Rad-8®

Pulse Oximeter

Signal Extraction Pulse Oximeter

OPERATOR'S MANUAL

PATIENT GUIDE

Masimo®

Rad-8

Pulse Oximeter

Signal Extraction Pulse Oximeter

OPERATOR'S MANUAL

The Rad-8 Operating Instructions provide the necessary information for proper operation of the Rad-8 device. General knowledge of pulse oximetry and an understanding of the features and functions of the Rad-8 are a prerequisite for its proper use. Do not operate the Rad-8 without completely reading and understanding the instructions in this manual.

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, 7,221,971, 7,215,986, 7,215,984, 7,186,966, 6,979,812, 6,861,639, 6,850,787, 6,826,419, 6,816,741, 6,745,060, 6,699,194, 6,684,090, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,515,273, 6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,157,850, 6,067,462, 6,011,986, 6,002,952, 5,919,134, 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.htm. Other patents pending.

SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES

The Rad-8 Pulse 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 Rad-8 in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- High intensity extreme lights (including pulsating strobe lights) directed on the sensor, may not allow the Pulse Oximeter to obtain readings.
- The Rad-8 is NOT intended for use as an apnea monitor.
- The Pulse 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.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- The Rad-8 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 Rad-8 device. 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 Rad-8 or accessories in any position that might cause it to fall on the patient. Do not lift the Rad-8 by the power cord or any other cable.
- Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter can not measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.
  - For increased COHb: COHb levels above normal tend to increase the level of SpO_2. The level of increase is approximately equal to the amount of COHb that is present.

  NOTE: *High levels of COHb may occur with a seemingly normal SpO_2. When elevated levels of COHb are suspected, laboratory analysis (co-oximetry) of a blood sample should be performed.*
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 measurements. When elevated levels of MetHb are suspected, laboratory analysis (co-oximetry) of a blood sample should be performed.
- Elevated levels of Carboxyhemoglobin (COHb) will lead to inaccurate SpO_2 measurements. When elevated levels of COHb are suspected, laboratory analysis (co-oximetry) of a blood sample should be performed.
- Elevated levels of Total Bilirubin may lead to inaccurate SpO_2 measurements.
- Severe anemia may cause erroneous SpO_2 readings.
- Do not use the Rad-8 or sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Rad-8 may affect the MRI image and the MRI device may affect the accuracy of the Pulse Oximetry parameters and measurements.

SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES

- If using Rad-8 during full body radiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
- For home use, ensure that the Rad-8 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 Rad-8 before bathing the patient.
- Additional information specific to Masimo sensors including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's Directions For Use (DFU).
- Do not place the Rad-8 where the controls can be changed by the patient.
- Do not place the Rad-8 face against a surface. This will cause the alarm to be muffled.
- Do not place the Rad-8 on electrical equipment that may affect the Pulse Oximeter, preventing it from working properly.
- Do not expose the Rad-8 to excessive moisture such as direct exposure to rain. Excessive moisture can cause the device to perform inaccurately or fail.
- Do not place containers with liquids on or near the Rad-8. Liquids spilled on the device may cause it to perform inaccurately or fail.
- If the Rad-8 fails any part of the setup procedures or leakage tests, remove the device from operation until qualified service personnel have corrected the situation.
- If a sensor is damaged in any way, discontinue use immediately.
- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- The Rad-8 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.
  - Consult the manufacturer for help.
- A functional tester cannot be utilized to assess the accuracy of the Pulse Oximeter or any sensors.
- Ensure the speaker is not covered or the device is not placed face-down on bedding or other sound absorbing surface.
- To protect against injury from electric shock, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Always turn off and disconnect the power cord from the AC power supply before cleaning the device.
  - Use cleaning solutions sparingly.

SECTION 4 - OPERATION (CONTINUED)

SECTION 5 - ALARMS AND MESSAGES

About This Manual

This manual explains how to set up and use the Rad-8 Pulse Oximeter. Important safety information relating to general use of the Rad-8 Pulse 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 pulse oximetry.
SECTION 2	**SYSTEM DESCRIPTION** describes the Rad-8 Pulse Oximeter system and its functions and features.
SECTION 3	**SETUP** describes how to setup the Rad-8 Pulse Oximeter for use.
SECTION 4	**OPERATION** describes the operation of the Rad-8 Pulse 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 Rad-8 Pulse Oximeter.
SECTION 8	**SENSORS AND PATIENT CABLES** outlines how to use and care for the Masimo SET LNOP and LNCS sensors and Masimo SET patient cables.
SECTION 9	**SERVICE AND MAINTENANCE** describes how to maintain, service and obtain repair for the Rad-8 Pulse Oximeter.
SECTION 10	**ACCESSORIES** list the available Rad-8 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 Rad-8 is a noninvasive, arterial oxygen saturation and pulse rate monitor. The Rad-8 features a multicolored LED display that continuously displays numeric values for SpO_2 and pulse rate, as well as LED indicator bars for Perfusion Index (PI) and Signal Identification and Quality Indicator (Signal IQ ®).

The device consists of two models: the vertical Rad-8 and the horizontal Rad-8.

FEATURES AND BENEFITS

These features are common to the Rad-8:

- Masimo SET is clinically proven to be the highest sensitivity and specificity pulse oximeter technology in the world.
- Applicable for use on neonate, infant, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, alarm, and perfusion index displays
- Signal I.Q. for signal identification and quality indication
- FastSat® tracks rapid changes in arterial O_2 saturation with high fidelity.
- Variable pitch provides tonal variance for every 1% change in saturation.
- Lightweight, convenient compact design
- Audible and visual alarm for no sensor, sensor-off and low battery
- One touch button access to alarms for High/Low saturation and High/Low pulse rate
- User definable alarm limit settings
- Sleep mode
- Home mode
- Stores up to 72 hours of trending memory
- Adjustable alarm volume
- Up to 7 hours Internal battery life with fully charged battery
- Serial output port

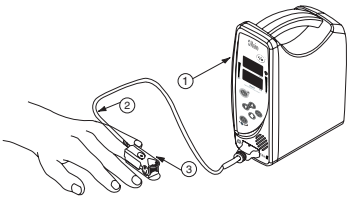
INDICATIONS FOR USE

The Rad-8 Pulse Oximeter and accessories are indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2). The Rad-8 Pulse Oximeter and accessories are indicated for use with adult, pediatric, infant and neonatal patients during both motion and no motion conditions, who are well or poorly perfused patients in hospitals, hospital-type facilities, mobile and home environments.

Pulse Oximetry

SpO_2 GENERAL DESCRIPTION

Pulse Oximetry is a continuous and noninvasive 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 Oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The following figure shows the general monitoring setup.

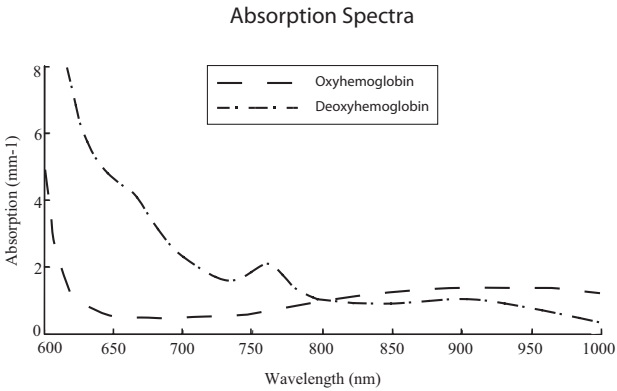


1. Instrument
2 Patient Cable
3. Sensor

PRINCIPLE OF OPERATION

Pulse Oximetry is governed by the following principles:

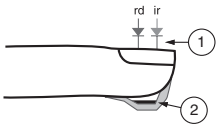
1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) constituents differ in their absorption of visible and infrared light (using spectrophotometry, see figure below).



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

PRINCIPLE OF OPERATION (CONTINUED)

The Rad-8 Pulse Oximeter uses a two-wavelength pulsatile system to distinguish between oxygenated and deoxygenated blood. Signal data is obtained by passing red (rd) (660 nm wavelength) and infrared (ir) (905 nm wavelength) light through a capillary bed (for example a fingertip, a hand or a foot) and measuring changes in light absorption during the pulsatile cycle. This information may be useful to clinicians. The radiant power of the light is rated at 0.79mW (max.). See figure below. The Rad-8 utilizes a sensor with red and infrared light-emitting diodes (LEDs) that pass light through the site to a photodiode (photodetector). The photodetector receives the light, converts it into an electronic signal and sends it to the Rad-8 for calculation.



1. Light Emitting Diodes (LEDs)
2. Recessed Photo Detector

Once the device receives the signal from the sensor, it utilizes Masimo SET signal extraction technology for calculation of the patient's functional oxygen saturation and pulse rate. 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.

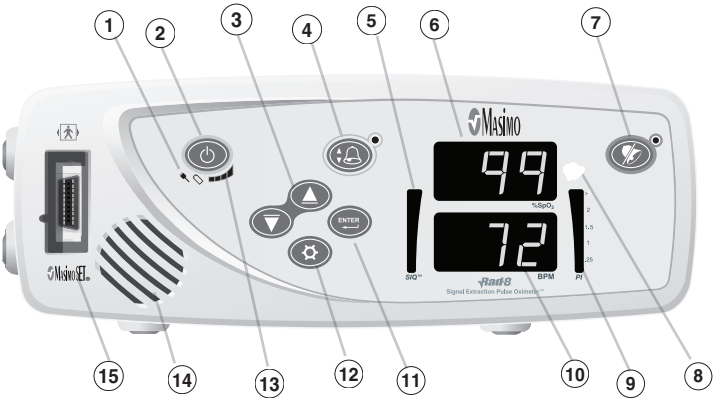
FUNCTIONAL SATURATION

The Rad-8 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.

RAD-8 VS. DRAWN WHOLE BLOOD MEASUREMENTS

When SpO_2 measurements obtained from the Rad-8 (noninvasive) are compared to drawn whole blood (invasive) measurements by blood gas and/or laboratory oximetry methods, caution should be taken when evaluating and interpreting the results. The blood gas and/or laboratory-oximetry measurements may differ from the SpO_2 measurements of the Rad-8 Pulse 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 (PO_2) and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. As blood samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation of the patient is stable and not changing over the period of time that the blood gas sample is taken. Subsequently, blood gas and laboratory oximetry measurements of SpO_2 may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn, whole-blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

RAD-8 FRONT PANEL (HORIZONTAL MODEL)



RAD-8 FRONT PANEL (VERTICAL MODEL)

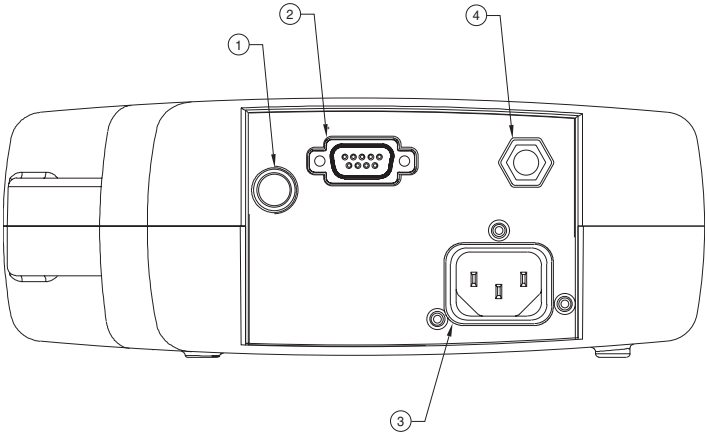
Front Panel Controls/Indicators

	CONTROL / INDICATOR		DESCRIPTION
1	AC Power Indicator		The AC Power Indicator is illuminated when the device is connected to AC power.
2	Power On/Off		Press to turn the unit on and off.
3	Up Button Down Button		Use these buttons to adjust the volume of the pulse beep tone. Within the menu/setup system, these buttons are used to select values within each menu option or the numeric value for the parameter/measurement alarm feature. *Pressing and holding down these buttons allow for the rapid scrolling of alarm limits.*
4	Alarm Limits Button		Used to enter the alarm limits menu in order to adjust Hi/Low SpO_2, PI, and pulse rate alarm limits. The LED indicator (located above the Alarm Limits Button) will illuminate when one or more of the factory default alarm settings is changed to alert the user to verify alarm settings.
5	Signal IQ/Pulse Bar		The Signal IQ provides an indication of the quality of the acquired signal as well as the timing of the pulse. A green vertical LED bar rises and falls with the pulse, where the height of the bar indicates the quality of the signal.
6	Saturation Display		The functional arterial hemoglobin oxygen saturation is displayed in units of % for SpO_2. When searching for a saturation and pulse, "----" scrolls across the screen as the system calibrates and obtains patient data (approximately 10 seconds).
7	Alarm Silence Button		Press the Alarm Silence Button to temporarily silence patient and low battery alarms. Press the Alarm Silence Button when the "SEN 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 silenced until the Pulse Oximeter starts measuring patient parameters/measurements again. ***NOTE:*** *The alarm silence time can be set for 120, 30, 60 and 90 seconds.* See Section 4, *Setup Menu Level 2.*
8	Alarm Bell		The alarm bell flashes to indicate an alarm condition.
9	Perfusion Index		The Perfusion Index provides an indication of the percentage of pulsatile signal to non pulsatile signal. The bar is highest when the quality of the perfused site is best.
10	Pulse Rate Display		The pulse rate in beats per minute (bpm). When searching for a saturation and pulse, "----" scrolls across the screen as the system calibrates and obtains patient data (approximately 10 seconds).
11	Enter Button		Used to enter the setup menus and to select/activate certain entries within the menu/setup system.
12	Brightness Button		Controls the level of the brightness for the LED display by providing 4 levels of brightness. Each press of the button increases the brightness one level. Once level 4 is accessed, an additional press of the button returns the brightness to level 1.

Front Panel Controls/Indicators continued

CONTROL / INDICATOR			DESCRIPTION
13	Battery Charge Level Indicator		Provides a visual representation of battery charge status. When unplugged, bars illuminate to indicate battery charge. A low battery status is indicated by a low audible beep- and the first battery bar to the left flashing green.
14	Speaker		Provides audible indication of alarm conditions, pulse tone and feedback for key-presses.
15	Patient Cable Connector		Connects to a Masimo Pulse Oximeter sensor or Masimo Pulse Oximeter Patient Cable with a sensor.

RAD-8 REAR PANEL



1	**NURSE CALL CONNECTOR**	Use the 1/4" round Connector to interface with a nurse call system. This is a mono output and should be utilized with a mono cable. All external device connections to the Nurse Call Connector must be IEC-60950 compliant.
2	**SERIAL OUTPUT CONNECTOR**	Use the Serial Output Connector to connect a serial device, including a serial printer, to the Rad-8. See Section 7, *Serial Interface Specifications*. All external device connections to the Serial Output Connector must be IEC-60950 compliant.
3	**POWER ENTRY MODULE**	The power entry module contains the input connector for AC power. The AC input provides power to the system from the AC line. Always connect the pulse oximeter to the main power for continuous operation and/or battery recharging.
4	**EQUIPOTENTIAL GROUND CONNECTOR**	Use the Equipotential Ground Connector for grounding.

SYMBOLS

The following symbols are found on the pulse oximeter or packaging and are defined below:

SYMBOLS	DEFINITION
RS-232	RS-232
	Equipotential Ground Terminal
	Caution, consult accompanying documents
	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)
	Year of manufacture
CLASSIFIED C UL US	Underwriter's Laboratories Inc. certification
5%-95% RH	Storage humidity range: 5% to 95%
+70 C -40 C +1600 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

Introduction

Before the pulse oximeter can be used in a clinical setting, it needs to be inspected and properly setup with the battery 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 Rad-8 Pulse Oximeter.

POWER REQUIREMENTS

Always use a hospital grade, AC power cable to connect the pulse oximeter to an AC power source.

CAUTION: DO NOT CONNECT THE RAD-8 PULSE OXIMETER TO AN AC OUTLET CONTROLLED BY A SWITCH.

Verify the AC power voltage and frequency before use. Verify that the power source can provide adequate power rating as indicated on the rear panel.

The pulse oximeter is designed to operate on 100 to 240VAC, 47-63 Hz. The device is rated at 20 VA max.

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

CAUTION:

- CONNECT THE RAD-8 ONLY TO A HOSPITAL-GRADE RECEPTACLE (FOR HOSPITAL USE).
- 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 battery needs to be fully charged.

To charge the internal battery, plug in the AC power cord. Verify that the battery is charging. The green AC power indicator on the device will illuminate while the battery is charging.

CAUTION: TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SERIAL PORT ON THE BACK PANEL UNLESS THE PULSE OXIMETER IS CONNECTED TO THE AC MAIN POWER SUPPLY.

INITIAL INSTALLATION

Place the Rad-8 on a stable hard flat surface near the patient. Always place the Rad-8 on a dry surface. Maintain a minimum of 1 inch (2.54 cm) free space around the device. Make sure that Rad-8 loudspeaker is not covered to avoid a muffled alarm sound.

The device should not be stored outside the following environmental conditions:

ENVIRONMENTAL CONDITIONS	
TEMPERATURE	+5°C to +40°C, +41°F to +104°F
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)

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

CAUTION: THE BATTERY SHOULD BE ADEQUATELY CHARGED TO ENSURE BACKUP POWER IN CASE OF AC POWER DISRUPTION.

Introduction

To operate the Rad-8 system effectively, the device must be set up correctly and the operator must

- Know how the oximeter derives its readings (see Section 1, *Pulse Oximetry*)
- Be familiar with its control components and operation (see Section 2, *System Description).*
- Understand its status and alarm messages (see Section 5, *Alarm Identification, System Messages* and Section 6, *Troubleshooting*).

Basic operation

GENERAL SETUP AND USE

1. Inspect the Rad-8 case for damage.
2. Connect a patient cable or a direct connect sensor to the Rad-8 device. Make sure it is a firm connection and the cable is not twisted, sliced or frayed.
3. If utilizing a patient cable, select a sensor that is compatible with the Rad-8 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 detector are properly aligned. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector.
4. Refer to the Directions for Use of the sensor before attaching the sensor to the patient.
5. Attach the Masimo sensor to the Patient. Connect the sensor to the patient cable with the logos lining up; make sure it is a firm connection.
6. Press the Power button to turn the Rad-8 on.
7. Verify all front-panel indicators momentarily illuminate and a tone is heard.
8. Verify the front-panel display is free of alarm and system failure messages (see Section 5, *Alarms and Messages*).
9. Verify the LED shows the following:
   - Mode setting: Standard (Std) or Sleep (SLP) or Home (Hnn).
   - SpO_2 Low Alarm Limit and SpO_2 High Alarm Limit,
   - Pulse Rate Low Alarm Limit and Pulse Rate High Alarm Limit.
10. On the display, verify the readings for SpO_2 and pulse rate.

NOTE: *"- - -" will flash on the numeric display until the SpO_2 and pulse rate readings have stabilized (approximately 10 seconds).*

11. On the LED, verify the alarm limit settings. (See *Setup Menu Level 1* in this section)
12. Verify that the patient alarms are functional by setting the high and low alarm limits beyond the patient readings.
    - An alarm tone sounds.
    - The Alarm Bell flashes red for high priority alarms.
    - The number value for the violated alarm limit will flash on the LED display.

GENERAL SETUP AND USE (CONTINUED)

13. Verify the sensor alarms are functional.
    - Remove the sensor from the sensor site.
    - The alarm tone sounds.
    - The Alarm Bell flashes red.
    - The display shows "SEN OFF" message.

    Disconnect the sensor from the patient cable or Rad-8.
    - The alarm tone sounds.
    - The Alarm Bell flashes red.
    - The display shows "NO SEN" message.

    NOTE: *"NO SEN" or "SEN OFF" conditions will only generate a high priority alarm if the Rad-8 is actively monitoring a patient when the sensor is disconnected.*
14. Verify that the audible alarm can be silenced when a parameter/measurement alarm is exceeded.
    - 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 120 seconds (default).
    - The Alarm Bell flashes red for a high pulse rate (high priority alarm).
15. To begin patient monitoring:
    - Adjust the alarm limits.
    - Adjust the alarm volume.
    - Adjust the pulse beep volume
16. Verify the sensor is applied correctly and that the measured data is appropriate, see Section 4, *Successful Monitoring.*
17. Monitor the patient.
18. After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to local laws. See the Directions for Use of the sensor.
19. Press and hold the Power Button for 2 seconds to turn the Rad-8 off (3 seconds in the Home Mode).

DEFAULT SETTINGS

The Rad-8 Pulse Oximeter stores two types of default values that the device automatically retains after a power cycle. Default Settings are described in detail in Setup Menu Level 3.

1. Factory defaults set by Masimo.
2. User Configurable Default settings that can be changed by the user which will be remembered after a power cycle.

FACTORY DEFAULT AND USER CONFIGURABLE SETTINGS

OPTION	FACTORY DEFAULT SETTINGS	USER CONFIGURABLE DEFAULT SETTINGS	USER CONFIGURABLE DEFAULT SETTINGS REFERENCE
SpO_2 high alarm limit*	"---" Off	2 to 99%	Section 4 Setup Menu Level 1
SpO_2 low alarm limit*	90%	1 to 99%	
Pulse rate high alarm limit*	140 BPM	35 to 235 BPM	
Pulse rate low alarm limit*	50 BPM	30 to 230 BPM	
LED Brightness	Level 3	Levels 1 thru 4	
Alarm Volume	Level 3 (70 dB min)	Levels 1 thru 4	Section 4 Setup Menu Level 2
Alarm Silence	120 seconds	30, 60, 90, or 120 seconds	
Alarm Delay	5 seconds	0, 5, 10, or 15 seconds	
Clear Trend	Clear Trend (No)	Clear Trend (Yes/No)	
Button Volume	Level 2	Levels 1 thru 4	
Sensitivity	APOD	Max/Normal/APOD ***NOTE:*** *MAX sensitivity will default to APOD after a power cycle.*	
FastSat	FastSat Off	FastSat (On/Off)	
Averaging Time	8 seconds (2 sec. in Sleep mode)	2, 4, 8, 10, 12, 14 and 16	Section 4 Setup Menu Level 3
Rapid Desat Alarm	5%	0, 5 and 10	
Alarm On/Off	Alarms active (On)	On/Off or muted with reminder	
Default Settings	No Change	User Default/Factory Default	
SmartTone On/Off	Off (Normal Tone)	On (SmartTone)	
Year	Internal Clock	Current year	
Month		Curent Month	
Day		Current Day	
Hour		Current Hour	
Minute		Current Minute	
Serial Out	ASCII 2	Philips/ASCII 1/ASCII 2	
Software Version	System Software	SET Software	
Interface Alarms	Alarms On	Alarms (On/Off)	
Nurse Call	Alarms	Alarms/SIQ/Alarms and SIQ	
Polarity	Normal	Normal/Invert	
Set Mode	Standard (Normal)	Standard/Sleep/Home**	Section 4 Setup Menu Level 4

* User configurable settings will change back to factory defaults when power is turned off and on, unless user settings are locked in as User Defaults. Refer to Setup Menu Level 3 in this section to save user defaults.

** Home default setting will not change when power is turned off and on.

Successful Monitoring

The following general points will aid in ensuring monitoring success.

NOTE: *See Safety Information, Warnings, Cautions and Notes for additional information.*

- Place the sensor on a site that has sufficient perfusion and provides proper alignment of the LED's and detector.
- 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 (electro-surgical device, for example).
- Read the sensor Directions for Use for proper sensor application.

MASIMO PULSE OXIMETRY SENSORS

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

Use only Masimo sensors for pulse 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 confidence 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. Inaccurate measurements may be caused by:

- Elevated levels of Carboxyhemoglobin.
- Elevated levels of Methemoglobin.
- Severe anemia.
- Elevated Total Bilirubin levels.
- Low arterial perfusion.
- Motion artifact.

NUMERIC DISPLAY - PULSE RATE

The Pulse Rate displayed on the Rad-8 Pulse 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 Rad-8 to be significantly different than the ECG heart rate.

NUMERIC DISPLAY - (PI)

The perfusion index (PI) bar graph indicator 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 motion artifact and changes in physiology and blood flow.

LOW PERFUSION

The device indicates perfusion on a 10-bar LED indicator. The lower two segments of the bar will turn red when the amplitude of the arterial pulsations is very low (low perfusion).

It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation[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 INDICATION 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 detector are aligned directly opposite each other.
- Select a site where the distance between the emitter and detector 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. Strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electro-surgical units or other electrical/electronic equipment
- 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 pulse oximeter integrated with Masimo 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 OXIMETER FOR PROPER FUNCTIONING.

SIGNAL IQ - (SIQ)

The 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 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.

The Signal IQ is shown as a "bouncing bar" indicator, where the peak of the bar coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the device locates the arterial pulsation. The pulse tone (when enabled) coincides with the peak of the Signal IQ bar. As saturation increases or decreases, the pulse tone will ascend or descend accordingly, for each 1% change in saturation.

The height of the Signal IQ bar 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. A "Low Signal IQ" is indicated by a bar height of two bars or less and the bars turn red. When this occurs, 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 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, as may occur while lifting or crossing their legs, during a diaper change.

After performing the above, if the "Low Signal IQ" indication occurs frequently or continuously, obtaining an arterial blood specimen for oximetry analysis may be considered to verify the oxygen saturation value.

SENSOR PLACEMENT

If the SpO_2, readings are questionable or unavailable, do the following:

- Make sure the emitter and detector are aligned directly opposite each other.
- Select a site where the distance between the emitter and detector 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 electro-surgical devices or other electrical/electronic equipment. If these solutions are not possible, operate the Rad-8 on battery power, or try plugging the device 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 Rad-8 with integrated Masimo 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 OXIMETER FOR PROPER FUNCTIONING.

SENSITIVITY

The Rad-8 Pulse 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 (NORM)** – 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 an intensive care unit (ICU).
- **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. Also, after a power off and on cycle, the sensitivity will change from the MAX to the factory default or user configured default setting of APOD or NORM.

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

LOW BATTERY AUDIBLE ALARM

If a low battery condition occurs during patient monitoring, a low priority alarm will sound, and can be silenced for 120 seconds (default) by pressing the Alarm Silence Button. Refer to Setup Menu Level 2 in this section to change setting.

If a low battery condition occurs while not monitoring a patient, a low priority audible alarm will sound and can be silenced by pressing the Alarm Silence Button. The audible alarm is silenced until the power is cycled or patient monitoring begins.

While audible alarms are silenced, the first Battery Level Indicator bar to the left flashes green.

When a low battery condition occurs, immediately discontinue patient monitoring and plug the Rad-8 into AC power. The AC Power Indicator on the Rad-8 illuminates and remains illuminated while the battery is charging, however, the Battery Charge Level Indicator does not illuminate. Once the battery is fully charged all Battery Charge Level Indicators illuminate green when unplugged.

During normal patient monitoring, the Battery Charge Bars (Battery Charge Level Indicator) illuminate green from left to right to indicate the approximate amount of battery charge when unplugged.

CAUTION: THE BATTERY SHOULD BE ADEQUATELY CHARGED TO ENSURE BACKUP POWER IN CASE OF AC POWER DISRUPTION.

Normal patient monitoring

FRONT PANEL CONTROL OPERATION

SETUP MENU

This section gives an overview of the Rad-8 menu selections available. To access the menu levels and navigate through the menu selections, use the front panel buttons, Enter Button and Up/Down Buttons as indicated in the following sections. Sub-sections describe each menu item in more detail. The Rad-8 has options that allow user configuration to accommodate specific needs.

MENU NAVIGATION

The Rad-8 set-up and configuration options are accessed through the menu system. Four levels of menus are available to the user. Once a menu level is accessed, a front panel button (Level 1 only) or the Enter Button (Level 2 and 3) is used to move from one option to the next allowing repeated cycling through the options. The Up and Down Buttons are used to adjust values within each option. The parameter/measurement value is set when the Enter Button is pressed. When accessing the Rad-8 menu, each selection will be communicated visually on the LED (front of device).

***NOTE**: The Rad-8 will automatically 'time out' of any setup menu after 10 seconds if no button is pressed.*

SETUP MENU LEVEL 1

ALARM LIMITS

To access alarm limits for parameters/measurements, press the Alarm Limits Button to access the Alarm Limits menu.

BUTTONS		SETTINGS	INSTRUCTIONS
Use the Alarm Limits Button to access the alarm limits options and move between options.	Press once	%SpO_2 LO	Use the Up Button to move between settings and the Enter Button to accept the setting and move to the next menu screen OR let the device time out for 10 seconds to exit without saving the new setting and to return to the home display screen. .
	Press 2x	%SpO_2 HI	
	Press 3x	Pulse rate (BPM) LO	
	Press 4x	Pulse rate (BPM) HI	

SETUP MENU LEVEL 1 (CONTINUED)

LED BRIGHTNESS

The Display screen and all active LED indicators are effected while adjusting this setting.

BUTTONS		SETTINGS	INSTRUCTIONS
Hold down the Brightness Button for 5 seconds to access LED to brightness options		LED Brightness Level 3 (default)	Use the Brightness Button to move between menu options and the Enter Button to accept the setting.
	Press 2x	LED Brightness Level 4	
	Press 3x	LED Brightness Level 1	
	Press 4x	LED Brightness Level 2	

SETUP MENU LEVEL 2

Level 2 menu contains parameters and settings that are not changed as frequently as Level 1. These include alarm volume, alarm silence, alarm delay, clear trend, button volume, sensitivity, and FastSat parameters. Use the Enter Button to access the menu. Press the Enter Button again to move to the next menu.

ALARM VOLUME

BUTTONS		SETTINGS	INSTRUCTIONS
Use the Enter Button to access the Alarm Volume menu and to move between Level 2 menus.		Alarm Volume Level 3 (default)	Use the Up Button to move between settings and the Enter Button to accept the setting and move to the next menu screen OR let the device time out for 10 seconds to exit without saving the new setting.
	Press Up Once	Alarm Volume Level 4	
	Press Up 2x	Alarm Volume Level 1	
	Press Up 3x	Alarm Volume Level 2	

SETUP MENU LEVEL 2 (CONTINUED)

ALARM SILENCE

BUTTONS		SETTINGS	INSTRUCTIONS
Press the Enter Button again to move to the next menu.		Alarm Silence 120 seconds (default)	Use the Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen OR let the device time out for 10 seconds to exit without saving the new setting.
	Press Up Once	Alarm Silence 30 seconds	
	Press Up 2x	Alarm Silence 60 seconds	
	Press Up 3x	Alarm Silence 90 seconds	

ALARM DELAY

Alarm delay allows the user to adjust the time in which the audible status indicator will occur after an alarm condition has been initiated.

BUTTONS		SETTINGS	INSTRUCTIONS
Press the Enter Button again to move to the next menu.		Alarm Delay 5 seconds (default)	Use the Up Button to move between settings and the Enter Button to accept the setting and move to the next menu screen OR let the device time out for 10 seconds to exit without saving the new setting.
	Press Up Once	Alarm Delay 10 seconds	
	Press Up 2x	Alarm Delay 15 seconds	
	Press Up 3x	Alarm Delay 0 seconds	

SETUP MENU LEVEL 2 (CONTINUED)

CLEAR TREND

The Rad-8 only stores data in the trend memory while the device is turned on. Trend data saves to the memory until the memory is full or cleared by the user.

NOTE: *It is recommended that you clear the trend prior to performing a new patient data collection procedure.*

BUTTONS		SETTINGS	INSTRUCTIONS
Press the Enter Button again to move to the next menu. ENTER		Clear Trend NO (default)	Confirm YES setting and press Enter. Use the Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen. OR let the device time out for 10 seconds to exit without saving the new setting.
	Press Up Once	Clear Trend YES	

NOTE: *The Clear Trend menu is used frequently. As a convenience, the Clear Trend menu may be accessed directly without going through the Setup Level 2 menu structure. (If Clear Trend is directly accessed from Setup Menu Level 2, Setup Menu Level 2 exits to the main display).*

To access the Clear Trend menu directly, hold down the Enter Button and Brightness Button for 5 seconds. Use the Up or Down Button to move between settings. Confirm the setting and press the Enter Button to accept the new setting.

BUTTON VOLUME

BUTTONS		SETTINGS	INSTRUCTIONS
Press the Enter Button again to move to the next menu. ENTER		Button Volume Level 2 (default)	Use the Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen OR let the device time out for 10 seconds to exit without saving the new setting.
	Press Up Once	Button Volume Level 3	
	Press Up 2x	Button Volume Level “Off”	
	Press Up 3x	Button Volume Level 1	

SETUP MENU LEVEL 2 (CONTINUED)

SENSITIVITY

BUTTONS		SETTINGS	INSTRUCTIONS
Press the Enter Button again to move to the next menu. ENTER		Sensitivity APOD (APO) (default)	Use the Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen OR let the device time out for 10 seconds to exit without saving the new setting.
	Press Up Once	Sensitivity NORM (NOr)	
	Press Up 2x	Sensitivity MAX	

FASTSAT

BUTTONS		SETTINGS	INSTRUCTIONS
Press the Enter Button again to move to the next menu. ENTER		FastSat Off (Default)	Use the Up or Down Button to move between settings and the Enter Button to accept the setting and move to the next menu screen OR let the device time out for 10 seconds to exit without saving the new setting.
	Press Up Once	FastSat On	

Alarm identification

The device visually and audibly indicates alarm conditions that the system detects. Audible alarms may be silenced, without affecting the operation of visual alarms.

The following table outlines the alarm priority specifications.

ALARM PRIORITY	PARAMETER	ALARM TYPE
High	Low arterial oxygen saturation	Audible and visual
	System failures	
	High pulse rate Low pulse rate	
	Sensor off and no sensor	
Low	Low battery High saturation	

CAUTION: FOR HOME USE, ENSURE THAT THE RAD-8 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.

Alarm indication

An alarm condition is indicated by:

- Audible alarm tone
- Visual Alarm Indicator (Alarm bell)
- Out-of-limit parameter will flash

The “no sensor” and “sensor off” indication will only generate an alarm condition after a pulse has been found.

Alarm limits

CAUTION: TO ENSURE THAT ALARM LIMITS ARE APPROPRIATE FOR THE PATIENT BEING MONITORED, CHECK THE LIMITS EACH TIME THE RAD-8 IS USED.

When an alarm limit is exceeded, an audible alarm activates and the Alarm Bell flashes red for high priority alarms. When a sensor is not connected to a patient, “SEN OFF” message will show on the display. When a sensor is not connected to its cable, “NO SEN” message will show on the display.

NOTE: *An audible alarm will accompany the visual indicators unless the Rad-8 has been set to Interface Alarms "Off" (only SpO_2 and BPM alarms muted) or to Sleep Mode (all alarms muted).*

SETTING	RANGE
SpO_2 High Limit	The SpO_2 high alarm limit can be set anywhere between 2% and 99%, then “----” (Off), with a 1% step size. In the “----” (Off) setting, the SpO_2 High Limit alarm is disabled.
SpO_2 Low Limit*	The SpO_2 low alarm limit can be set anywhere between 1% and 98%, with a 1% step size.
Pulse Rate High Limit (BPM)	The pulse rate high alarm limit can be set anywhere between 35 BPM and 235 BPM, with a 5 BPM step size..
Pulse Rate Low Limit (BPM)*	The pulse rate low alarm limit can be set anywhere between 30 BPM and 230 BPM, with a 5 BPM step size.

* *The low alarm limit must always be set below the high alarm setting. Attempting to set the high alarm limit below the low alarm limit, the low alarm limit will automatically adjust the low limit to the next setting below the newly entered high alarm limit setting.*

NOTE: *Pressing and holding down the up and down buttons allow for the rapid scrolling of changing SpO_2 and BPM alarm limits.*

NOTE: *If there is a loss of power for any length of time, the Alarm settings will be set back to the User set defaults. If the user has not utilized this option, then they will be set back to the factory defaults.*

ALARM SILENCE

Audible alarms may be silenced, while visual alarms remain active. The alarm silence function is controlled by pressing the Alarm Silence Button.

The Alarm Bell provides visual feedback when the Rad-8 audible alarms are silenced.

Alarm Silence function when monitoring a patient:

Power-On – Alarms active, Alarm Bell flashes red for high priority alarms

Press Once – Alarm suspended for 120 seconds. Audible alarms are silenced. The Alarm Bell flashes red for high priority alarms.

Press Twice - Returns to audible alarms active. Audible alarms return,

Repeated pressing of the Alarm Silence Button will cycle through alarm silence options above.

Alarm Silence function when not monitoring a patient:

Power-On – Alarms active, Alarm Bell is not flashing.

Press Once – Device is silenced until it is cycled off/on or until monitoring begins. The Alarm Bell is not flashing

ALARM BELL

The Alarm Bell flashes red for high priority alarms. Pressing the Alarm Silence Button once silences the audible alarm for 120 seconds (default) while the Alarm Bell flashes to indicate an alarm condition. If the high priority alarm condition is resolved during the Alarm silence interval, the Alarm Bell stops flashing. If the high priority alarm condition remains (Alarm Bell flashing red), pressing the Alarm Silence button again activates the audible alarms and the Alarm Bell continues to flash red. The Alarm Bell stops flashing when the high priority alarm conditions are resolved.

ALARM ON/OFF

Alarm OFF: All audible alarms are muted and visual alarms are active. Audible alarms are restored when power is turned off and back on.

Alarm Off (re): Audible alarms are muted, but the alarm “beeps” twice every three minutes to remind the user that the Rad-8 is currently in an alarm status but that the audible alarm is muted. Visual alarms are active in this mode. If the alarm is violated, the associated parameter/measurement label and value flash, and the alarm bell flashes red for high priority alarms. Audible alarms are restored when power is turned off and back on.

MESSAGES

The Rad-8 will indicate other data or system errors. Message conditions are as follows:

DISPLAY	TYPE	SOLUTION
THREE DASHES ("---")	Calibration and Pulse Search	Wait for found pulse. (This search should occur whenever a sensor is first applied to a patient).
PULSE BAR (SIQ) TURNS RED	Low Signal IQ	1. Rule out occlusion of blood flow. 2. Verify placement of sensor. 3. Re-apply sensor or move to a different site. 4. Replace sensor or cable.
PERFUSION BAR (PI) TURNS RED	Low Perfusion	1. Rule out occlusion of blood flow. 2. Attempt to warm patient. 3. Move sensor to better perfused site. ***NOTE:*** *Masimo recommends using an adhesive sensor whenever low perfusion is expected or evident.*
PARAMETER/MEASUREMENT LABEL AND NUMBER FLASH	Alarm Limit Exceeded	Assess /address patient condition. Re-set alarm limits if indicated.
Err ##	System Fault	Return for service. There are several error codes. All error codes require return of the device to an authorized service center for repair. See Section 9, *Service and Repair.*
bAd SEn	Defective Sensor	Replace sensor.
SEn (Blinking)	Unrecognized Sensor	Connect appropriate sensor.
Int dEt (Blinking)	Interference Detected	Ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required.

MESSAGES (CONTINUED)

DISPLAY	TYPE	SOLUTION
NO SEN	No Sensor Connected	Connect sensor to cable.
SEN OFF	Sensor off patient	1. Reattach sensor to patient. 2. Verify proper sensor placement.
SINGLE BATTERY LEVEL INDICATOR FLASHES (WITH AUDIBLE ALARM)	Battery level too low	Connect device to AC Power to charge the battery.
NO CbL	No Cable Connected	Connect appropriate cable to unit.
bAd CbL	Defective cable	Replace cable

Troubleshooting

The following chart describes what to do if the Rad-8 system does not operate properly or fails.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
DEVICE DOES NOT POWER ON	Low battery/ not plugged into AC power supply	Connect the AC Power Cord to the Rad-8 and to an AC outlet. Make sure that the AC Power Indicator light is on.
BATTERY RUN-TIME IS SIGNIFICANTLY REDUCED	Low battery	Contact Technical Services or your local Masimo representative.
CONTINUOUS SPEAKER TONE	Internal Failure	Device requires service. Press the Alarm Silence Button. If alarm continues to sound, power down device. If the power button does not turn the device off, press and hold the Power Button for 5 seconds. Return the device for service.
NO SPEAKER TONE	Pulse tone set to “mute”	Press Up Arrow or Alarm Volume Adjust.
NO ALARM TONE	Alarm Silence Enabled	See Section 4, *Alarm Silence*.
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 (PI BAR TURNS RED)	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.
LOW SIGNAL QUALITY	Improper sensor type or application. Excessive motion relative to perfusion, or poor perfusion. Sensor or cable 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. Replace sensor or cable.

Troubleshooting continued

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
SpO_2 VALUES DO NOT CORRELATE WITH CLINICAL ASSESSMENT OR ABGs	Low perfusion or sensor displacement.	Check for error messages. See section 5 *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 OR "----"	Device is searching for pulse.	If device fails to display within 30 seconds, disconnect and reconnect sensor to patient. If pulse search continues, move sensor to better perfused site.
UNEXPECTED SpO_2 READING	Low SIQ or Perfusion Index (PI) values.	Reposition sensor to site with strong SIQ and PI. Submit blood sample for laboratory oximetry test for comparison.
	Inappropriate sensor size or sensor measurement location.	Verify proper sensor for patient size. Verify proper sensor site.
DIFFICULTY OR NO SpO_2 READING	Low battery/not plugged into AC power supply.	Connect the AC Power Cord to the Rad-8 and to an AC outlet. Make sure that the AC Power Indicator light is on.
	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.	
PRINT FUNCTION DOES NOT WORK	Wrong serial cable is used.	Make sure a null modem cable is used.

Rad-8 specifications

PERFORMANCE

Measurement Range	
Arterial Oxygen Saturation (%SpO_2):	1-100%
Pulse Rate:	25-240 beats per minute (bpm)
Perfusion Index	0.02% - 20%
Response time:	<1 second delay
ACCURACY	
Arterial Oxygen Saturation Accuracy[1]	
Saturation	60% to 80%
No Motion[2]	
Adults, Infants, Pediatrics	±4%
Saturation	70% to 100%
No Motion[3]	
Adults, Infants, Pediatrics	± 2%
Neonates	± 3%
Motion[4]	
Adults, Infants, Pediatrics, Neonates	± 3%
Low Perfusion[5]	
Adults, Infants, Pediatrics, Neonates	± 2%
Pulse Rate Accuracy[6]	
Pulse Rate:	25 - 240 (bpm)
No Motion	
Adults, Infants, Pediatrics, Neonates	± 3 bpm
Motion[5]	
Adults, Infants, Pediatrics, Neonates	± 5 bpm
Low Perfusion	
Adults, Infants, Pediatrics, Neonates	± 3 bpm
Resolution	
Arterial Oxygen Saturation (%SpO_2)	1%
Pulse Rate	1 bpm

ELECTRICAL

AC Power requirements:	100-240 VAC, 47-63 Hz
Power consumption:	20 VA max.
Battery	
Type:	Sealed lead acid
Capacity: (battery life)	up to 7 hours[7]
Charging time:	8 hours

ENVIRONMENTAL

Operating Temperature:	41°F to 104°F (5°C to 40°C)
Transportation/Storage Temperature:	-40°F to 158°F (-40°C to +70°C)[8]
Storage 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)

Rad-8 specifications continued

PHYSICAL CHARACTERISTICS	
Dimensions:	8.2" x 6.0" x 3.0" (20.8 cm x 15.2cm x 7.6 cm)
Weight:	2.1 lbs. = .908 Kg. = 32 oz
Trending	
72 hours of trending at 2 second resolution	
Mode	
Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds[9]
Sensitivity:	Normal, Maximum, and APOD
Alarms	
Audible and visual alarms for high and low saturation and pulse rate (SpO_2 range 1-99%, pulse rate range 30-235 bpm)	
Sensor condition, system failure and low battery alarms	
High Priority Audible Alarm	800 Hz tone, 5 pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time:10s
Low Priority Audible Alarm	500 Hz tone, 3 pulse, repeat time: 5s
High Priority Visual Alarm	Red flashing 2 seconds (0-5 Hz)
Alarm Volume:	High: 85 dB (min) Low: 45 dB (min)
Display/Indicators	
Data display: %SpO_2, pulse rate, alarm status, alarm silenced status, AC power, Signal IQ/pleth bar, perfusion index bar, battery status	
Type:	LED
Display update rate	1 second
Output Interface	
Serial RS-232, Philips VueLink, Nurse Call	
Compliance	
Safety Standard for Medical Equipment	IEC 60601-1 2nd Edition
	UL 60601-1
	CAN/CSA C22.2 No. 601-1
	JIS 0601-1
Type of Protection	Class 1 (AC power), Internally powered (battery power)
Degree of Protection-Patient Cable:	Type BF, Defib Proof -Applied Part
Rad-8 Mode of Operation:	Continuous
EMC Standard	EN60601-1-2, Class B

1 SpO_2 was determined by testing on healthy adult volunteers in the range 60%-100% SpO_2 against a laboratory CO-Oximeter. SpO_2 accuracy was determined on 16 neonatal NICU patients ranging in age from 7 to 135 days old and weighting between 0.5 and 4.25 kgs. Seventy-nine (79) data samples were collected over a range of 70 - 100% SaO2 with a resultant accuracy of 2.9% SpO_2. Contact Masimo for testing specifications.

2. The arterial oxygen saturation accuracy during no motion only applies to LNOP® Blue SpO_2 adhesive sensors.

Rad-8 specifications continued

3 Masimo SET technology 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 4Hz 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 which encompasses 68% of the population. The saturation accuracy of the neonatal sensors were validated on adult male and female volunteers with light to dark skin pigmentation and 1% was added to account for the properties of fetal hemoglobin.

4 The Masimo sensors have 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.

5 Masimo SET technology 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 which encompasses 68% of the population.

6 Masimo sensors have 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.

7 Battery capacity varies based on device settings.

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

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

Serial interface specifications

The digital interface for serial communication is based on the standard RS-232 protocol. The Rad-8 Pulse Oximeter by default always outputs ASCII2 text data through the serial port, unless the user selects a different output mode in the Output menu. To interface with the Rad-8 and receive serial text data, simply connect a serial interface cable to the serial output connector located on the back of the Rad-8.

NOTE: *Trend data packets are collected at 2 second intervals. Each data packet contains: the date, time, SpO_2, pulse rate, perfusion index and alarm and exception values (in ASCII format).*

SERIAL INTERFACE SETUP

To interface with the Rad-8 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

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 sensors and cables with the Rad-8 Pulse Oximeter. Other transducers, sensors and cables may affect Rad-8 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 COMPATIBILITY 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 tables 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 (DFU) accompanying the sensor. Monitor, cables and sensors must be compatible to ensure optimal performance. Incompatible components effect operation or data recovery.

High intensity extreme lights (such as pulsating strobe lights) directed on the Pulse Oximeter sensors, 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 SpO_2 Sensors

Before use of any sensor or cable, carefully read the sensor or cable Directions for Use.

Use only Masimo oximetry sensors and cables for SpO_2 measurements. Other oxygen transducers or sensors may cause improper Rad-8 Pulse Oximeter performance.

Tissue damage can be caused by incorrect application or use of a Masimo 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, OR ETHYLENE OXIDE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE MASIMO 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, OR ETHYLENE OXIDE.
- 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.
- DO NOT USE ADDITIONAL TAPE TO WRAP SENSOR.

RED DIRECT CONNECT SENSORS

Masimo Red Direct sensors can be used with the Rad-8 to enable measurement of SpO_2 and pulse rate only. Red Direct Connect sensors will only function with oximeter devices equipped with Masimo SET technology. Red Direct Connect sensors connect to the device directly.

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
DC-3 DC-12	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
DCP-3 DCP-12	10 - 50 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
Red DCI-dc3	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
Red DCI-dc12	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
Red DCIP-dc3	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
Red DCIP-dc12	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

LNOP® REUSABLE SENSORS

LNOP reusable 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 (Adults/Pediatrics)	> 1 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	N/A	N/A
LNOP YI (Neonates)		± 3%					
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.*

LNOPv™ ADHESIVE SENSORS

LNOPv adhesive 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 specialty 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 (thumb or great toe)	3 - 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
Infant (finger or toe)	10 - 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Newborn Neonatal	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Trauma	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
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 reusable sensors must be used in conjunction with Red LNC cables

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNCS DCI	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS DCIP	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
LNCS YI (Adult/Pediatric)	> 1 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	N/A	N/A
LNCS YI (Neonates)		± 3%					

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 cables

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNCS Adtx LNCS Adtx-3	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Pdtx LNCS Pdtx-3	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Inf-L LNCS Inf LNCS Inf-3	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNCS Neo-L LNCS Neo LNCS Neo-3	< 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 LNCS NeoPt-L LNCS NeoPt-3	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNCS NeoPt-500	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm

M-LNCS™ DCI® & DCIP SENSORS

SpO_2 and pulse rate accuracy for the M-LNCS sensors is specified in the following table. These sensors must be used in conjunction with M-LNC™ cables.

SENSOR	Masimo SET Technology		Nellcor Technology	
	M-LNCS DCI	M-LNCS DCIP	M-LNCS DCI	M-LNCS DCIP
Weight Range	> 30 kg	10 - 50 kg	> 30 kg	10 - 50 kg
Saturation Accuracy, No Motion	± 2%	± 2%	± 2%	± 2%
Saturation Accuracy, Motion	± 3%	± 3%	N/A	N/A
Pulse Rate Accuracy, No Motion	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm
Pulse Rate Accuracy, Motion	± 5 bpm	± 5 bpm	N/A	N/A
Low Perfusion Accuracy	SpO_2 ± 2%	SpO_2 ± 2%	N/A	N/A
	Pulse ± 3 bpm	Pulse ± 3 bpm	N/A	N/A

SENSOR ACCURACY

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

Complete accuracy specifications are located in the sensor Directions For Use (DFU) and are specific for the type of Masimo sensor used.

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.

CAUTION: TO PREVENT DAMAGE, DO NOT SOAK OR IMMERSE THE SENSOR IN ANY LIQUID SOLUTION. DO NOT ATTEMPT TO STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE OR ANY METHOD OTHER THAN ETHYLENE OXIDE AS INDICATED.

Introduction

This chapter covers how to test the operation, properly clean and how to obtain service for the Rad-8 Pulse Oximeter.

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.

The Rad-8 Pulse Oximeter is a reusable device. The device is supplied and used non-sterile.

WARNING: ELECTRICAL SHOCK AND FLAMMABILITY HAZARD - BEFORE CLEANING THE RAD-8, ALWAYS TURN IT OFF AND DISCONNECT THE POWER CORD FROM THE AC POWER SUPPLY.

Cleaning

The outer surface of the Rad-8 Pulse Oximeter can be cleaned with a soft cloth dampened with a mild detergent and warm water solution. Do not allow liquids to enter the interior of the instrument. The outer surface of the instrument can also be wiped down using the following solvents: Cidex Plus (3.4% Glutaraldehyde), 0.25% Ammonium Chloride, 10% Bleach, and 70% Isopropyl Alcohol.

CAUTIONS:

- DO NOT AUTOCLAVE, PRESSURE STERILIZE, OR GAS STERILIZE THE RAD-8.
- 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 AFFECT THE DEVICE'S MATERIALS AND DEVICE FAILURE CAN RESULT.

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

Battery Service

WARNING: THE BATTERY SHOULD BE INSTALLED AND/ OR REMOVED FROM THE RAD-8 BY QUALIFIED PERSONNEL ONLY.

Performance verification

To test the performance of the Rad-8 after repairs or during routine maintenance, follow the procedure outlined in this section. If the Rad-8 fails any of the described tests, discontinue its use and correct the problem before returning the device back to the user.

Before performing the following tests verify that the device is connected to AC power. Also disconnect any patient cables or probes or serial cables from the instrument.

POWER-ON SELF-TEST:

1. Turn the monitor on by depressing the Power. For about 2 seconds all available LEDs are illuminated and a brief beep tone sounds.
2. The Rad-8 begins normal operation.

KEY PRESS BUTTON TEST:

1. With the exception of the Power, press each button and verify that the device 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, depress the alarm limits button and enter the alarm menu. Change the High Saturation Alarm parameter to a value below the currently selected value, and accept the change.
2. Verify that the newly set parameter is shown on the Saturation Alarm Limit 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
   - Low and High pulse rate
5. Reset the alarm limits again to the original settings.

Performance verification continued

LED BRIGHTNESS:

1. With the monitor turned on, press the Brightness Button once to enter the LED Brightness menu. The display will show the default setting Level 2.
2. Continue pressing the Brightness Button to scroll through the settings.
3. Press the Enter Button to accept the desired setting. Let the device time out for 10 seconds to exit to the home display screen.

TESTING THE RAD-8 WITH MASIMO SET TESTER (OPTIONAL):

1. Turn the Rad-8 off and then on again.
2. Connect the Masimo SET Tester to the Pulse Oximeter Patient Cable Connector.
3. Verify that within 20 seconds all available pulse bars display.
4. Verify that the SpO_2 measurement is between 79% and 84%.
5. Verify that the pulse rate measurement is between 55 bpm and 65 bpm.
6. Set the SpO_2 low alarm limit to 90 (see Section 4, *Setup Menu Level 1, Parameter/ Measurement Alarm Limits* and *Setup Menu Level 2, Alarm Volume*).
7. Verify that an audible alarm activates, the SpO_2 measurement and the SpO_2 parameter label are flashing, and the Alarm Bell.
8. Press the Alarm Silence Button once and verify that the alarm is silenced and the Alarm Bell is flashing red.
9. Wait 120 seconds and verify that the alarm silence times out, the audible alarm is activated again and the Alarm Bell.
10. Press the up arrow button several times and verify that the loudness of the pulse beep tone increases.
11. Press the down arrow button and verify that the loudness of the pulse beep tone decreases until the pulse beep tone is turned off.
12. Reset the device to original settings and remove the tester to complete the procedure.

Service and repair

REPAIR POLICY

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

WARNING: 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 the equipment is fully dry before packing.

To return the Rad-8 Pulse Oximeter 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 Rad-8. 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 device 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 Rad-8 has been decontaminated for bloodborne pathogens.

Return the Rad-8 to the following shipping address:

For USA, Canada & Asia Pacific:	For Europe:	All other locations:
Masimo Corporation 40 Parker Irvine, California 92618 Tel: 949-297-7000 FAX: 949-297-7001	Masimo Europe Limited 304 RN6, Le Bois des Cotes 2 69760 Limonest France Tel: +33 (0) 472 17 93 70 FAX: +33 (0) 478 35 78 08	Contact your local Masimo Representative

Sales & End-User License Agreement

THIS DOCUMENT IS A LEGAL AGREEMENT BETWEEN YOU (“PURCHASER”) AND MASIMO CORPORATION (“MASIMO”) FOR THE PURCHASE OF THIS PRODUCT (“PRODUCT”) AND A LICENSE IN THE INCLUDED OR EMBEDDED SOFTWARE (“SOFTWARE”). EXCEPT AS OTHERWISE EXPRESSLY AGREED IN A SEPARATE CONTRACT FOR THE ACQUISITION OF THIS PRODUCT, THE FOLLOWING TERMS ARE THE ENTIRE AGREEMENT BETWEEN THE PARTIES REGARDING YOUR PURCHASE OF THIS PRODUCT. IF YOU DO NOT AGREE TO THE TERMS OF THIS AGREEMENT, PROMPTLY RETURN THE ENTIRE PRODUCT, INCLUDING ALL ACCESSORIES, IN THEIR ORIGINAL PACKAGES, WITH YOUR SALES RECEIPT TO MASIMO FOR A FULL REFUND.

Warranty

Masimo warrants to the initial Purchaser for a period of one (1) year from the date of purchase that: (i) each new Product and the Software media as delivered are free from defects in workmanship or materials, and (ii) the Product and Software will perform substantially as labeled in the directions for use. Masimo’s sole obligation under this warranty is to repair or replace any Product or Software that is covered under warranty.

Batteries are warranted for six (6) months.

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

Exclusions

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

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