
<tr><td></td><td>NOTE: Limits are set at the factory to the values listed in this table.
*Once Custom values are changed by the user, they will be retained after a power cycle.
†Adult and Neo settings can be changed (via a password protected screen, see Section 4 under Password Operation) to specific hospital/unit requirements. If the settings are changed, then any values changed by the user will be returned to the unit's default values after it is powered down.</td></tr>
</table>

Rotate Screen

MENU ITEMS	DESCRIPTION
LANDSCAPE 1	The viewing screen will be in a horizontal fashion when the Radical-7 is in the upright, horizontal position.
VERTICAL 1	The viewing screen will be in a vertical fashion when the Radical-7 is in the upright, vertical position.
LANDSCAPE 2	The viewing screen will be in an inverted horizontal fashion (rotated 180^{o}) when the Radical-7 is in the upright, horizontal position.
VERTICAL 2	The viewing screen will be in an inverted vertical fashion (rotated 180o) when the Radical-7 is in the upright, vertical position.

Display

MENU ITEMS	DESCRIPTION
VIEW	Five views are available: PVI Pleth and Signal IQ, PVI Pleth, Pleth and Signal IQ, Numbers and Pleth Only. **PVI PLETH + SIGNAL IQ / PLETH + SIGNAL IQ** Shows the SpO_2 and pulse rate numbers on the left or top of the screen. The PVI plethysmograph-Signal IQ and plethysmograph-Signal IQ waveforms are on the right, two-thirds or bottom of the screen. The screen also indicates the signal strength of the measured signal as a perfusion index (PI). The PI is calculated as the relation of arterial pulsatile signal to the non-pulsatile signal component. The percentage measurements of methemoglobin (SpMet) and carboxyhemoglobin (SpCO) are displayed in the middle upper third of the screen above the PI measurement. The PVI measurement is displayed under the SpCO measurement. **PVI PLETH / PLETH ONLY** Shows the SpO_2 and pulse rate numbers on the left or top of the screen. The PVI plethysmograph and plethysmograph waveform are on the right, two-thirds or bottom of the screen. The screen also indicates the signal strength of the measured signal as a perfusion index (PI). The PI is calculated as the relation of arterial pulsatile signal to the non-pulsatile signal component. The percentage measurements of methemoglobin (SpMet) and carboxyhemoglobin (SpCO) are displayed in the middle upper third of the screen above the PI measurement. The PVI measurement is displayed under the SpCO measurement. **NUMBERS** Shows the SpO_2 and pulse rate numbers and the signal IQ in the form of a pulse bar on the screen. The Screen also indicates the signal strength of the measured signal as a perfusion index (PI). The PI is calculated as the relation of arterial pulsatile signal to the non-pulsatile signal component. The percentage measurements of methemoglobin (SpMet) and carboxyhemoglobin (SpCO) are displayed in the middle of the screen in line with the PI measurement. The PVI measurement is displayed under the PI measurement.
TREND	This allows the user to select and view the Trend data between: ■ SpO_2 and pulse rate (%SpO_2 + BPM) ■ SpO_2 and perfusion index (%SpO_2 + PI) ■ SpO_2 and methemoglobin (%SpO_2 + MET) ■ SpO_2 and carboxyhemoglobin (%SpO_2 + CO) ■ SpO_2 and Pleth Variability Index (%SpO_2 + PVI) ■ Pulse rate and perfusion index (BPM + PI) ■ Pulse rate and methemoglobin (BPM + MET) ■ Pulse rate and carboxyhemoglobin (BPM + CO) ■ Pulse rate and Pleth Variability Index (BPM + PVI) ■ Perfusion index and methemoglobin (PI + MET) ■ Perfusion index and carboxyhemoglobin (PI + CO) ■ Perfusion index and Pleth Variability Index (PI + PVI) ■ Methemoglobin and carboxyhemoglobin (MET + CO) ■ Methemoglobin and Pleth Variability Index (MET + PVI) ■ Carboxyhemoglobin and Pleth Variability Index (CO + PVI) ■ %SpO_2 ■ Pulse Rate (BPM)

Display continued

MENU ITEMS	DESCRIPTION
TREND (cont.)	■ Perfusion Index (PI) ■ Pleth Variability Index (PVI) ■ Methemoglobin (MET) ■ Carboxyhemoglobin (CO) ***NOTE:*** *These parameters are viewed when utilizing the Trend Display function and not the Trend Graph function.*
CONTRAST	Allows the user to set the contrast of the LCD display. Contrast ranges from 0 to 63. ***NOTE:*** *The contrast can also be set by pressing and holding the Backlight/ Contrast Button on the front panel.*
LANGUAGE	Allows the user to select from the following languages to be displayed on the screen: ■ French ■ Spanish ■ German ■ Italian ■ Portuguese ■ Danish ■ Dutch ■ Swedish
VERTICAL LAYOUT	**DEFAULT** Displays the alarm parameters in vertical sequence of SpO_2, SpMet, SpCO, BPM, PVI and PI. **TRADITIONAL** Displays the alarm parameters in vertical sequence of SpO2, BPM, PI, SpMet, SpCO and PVI.
DEFAULT	Allows the user to select user mode or reset the settings to factory defaults. ***NOTE:*** *A password is required to access these menu options. Refer to* Section 4 *Password Operation* **LOW % SpO_2 LIMIT** Allows the qualified user to set a custom default minimum low SpO_2 limit. When set, it will be the lowest value that the low SpO_2 alarm limit can be set to. For example, if the limit is set to 85%, then it cannot be set lower than 85% through the main Alarm menu. The unit will return to this setting after a power cycle. **SAVE LAST** This allows the user to either use Custom setting or Adult/Neonatal settings. Select "Yes" to use custom settings. **SAVE AS ADULT** Store current settings as Adult default setting. **SAVE AS NEO** Store current settings as Neonatal default setting. **RESTORE FACTORY** Recall factory setting for Custom, Adult and Neonatal.

General

MENU ITEMS	DESCRIPTION
AVERAGING TIME	The signal averaging time of this device can be set to: 2, 4, 8, 10, 12, 14 and 16 seconds*. *With FastSat the averaging time is dependent on the input signal. For the 2 and 4 second settings, the averaging times may range from 2 to 4 and 4 to 6 seconds, respectively.
FASTSAT	Select **Yes** to activate the FastSat algorithm. In the 2 and 4 seconds averaging mode, the FastSat algorithm is automatically enabled.
HOME USE	Set the Radical-7 to the Home Mode. The Radical-7 will remain in the Home Mode until the **No** setting is selected. A password is required to activate or deactive this mode. See Section 4, *Home Mode Operation*, for a detailed description.
INTERFACE ALARMS	During SatShare, Philips Vuelink, Spacelabs Flexport and RadNet operation, the audible alarms can be enabled or disabled by selecting **Yes** or **No**. The Interface Alarms cannot be disabled if the SpCO and/or SpMet parameters are present in the Radical-7.
SATSHARE NUMBERS	During SatShare operation the saturation and pulse rate measurements can be displayed on the Radical-7 by selecting a SatShare Numbers setting of **Yes**.
POWER SAVE	Select **Yes** to maximize battery-operating time of the Radical-7 while powered by the Handheld battery or optional Docking Station battery. Selecting **Yes** will disable Docking Station functions such as SatShare, Serial and Analog output. Selecting **No** will activate these Docking Station functions while operating on battery power. (While operating in the Power Save mode, a power cycle of the Radical-7 may be required to activate the Docking Station again after it has been disabled.)
SMART TONE	Select **Yes** to activate the SmartTone function. This will allow the audible pulse to continue to beep when the pleth graph shows signs of motion. Select **No** to turn off SmartTone.
PVI	Select **Yes** to display the PVI parameter. The PVI will display numerically on the main screen and also will allow to the user to change the maximum and minimum PVI settings in the Trend Setup menu. Select **NO** to deselect the parameter.

Clock

MENU ITEMS	DESCRIPTION
TIME	Set the time - hour, minutes and seconds - in 24 hour format.
TIME FORMAT	Set the format of the time display as it will be shown on the front panel. Available options are 12 hour (default) and 24 hour display.
DAY	Set the numerical day.
MONTH	Set the numerical month.
YEAR	Set the numerical year.
DAY FORMAT	Set the format of the date display as it will be shown on the front panel. Available options are mm/dd/yy (default) and dd/mm/yy.
DISPLAY CLOCK	Set to display the date and time on the front panel by selecting **Yes** or **No**.

About

This displays the copyright and software versions of the Handheld and Docking Station.

MENU ITEMS	DESCRIPTION
MORE	Allows the user to view the current Line Frequency setting without a password.

Config

MENU ITEMS	DESCRIPTION
ENTER PASSWORD	Enter password. See Section 4, *Password Operation*. Set to match regional power line frequency (50 or 60 Hz) to allow for cancellation of noise introduced by fluorescent lights and other sources. Default is 60 Hz (standard for the United States).
RAPID DESAT LIMIT	Enter password. See Section 4, *Password Operation*. The Rapid Desat Limit will ignore the Alarm Delay setting if desaturation falls below the Low SpO_2 alarm threshold per a user-defined percentage. Audible tones are generated immediately, along with all visual indicators. The Rapid Desat Limit can be set to the following: **OFF:** The Alarm Delay setting will delay audible alarm tones regardless of how deep the desaturation is below the alarm threshold. **-5:** The Alarm Delay setting is ignored if the desaturation is 5% (meaning 5 saturation units) below the Low SpO_2 alarm threshold. **-10:** The Alarm Delay setting is ignored if the desaturation is 10% (meaning 10 saturation units) below the Low SpO_2 alarm threshold.

3D Alarm System (optional)

Refer to Section 5, *3D Alarm System option*.

Output

NOTE: *The output menu selections are only available when the Radical-7 Handheld is interfaced to the Docking Station.*

MENU ITEMS	DESCRIPTION
SERIAL	The following serial output modes are supported. All serial output is RS-232 based. See the interface specifications in Section 7, *Specifications*. **ASCII 1** ASCII text data is sent to the serial interface at one-second intervals. The ASCII text includes: date and time stamp, SpO_2 pulse rate, PI, SpMet, SpCO and alarm and exception values. All text is single line followed by a line feed character and a carriage return. **ASCII 2** ASCII text data is sent to the serial interface following a query from the connecting computer. This mode will need to be active for RadNet data output. **BINARY** Compressed binary data is sent to the serial interface following a query from the connecting computer. **PHILIPS VUELINK** SpO_2, pulse rate and plethysmographic waveform data are sent in Philips VueLink format to the serial port. **SPACELABS FLEXPORT** SpO_2, pulse rate and plethysmographic waveform data are sent in Spacelabs Flexport format to the serial port.
ANALOG1 OR ANALOG 2	**SpO_2 0 - 100%** Scales the saturation measurement with 0% being equal to 0 Volt and 100% equal to 1 Volt. **SpO_2 50 - 100%** Scales the saturation measurement with 50% being equal to 0 Volt and 100% equal to 1 Volt. **PULSE RATE** Scales the pulse rate measurement with 0 BPM being equal to 0 Volt, and 250 BPM equal to 1 Volt. **PLETH** Traces the plethysmographic waveform as shown on the Radical-7 display. **SIGNAL IQ** Traces the Signal IQ waveform as shown on the Radical-7 display. A full scale Signal IQ signal (100%) is represented as 1 Volt, while a zero Signal IQ signal (0%) is represented as 0 Volt.

Output continued

MENU ITEMS	DESCRIPTION
ANALOG1 OR ANALOG 2 (CONTINUED)	**0V OUTPUT** A 0 Volt calibration signal is mapped to the analog output. Use this signal for calibration of recording devices. (0 Volts represents a saturation of 0% and a pulse rate of 0 bpm). **1V OUTPUT** A 1 Volt calibration signal is mapped to the analog output. Use this signal for calibration of recording devices. (1 Volt represents a saturation of 100% and a pulse rate of 250 bpm).
NURSE CALL	**ALARMS** The nurse call output will be activated based on alarm events. **LOW SIGNAL IQ** The nurse call output will be activated based on Low Signal IQ events. **ALARM & SIGNAL IQ** The nurse call output will be activated based on alarm and Low Signal IQ events.
POLARITY	**NORMAL** Standard polarity. See section 7, Analog output / nurse call specifications. **INVERT** This setting reverses the Normally Open and Normally closed contacts. See section 7, Analog output / nurse call specifications.

CAUTION: TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SERIAL PORT ON THE BACK PANEL UNLESS THE RADICAL-7 IS CONNECTED TO THE AC MAINS POWER SUPPLY.

Service

NOTE: *The Service menu selections are only available when the Radical-7 Pulse CO-Oximeter Handheld is interfaced to the Docking Station.*

Only qualified Biomedical or Clinical Engineering department personnel should access the service menu. See Section 4, *Password Operation*, on how to enter the password.

MENU ITEMS	DESCRIPTION
HANDHELD BATTERY DISCHARGE	To deep discharge the Handheld battery, select this menu item. See Section 9, *Battery Operation and Maintenance*, for more information.
DS BATTERY DISCHARGE	To deep discharge the optional Docking Station battery, select this menu item. See Section 9, *Battery Operation and Maintenance*, for more information.

The discharge cycle will take approximately 16 hours to complete for the Handheld battery. The Docking Station battery will take approximately 30 hours to complete. A message will appear in the service screen when the discharge cycle is complete. The batteries will be fully charged after completion of the cycle.

When deep discharge is started, the backlight will automatically turn down to the default handheld battery powered level. Wait until the message changes from (In Progress) to (Done).

NOTE: *In order for the discharge cycle to be properly completed, AC power must be supplied to the instrument throughout the cycle.*

WARNING: WHEN DEEP-DISCHARGING THE HANDHELD OR DOCKING STATION BATTERY, MAKE SURE THAT THE DEVICE HAS BEEN REMOVED FROM SERVICE UNTIL FULL BATTERY CAPABILITY CAN BE RESTORED.

Trend Display

Once the Trend Display touch key icon is selected, the trend data is displayed on the main screen. The Radical-7 Pulse CO-Oximeter stores one data set of SpO_2, pulse rate, SpMet, SpCO, PI, PVI and system messages in a dedicated memory area. Depending on the Trend Period, a setting for how often the data is stored in the trend memory, the Radical-7 Pulse CO-Oximeter can store between 72 hours and 18 days of trend data. The Radical-7 Pulse CO-Oximeter also employs a sophisticated data compression scheme. The actual amount of trend data that is stored is dependent on the type of data that is collected.

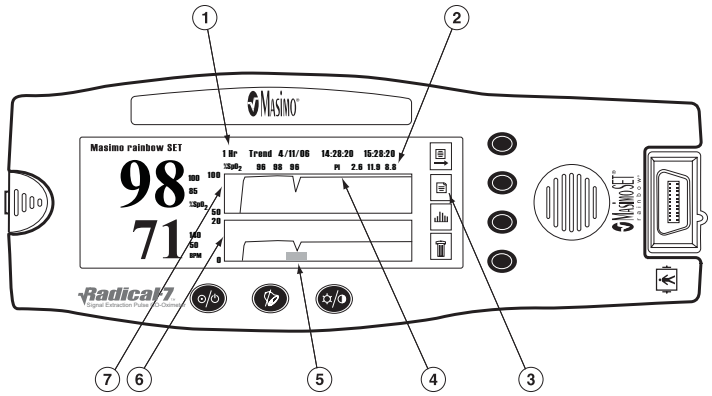
The Radical-7 Pulse CO-Oximeter only stores data in the trend memory while the device is turned on, and the trend data remains in memory until the memory fills up, or is cleared by the user.

CAUTION: CHANGING THE DATE AND TIME OF THE SYSTEM CLOCK, OR CHANGING THE TREND PERIOD, WILL ALSO CLEAR THE DATA IN THE TREND MEMORY.

The following table outlines the trend capacity for sample Trend Period settings:

TREND PERIOD	TREND MEMORY CAPACITY
2 SECONDS	MINIMUM OF 72 HOURS (3 DAYS)
10 SECONDS	TYPICALLY 435 HOURS (18 DAYS)

The Trend Display can be configured to display one or two of any of the six available trend parameters (SpO_2, SpMet, SpCO, pulse rate, PI or PVI) that are selected by the user. The unit is storing all 6 parameters in trend memory, but can only display one or two user selected parameters at any one time. The Trend Display can be adjusted to the desired parameter by selecting **Trend** from the **Display** menu.



1	The top line on the trend display shows the time scale of the trend graph, followed by the starting date, starting time and end time of the data set that is displayed on the screen.
2	The second line of the display shows the minimum, maximum and average SpO_2, SpMet, SpCO, PI, pulse rate or PVI measurements contained in the displayed data set (excluding zero measurements).
3	The scale range of SpO_2, BPM, PI, SpMet and SpCO graphs can be set in the Trend Setup menu. For other settings, see Trend Setup in the following pages.
4	A vertical line shows the start of the trend rising to the averaging of the parameter data. The averaged data is displayed between the user set minimum and maximum values. The horizontal show beginning and ending periods of the trend or when the sensor was removed from the patient.
5	A grayed-out box or line located on the bottom axis of the saturation graph indicates a period of time for which the Low Signal IQ indicator was active, indicating the signal quality was very low and the accuracy of the measurement may have been compromised.
6 7	The available trend graphs show two of the desired trend parameter measurements displayed versus time.

By default, the trend display automatically refreshes, at a rate of once every 10 seconds, to show the latest measured SpO_2, SpMet, SpCO, PI or pulse rate data. This feature is only available while the trend view is 2 hours or less, and the latest measured data is shown. If the user scrolls through the data set to display previously recorded trend data, or if the trend scale is greater than 2 hours, the trend display will time out after 1 minute of inactivity (i.e. the user does not press any of the touch key control buttons) and the normal Radical-7 Pulse CO-Oximeter display will be shown.

NAVIGATING THE TREND DISPLAY

In the Trend Display view there are a total of 10 touch key icon selections on 3 pages of menu selections. These menu screens are not accessible when using the Simplified User Interface.

FIRST PAGE

NEXT MENU PAGE	Press the Next Menu Page button to access the next page of menu selections.
EXIT	Press the Exit button to return to the normal display screen.
SCROLL RIGHT	Press the Scroll Right button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Right button will scroll the displayed data by 1 hr to the right.
SCROLL LEFT	Press the Scroll Left button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Left button will scroll the displayed data by 1 hr to the left.

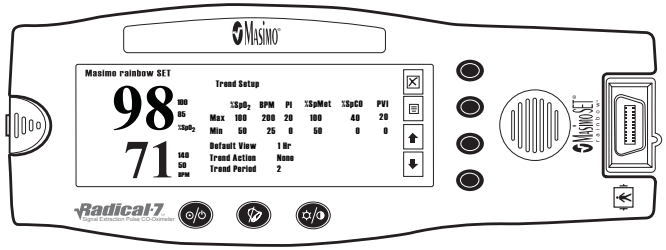
SECOND PAGE

NEXT MENU PAGE	Press the Next Menu Page button to access the next page of menu selections.
ZOOM	Press the Zoom button to change the time scale of the trend view. The available time scales are 24 hrs, 12 hrs, 8 hrs, 4 hrs, 2 hrs, 1 hr, 30 minutes, 10 minutes, 1 minute and 20 seconds. The Zoom button uses the last recorded data point as the zoom reference point. In other words, the last recorded data point is always shown as the right-most data point on the display.
ZOOM FROM LEFT	Press the Scroll Right button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Right button will scroll the displayed data by 1 hr to the right.
ZOOM FROM RIGHT	Press the Scroll Left button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Left button will scroll the displayed data by 1 hr to the left.

THIRD PAGE

NEXT MENU PAGE	Press the Next Menu Page button to return to the first page of menu selections.
TREND SETUP	Press the Trend Setup button to enter the Trend Setup Menu.
HISTOGRAM	Press the Histogram button to display the selected data set (the data set shown in the trend view) in histogram format.
CLEAR TREND DATA	Press the clear Trend Data button to clear the data stored in the trend memory.

TREND SETUP



This menu allows the user to set the default trend settings or download the trend data. The default settings are used to scale the trend graphs when the trend data button, located on the main display, is accessed.

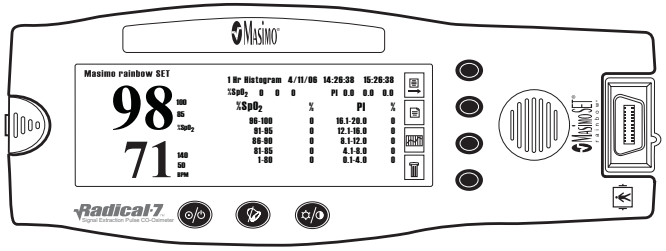
MENU ITEMS	DESCRIPTION
%SpO_2 MAX SCALE	Sets the maximum scale of the SpO_2 trend graph.
%SpO_2 MIN SCALE	Sets the minimum scale of the SpO_2 trend graph.
PR MAX SCALE (BPM)	Sets the maximum scale of the pulse rate trend graph.
PR MIN SCALE (BPM)	Sets the minimum scale of the pulse rate trend graph.
PI MAX SCALE	Sets the maximum scale of the PI trend graph.
PI MIN SCALE	Sets the minimum scale of the PI trend graph.
%SpMet MAX SCALE	Sets the maximum scale of the SpMet trend graph.
%SpMet MIN SCALE	Sets the minimum scale of the SpMet trend graph.
%SpCO MAX SCALE	Sets the maximum scale of the SpCO trend graph.
%SpCO MIN SCALE	Sets the minimum scale of the SpCO trend graph.
PVI MAX SCALE	Sets the maximum scale of the PVI trend graph.
PVI MIN SCALE	Sets the minimum scale of the PVI trend graph.
DEFAULT VIEW	Selects the default time scale of the trend view. This setting only selects the time scale of the trend view when the trend data is initially displayed, (i.e. when the trend data is initially accessed). The selections are 24 hrs, 12 hrs, 8 hrs, 4 hrs, 2 hrs, 1 hr, 30 minutes, 10 minutes, 1 minute and 20 seconds.

MENU ITEMS	DESCRIPTION
TREND ACTION	**SERIAL DUMP** To send all the data that is stored in trend memory to the serial port, select the Serial Dump option. Use this option to communicate the stored data set to trend graphing software applications. **ANALOG DUMP** To send all the data that is stored in the trend memory to the analog output select the Analog Dump option. Use this option to print the trend information on an analog chart recorder. **PRINT** To print the trend data that is shown in the Trend View select the Print option. The trend data is first printed in histogram format, followed by a table of data that shows the time and date stamp of a trend record, and the SpO_2, pulse rate, SpMet, SpCO, PI and PVI measurement. Each trend record is printed on a single line followed by a carriage return and line feed character.
TREND PERIOD	The Trend period setting determines how often a set of SpO_2, pulse rate, SpMet, SpCO and PI data points is stored in trend memory. A setting of 2, for example, sets the Radical-7 Pulse CO-Oximeter to store one set of SpO_2, pulse rate, SpMet, SpCO, PI and PVI measurements every 2 seconds, resulting in a minimum trend capacity of 72 hours. A setting of 10, for example sets the Radical-7 Pulse CO-Oximeter to store one set of data points every 10 seconds, resulting in a typical trend storage capacity of 18 days.

NOTE: *Since the Radical-7 Pulse CO-Oximeter employs a sophisticated data compression scheme, the actual trend capacity is dependent on the type of data that is collected.*

HISTOGRAM

The figure below is an example of the display output of the Histogram function. The Histogram displays the trend data of selected parameters as numerical percentages shown in specific ranges.



Backlight/Contrast Operation

The backlit LCD screen of the Radical-7 Pulse CO-Oximeter Handheld can be set to four levels of illumination, in addition to no illumination, when the Radical-7 Pulse CO-Oximeter operates as a standalone Pulse CO-Oximeter. The Radical-7 Pulse CO-Oximeter temporarily indicates the illumination level on the display following a change in illumination level. To select the level of illumination, simply press the Backlight/Contrast button located on the front panel of the Handheld.

When the Radical-7 Pulse CO-Oximeter Handheld unit is released from the Docking Station, the illumination of the LCD screen automatically reverts to the lowest level to conserve battery power. To select a different level of illumination, press the Backlight/Contrast button again. In the Handheld mode, three levels of illumination are available.

When the Handheld unit is re-attached to the Docking Station, as well as when the Radical-7 Pulse CO-Oximeter is powered on in the Standalone configuration, the backlight is automatically set to the maximum illumination when the unit is AC line powered.

To change the contrast of the LCD screen, select the Contrast parameter of the Display menu. While changing the contrast setting, the screen will refresh to reflect the current setting.

The contrast of the LCD screen can also be changed by depressing and holding the Backlight/Contrast button located on the front panel of the Handheld. While holding the Backlight/Contrast button, the screen will refresh to reflect the current setting. Release the button at the desired setting.

Satshare Operation

When the SatShare cable is connected to the Radical-7 Pulse CO-Oximeter and to a multiparameter patient monitor, the Radical-7 Pulse CO-Oximeter automatically starts to operate in the SatShare mode.

In the SatShare mode, Radical-7 Pulse CO-Oximeter operates as follows:

- All visual alarms remain active.
- All audible alarms may be disabled by software configuration of the Radical-7 Pulse CO-Oximeter. Refer to Section 4 *Alarms.*
- The SpO_2 and pulse rate numbers may or may not be displayed on the Radical-7 Pulse CO-Oximeter display depending on the SatShare Numbers setting of the General menu. Refer to Section 3 *SatShare Setup.*
- All other items are displayed, including the alarm limits, the plethysmogram and Signal IQ waveform.
- The user can access the menu system.
- If the SatShare cable is connected to the Radical-7 Pulse CO-Oximeter only, and not to a patient monitor, the SatShare cable type is flashing on the LCD screen.
- Once the Radical-7 Pulse CO-Oximeter detects the presence of a patient monitor, the SatShare cable type remains constantly displayed on the LCD screen.
- Patient Alarms of the multiparameter patient monitor will be triggered by the alarm setting of the patient monitor and not the Radical-7 Pulse CO-Oximeter. To synchronize the alarm events set the alarm limits of the Radical-7 Pulse CO-Oximeter to those of the patient monitor, or vice versa.

- Once the Radical-7 Pulse CO-Oximeter detects that the SatShare cable is disconnected from the patient monitor, or if the patient monitor is turned off, the Radical-7 automatically returns to normal, standalone operation.
- In the SatShare mode, the pulse beep tone of the Radical-7 Pulse CO-Oximeter is initially set to the lowest volume (mute). The pulse beep volume can be manually increased. Refer to Section 4 *Traditional User Interface.*
- The Radical-7 Pulse CO-Oximeter may automatically set the averaging time during SatShare operation. For averaging times of 10 seconds and higher, the Radical-7 Pulse CO-Oximeter will automatically set the averaging time to 8 seconds during SatShare operation. Averaging times of 2, 4 or 8 seconds remain unchanged during SatShare operation. When the Radical-7 Pulse CO-Oximeter returns to non-SatShare operation, the Radical-7 Pulse CO-Oximeter will maintain the averaging time setting used in the SatShare mode.
- When the Radical-7 Pulse CO-Oximeter starts to operate in the SatShare mode the sensitivity mode is set to Normal sensitivity. The sensitivity mode can manually be set to Maximum or APOD sensitivity. Refer to Section 2 *Handheld Front Panel.*
- While operating in the SatShare mode, the Radical-7 Pulse CO-Oximeter may automatically disable the SatShare interface if the perfusion index drops below 0.1% while the sensitivity is set to Max sensitivity. To enable the SatShare interface again, set the Radical-7 Pulse CO-Oximeter to the Normal or APOD sensitivity mode, increase the perfusion at the measurement site (by warming the patient or sensor site), or move the sensor to a site with better perfusion.

CAUTIONS:

- SATSHARE SIGNALS ARE IDEAL SIMULATED WAVEFORMS CORRESPONDING TO THE CALCULATED SATURATION AND PULSE RATE VALUES AND DO NOT CONTAIN ALL OF THE INFORMATION CONTAINED IN PHYSIOLOGICAL WAVEFORMS. THE MULTIPARAMETER PATIENT MONITOR DECODES THESE SIGNALS INTO SATURATION AND PULSE RATE VALUES.
- DURING SATSHARE OPERATION, THE AUDIBLE ALARMS MAY BE MUTED ON THE RADICAL-7 PULSE CO-OXIMETER. WHEN THE AUDIBLE ALARM IS MUTED (INDICATED BY A BELL WITH A SLASH THROUGH IT) ON THE RADICAL-7 PULSE CO-OXIMETER, USE THE MULTIPARAMETER MONITOR FOR AUDIBLE ALARM INDICATION.
- DURING SATSHARE OPERATION DO NOT USE THE PLETH WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR FOR DIAGNOSTIC PURPOSES. INSTEAD, USE THE PLETH WAVEFORM DISPLAYED ON THE RADICAL-7 SCREEN.
- TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SATSHARE CONNECTOR UNLESS THE RADICAL-7 IS CONNECTED TO THE AC MAINS POWER SUPPLY.
- ONLY USE A SATSHARE CABLE THAT HAS A FERRITE BEAD INSTALLED.
- SpMet, SpCO, PI AND PVI CANNOT BE DISPLAYED ON THE MULTIPARAMETER MONITOR WITH SATSHARE.

To return from SatShare operation to normal standalone operation, simply disconnect the SatShare cable from the patient monitor or disconnect the SatShare cable from the SatShare connector on the back of the Radical-7 Pulse CO-Oximeter.

Home Mode Operation

The Radical-7 Pulse CO-Oximeter can be placed into the Home Mode to protect unqualified users from changing the Radical-7 Pulse CO-Oximeter alarm settings and operation. Entering a password does not automatically reset the Radical-7 Pulse CO-Oximeter to the Normal operating mode. In the Home Mode, a password is required to access the menu system and the touch key control buttons and icons.

NOTE: *When the Radical-7 Pulse CO-Oximeter is set to operate in the Home mode the default values that the Radical-7 reverts to after a power cycle are set according to Section 3, Monitor Setup, with the exception of the Alarm Silence setting, which is set to the pre-power down setting.*

Password Operation

The Radical-7 Pulse CO-Oximeter password is 2-3-1. To enter the password use the touch-key control buttons to the right or bottom of the LCD display and press the buttons in the sequence shown in the following figure:

System Messages

The following chart alphabetically lists all system messages displayed on the LCD screen, the cause of the message and the action(s) to be taken.

The operator should become thoroughly familiar with this information before using the oximeter for patient monitoring.

MESSAGE	POSSIBLE CAUSE(S)	RECOMMENDATION
AMBIENT LIGHT	• Too much light on patient (sensor). • Inadequate tissue covering sensor detector.	• Remove or reduce lighting. • Cover sensor from light. • Reposition sensor.
DEFECTIVE CABLE	• Oximeter cannot identify the connected cable or the cable has failed.	• Inoperative or faulty cable • Replace cable. • Refer to the Directions for Use of the cable being used.
INCOMPATIBLE SENSOR	• Not a proper Masimo sensor.	• Replace with a proper Masimo sensor. • Refer to Section 8.
INVALID SENSOR	• Oximeter cannot identify the connected sensor.	• Broken sensor cable wire or inoperative LEDs or faulty detector. • The sensor has failed. • Replace sensor. • Refer to the instructions for the sensor being used.
LOW BATTERY	• Battery charge is low.	• Charge battery by placing the Radical-7 Handheld into the Docking Station and powering the unit with AC line power. • Replace battery if necessary.
LOW PERFUSION	• Signal too small.	• Move sensor to better perfused site. • Refer to Section 4, *Low Perfusion*.
LOW SIGNAL IQ	• Low signal quality.	• Ensure proper sensor application. • Move sensor to a better perfused site. • Refer to Section 4, *Signal IQ*.
LOW SpCO CONF	• SpCO measurement reading is obscured.	• Ensure proper sensor application. • Check sensor to see if it is working properly. • If not, replace the sensor.
LOW SpMet CONF	• SpMet measurement reading is obscured.	• Ensure proper sensor application. Check sensor to see if it is working properly. • If not, replace the sensor
SPEAKER FAILURE	• Unit requires service	• Contact Masimo Tech Support. • Refer to Section 9 *Service and repair.*
NO CABLE	• Cable not attached or not fully inserted into the connector.	• Disconnect and reconnect cable into connector.

MESSAGE	POSSIBLE CAUSE(S)	RECOMMENDATION
NO SENSOR	• Sensor not fully inserted into the connector.	• Maybe an incorrect sensor, or a defective sensor or cable. • Insert sensor into connector. • Disconnect and reconnect sensor. • Refer to the instructions for the sensor being used.
	• Unit is searching for patient's pulse.	• Disconnect and reconnect the sensor into the Patient Cable Connector.
PULSE SEARCH	• Unit is searching for patient's pulse.	• If values are not displayed within 30 seconds, disconnect and reconnect sensor. • If pulse search continues, remove sensor and replace on a better perfused site.
SENSOR CALIBRATING	• Unit is checking the sensor for proper functioning and performance.	• If values are not displayed within 30 seconds, disconnect and reconnect sensor. • If values are still not displayed, replace with a new sensor.
SENSOR OFF	• Sensor off patient.	• Disconnect and reconnect sensor. • Reattach sensor.
SERVICE REQUIRED*	• Internal Failure.	• Unit requires service.
UNRECOGNIZED CABLE	• Not a proper cable.	• Replace with a proper cable. Refer to Section 8.

*The SERVICE REQUIRED message fills the entire display. This is a numeric error code. Contact Masimo for service.

3D Alarm System Option

This section applies only if you have purchased the optional 3D Alarm System. Contact Masimo if you are interested in purchasing this option.

Purpose

The purpose of this section is to familiarize clinicians with the optional 3D Alarm System of the Radical-7 Pulse CO-Oximeter.

3D Alarm System Overview

The Radical-7 Pulse CO-Oximeter includes user-selectable High and Low alarm limits for SpO_2 and pulse rate to provide audible and visual indication of specific levels of these vital signs that the clinician has determined merits their attention as described in Section 4 of this manual. The 3D Alarm System enables clinicians to be alerted to changes in multiple interacting factors to provide an additional level of vigilance and flexibility to manage their patients.

The following is a summary of each of the 3D Alarm System features:

DESAT INDEX ALARM

The 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.

NOTE: *The alarms in this option are considered to be Medium priority.*

PERFUSION INDEX (PI) DELTA ALARM

The 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.

NOTE: *The alarms in this option are considered to be Medium priority.*

Desat Index Alarm

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. 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 and moderate desaturations, the 3D Alarm System option includes a user-selectable Desat Index Alarm. This 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. The desaturation variables are selectable by the user within the ranges established below:

Desat Index Threshold:	Range of 2% to 10% in 1% increments, default of 4%
Desat Index Timeframe:	Range of 1 to 4 hrs in 1-hr increments, default of 1 hr
Desat Index Alarm/Quantity:	Range of 1 to 25 desaturations, default is OFF

To translate the above Desat Index variables and ranges into perspective, consider a patient at risk of respiratory compromise with the definition for respiratory compromise of 5 or more transient moderate desaturations (associated with a 4% drop in SpO_2) per hour. To request a Desat Index alarm for this situation, the clinician would set the Desat Index variables as follows:

Desat Index Threshold:	4%
Desat Index Timeframe:	1 hour
Desat Index Alarm	5 (desaturations)

Post-operative patients receiving pain medication may be predisposed to respiratory depression. If the patient has an underlying respiratory condition, pain medication may cause the patient to spiral into a cascade of cyclic desaturations, which initially are mild but may worsen quickly. The Desat Index Alarm may give an early warning of this type of respiratory disturbance that can lead to respiratory depression and even arrest.

CAUTION: THE DESAT INDEX ALARM IS INTENDED AS AN ADJUNCT RATHER THAN IN PLACE OF THE LOW SATURATION ALARM

USER INTERACTION TO IMPLEMENT DESAT INDEX ALARM

The Desat Index Alarm function is enabled in the Radical-7 by the following method:

1. Select the 3D ALARMS menu from the main menu page.
2. Select Desat Index.
3. The Desat Index Alarm menu will be displayed and the user can select from the following entries:

Desat Index Threshold:	Range of 2% to 10% in 1% increments, default of 4%
Desat Index Time:	Range of 1 hr to 4 hrs in 1-hr increments, default of 1 hr
Desat Index Alarm:	Range of 1 to 25 desaturations, default is OFF

If the measured Desat Index parameter is greater than the configured Desat Index Alarm level selected, the Radical-7 will make a MEDIUM priority alarm tone and post an alarm message as follows:

DESAT INDEX = ##

where ## is equal to the current Desat Index and updates real time.

If the Alarm Suspend key is pressed during the Desat Index alarm, the tone is silenced and will not return when the Alarm Suspend time expires unless the condition is removed and then returns. The message will remain on the screen until the Alarm condition is removed.

Perfusion Index (PI) Delta Alarm

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 [2]. If PI decreases over time, there may be underlying physiological reasons that may need to be addressed.

[2] 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.

The 3D Alarm System 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 3D Alarm System option 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 below:

Set Baseline:	Select OFF or SET. Default is OFF.
PI Delta % Change:	Range of 10% to 100%. Default is 50%.
PI Delta Timeout	Range of 1 min, 5 min, 30 min, 1 hr, 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr and NONE. Default is NONE.
PI Delta Baseline	Displays OFF, the current PI baseline or TIMEOUT. If the baseline is activated and then turned off, TIMEOUT will display. ***NOTE:*** *This is a Read Only display and not user interactive.*

USER INTERACTION TO IMPLEMENT PI DELTA ALARM

The PI Delta Alarm function is enabled in the Radical-7 by the following method:

1. Select the 3D ALARMS menu from the main menu page.
2. Select PI Delta.
3. The PI Delta Alarm menu will be displayed and the user can select from the following entries:

Set Baseline:	Select OFF or SET. Default is OFF.
PI Delta % Change:	Range of 10% to 100%. Default is 50%.
PI Delta Timeout	Range of 1 min, 5 min, 30 min, 1 hr. 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr and NONE. Default is NONE.
PI Delta Baseline	Displays OFF, the current PI baseline or TIMEOUT. ***NOTE:*** *This is a Read Only display and not user interactive.*

If the PI Delta parameter is greater (more negative) than the configured PI Delta Alarm, then the Radical-7 will make a MEDIUM priority alarm tone, and post an alarm message as follows:

PI DELTA = ##%

where ## is equal to the current PI Delta percentage and updates real time.

The PI trend graph will also display.

If the Alarm Suspend key is pressed during this alarm, the tone shall be silenced and not returned when the Alarm Suspend time expires unless the condition is removed and then returns. The message will remain on the screen until the Alarm condition is removed.

3D Alarm menu

PARAMETER	MENU ITEM	DESCRIPTION
DESAT INDEX ALARM	**DESAT THRESHOLD**	The Desat Threshold can be set in the range of 2% to 10% in 1% increments. Default is 4%
	DESAT INDEX TIME	The Desat Index Time can be set in the range of 1 hr to 4 hrs in 1-hr increments. Default is 1 hr.
	DESAT INDEX ALARM	The Desat Index Alarm can be set in the range of 1 to 25 desaturations. Default is OFF.
PI DELTA ALARM	**SET BASELINE**	The Set Baseline can be turned on by selecting SET. Selecting OFF disables the alarm. Default is OFF.
	PI DELTA % CHANGE	The PI Delta % Change can be set in the range of 10% to 100%. Default is 50%.
	PI DELTA TIMEOUT	The PI Delta Timeout can be set in the range of the following increments: 1 min, 5 min, 30 min, 1 hr. 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr and NONE. Default is NONE.
	PI DELTA BASELINE	The PI Delta Baseline displays OFF, the current PI baseline or TIMEOUT. ***NOTE:*** *This is a Read Only display and not user interactive.*

Troubleshooting

The following chart describes what to do if the Radical-7 Pulse CO-Oximeter system does not operate properly or fails.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
UNIT DOES NOT POWER ON.	One or both of the fuses have blown.	Replace the fuses.
UNIT POWERS ON BUT THE GRAPHIC DISPLAY IS BLANK.	The viewing contrast is not correct.	Use the Backlight/Contrast button to adjust the viewing angle. If the condition persists, the unit requires service.
CONTINUOUS SPEAKER TONE.	Internal failure.	Unit requires service. Press the Alarm Silence button to silence the alarm. If alarm continues to sound, power down unit and remove Handheld battery if necessary.
BUTTONS DON'T WORK WHEN PRESSED	Internal failure.	Unit requires service.
DEFECTIVE SENSOR MESSAGE	Sensor or cable is broken.	Visually check the sensor LED if it is flashing on and off. If not, reconnect the cable and check the LED again. If the LED still fails to come on, replace the sensor and/or cable.

The following chart describes what to do when encountering common problems:

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
SpO_2 NUMBER FLASHES	Saturation alarm limit exceeded.	Assess/address patient condition Re-set alarm limits if indicated.
SENSOR OFF MESSAGE	Sensor not connected to patient properly. Sensor is damaged.	Properly reapply the sensor on the patient and reconnect the sensor to the unit or patient cable. If the sensor is damaged, replace the sensor.
NO SENSOR MESSAGE	Sensor is disconnected from patient cable. Sensor connected upside down into patient cable.	Check to see if the sensor LED is flashing. Disconnect and reconnect the sensor. If the LED fails to operate, replace the sensor.
LOW PERFUSION	Improper sensor type. Poorly perfused site. Sensor is too tight. A disorder such as hypothermia, vasoconstriction, hypovolemia, peripheral vascular disease or anemia. Sensor is damaged.	Verify proper sensor and sensor size for the patient. Check and see if blood flow to the site is restricted. Be sure that the sensor is not on too tight. Set unit to MAX sensitivity. Warm the patient or sensor site. Move sensor to better perfused site.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
LOW SIGNAL QUALITY	Improper sensor type or application. 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. Re-apply sensor or move to a different site.
SpO_2 VALUES DO NOT CORRELATE WITH CLINICAL ASSESSMENT OR ABGs.	Low perfusion or sensor displacement.	Check for error messages. See section 5 *System Messages* for recommended corrections. 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. Refer to sensor Directions For Use.
PULSE SEARCH MESSAGE	Unit is searching for pulse.	If unit fails to display within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.
UNEXPECTEDLY HIGH SpO_2, SpCO OR SpMet READING	Low SIQ or Perfusion Index (PI) values.	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.	Verify proper sensor for patient size. Verify proper sensor site.
UNEXPECTEDLY HIGH SpCO READING	Possible elevated methemoglobin level*.	Submit blood sample for laboratory CO-Oximetry test.
DIFFICULTY OR NO SpO_2/ SPCO/SPMET READING	Low battery/ not plugged into AC power supply.	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.	Verify/set 50/60hz menu setting. Refer to Section 3, Initial Setup for details.
	Inappropriate sensor or sensor size.	Verify proper sensor and sensor size for the patient.
	Excessive ambient or strobing light.	Shield the sensor from excessive or strobing light.
	Also, see Section 4, Successful Monitoring for additional information.	

* As with all CO-Oximeters, elevated methemoglobin levels may cause falsely elevated carboxyhemoglobin values.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
DIFFICULTY OR NO SpCO/ SpMet READING	Excessive motion.	Minimize or eliminate motion at the monitoring site.
	Inappropriate sensor or sensor size.	Verify use of an SpCO/SpMet capable sensor. Verify proper sensor size for the patient.
	Excessive ambient or strobing light.	Shield the sensor from excessive or strobing light.
HANDHELD BATTERY DOES NOT CHARGE	AC power cable may be disconnected.	Restore power to the device.
PRINT FUNCTION DOES NOT WORK	Wrong serial cable is used.	Make sure a null modem cable is used.
LED LIGHTS ON LEFT SIDE OF DOCKING STATION CONTINUOUSLY FLASH	Incompatable version of software on Radical-7 handheld and docking station.	Upgrade to current software versions. Match handheld to docking station with compatable software versions.
BATTERY RUN-TIME IS SIGNIFICANTLY REDUCED	Battery Memory effects.	Use Battery Discharge function as described in Section 4, *Service*.

Radical-7 specifications

PERFORMANCE

Measurement Range	
Oxygen Saturation (%SpO_2):	0 -100%
Carboxyhemoglobin Saturation (%SpCO):	0 - 99%
Methemoglobin Saturation (%SpMet):	0 - 99.9%
Pleth Variability Index	0 - 99%
Pulse Rate:	25 - 240 beats per minute (bpm)
Perfusion Index:	0.02% - 20%

ACCURACY

Saturation	70% to 100%
No Motion[1]	
Adults, Pediatrics	±2 digits
Neonate[2]	±3 digits
Motion[3]	
Adults, Pediatrics	±3 digits
Neonate	±3 digits
Low Perfusion[4]	
Adults, Pediatrics	±2 digits
Neonate	±3 digits
Carboxyhemoglobin Saturation Accuracy (%SpCO)[5]	1% - 40% ±3 digits
Methemoglobin Saturation Accuracy (%SpMet)[5]	1% - 15% ±1 digit
Pulse Rate Accuracy[10]	
Pulse rate:	25 - 240 bpm
No Motion[1]	
Adults, Pediatrics, Neonate	±3 digits
Motion[3]	
Adults, Pediatrics, Neonate	±5 digits
Low Perfusion[4]	
Adults, Pediatrics, Neonate	±3 digits
Resolution	
Saturation (%SpO_2)	1%
Carboxyhemoglobin saturation (%SpCO), digital display	1%
Methemoglobin saturation (%SpMet), digital display	.1%
Pulse Rate (bpm)	1 bpm

ELECTRICAL

Standalone	
AC Power requirements:	100 - 240 VAC, 47-63 Hz
Power consumption:	55 VA
Fuses:	1 Amp, Fast Acting, Metric, (5x20mm), 250V
Batteries	
Handheld:	
Type:	NiMH
Capacity:	4 hours[6]
Charging time:	3 hours

Docking Station (RDS-1B, RDS-3B):	
Type:	NiMH
Capacity:	10 hours[6]
Charging time:	6 hours

ENVIRONMENTAL

Operating Temperature:	41°F to 104°F (5°C to 40°C)
Transport/Storage Temperature:	-40°F to 158°F (-40°C to +70°C)[7]
Operating Humidity:	5% to 95%, non-condensing
Operating Altitude:	500 mbar to 1060 mbar pressure -1000 ft to 18,000 ft (-304 m to 5,486 m)

PHYSICAL CHARACTERISTICS

Dimensions:	
Handheld:	8.9" x 3.3" x 2.1" (22.6 cm x 8.4cm x 5.3 cm)
Standalone:	3.5" x 10.5" x 7.7" (8.9 cm x 26.7cm x 19.6cm)
Weight	
Handheld:	1.3 lbs. (0.59 kg)
Docking Station (RDS-1, RDS-2, RDS-3):	2.5 lbs. (1.14 kg)
Docking Station (RDS-1B):	4.11 lbs (1.86 kg)
Standalone (RDS-1, RDS-2, RDS-3):	3.8 lbs. (1.73 kg)
Standalone (RDS-1B):	5.4 lbs. (2.45 kg)
Trending	
72 hours of trending at 2 second resolution, up to 18 days of trending at 10 second resolution, output to serial printer or other serial devices	
Mode	
Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds[8]
Sensitivity:	Normal and Maximum[9] and APOD
Alarms	
Audible and visual alarms for high/low saturation and pulse rate (SpO_2 range 1-100%, pulse rate range 25-240 bpm, SpCO range 1%-99%, SpMet range 1%-99.9%)	
Sensor condition, system failure and low battery alarms	
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 Muted reminder:	500Hz tone, 2 pulse burst, pulse spacing 0.375s, repeat time: 3min.
Alarm Volume:	High Priority: 70 dB (min), Medium Priority: 70 dB (min), Low Priority: 45 dB (min)

Display/Indicators	
Data display:	$\%SpO_2$, %SpCO, %SpMet, pulse rate, pleth waveform, alarm status, trends, status messages, Signal IQ, perfusion index, pleth variability index, APOD and FastSat
Display update rate:	1 second
Response Time:	< 20 second delay
Display Color:	Blue
Type:	Backlit LCD
Pixels:	480 x 160 dots
Dot Pitch:	0.25 mm
Output Interface	
SatShare (RDS-1, RDS-1B)	
Serial RS-232 (RDS-1, RDS-1B, RDS-3)	
Nurse Call/Analog Output (RDS-1, RDS-1B, RDS-3)	
Philips Vuelink, Spacelabs Universal Flexport, RadNet, RadLink (RDS-1, RDS-1B, RDS-3)	
Compliance	
EMC Compliance:	EN60601-1-2, Class B
Equipment Classification:	IEC 60601-1 / UL 60601-1
Type of Protection	Class 1 (on AC power), Internally powered (on battery power)
Degree of Protection-Patient Cable:	Type BF-Applied Part
Degree of Protection-SatShare Cable:	Type CF-Applied Part
Mode of Operation:	Continuous

1 The Radical-7 with LNOP Adt 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. Plus or minus one standard deviation encompasses 68% of the population weight.

2 The Radical-7 with LNOP Neo 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. Plus or minus one standard deviation encompasses 68% of the population weight. 1% has been added to the saturation accuracy to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

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

5 SpMet and SpCO accuracy has been validated on healthy adult male and female volunteers with light to dark skin pigmentation in the range of 0% - 40% SpCO and 0% - 15% SpMet against a laboratory CO-Oximeter. This variation equals plus or minus one standard deviation, which encompasses 68% of the population. The SpCO accuracy and SpMet accuracy have not been validated under motion conditions.

6 This represents approximate run time with the backlight at minimum and Power Save mode on, using a new, fully charged battery.

7 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.

8 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.

9 Maximum sensitivity mode fixes perfusion limit to 0.02%.

10 Masimo Rainbow SET technology with LNOP, LNOPv, LNCS and Rainbow 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.

Serial interface specifications

The digital interface for serial communication is based on the standard RS-232 protocol. The Radical-7 Pulse CO-Oximeter by default always outputs ASCII 1 text data through the serial port, unless the user selects a different output mode in the Output menu. To interface with the Radical-7 Pulse CO-Oximeter and receive serial text data, simply 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.

NOTE: *The Radical-7 Pulse CO-Oximeter serial interface is only available when the Radical-7 Pulse CO-Oximeter Handheld is properly attached to the Radical-7 Pulse CO-Oximeter Docking Station.*

NOTE: *The serial interface is not available in all versions of the docking station.*

Once serial communication is established, packets of data are communicated at 1 second intervals. The data packets contain: the date, time, SpO_2, pulse rate, perfusion index and alarm and exception values. (in ASCII format).

WARNING: ALL EXTERNAL DEVICE CONNECTIONS TO THE ANALOG OUTPUT/ NURSE CALL CONNECTOR MUST BE IEC-60950 COMPLIANT.

SERIAL INTERFACE SETUP

To interface with the Radical-7 Pulse CO-Oximeter 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
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

SERIAL PRINTER SETUP

To print the SpO_2 and pulse rate data in ASCII 1 format on a serial printer, simply connect the laser printer to the serial port. Once serial communication is established, the Radical-7 Pulse CO-Oximeter will automatically start printing the ASCII1 text data.

WARNING: ALL EXTERNAL DEVICE CONNECTIONS TO THE RS-232 SERIAL PORT MUST BE IEC-60950 COMPLIANT.

Analog Output / Nurse Call Specifications

The Analog Out and Nurse Call are features accessible on the same female high density DB-15 connector.

NOTE: *The Radical-7 Pulse CO-Oximeter analog output / nurse call interface is only available when the Radical-7 Pulse CO-Oximeter Handheld is properly attached to the Radical-7 Pulse CO-Oximeter Docking Station. Only use an analog / nurse call cable that has a ferrite bead installed.*

NOTE: *The analog output / nurse call interface is not available in all versions of the Docking Station.*

The following table shows the pinout 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
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 and/or strip chart recorders through its Analog Output connector located on the back of the Docking Station. Depending on the configuration of the Output menu, the following parameters are output continuously on the Analog 1 and Analog 2 channels:

- SpO_2
- Pulse rate
- Pleth waveform
- Signal IQ

The output signals vary from approximately 0 to 1 volt in a linear fashion.

NOTE: *The actual Analog 1 and Analog 2 output voltage that are generated may not exactly range between 0.0V to 1.0V. A variance of ± 40 mV is acceptable.*

CALIBRATION

For measurement device calibration purposes, the analog output signals can be set to either 0 Volts or 1 Volt in the menu system under Output/Analog Output Mode. Calibrate your analog recording system to those levels before use.

NURSE CALL

The nurse call feature is available when Radical-7 Pulse CO-Oximeter is operating in its standalone configuration. The nurse call feature on the Radical-7 Pulse CO-Oximeter 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 of the output menu, the normally open pin will be connected to the common pin and the normally closed will be disconnected. In addition the nurse call polarity can be inverted to accommodate various nurse call stations requirements.

The nurse call relays have the following electrical specifications per switch:

PARAMETER	SPECIFICATION
MAX VOLTAGE	100VDC or AC peak
MAX CURRENT	100mA

WARNING: THE NURSE CALL FEATURE IS DISABLED WHEN THE AUDIBLE ALARMS ARE SILENCED WHILE THE NURSE CALL SETTING IN THE OUTPUT MENU IS SET TO "ALARMS".

Introduction

This section covers the use and cleaning of Masimo sensors and patient cables.

Before use of any sensor, carefully read the sensor's Directions for Use.

Use only Masimo oximetry sensors and cables for SpO_2, SpMet and SpCO measurements. Other oxygen transducers or sensors may cause improper Radical-7 Pulse CO-Oximeter performance.

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor Directions for Use to ensure skin integrity, correct positioning and adhesion of the sensor.

CAUTIONS:

- DO NOT USE DAMAGED SENSORS OR PATIENT CABLES. DO NOT USE A SENSOR OR PATIENT CABLE WITH EXPOSED OPTICAL OR ELECTRICAL COMPONENTS.
- DO NOT IMMERSE THE SENSOR OR PATIENT CABLE IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE SENSORS AND CONNECTORS ARE NOT WATERPROOF).
- UNLESS OTHERWISE SPECIFIED, DO NOT STERILIZE SENSORS OR PATIENT CABLES BY IRRADIATION, STEAM, AUTOCLAVE OR ETHYLENE OXIDE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE MASIMO SENSORS.
- DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY MASIMO SENSORS OR PATIENT CABLES AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.
- ALL SENSORS AND CABLES ARE DESIGNED FOR USE WITH SPECIFIC MONITORS. VERIFY THE COMPATIBILIY OF THE MONITOR, CABLE AND SENSOR BEFORE USE, OTHERWISE PATIENT INJURY CAN RESULT.

SELECTING A MASIMO SET SENSOR

When selecting a sensor, consider, the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. For more information refer to the following table or contact your Sales Representative. Use only Masimo sensors and sensor cables. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the Directions for Use accompanying the sensor.

High intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the sensor to obtain vital sign readings. High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

SENSOR APPLICATION INSTRUCTIONS

Unless indicated otherwise in the directions for use, reposition reusable sensors at least every 4 hours and for adhesive sensors inspect the site at least every 8 hours or sooner. If indicated by circulatory condition or skin integrity, reapply to a different monitoring site.

Masimo Rainbow Sensors

Masimo Rainbow sensors must be used with the Radical-7 Pulse CO-Oximeter to enable measurement of Carboxyhemoglobin (SpCO) and Methemoglobin (SpMet). Rainbow sensors will only function with instruments containing Masimo Rainbow SET Technology or licensed to use Rainbow compatible sensors.

Rainbow sensors connect to the device directly or with a patient cable.

RAINBOW REUSABLE SENSORS

SpO_2, SpCO, SpMet and pulse rate accuracy for the Rainbow sensors is specified in the following table.

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpCO Accuracy	SpMet Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	No Motion	No Motion
DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%
DCIP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3%	± 1%

RAINBOW ADHESIVE SENSORS

SpO_2, SpCO, SpMet and pulse rate accuracy for the Rainbow sensors is specified in the following table.

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpCO Accuracy	SpMet Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	No Motion	No Motion
R25	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%
R25-L	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%
R20	3 - 10 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%
R20-L	3 - 10 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%
	10 - 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 3.5%	± 1%

Masimo SpO_2 Sensors

The Radical-7 Pulse CO-Oximeter may use standard Masimo LNOP, LNOPv and LNCS SpO_2 sensors, when used with Red PC, Red LNC or Rainbow Patient Cables respectively.

Select the appropriate patient cable to attach the LNOP or LNCS sensor to the device.

RED REUSABLE SENSORS

Masimo Red sensors can be used with the Radical-7 Pulse CO-Oximeter to enable measurement of SpO_2 only. Red sensors will only function with oximeter devices equipped with Masimo Rainbow SET technology.

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
DCIP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

LNOP® REUSABLE SENSORS

(LNOP sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP DCIP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP YI	> 1 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	N/A	N/A
LNOP TC-I	> 30 kg	± 3.5%	N/A	± 3 bpm	N/A	± 3.5%	± 3 bpm
LNOP DC-195	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP TF-I	> 30 kg	± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm

NOTE: *The LNOP TF-I and TC-I sensors were not validated under motion conditions.*

LNOP® ADHESIVE SENSORS

(LNOP sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP Adt	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Adtx	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Pdt	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Pdtx	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Neo	< 10 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP NeoPt	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Neo-L	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 40 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP NeoPt-L	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Inf-L	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

LNOPv™ ADHESIVE SENSORS

(LNOPv sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOPv In	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOPv Ne	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOPv Ad	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

LNOP® SPECIALTY SENSORS

(LNOP sensors must be used in conjunction with Red PC cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP Newborn Infant	3 - 10 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
	10 - 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Newborn Neonatal	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNOP Blue	2.5 - 30 kg	60 - 80% ± 4%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm
		70 - 100% ± 3.3%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm
		80 - 100% ± 3%	N/A	± 3 bpm	N/A	± 3%	± 3 bpm

LNCS™ REUSABLE SENSORS

(LNCS sensors must be used in conjunction with Red LNC or Rainbow patient cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNCS DC-I	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS DC-IP	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS TC-I	> 30 kg	± 3.5%	N/A	± 3 bpm	N/A	± 3.5%	± 3 bpm
LNCS TF-I	> 30 kg	± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm

NOTE: *The LNCS TF-I and TC-I sensors were not validated under motion conditions.*

LNCS™ ADHESIVE SENSORS

(LNCS sensors must be used in conjunction with Red LNC or Rainbow patient cables)

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNCS Adtx	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Pdtx	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Inf-L	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Neo-L	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 40 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS NeoPt-L	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm

SENSOR ACCURACY

Refer to Section 7, *Specifications* for SpO_2, SpMet, SpCO and pulse rate accuracy. Unless otherwise specified in the previous tables:

The sensor accuracy specified is when used with Masimo Rainbow SET technology Pulse CO-Oximetry monitors or with licensed Masimo SET pulse oximetry modules during no motion. Accuracy range variation equals ± 1 standard deviation. Plus or minus one standard deviation represents 68% of the population. SpO_2 accuracy represents from 70% to 100%, pulse rate accuracy represents from 25 to 240 bpm, SpCO accuracy represents from 1% to 40% and SpMet accuracy represents from 1% to 15%.

CLEANING AND REUSE OF MASIMO REUSABLE SENSORS AND CABLES

Reusable sensors and patient cables can be cleaned per the following procedure:

1. Remove the sensor from the patient.
2. Disconnect the sensor from the patient cable.
3. Disconnect the patient cable from the monitor.
4. Wipe the entire sensor and/or patient cable clean with a 70% isopropyl alcohol pad.
5. Allow to air dry thoroughly before returning it to operation.

CAUTION: CAREFULLY ROUTE PATIENT CABLES TO REDUCE THE POSSIBILITY OF PATIENT ENTANGLEMENT OR STRANGULATION.

REATTACHMENT OF SINGLE USE ADHESIVE SENSORS

- Single use sensors may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

NOTE: *If the sensor fails to track the pulse consistently, the sensors may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.*

CAUTION: DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY MASIMO SENSORS OR PATIENT CABLES AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.

Introduction

This section covers:

- How to test the operation of the Radical-7 Pulse CO-Oximeter and the SatShare interface
- How to properly clean the Radical-7 Pulse CO-Oximeter
- How to recharge and replace the batteries
- How to replace the fuses
- How to obtain service

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.

WARNING: ELECTRICAL SHOCK AND FLAMMABILITY HAZARD - BEFORE CLEANING THE OXIMETER, ALWAYS TURN IT OFF AND DISCONNECT THE POWER CORD FROM THE AC POWER SUPPLY.

Cleaning

To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.

To clean the outer surface of the oximeter, use a soft cloth dampened with a mild soap and water. Do not allow liquids to enter the interior of the instrument.

CAUTIONS:

- DO NOT AUTOCLAVE, PRESSURE STERILIZE, OR GAS STERILIZE THIS OXIMETER..
- DO NOT SOAK OR IMMERSE THE MONITOR IN ANY LIQUID.
- USE THE CLEANING SOLUTION SPARINGLY. EXCESSIVE SOLUTION CAN FLOW INTO THE MONITOR AND CAUSE DAMAGE TO INTERNAL COMPONENTS.
- 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 PANEL.
- DO NOT USE PETROLEUM-BASED OR ACETONE SOLUTIONS, OR OTHER HARSH SOLVENTS, TO CLEAN THE OXIMETER. THESE SUBSTANCES ATTACK THE DEVICE'S MATERIALS AND DEVICE FAILURE CAN RESULT.

Refer to Section 8, *Cleaning and Reuse of Masimo Sensors* for cleaning instructions of the sensor.

Battery Operation and Maintenance

The Radical-7 Pulse CO-Oximeter Handheld includes a 1.5 Amp-Hour Nickel Metal Hydride battery. The Radical-7 Pulse CO-Oximeter Docking Station may include the optional 6.5 Amp-Hour Nickel Metal Hydride battery.

Before using the Radical-7 Pulse CO-Oximeter as a Handheld or transport monitor, the Handheld battery and the optional Docking Station battery need to be fully charged.

To charge the battery(s), attach the Handheld unit to the Docking Station. Ensure that AC power is attached to the Docking Station. Verify that the battery(s) are charging; the battery charging LED indicators on the Docking Station flash prior to charging and remain illuminated while the battery(s) are charging. A continuously flashing battery charging LED indicates that the internal battery temperature exceeds recommended operating conditions for proper battery charging. Proper battery charging will proceed when the temperature returns to recommended operating conditions.

The Handheld battery requires approximately 2 to 3 hours for charging. The optional Docking Station battery requires approximately 6 hours for charging.

When the battery charging LED indicators turn off, additional trickle charging may occur to complete charging. Although battery charging can occur while the Handheld is docked and powered on, most efficient charge times are achieved with the Handheld unit turned off.

CAUTIONS:

- ALL BATTERIES LOSE CAPACITY WITH AGE, THUS THE AMOUNT OF RUN TIME LEFT AT LOW BATTERY WILL VARY DEPENDING UPON THE AGE OF THE BATTERY.
- AT LOW BATTERY CONNECT THE RADICAL-7 PULSE CO-OXIMETER TO AC POWER TO PREVENT LOSS OF POWER.

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

- ILLUMINATION OF THE BACKLIT LCD SCREEN. TO CONSERVE BATTERY POWER, KEEP THE BACKLIT LCD SCREEN AT MINIMUM ILLUMINATION.
- VOLUME OF THE ALARM TONES. TO CONSERVE BATTERY POWER, KEEP THE FREQUENCY OF THE AUDIBLE ALARMS TO A MINIMUM AND AT MINIMUM VOLUME.
- THE SATSHARE FEATURE. TO CONSERVE BATTERY POWER, ALWAYS KEEP THE UNIT ON AC LINE POWER.

Memory effects of the battery pack may shorten run-time. When battery run time is significantly reduced, it is advisable to completely discharge and fully recharge the battery pack. To properly discharge the battery pack, use the Battery Discharge function as described in Section 4, Service.

CAUTION:

- IF THE RADICAL-7 PULSE CO-OXIMETER HANDHELD HAS NOT BEEN USED OR CHARGED WITHIN SEVEN (7) DAYS OR MORE, THEN RECHARGE THE BATTERY PRIOR TO USE.
- IT IS RECOMMENDED THAT THE RADICAL-7 PULSE CO-OXIMETER HANDHELD IS DOCKED TO THE DOCKING STATION ATTACHED TO AN AC POWER SOURCE WHEN IT IS NOT IN USE TO ENSURE THAT THE BATTERY REMAINS FULLY CHARGED.

The following tables outline the estimated run times of the battery powered Radical-7 Pulse CO-Oximeter. The time estimates are based on a Radical-7 Pulse CO-Oximeter with fully charged batteries. The time estimates are also based on a Radical-7 with and without backlight lit, and the power save feature enabled and disabled.

The Radical-7 Pulse CO-Oximeter is always configured to include the Handheld battery. It may optionally be configured to include the Docking Station battery. Please determine the configuration of your system before referencing the following tables.

Configuration #1:

Radical-7 Pulse CO-Oximeter configured to only include the Handheld battery (standard configuration); the Docking Station battery is excluded.

NOTE: *For this configuration, it is advisable to operate only the Radical-7 Handheld unit when running on battery power. Although it is possible to operate the entire Standalone unit (the Handheld attached to the Docking Station, with the Handheld battery powering the Docking Station as well) on battery power, the capacity of the Handheld battery pack is insufficient to support this mode for long periods of time. The Power Save setting in the General menu determines whether the Docking Station is powered or not during battery operation. See Section 4, General, for a detailed description on proper use of the Power Save setting.*

RADICAL-7 CONFIGURATION	OPERATION MODE	MINIMUM RUN-TIME
HANDHELD ONLY	Power Save "yes" Backlight turned "off"	4 hrs
STANDALONE	Power Save "no" Backlight turned "on"	1 hr

CONFIGURATION #2:

Radical-7 configured to include the Handheld and the Docking Station battery:

RADICAL-7 CONFIGURATION	OPERATION MODE	MINIMUM RUN-TIME
STANDALONE	Power Save "yes" Backlight turned "off"	10 hrs
STANDALONE	Power Save "no" Backlight turned "on"	6 hr

REPLACING THE BATTERIES

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

To replace the Handheld battery, follow these instructions:

1. Turn the Radical-7 Pulse CO-Oximeter Handheld off and remove the patient cable connection. Detach the Radical-7 Pulse CO-Oximeter Handheld from the Docking Station (if docked).
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 Handheld into Docking Station, turn on line power and charge battery according to this Section, Battery Operation and Maintenance.

CAUTION: FOLLOW LOCAL GOVERNING GUIDELINES FOR PROPER DISPOSAL OF INTERNAL BATTERIES. DO NOT INCINERATE.

WARNING: THE DOCKING STATION BATTERY SHOULD BE INSTALLED AND/OR REMOVED FROM DOCKING STATION BY QUALIFIED PERSONNEL ONLY.

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.

To replace the fuse(s), you will need a flat-blade screwdriver (5mm; 3/16").

To replace the fuses:

1. Disconnect unit from AC power.
2. Remove AC power cord from the power entry module at the rear of the docking station.
3. Use the small flat-blade screwdriver and gently pry loose the fuse cover in the left portion of the power entry module, exposing the fuse holder.
4. Using the small flat-blade screwdriver, gently pry out 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) (1 Amp, Metric, fast acting, 5x20mm, 250V) in the fuse holder, properly orienting the fuse(s).
8. Slide the fuse holder back into the power entry module and press firmly to make sure it is completely seated.
9. Close the fuse cover and press gently until it seats completely, flush with the back of the docking station.
10. The unit is ready to be reconnected to AC power.

NOTE: *If the fuses blow shortly after replacement, the unit requires service.*

WARNING: FIRE HAZARD: TO PROTECT AGAINST FIRE HAZARD, REPLACE ONLY WITH FUSES OF THE SAME TYPE, CURRENT RATING, AND VOLTAGE RATING.

Performance verification

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

Before performing the following tests place the Radical-7 Pulse CO-Oximeter Handheld into the Docking Station, connect the Radical-7 to AC power and fully charge the Radical-7 Pulse CO-Oximeter Handheld battery. Also disconnect any patient cables or pulse oximetry probes, as well as SatShare, serial or analog output cables from the instrument. Set the Radical-7 Pulse CO-Oximeter to normal operating mode by selecting the Home Use parameter in the General Menu to "No".

Power-On Self-Test:

1. Connect the monitor to AC power and verify that the AC Power Indicator is lit.
2. Turn the monitor on by depressing the Power/Standby Button. Within 5 seconds all available LEDs are illuminated, a 1-second beep tone sounds, and the Masimo SET logo is displayed.
3. The blue Docking Indicator LED is illuminated and the Radical-7 begins normal operation.

Key Press Button Test:

1. With the exception of the Power/Standby Button, press each soft key button and verify that the Radical-7 acknowledges each key-press with an audible beep tone or by indicating a change on the display.

Alarm Limit Test:

1. With the monitor turned on, select the Menu Access key and enter the Alarm menu. Change the High SpO_2 Alarm parameter to a value two points below the currently selected value, and accept the change.
2. Verify that the newly set parameter is shown on the Saturation Alarm Limit Display, next to the SpO_2 or pulse rate measurement display.
3. Return the High Saturation Alarm parameter to its original setting.
4. Repeat steps 1 to 3 for the following alarm parameters:

- Low SpO_2
- High and Low BPM
- High and Low SpMet
- High and Low SpCO

5. Reset the alarm limits again to the original settings.

Display Contrast Test:

1. With the monitor turned on, select the Menu Access key and enter the Display menu. Change the Contrast parameter by scrolling through the contrast settings.
2. Return the Contrast setting to the original value, or a value that allows maximum viewing contrast.
3. Exit the Menu system and press and hold down the Backlight/Contrast button for several seconds. The display will scroll again through all the contrast settings.
4. Release the Backlight/Contrast button again when the display shows maximum viewing contrast.

Testing with Masimo SET Tester (Optional):

1. Turn the Radical-7 off and then on again.
2. Set the alarm limits to:

	% SpO_2	Pulse Rate
High	100	140
Low	90	50

3. Connect the Masimo SET Tester to the Red Patient Cable Connecter.
4. Verify that within 20 seconds a plethysmographic and a Signal IQ waveform displays. (may require the Radical-7 to be set to the Pleth and Signal IQ display setting).
5. Verify that the SpO_2 measurement is between 79% and 84%.
6. Verify that the pulse rate measurement is between 55 bpm and 65 bpm.
7. Verify that an audible alarm occurs and that the SpO_2 measurement and the low SpO_2 alarm are flashing
8. Press the Alarm Silence button once and verify that the alarm is silenced.
9. Wait 120 seconds and verify that the alarm silence times out and the audible alarm is activated again.
10. Press the Increase Loudness button several times and verify that the loudness of the pulse beep tone increases.
11. Press the Decrease Loudness button and verify that the loudness of the pulse beep tone decreases. Press the Decrease Loudness button and verify that the loudness of the pulse beep tone can be turned off.

Nurse Call Test:

1. Disconnect the Red patient cable or the Masimo SET Tester from the Radical-7 and turn the instrument on. Ensure that there are no audible alarms and that the audible alarms are not silenced. Verify the nurse call polarity is set to normal (default).
2. Connect the common lead of a digital multi-meter to the pin 12 (Nurse Call - Common) of the analog output connector on the Radical. 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).
3. Trigger an alarm on the monitor (e.g. by disconnecting a sensor after it was measuring data) and verify that the resistance is less than 35 ohms.

Analog Output Test

1. Disconnect all patient cables and sensors from the Radical-7. Turn the Radical-7 off and then 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. Enter the menu system and set the "Output", "Analog 1" to "0V Signal". Verify that the voltmeter measures a voltage of approximately 0V.
4. Enter the menu system and set the "Output", "Analog 1" to "1V Signal". Verify that the voltmeter measures a voltage of approximately 1.0V.
5. Repeat Steps 3 and 4, with the positive lead of the voltmeter connected to pin 15 (Analog 2).
6. 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

1. Fully charge the Radical-7 by placing the Handheld into the Docking Station and connecting the AC power.
2. Verify that the green Handheld Battery Indicator LED is lit up.
3. When the Radical-7 is fully charged the green Handheld Battery Indicator turns off.
4. Turn the Radical-7 on and verify that the Battery indicator shows a full charge.

Service and repair

REPAIR POLICY

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the unit repaired.

WARNING: DO NOT REMOVE THE COVER OF THE MONITOR EXCEPT FOR BATTERY REPLACEMENT. AN OPERATOR MAY ONLY PERFORM MAINTENANCE PROCEDURES SPECIFICALLY DESCRIBED IN THIS MANUAL. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL TRAINED IN THE REPAIR OF THIS EQUIPMENT.

Please clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in Section 9, Cleaning. Make sure it is fully dry before packing the equipment.

To return the Radical-7 unit for service, please follow the Return Procedure.

RETURN PROCEDURE

Please clean contaminated/dirty equipment before returning and make sure it is fully dry before packing the equipment. 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 Pulse CO-Oximeter. Please 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 oximeter 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 oximeter has been decontaminated for bloodborne pathogens.

Return Radical-7 pulse oximeter to the following shipping address:

For USA and Asia Pacific:

Masimo Corporation
40 Parker
Irvine, California 92618
Tel: 949-297-7000
FAX: 949-297-7001

For Europe:

Masimo Europe Limited
304 RN6, Le Bois des Cotes 2
69760 Limonest
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Warranty

Masimo warrants to the initial purchaser that each new Pulse CO-Oximeter will be free from defects in workmanship or materials for a period of one (1) year from the date of purchase. Masimo's sole obligation under this warranty is to repair or replace any product that Masimo deems to be covered under warranty with a repaired or a replacement Pulse CO-Oximeter.

Batteries are warranted for six (6) months.

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

Exclusions

This warranty does not extend to any product that has been subject to misuse, neglect or accident; that has been damaged by causes external to the Product; that has been used in violation of the operating instructions supplied with the Product. The warranty does not extend to any product that has been connected to an unlicensed instrument system, modified accessories or any unit that has been disassembled or reassembled by anyone but an authorized Masimo agent. This warranty does not extend to sensors or patient cables that have been reprocessed, reconditioned or recycled.

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Accessories

The following accessories and re-order parts are available with the Radical-7 Signal Extraction Pulse CO-Oximeter:

PART NUMBER	DESCRIPTION
1315	REPLACEMENT BATTERY, RADICAL-7 HANDHELD
1317	RADICAL-7 POLE CLAMP
1395	RADICAL-7 HANDHELD LOCK
1584	RADICAL-7 POWER CORD LOCK, 5/PACK
1595	SATSHARE CABLE, AT01
1324	SATSHARE CABLE, DO01
1326	SATSHARE CABLE, DO02
1528	SATSHARE CABLE, DO03
1533	SATSHARE CABLE, DO04
2023	SATSHARE CABLE, DO05
1325	SATSHARE CABLE, DS01
1539	SATSHARE CABLE, DS02
1528	SATSHARE CABLE, DS03
1357	SATSHARE CABLE, HP03
1321	SATSHARE CABLE, MQ01
1789	SATSHARE CABLE, MS01
1367	SATSHARE CABLE, NK01
1368	SATSHARE CABLE, NK02
1366	SATSHARE CABLE, OH01
1646	SATSHARE CABLE, OH02
1840	SATSHARE CABLE, PM01
1323	SATSHARE CABLE, SL01
1362	SATSHARE CABLE, SL02
1322	SATSHARE CABLE, SM01
1605	SATSHARE EXTENSION CABLE
31347	RADICAL-7 OPERATOR'S MANUAL - ENGLISH
31482	RADICAL-7 OPERATOR'S MANUAL - FRENCH
31483	RADICAL-7 OPERATOR'S MANUAL - GERMAN
31484	RADICAL-7 OPERATOR'S MANUAL - ITALIAN
31485	RADICAL-7 OPERATOR'S MANUAL - SPANISH
31486	RADICAL-7 OPERATOR'S MANUAL - SWEDISH
31487	RADICAL-7 OPERATOR'S MANUAL - DUTCH
31488	RADICAL-7 OPERATOR'S MANUAL - DANISH
31489	RADICAL-7 OPERATOR'S MANUAL - PORTUGUESE
31490	RADICAL-7 OPERATOR'S MANUAL - CHINESE
31491	RADICAL-7 OPERATOR'S MANUAL - JAPANESE
30475	RADICAL-7 HANDHELD CASE

Please visit our website, www.masimo.com, for updated information about accessories.

31347/4225B-0607

Masimo SET® rainbow

www.masimo.com

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