The Rad-8 Operating Instructions provide the necessary information for proper operation of all Rad-8 pulse oximeter models.

General knowledge of pulse oximetry and an understanding of the features and functions of the Rad-8 pulse oximeter are prerequisites for its proper use.

Do not operate the Rad-8 pulse oximeter 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 with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

CAUTION:
FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

For further information contact:
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Irvine, CA 92618
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Tel.: 949-297-7000
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EC REP

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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
80FK

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, 6,684,000, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,501,975,
6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,672, 6,229,856, 6,206,830, 6,157,850, 6,077,462,
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/pat-
ents. Other patents pending.

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FastSat, Rad-8, Radlink, FastSat, SIQ, LNOP, LNCS and are federally registered trademarks of
Masimo Corporation.

RadNet, PI, APOD and LNOPv are trademarks of Masimo Corporation.
SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES

The Rad-8 Compact 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 pulse 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 oximeter to obtain vital sign readings.**
- The pulse oximeter is NOT intended for use as an apnea monitor.
- A 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.
- The pulse oximeter is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read and understood before use.
- **Electric shock hazard.** Do not open the pulse oximeter cover except to replace the battery of the unit. Only a qualified operator may perform maintenance procedures specifically described in this manual. Refer servicing to Masimo for repair of this equipment.
- 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 oximeter or accessories in any position that might cause it to fall on the patient. Do not lift the pulse oximeter by the patient cable.
- **Interfering Substances:** Carboxyhemoglobin and Methemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Severe anemia may cause erroneous SpO$_2$ readings.
- Do not use the pulse oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- If using pulse oximetry during full body irradiation, keep the sensor out of the irradiation field. If 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.
- Always remove the sensor from the patient and completely disconnect the patient from the pulse oximeter before bathing the patient.
- Do not place the pulse oximeter where the controls can be changed by the patient.
- Do not place the pulse oximeter face against a surface. This will cause the alarm to be muted.

- **Do not place the pulse oximeter on electrical equipment that may affect the pulse oximeter, preventing it from working properly.**
- **Do not expose the pulse oximeter to excessive moisture such as direct exposure to rain. Excessive moisture can cause the pulse oximeter to perform inaccurately or fail.**
- Do not place containers containing liquids on or near the pulse oximeter. Liquids spilled on the pulse oximeter may cause it to perform inaccurately or fail.
- Failure of Operation - If the pulse oximeter fails any part of the setup procedures remove the pulse oximeter from operation until qualified service personnel have corrected the situation.
- Patient Safety - If a sensor or cable 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 oximeter can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.
- **Failure of Operation** - When the pulse oximeter fails any part of the setup procedures, remove the pulse oximeter from operation until qualified service personnel have corrected the situation.
- **Patient Safety** - If a sensor or cable 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 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.
  - Consult the manufacturer for help.
- **A functional tester cannot be utilized to assess the accuracy of the pulse oximeter or any sensors.**
# Rad-8 Signal Extraction Pulse Oximeter Operator’s Manual

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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 family of pulse oximeters are noninvasive, arterial oxygen saturation and pulse rate monitors. The Rad-8 family features a multicolored LED display that continuously displays numeric values for SpO\textsubscript{2} and pulse rate, as well as LED indicator bars for Perfusion Index (PI) and Signal Identification and Quality Indicator (Signal IQ\textsuperscript{®}).

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

**FEATURES AND BENEFITS**

These features are common to the Rad-8 family:

- Clinically proven Masimo SET\textsuperscript{®} technology performance
- Applicable for use on neonate, infant, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO\textsubscript{2}, pulse rate, alarm, and perfusion index displays
- Signal I.Q. for signal identification and quality indication
- 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
- Trauma mode
- FastSat\textsuperscript{®} mode
- User defineable alarm limit settings
- Sleep study mode
- Three sensitivity levels - Max, Normal and APOD\textsuperscript{TM}
- Stores up to 72 hours of trending memory
- Adjustable alarm volume
- Adjustable averaging 2 to 16 seconds
- Nurse call connection port
- 8 hours internal battery life with fully charged battery
- Serial output port
- Display capability on Philips/Agilent monitor through Philips VueLink function.
- RadNet\textsuperscript{TM} and RadLink\textsuperscript{®} capability.

**INDICATIONS FOR USE**

The Rad-8 family of pulse oximeters and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO\textsubscript{2}) and pulse rate (measured by an SpO\textsubscript{2} sensor). The Rad-8 family of pulse oximeters and accessories are indicated for use with adult, pediatric, infant 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.
FUNCTIONAL VS. FRACTIONAL SATURATION

The Rad-8 is calibrated to measure and display functional saturation which is the amount of oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. The Rad-8 does not measure fractional saturation which is oxygenated hemoglobin expressed as a percentage of all measured hemoglobin. This includes measured dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin. To convert fractional saturation to functional saturation, the fractional saturation measurements must be converted according to:

\[
\text{Functional saturation} = \frac{\text{Fractional saturation}}{1 - (\% \text{ carboxyhemoglobin} + \% \text{ methemoglobin})} \times 100
\]

MEASURED VS. CALCULATED SATURATION

Oxygen saturation measurements obtained from a pulse oximeter are commonly compared to saturations calculated from the partial pressure of oxygen (PO$_2$) obtained from an arterial blood gas sample. When comparing the two measurements and interpreting values, caution should be used, as the calculated value obtained from the blood gas sample may differ from the SpO$_2$ measurement of the pulse oximeter. Different results are usually obtained from the blood gas sample if the calculated saturation is not appropriately corrected for the effects of variables that shift the relationship between PO$_2$ and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO$_2$), 2,3-DPG, and fetal hemoglobin. Also, as blood gas samples are usually taken over a period of 20 seconds (the time it takes to draw blood) a meaningful comparison can only be achieved if the core oxygen saturation of the patient is stable and not changing over the period of time that the blood gas sample is taken.

MASIMO SET SIGNAL EXTRACTION TECHNOLOGY

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.
Introduction

The Rad-8 family of pulse oximeters are full featured pulse oximeters designed for ease of operation. All pulse oximetry measurement information, as well as device status data, is displayed on the front panel of the device. All user input is handled by control buttons on the front panel and the sensor cable connection is located on the left side of the Rad-8 horizontal and the bottom of the Rad-8 vertical.

- Rad-8 family offers full Masimo SET technology in a small compact device
- Rad-8 family supports the full line of Masimo sensors and patient cables (see Section 8, Sensors and Patient Cables)
- Rad-8 family supports standardization of sensors and pulse oximetry technology throughout the hospital
CONTROL / INDICATOR | DESCRIPTION
---|---
1 | Power On / Off
2 | Up button / Down button
3 | Next Button
4 | Mode / Enter Button
5 | Alarm Limits Button
6 | Alarm Silence Button
7 | Pulse Rate Display
8 | Signal IQ / Pulse Bar
9 | Saturation Display
10 | Sensitivity Mode Button / Indicator
11 | FastSat Button / Indicator
12 | Perfusion Index
13 | Trauma Button
14 | Sensor Off Indicator
15 | No Sensor Indicator
16 | Battery Low Indicator
17 | AC Power Charging Indicator
18 | Speaker
19 | Patient Cable Connector
**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, RadNet Interface Module, RadLink Interface Module or PC, 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 back of the Rad-8 pulse oximeter or packaging and are defined below:

<table>
<thead>
<tr>
<th>SYMBOLS</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="RS-232" /></td>
</tr>
<tr>
<td><img src="image" alt="Equipotential Ground Terminal" /></td>
</tr>
<tr>
<td><img src="image" alt="Caution, consult accompanying documents" /></td>
</tr>
<tr>
<td><img src="image" alt="Nurse Call Interface" /></td>
</tr>
<tr>
<td><img src="image" alt="WEEE compliant" /></td>
</tr>
<tr>
<td><img src="image" alt="Defibrillation Proof (see front panel)" /></td>
</tr>
<tr>
<td><img src="image" alt="Mark of Conformity to European Medical Device Directive 93/42/EEC" /></td>
</tr>
<tr>
<td><img src="image" alt="Rx Only" /></td>
</tr>
<tr>
<td><img src="image" alt="Year of manufacture" /></td>
</tr>
<tr>
<td><img src="image" alt="Underwriter's Laboratories Inc. approved" /></td>
</tr>
<tr>
<td><img src="image" alt="Storage humidity range: 5% to 95%" /></td>
</tr>
<tr>
<td><img src="image" alt="Storage temperature range: +70°C to -40°C" /></td>
</tr>
<tr>
<td><img src="image" alt="Storage altitude range: +1600hPa to +500hPa" /></td>
</tr>
<tr>
<td><img src="image" alt="Keep dry" /></td>
</tr>
<tr>
<td><img src="image" alt="Fragile/breakable, handle with care" /></td>
</tr>
</tbody>
</table>
Introduction

Before the Rad-8 pulse oximeter can be used in a clinical setting, it needs to be inspected and properly

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.

RAD-8 POWER REQUIREMENTS

Always use a hospital grade, AC power cable to connect the Rad-8 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 of the Rad-8.

The Rad-8 pulse oximeter is designed to operate on 100 to 240VAC, 50-60 Hz. The device is rated at 15 VA max.

Connect a hospital grade power cable to the power entry module of the Rad-8 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 Rad-8 is illuminated.

CAUTION:

■ CONNECT THE OXIMETER ONLY TO A HOSPITAL-GR ADE 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.
Introduction

To operate the Rad-8 pulse oximeter effectively, the operator must:

■ Know how the oximeter derives its readings (see Section 1, Pulse Oximetry)
■ Be familiar with its controls and operation.
■ 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 oximeter case for damage.
2. Connect a patient cable or a direct connect sensor to the Patient Cable Connector of the Rad-8 pulse oximeter. 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 oximeter and the patient before connecting it to the patient cable. See Section 8, Sensors and Patient Cables. If using a reusable sensor, make sure it opens and closes smoothly. Remove any substances that may interfere with the transmission of light between the sensor’s light source and photodetector.
4. Refer to the Directions for Use of the sensor before attaching the sensor to the patient. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the photodetector are properly aligned.
5. 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.
6. Press the Power button to turn the oximeter 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 display shows the following:
   ■ Mode setting: Standard (STD) or Sleep (SLP) or Home (HNN)
   ■ SpO₂ Low Alarm Limit and SpO₂ High Alarm Limit
   ■ Pulse Rate Low Alarm Limit and Pulse Rate High Alarm Limit
   ■ Averaging Time.
10. On the display, verify the readings for SpO₂ and pulse rate.

NOTE: "---" will flash on the numeric display until the SpO₂ and pulse rate readings have stabilized (approximately 10 seconds).
11. Verify that the patient alarms are functional by setting the high and low \( \text{SpO}_2 \) and pulse rate alarm limits beyond the patient readings.
   - An alarm tone sounds.
   - The violated alarm limit and reading flash on the display.
   - The Visual Alarm Indicator flashes.

12. Verify the sensor alarms are functional by removing the sensor from the sensor site.
   - "Sensor off" indicator illuminates.
   - The alarm tone sounds.
   - The Visual Alarm Indicator flashes.
   - Disconnect the sensor from the patient cable or oximeter.
   - Confirm that the "no sensor" indicator illuminates.

   **NOTE:** "No sensor" and "sensor off" will only generate an alarm if the Rad-8 was actively monitoring a patient when the sensor was disconnected.

13. Verify parameter-violation alarm silence operation.
   - Create an alarm condition by lowering the \( \text{SpO}_2 \) or pulse rate high alarm limits beyond the patient readings.
   - Press the Alarm Silence button.
   - The alarm tone ceases for 120 seconds (default).

14. 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 \( \text{SpO}_2 \) 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/Standby Button for 2 seconds to turn the oximeter off (3 seconds in the Home Mode).

   **NOTE:** Turn the oximeter off between patients so that it can re-calibrate in order to interpret new physiological data.

---

### FACTORY DEFAULT SETTINGS

The Rad-8 oximeters store two types of default values: those that the device automatically reverts to after a power cycle, and those that can be changed by the user which will be remembered after a power cycle.

The following table outlines the default values that the Rad-8 reverts to after a power cycle if not changed by the user:

<table>
<thead>
<tr>
<th>OPTION</th>
<th>FACTORY DEFAULT SETTING</th>
<th>CONFIGURABLE SETTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \text{SpO}_2 ) high alarm limit</td>
<td>Set to Off</td>
<td>2 to 100%</td>
</tr>
<tr>
<td>( \text{SpO}_2 ) low alarm limit</td>
<td>Set to 90%</td>
<td>1 to 100%</td>
</tr>
<tr>
<td>Pulse rate high alarm limit</td>
<td>Set to 140 BPM</td>
<td>30 to 240 BPM</td>
</tr>
<tr>
<td>Pulse rate low alarm limit</td>
<td>Set to 50 BPM</td>
<td>25 to 235 BPM</td>
</tr>
<tr>
<td>Averaging Time</td>
<td>Set to 8 seconds</td>
<td>2, 4, 8, 10, 12, 14, or 16 seconds</td>
</tr>
<tr>
<td>Trauma</td>
<td>Set to Off</td>
<td>Off/On</td>
</tr>
<tr>
<td>FastSat</td>
<td>Set to Off</td>
<td>Off/On</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>Set to Norm setting</td>
<td>Max/Normal/APOD</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>NOTE:</strong> Defaults to APOD and Normal only. Max sensitivity will default to Normal after a power cycle.</td>
</tr>
<tr>
<td>Display brightness</td>
<td>Set to level 2</td>
<td>Levels 1 thru 4</td>
</tr>
<tr>
<td>Pulse tone volume</td>
<td>Set to level 2</td>
<td>Off, Levels 1 thru 3</td>
</tr>
<tr>
<td>Alarm Silence Time</td>
<td>Set to 120 seconds</td>
<td>30, 60, 90, or 120 seconds</td>
</tr>
<tr>
<td>Alarm Volume</td>
<td>Set to level 1</td>
<td>Levels 1 thru 3</td>
</tr>
<tr>
<td>Sleep Study Mode(^*)</td>
<td>Set to Standard</td>
<td>Standard/Sleep/Home</td>
</tr>
<tr>
<td>Home Mode(^†)</td>
<td>Set to Standard</td>
<td></td>
</tr>
<tr>
<td>Audible Alarm off</td>
<td>Set to alarms active</td>
<td>On/Off or muted with reminder</td>
</tr>
<tr>
<td>Alarm Delay</td>
<td>Set to level 5</td>
<td>0, 5, or 10 seconds</td>
</tr>
<tr>
<td>Serial out</td>
<td>Set to ASCII 2</td>
<td>Philips/ASCII 1/ASCII 2</td>
</tr>
<tr>
<td>Interface Alarm</td>
<td>Set to Alarm</td>
<td>Alarm, Off/On</td>
</tr>
<tr>
<td>Nurse Call Type</td>
<td>Set to Alarm</td>
<td>Alarm and Signal IQ/ Low Signal IQ/ Alarm</td>
</tr>
<tr>
<td>Nurse Call Polarity</td>
<td>Set to Normal</td>
<td>Normal/Invert</td>
</tr>
</tbody>
</table>

\(^*\) **CAUTION:** ALARMS ARE DISABLED IN THIS MODE.

\(^†\) If the unit is connected to a RadNet system, there will be no communication with RadNet in this mode.
Successful $\text{SpO}_2$ monitoring

The following general points will aid in ensuring oximetry monitoring success.

- Place the sensor on a site that is not too thick, 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 select a site near potential electrical interference (electrosurgical unit, for example).
- Read the sensor Directions for Use for proper sensor application.

NUMERIC DISPLAY - $\text{SpO}_2$

Stability of the $\text{SpO}_2$ 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 $\text{SpO}_2$ and PR.

MASIMO SENSORS

Before use, carefully read the LNOP, LNOPv and LNCS sensor Directions for Use.

Use only Masimo oximetry sensors for $\text{SpO}_2$ measurements.

Tissue damage can be caused by incorrect application or use of an LNOP, LNOPv or LNCS 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 ON THE SENSOR DIRECTIONS FOR USE). 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, AUTOCLAVE OR ETHYLENE OXIDE.
- DO NOT USE ADDITIONAL TAPE TO SECURE SENSOR TO PATIENT.

NUMERIC DISPLAY - PULSE RATE

The Pulse Rate displayed on the Rad-8 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 be additive to the pulse rate displayed on the pulse oximeter.
LOW PERFUSION
The Rad-8 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. 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.

ACTIONS TO BE TAKEN
If the SpO2 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. 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 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 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 AND PULSE BAR
The Rad-8 display provides a visual indicator of the plethysmogram signal quality and an alert when the displayed SpO2 values are not based on adequate signal quality. The signal quality indicator displayed on the Rad-8 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 Rad-8 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 SpO2 measurement is based on a good quality signal. A small vertical bar indicates that the SpO2 measurement is based on data with low signal quality. When the signal quality is very low the accuracy of the SpO2 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 for the Rad-8 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 oximeter 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” indication occurs frequently or continuously, obtaining an arterial blood specimen for CO-Oximetry analysis may be considered to verify the oxygen saturation value.
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 1 in this section to change setting.

If a low battery condition occurs while not monitoring a patient, pressing the Alarm Silence Button will suspend the audible alarm until the power is cycled or patient monitoring begins.

A visual low battery indicator will continue to blink while audible alarms are silenced.

If a low battery condition occurs, immediately discontinue patient monitoring and plug the monitor into AC power.

Normal patient monitoring
During normal operation, the Rad-8 Display shows oxygen saturation (as % SpO₂) and Pulse Rate (in beats per minute).

The following sections describe the function of the Rad-8 front panel controls during normal patient monitoring.

RAD-8 FRONT PANEL CONTROL OPERATION

<table>
<thead>
<tr>
<th>BUTTON</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power on/off. Press to turn Rad-8 on. Press-and-hold for 2 seconds to turn Rad-8 off.</td>
<td></td>
</tr>
<tr>
<td>Enters the Rad-8 setup/menu system. See Section 4, Setup menu.</td>
<td></td>
</tr>
<tr>
<td>Allows movement from one menu option to the next.</td>
<td></td>
</tr>
<tr>
<td>Alarm Silence. Pressing this button one time will silence the alarm for 120 seconds (default). A second press will return the unit to standard alarm monitoring. Pressing this button will acknowledge and permanently silence a ‘sensor-off’ and ‘no-sensor’ audible alarm except in the Home and Sleep modes. In Sleep mode, all alarms are disabled. It will also permanently silence a low battery audible alarm if the Rad-8 is not monitoring a patient. If a low battery alarm occurs during patient monitoring, pressing the Alarm Silence button will silence the audible alarm for 120 seconds (default).</td>
<td></td>
</tr>
<tr>
<td>During normal patient monitoring the Up and Down Arrow keys control the Pulse Tone volume. At the lowest setting, the pulse tone is muted. A low-pitch tone indicates the highest or lowest setting has been reached. In the setup/menu system, the Up and Down Arrow keys select among the options for each setting and allows navigation through the menu(s).</td>
<td></td>
</tr>
</tbody>
</table>

Setup menu
This section gives an overview of the Rad-8 menu selections available. To navigate through the menus, use the Mode/Enter, Next, Up and Down keys located on the front panel of the oximeter. The following sub-sections describe each menu item in more detail. The oximeter has options that allow user configuration to suit specific needs.

MENU NAVIGATION
The Rad-8 set-up and configuration options are accessed through the menu system. The Mode/Enter key is used to enter the menu system and to move through the different menu levels. Within each level of the system, the Next key is used to move from one option to the next. The Up and Down arrow keys are used to select values within each option. The parameter is set/selected when either the Mode/Enter or Next keys are pressed.

NOTE: The Rad-8 will automatically ‘time out’ of the setup menu after 10 seconds with no key presses.

SETUP MENU LEVEL 1 – ALARM FEATURES AND SENSITIVITY.
Push the Mode/Enter button to enter menu level 1.

<table>
<thead>
<tr>
<th>BUTTON</th>
<th>SETTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarm Volume</td>
<td></td>
</tr>
<tr>
<td>Alarm Silence Duration 30, 60, 90 and 120 seconds (Default 120 seconds)</td>
<td></td>
</tr>
<tr>
<td>Alarm on / off Alarm muted with reminder (Default on)</td>
<td></td>
</tr>
<tr>
<td>Alarm Delay *0, 5, 10 seconds (Default 5 seconds)</td>
<td></td>
</tr>
<tr>
<td>Averaging. The signal averaging time of this device can be set to: 2, 4, 8, 10, 12, 14 or 16 seconds (Default 8 seconds)</td>
<td></td>
</tr>
</tbody>
</table>

* Alarm delay allows the user to adjust the time in which the audible status indicator will occur. Alarm delay applies only when the saturation limit is exceeded by less than 5%.

Notes:
- FastSat is automatically enabled in 2 and 4 second averaging.
SETUP MENU LEVEL 2 - BUTTON VOLUME, LED BRIGHTNESS AND FACTORY DEFAULT SETTINGS
Push the Mode/Enter button again to enter menu level 2.

<table>
<thead>
<tr>
<th>BUTTONS</th>
<th>SETTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Button Volume (Off, 3 Levels)</td>
<td></td>
</tr>
<tr>
<td>LED Display Brightness (4 levels)</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Active LED indicators are affected while adjusting this setting.

**NOTE:** Use Up or Down Arrow Keys to adjust parameter to desired setting. The parameter is set/selected when Mode Enter or Next are pressed.

**NOTE:** The parameter is set/selected when Mode Enter or Next are pressed.

**NOTE:** User default settings can be changed for specific patient environments.

SETUP MENU LEVEL 3 - CLEAR TREND
Push the Mode/Enter button again to enter menu level 3.

<table>
<thead>
<tr>
<th>BUTTONS</th>
<th>SETTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear Trend Yes / No</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Use Up or Down Arrow Keys to adjust parameter to desired setting. The parameter is set/selected when Mode Enter or Next are pressed.

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

The Rad-8 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 cleared by the user.

SETUP MENU LEVEL 4 - SET DATE AND TIME
Push the Mode/Enter button again to enter menu level 4.

<table>
<thead>
<tr>
<th>BUTTONS</th>
<th>SETTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select Clock</td>
<td></td>
</tr>
<tr>
<td>Set Year</td>
<td></td>
</tr>
<tr>
<td>Set Month</td>
<td></td>
</tr>
<tr>
<td>Set Day</td>
<td></td>
</tr>
<tr>
<td>Set Hour</td>
<td></td>
</tr>
<tr>
<td>Set Minute</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Use Up or Down Arrow Keys to adjust parameter to desired setting.

**NOTE:** The parameter is set/selected when Mode Enter or Next are pressed.

SETUP MENU LEVEL 5 - OUTPUT
Push the Mode/Enter button again to enter menu level 5.

<table>
<thead>
<tr>
<th>BUTTONS</th>
<th>SETTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software Version</td>
<td></td>
</tr>
<tr>
<td>Serial out - Philips, ASCII 1, ASCII 2</td>
<td></td>
</tr>
<tr>
<td>Alarm Monitor Interface On / Off</td>
<td></td>
</tr>
<tr>
<td>Nurse Call Polarity-Normal / Invert</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** See tables below for further description of features.
SYSTEM INTERFACES

PHILIPS VUELINK SETUP
1. Select the Philips VueLink selection from the Output menu on the Rad-8. After selecting, choose the preferred settings by stepping through menu options. Refer to Section 5, Output.
2. Connect one end of the VueLink cable to the Serial Output connector on the back of the Rad-8.
3. Connect the other end of the VueLink cable to the VueLink module and insert the module into the Philips/Agilent monitor rack.
4. The SpO\textsubscript{2} and pulse rate values will automatically appear on the HP/Agilent monitor.
5. In order for the pleth waveform to be displayed on the Philips/Agilent monitor and for the Philips/Agilent monitor to indicate the alarm conditions measured by the pulse oximeter, the user must configure the Philips/Agilent monitor. Please see the Philips/Agilent Operator's manual for complete instructions.
6. The Rad-8 pulse oximeter can be set up to audibly indicate all patient alarms while communicating with the Philips/VueLink module. Use the Interface Alarms setting in the Output menu to enable and disable audible alarms on the Rad-8.

RADNET SETUP
1. Select the ASCII 2 selection from the Serial options on the Rad-8 pulse oximeter.
2. Connect one end of the serial cable to the Serial Output connector on the back of the Rad-8.
3. Connect the other end of the serial cable to the RadNet Interface Module connector.
4. Turn the RadNet Interface Module on. A proper connection is shown by the RadNet Interface Module's Online LED being solid.
5. With a properly configured RadNet Interface Module, the Rad-8 will automatically display the SpO\textsubscript{2} and Pulse Rate parameters on the screen at the RadNet Central Station.
6. The Rad-8 pulse oximeter can be set up to audibly indicate all patient alarms while communicating with the RadNet Interface module.

RADLINK SETUP
1. Select the ASCII 1 selection from the Serial options on the Rad-8 pulse oximeter.
2. Connect one end of the serial cable to the Serial Output connector on the back of the Rad-8.
3. Connect the other end of the serial cable to the RadLink Bedside Radio serial connector.
4. Complete setup in accordance with the RadLink Operator's manual.

CAUTION: TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SERIAL PORT ON THE BACK PANEL UNLESS THE RAD-8 PULSE OXIMETER IS CONNECTED TO THE AC MAIN POWER SUPPLY.

Pressing \( \text{a sixth time returns the Rad-8 to patient monitoring in the Saturation/Pulse Rate Mode. Additionally, the Rad-8 will automatically return to patient monitoring display from any menu level/setting after 10 seconds with no key presses.} \)
Special Menu

This section gives an overview of the Rad-8 special menu selections available. To navigate through the menus, use the Mode/Enter, Next, Up and Down keys located on the front panel of the oximeter. The following sub-sections describe each menu item in more detail. The oximeter has options that allow user configuration to suit specific needs.

SPECIAL MENU – STANDARD, HOME AND SLEEP MODE

Turn instrument on, then push and hold the Mode/Enter and Next buttons simultaneously for 3 seconds to enter the special menu levels.

<table>
<thead>
<tr>
<th>BUTTONS</th>
<th>SETTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press to toggle to Enter Standard Mode - (STD) Use Up or Down Arrow Keys to adjust parameter to desired setting. NOTE: Only available indicators are illuminated while adjusting setting.</td>
<td></td>
</tr>
<tr>
<td>Press to toggle to Home Mode - (Hnn) NOTE: The parameter is set/selected when Mode Enter or Next are pressed.</td>
<td></td>
</tr>
<tr>
<td>Press to toggle to Sleep Mode* - (SLP)</td>
<td></td>
</tr>
</tbody>
</table>

*CAUTION: ALARMS ARE DISABLED IN THIS MODE.

HOME MODE OPERATION

The Rad-8 can be placed into the Home Mode to protect unqualified users from changing the Rad-8 alarm settings and operation. Only the following menu and front panel functions are available: display brightness (press + to adjust brightness), pulse beep volume adjustment and alarm suspend. Alarm volume is at highest setting. All default and user defined default settings are locked to their current values when home mode is selected and return to those values after a power cycle. Upon power up, the Hmm mode will be displayed along with a 10 second display of parameters. To turn the unit off the power key must be depressed and held for 3 seconds. The Mode Enter and Next key held simultaneously for 3 second will put it back into the special menu to select a different mode.

SLEEP MODE OPERATION

The Rad-8 can be placed into the Sleep Mode to allow the unit to capture normal and abnormal patient data without triggering the alarms. This mode will blank out the unit display with the exception of the Battery Level Indicator and the Alarm Silenced Indicator and disable the alarms even after a power cycle. However, any single key press will bring the display back for 10 seconds. Upon power up, the SLP mode will be displayed along with a 10 second display of parameter settings. The Mode Enter and Next key held simultaneously for 3 seconds (select next (STD), Mode Enter) will put it back into the special menu to exit.

CAUTION: ALARMS ARE DISABLED IN THIS MODE.

NOTE: If the unit is connected to a RadNet system, there will be no communication with RadNet in Home and Sleep mode.

Trend setup and use

INTRODUCTION

The Rad-8 can store up to 72 hours of SpO2, pulse rate, and perfusion index trend data captured at 2 second intervals. The trend data can then be transferred to a PC for evaluation.

A serial cable is required to connect the Rad-8 to a PC. Patient monitoring is not possible while trend memory is being transferred to a PC.

Trend data is stored in non-volatile memory, so it is not erased when the unit is shut off. Trend data download is initiated using the TrendCom utility which downloads the trend data and saves it to an ASCII text (.out) file with an output delimiter option.

TRENDCOM UTILITY INSTALLATION

Copy the TrendCom utility from the TrendCom CD onto a PC running MS-Windows.

TRENDCOM UTILITY OPERATION

1. Turn Rad-8 off if not already off.
2. Connect serial cable to Rad-8 and other end to a com port on the PC.
3. Turn the Rad-8 on.
4. Start the TrendCom utility on the PC.
5. Select Rad-8 from the first pull-down menu.
6. Select the appropriate com port number from the second pull-down menu, if necessary.
7. Select the Output Delimiter Option (Tab, Comma or Space).
8. Select the RETRIEVE TREND button on the TrendCom utility. Select the desired location and assign a file name for the trend file. Select SAVE.
9. The Rad-8 will display “dat out” while trend data is being transferred. A progress bar will advance to indicate the status of the download. Larger trend files will take longer to download. Transfer time is approximately 20 seconds per hour of trend data.

NOTE: During download of trend information, all normal Rad-8 functions are unavailable and the keypad is locked, except for the power button.

SPECIAL MENU – SpO2 AND BPM ALARM LIMITS

<table>
<thead>
<tr>
<th>BUTTONS</th>
<th>SETTINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2 High Alarm Limit Use Up or Down Arrow Keys to adjust parameter to desired setting.</td>
<td></td>
</tr>
<tr>
<td>SpO2 Low Alarm Limit NOTE: The parameter is set/selected when the Mode Enter or Next are pressed.</td>
<td></td>
</tr>
<tr>
<td>Pulse Rate High Alarm Limit</td>
<td></td>
</tr>
<tr>
<td>Pulse Rate Low Alarm Limit</td>
<td></td>
</tr>
</tbody>
</table>
alarms and messages

Alarm identification

The Rad-8 visually and audibly indicates alarm conditions that the system detects. Audible alarms may be silenced, without affecting the operation of visual alarms. Two levels of alarm priority are implemented: high and low priority. The following table outlines the alarm priority specifications.

<table>
<thead>
<tr>
<th>ALARM PRIORITY</th>
<th>PARAMETER DESCRIPTION</th>
<th>ALARM TYPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Low saturation (SpO2 range 1-100%)</td>
<td>Audible and visual</td>
</tr>
<tr>
<td></td>
<td>System failures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High pulse rate (pulse rate range 30-240 bpm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low pulse rate (pulse rate range 25-235 bpm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sensor off and no sensor</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>Low battery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High saturation (SpO2 range 2-100%)</td>
<td></td>
</tr>
</tbody>
</table>

Alarm indication

An alarm condition is indicated by:
- Audible alarm tone
- Visual Alarm Indicator
- Out-of-limit parameter will flash

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

ERASING TREND MEMORY

To erase (clear) the trend memory, see section 4, menu navigation, “clear trend” and follow the instructions. The Rad-8 continuously trends data. When performing a new study and gathering data on a new patient, it is highly recommended the “clear function” be utilized in order for the results to be separate. Turning the Rad-8 off will not erase the trend data.

TREND DATA FORMAT

After a successful download of the trend data, a .out file will be created containing the trend-dump information in ASCII delimited format. The format is defined in the following table.

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>MM/DD/YY</td>
</tr>
<tr>
<td>Time</td>
<td>HH:MM:SS</td>
</tr>
<tr>
<td>SpO2</td>
<td>001 to 100, or &quot;---&quot; meaning parameter not available</td>
</tr>
<tr>
<td>Pulse Rate</td>
<td>001 to 240, or &quot;---&quot; meaning parameter not available</td>
</tr>
<tr>
<td>PI</td>
<td>00.00 to 20.00</td>
</tr>
</tbody>
</table>

The exceptions are displayed as a 3 digit, ASCII encoded, hexadecimal value. The binary bits of the hexadecimal value are encoded as follows:

- 000 = Normal operation; no exceptions
- 001 = No Sensor
- 002 = Defective Sensor
- 004 = Low Perfusion
- 008 = Pulse Search
- 010 = Interference
- 020 = Sensor Off
- 040 = Ambient Light
- 080 = Unrecognized Sensor
- 100 = reserved
- 200 = reserved
- 400 = Low Signal IQ
- 800 = Masimo SET. This flag means the algorithm is running is full SET mode. It requires a SET sensor and needs to acquire some clean data for this flag to be set.

SAMPLE TREND OUTPUT

07/21/04 09:15:18 SpO2=094 Pr=078 PI=00.00 EXO=800:OFF Pat,SET
07/21/04 09:15:20 SpO2=096 Pr=078 PI=00.00 EXO=800:OFF Pat,SET
07/21/04 09:15:22 SpO2=097 Pr=078 PI=00.00 EXO=800:OFF Pat,SET
07/21/04 09:15:24 SpO2=099 Pr=078 PI=00.00 EXO=800:OFF Pat,SET
07/21/04 09:15:26 SpO2=100 Pr=078 PI=00.00 EXO=800:OFF Pat,SET
ALARMS AND MESSAGES

Alarm limits

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

An audible alarm and a flashing alarm status indicator will occur when an alarm limit is exceeded for greater than five seconds (See section 4, Alarm Features and Sensitivity to adjust this setting). It is best that the operator be within a minimum of 10 feet from the unit. Directions for alarm suspension are indicated below. When a sensor is not connected to a patient the “no sensor” indicator will illuminate. When a sensor is not connected to its cable, “sensor off” indicator will illuminate. An audible alarm will accompany the visual indicator unless the oximeter has been set to Alarm Suspend Mode.

<table>
<thead>
<tr>
<th>SETTING</th>
<th>RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SpO₂ High Limit</strong></td>
<td>The SpO₂ high alarm limit can be set anywhere between 2% and 99%, with a 1% step size. In the “----” (off) setting, the SpO₂ High Limit alarm is disabled.</td>
</tr>
</tbody>
</table>
| **SpO₂ Low Limit**   | The SpO₂ low alarm limit can be set anywhere between 1% and 99%, with a 1% step size.  
  **NOTE:** 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. |
| **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 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 SpO₂ 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.

ALARMS AND MESSAGES

ALARM SILENCE

Audible alarms may be suspended, while visual alarms may not. With the exception of Sleep Mode, there are two audible alarm suspension settings, all controlled by the Alarm Suspend Button. Repeated pressing of the Alarm Suspend button will cycle through two alarm suspend options.

Power-On – Alarms are active and Alarm Suspend Indicator is off.

Push Once – Alarm is suspended for 120 seconds and Alarm Suspend Indicator flashes (See section 4 “Alarm features and sensitivity” to adjust alarm suspension time period).

Push Twice - Return to Audible Alarm Active.

ALARM SILENCED INDICATOR

The Alarm Silenced Indicator provides visual feedback when illuminated, the Rad-8 audible alarms are muted.

While monitoring a patient, acknowledging an alarm condition by pressing the Alarm Silence Button (one time) will silence the alarm tone for 120 seconds (default) and the Alarm Silenced Indicator will flash. Pressing the Alarm Silence Button a second time (while the Alarm Silenced Indicator is still flashing) will activate alarms and alarm silenced indicator is off.

While not monitoring a patient, acknowledging an alarm condition by pressing the Alarm Silence Button (one time) will permanently silence the alarm tone, and the Alarm Silenced Indicator will remain illuminated until the power is cycled or patient monitoring begins. While in the Home Mode and not monitoring a patient, the alarm will be suspended for 120 seconds (default).

Should the alarm condition be created by a low battery condition, plug the unit into AC power immediately.
### Troubleshooting

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

<table>
<thead>
<tr>
<th>DISPLAY TYPE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LEDS FLASH HORIZONTAL BARS</strong></td>
<td>Pulse Search&lt;br&gt;Wait for found pulse. (This Search should occur whenever a sensor is first applied to a patient).</td>
</tr>
<tr>
<td><strong>PULSE BAR TURNS RED (Bottom two LEDs only)</strong></td>
<td>Low Signal IQ&lt;br&gt;1. Rule out occlusion of blood flow.&lt;br&gt;2. Verify placement of sensor.</td>
</tr>
<tr>
<td><strong>PERFUSION BAR TURNS RED (Bottom two LEDs only)</strong></td>
<td>Low Perfusion&lt;br&gt;1. Rule out occlusion of blood flow.&lt;br&gt;2. Attempt to warm patient.&lt;br&gt;3. Move sensor to better perfused site.</td>
</tr>
<tr>
<td><strong>SpO₂ NUMBER FLASHES</strong></td>
<td>Saturation limit alarm&lt;br&gt;Assess / address patient condition. Re-set alarm limits if indicated.</td>
</tr>
<tr>
<td><strong>PULSE RATE NUMBER FLASHES</strong></td>
<td>Pulse Rate limit alarm&lt;br&gt;Assess / address patient condition. Re-set alarm limits if indicated.</td>
</tr>
<tr>
<td><strong>Err # #</strong></td>
<td>System Fault&lt;br&gt;There are several error codes, all error codes require return of the unit to an authorized service center for repair. See Section 9, Service and Repair.</td>
</tr>
<tr>
<td><strong>Bad Sen</strong></td>
<td>Defective sensor&lt;br&gt;Replace sensor</td>
</tr>
<tr>
<td><strong>Sen (Blinking)</strong></td>
<td>Unrecognized sensor&lt;br&gt;Connect appropriate cable</td>
</tr>
<tr>
<td><strong>Int det (Blinking)</strong></td>
<td>Interference detected&lt;br&gt;Ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required.</td>
</tr>
</tbody>
</table>

### Messages

The Rad-8 will indicate other data or system errors. Message conditions for the Rad-8 follow:

<table>
<thead>
<tr>
<th>DISPLAY TYPE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DISPLAY TYPE</strong></td>
<td><strong>SOLUTION</strong></td>
</tr>
<tr>
<td><strong>UNIT DOES NOT POWER ON</strong></td>
<td>Low battery/ not plugged into AC power supply&lt;br&gt;Check / plug into AC power supply.</td>
</tr>
<tr>
<td><strong>CONTINUOUS SPEAKERTONE</strong></td>
<td>Internal Failure&lt;br&gt;Unit requires service. Press the Alarm Silence button. If alarm continues to sound, power down unit. If the power button does not turn the unit off, press and hold the sensitivity and alarm suspend buttons simultaneously. Return the unit for service.</td>
</tr>
<tr>
<td><strong>NO SPEAKER TONE</strong></td>
<td>Pulse tone set to “mute”&lt;br&gt;Press Up Arrow (Rad-8) or Alarm Volume Adjust (Rad-8).</td>
</tr>
<tr>
<td><strong>BUTTONS DON’T WORK WHEN PRESSED</strong></td>
<td>Internal Failure&lt;br&gt;Use auxiliary power down method by pressing and holding sensitivity and Alarm Suspend buttons simultaneously. Return for service.</td>
</tr>
</tbody>
</table>
## Rad-8 specifications

### PERFORMANCE

#### Measurement Range

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO₂</td>
<td>1-100%</td>
</tr>
<tr>
<td>Pulse Rate</td>
<td>25-240 beats per minute (bpm)</td>
</tr>
<tr>
<td>Perfusion</td>
<td>0.02% - 20%</td>
</tr>
<tr>
<td>Response time</td>
<td>&lt;1 second delay</td>
</tr>
</tbody>
</table>

### ACCURACY

#### Saturation

<table>
<thead>
<tr>
<th>Category</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults, Pediatrics</td>
<td>±2 digits</td>
</tr>
<tr>
<td>Neonate</td>
<td>±3 digits</td>
</tr>
<tr>
<td>No Motion¹</td>
<td>±2 digits</td>
</tr>
<tr>
<td>Motion²</td>
<td>±3 digits</td>
</tr>
<tr>
<td>Motion³</td>
<td>±3 digits</td>
</tr>
<tr>
<td>Low Perfusion³</td>
<td>±3 digits</td>
</tr>
</tbody>
</table>

#### Pulse Rate Accuracy

<table>
<thead>
<tr>
<th>Category</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults, Pediatrics, Neonate</td>
<td>±2 digits</td>
</tr>
<tr>
<td>Motion¹</td>
<td>±3 digits</td>
</tr>
<tr>
<td>Motion²</td>
<td>±3 digits</td>
</tr>
<tr>
<td>Low Perfusion³</td>
<td>±3 digits</td>
</tr>
</tbody>
</table>

### Resolution

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saturation (%) SpO₂</td>
<td>1%</td>
</tr>
<tr>
<td>Pulse Rate (bpm)</td>
<td>1 bpm</td>
</tr>
</tbody>
</table>

### ELECTRICAL

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC Power requirements</td>
<td>100-240 VAC, 50-60 Hz</td>
</tr>
<tr>
<td>Power consumption</td>
<td>15 VA max</td>
</tr>
<tr>
<td>Battery</td>
<td>Sealed lead acid</td>
</tr>
<tr>
<td>Capacity</td>
<td>8 hours⁴</td>
</tr>
<tr>
<td>Charging time</td>
<td>8 hours</td>
</tr>
</tbody>
</table>

### ENVIRONMENTAL

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temperature</td>
<td>41°F to 104°F (5°C to 40°C)</td>
</tr>
<tr>
<td>Transportation/Storage Temperature</td>
<td>-40°F to 158°F (-40°C to +70°C)³</td>
</tr>
<tr>
<td>Operating/Storage Humidity</td>
<td>5% to 95%, non-condensing</td>
</tr>
<tr>
<td>Operating Altitude</td>
<td>500 mbar to 1080 mbar pressure, -1000 ft to 18,000 ft (-304 m to 5,486 m)</td>
</tr>
</tbody>
</table>
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, \(\text{SpO}_2\), 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:

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>SETTING</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BAUD RATE</strong></td>
<td>9600 Baud bi-directional</td>
</tr>
<tr>
<td><strong>NUMBER OF BITS PER CHARACTER</strong></td>
<td>8</td>
</tr>
<tr>
<td><strong>PARITY</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>BITS</strong></td>
<td>1 start, 1 stop</td>
</tr>
<tr>
<td><strong>HANDSHAKING</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>CONNECTOR TYPE</strong></td>
<td>Female DB-9</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>PIN</th>
<th>SIGNAL NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No Connection</td>
</tr>
<tr>
<td>2</td>
<td>Receive data – RS-232 ±9 V (±5 Vmin)</td>
</tr>
<tr>
<td>3</td>
<td>Transmit data – RS-232 ±9 V (±5 Vmin)</td>
</tr>
<tr>
<td>4</td>
<td>No Connection</td>
</tr>
<tr>
<td>5</td>
<td>Signal Ground Reference for COM signals</td>
</tr>
<tr>
<td>6</td>
<td>No Connection</td>
</tr>
<tr>
<td>7</td>
<td>No Connection</td>
</tr>
<tr>
<td>8</td>
<td>No Connection</td>
</tr>
<tr>
<td>9</td>
<td>No Connection</td>
</tr>
</tbody>
</table>
sensors & patient cables

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

Masimo SpO2 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 SpO2 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 COMPATIBILITY OF THE MONITOR, CABLE AND SENSOR BEFORE USE, OTHERWISE PATIENT INJURY CAN RESULT.

■ DO NOT USE ADDITIONAL TAPE TO WRAP SENSOR.

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 SET 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 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 an SpO2 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.

SERIAL PRINTER SETUP

To print the SpO2 and pulse rate data in ASCII1 format on a serial printer, simply connect the laser printer to the serial port and set output mode to ASCII1. Once serial communication is established, the Rad-8 automatically will start printing the ASCII1 text data.

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

Nurse call specifications

The nurse call features are accessible via the 1/4" round female connector on the back of the unit.

NURSE CALL

The nurse call feature on the Rad-8 pulse oximeter is based on the relay closing or opening depending on alarm, Low Signal IQ events or both. In addition the nurse call polarity can be inverted to accommodate various nurse call stations requirements.

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

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAX VOLTAGE</td>
<td>36 VDC or 24 VAC peak</td>
</tr>
</tbody>
</table>

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".
### 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.

### LNOP® DIRECT CONNECT REUSEABLE SENSORS

<table>
<thead>
<tr>
<th>SENSOR</th>
<th>Weight Range</th>
<th>Saturation Accuracy</th>
<th>Pulse Rate Accuracy</th>
<th>Low Perfusion Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNOP DC-SC</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
<tr>
<td>LNOP DC-12</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
</tbody>
</table>

### LNOP® REUSEABLE SENSORS

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

<table>
<thead>
<tr>
<th>SENSOR</th>
<th>Weight Range</th>
<th>Saturation Accuracy</th>
<th>Pulse Rate Accuracy</th>
<th>Low Perfusion Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNOP DC-1</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
<tr>
<td>LNOP DC-12</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
</tbody>
</table>

### 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 PC cables)

<table>
<thead>
<tr>
<th>SENSOR</th>
<th>Weight Range</th>
<th>Saturation Accuracy</th>
<th>Pulse Rate Accuracy</th>
<th>Low Perfusion Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNOP Adt</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
<tr>
<td>LNOP Adtx</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
</tbody>
</table>

### LNOP® SPECILITY SENSORS

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

<table>
<thead>
<tr>
<th>SENSOR</th>
<th>Weight Range</th>
<th>Saturation Accuracy</th>
<th>Pulse Rate Accuracy</th>
<th>Low Perfusion Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNOP Blue</td>
<td>2.5 - 30 kg</td>
<td>60 - 80%</td>
<td>± 3 bpm</td>
<td>± 3%</td>
</tr>
<tr>
<td>LNOP Newborn</td>
<td>&lt; 3 kg</td>
<td>± 3%</td>
<td>± 3 bpm</td>
<td>± 3 bpm</td>
</tr>
</tbody>
</table>

### LNOPv™ ADHESIVE SENSORS

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

<table>
<thead>
<tr>
<th>SENSOR</th>
<th>Weight Range</th>
<th>Saturation Accuracy</th>
<th>Pulse Rate Accuracy</th>
<th>Low Perfusion Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNOPv In</td>
<td>3 - 20 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
<tr>
<td>LNOPv Ne</td>
<td>&lt; 3 kg</td>
<td>± 2%</td>
<td>± 3 bpm</td>
<td>± 3 bpm</td>
</tr>
</tbody>
</table>

### LNCS® REUSEABLE SENSORS

(LNCS sensors must be used in conjunction with LNC cables)

<table>
<thead>
<tr>
<th>SENSOR</th>
<th>Weight Range</th>
<th>Saturation Accuracy</th>
<th>Pulse Rate Accuracy</th>
<th>Low Perfusion Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNCS DC-1</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
<tr>
<td>LNCS DC-12</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
</tbody>
</table>

### 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 LNC cables)

<table>
<thead>
<tr>
<th>SENSOR</th>
<th>Weight Range</th>
<th>Saturation Accuracy</th>
<th>Pulse Rate Accuracy</th>
<th>Low Perfusion Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNCS Adt</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
<tr>
<td>LNCS Adtx</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
</tbody>
</table>

### LNCS™ REUSEABLE SENSORS

(LNCS sensors must be used in conjunction with LNC cables)

<table>
<thead>
<tr>
<th>SENSOR</th>
<th>Weight Range</th>
<th>Saturation Accuracy</th>
<th>Pulse Rate Accuracy</th>
<th>Low Perfusion Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNCS DC-1</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
<tr>
<td>LNCS DC-12</td>
<td>&gt; 30 kg</td>
<td>± 2%</td>
<td>± 3%</td>
<td>± 3 bpm</td>
</tr>
</tbody>
</table>
CLEANING AND REUSE OF MASIMO SENSORS

Reusable sensors can be cleaned per the following procedure:

- Remove the sensor from the patient.
- Disconnect the sensor from the monitor.
- Wipe the entire sensor clean with a 70% isopropyl alcohol pad.
- Allow the sensor to air dry before returning it to operation.

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.
- The adhesive can be partially rejuvenated by wiping with a 70% isopropyl alcohol wipe and allowing the sensor to thoroughly air dry prior to replacement on the patient.

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.

WARNING: TO AVOID CROSS CONTAMINATION ONLY USE MASIMO SINGLE USE SENSORS ON THE SAME PATIENT.

CAUTIONS:

- DO NOT REPROCESS ANY SINGLE USE SENSORS.
- DO NOT SOAK OR IMMERSE THE SENSOR IN ANY LIQUID SOLUTION. DO NOT STERILIZE ANY MASIMO SENSOR BY IRRADIATION, STEAM, OR ETHYLENE OXIDE.

Masimo SET patient cables

Reusable patient cables of various lengths are available. Only use appropriate Masimo oximetry patient cables for SpO₂ measurements. Other patient cables may cause improper Rad-8 pulse oximeter performance.

CLEANING AND REUSE OF MASIMO SET PATIENT CABLES

Patient cables can be cleaned per the following procedure:

- Remove the cable from the sensor.
- Disconnect the cable from the monitor.
- Wipe clean with a 70% isopropyl alcohol pad.
- Allow the cable to dry before returning it to operation.

CAUTIONS:

- CAREFULLY ROUTE PATIENT CABLES TO REDUCE THE POSSIBILITY OF PATIENT ENTANGLEMENT OR STRANGULATION.
- DO NOT SOAK OR IMMERSE PATIENT CABLES IN ANY LIQUID SOLUTION. DO NOT STERILIZE PATIENT CABLES BY IRRADIATION, STEAM, OR ETHYLENE OXIDE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE MASIMO PATIENT CABLES.
- DO NOT REPROCESS ANY MASIMO SET PATIENT CABLES.
service / maintenance

Introduction

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

Under normal operation, no internal adjustment or recalibration is required.

WARNING: BEFORE CLEANING THE OXIMETER, ALWAYS TURN IT OFF AND MAKE SURE THE AC POWER CORD IS DISCONNECTED.

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, the following solutions may be used to wipe the instrument for 30 seconds. Do not allow liquids to enter the interior of the instrument.

- Glutaraldehyde Solution
- Ammonium Chloride Wipe
- 10% Chlorine bleach in H₂O
- 70% Isopropyl alcohol

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 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 pulse oximeter following 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 unit back to the user.

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

**Power-On Self-Test:**
1. Turn the monitor on by depressing the Power Button. For about 5 seconds all available LEDs are illuminated and a brief beep tone sounds.
2. The oximeter begins normal operation.

**Key Press Button Test:**
1. With the exception of the Power Button, press each button and verify that the oximeter 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 depress alarm limits button and enter alarm menu. Change the High Saturation 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.
3. Return the High Saturation Alarm parameter to its original setting.
4. Repeat steps 1 to 3 with the Low Saturation Alarm parameter.
5. Repeat steps 1 to 3 with the High Pulse Rate Alarm parameter.
6. Repeat steps 1 to 3 with the Low Pulse Rate Alarm parameter.
7. Reset the alarm limits again to the original settings.

**LED Brightness:**
1. With the monitor turned on, select menu level 2 (see Section 4, Setup Menu Level 2 - button volume LED Brightness and Factory Defaults) and use the Up and Down Arrow keys to cycle through all 4 brightness levels.
2. Exit the Menu system by pressing the Mode/Enter key or waiting for the normal time-out.

Testing the Rad-8 with Masimo SET Tester (Optional):
1. Turn the Oximeter off and then on again.
2. Connect the Masimo SET Tester to the Patient Cable Connecter.
3. Verify that within 20 seconds a Signal IQ/pulsebar is displayed.
4. Verify that the SpO₂ measurement is between 79% and 84%.
5. Verify that the pulse rate measurement is between 55 bpm and 65 bpm.
6. Set the SpO₂ low alarm limit to 90 (see Section 4, Setup Menu Level 1 - Alarm Limits and Alarm Volume).
7. Verify that an audible alarm occurs and the SpO₂ measurement and the Alarm indicator are both flashing.
8. Press the Alarm Silence button once and verify that the alarm is silenced and the Alarm Silence Indicator is flashing.
9. Wait 120 seconds and verify that the alarm silence times out and the audible alarm is activated again and the Alarm Silence Indicator is off.
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.
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.

Please clean contaminated/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 Rad-8 unit for service, please follow the Return Procedure.

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.

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 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 Rad-8 pulse oximeter to the following shipping address:

For USA: 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 France
Tel: +33 (0) 472 17 93 70
FAX: +33 (0) 478 35 78 08

For Asia Pacific: Masimo Japan Corporation
World Times Bldg. 4F
10-7, Ichiban-cho, Chiyoda-ku,
Tokyo 102-0082 JAPAN
Tel: 03 3237 3057
FAX: 03 3238 1110

End-user license agreement

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Warranty

Masimo warrants to the initial purchaser that each new pulse 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 oximeter.

Batteries are not warrantied. To request a replacement or repair of an instrument under warranty, contact Masimo for a returned goods authorization. If Masimo determines that a product must be replaced or repaired under warranty, it will be replaced or repaired 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.

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## Rad-8 Units and Accessories

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Instruments and sensors containing Masimo SET technology are identified with the Masimo SET logo. Look for the Masimo SET designation on both the sensors and monitors to ensure accurate pulse oximetry when needed.