

Rad-5[®] Rad-5v[™]

signal extraction pulse oximeter

OPERATOR'S MANUAL



Rad-5[®]

Rad-5v[™]

Signal Extraction Pulse Oximeter

OPERATOR'S MANUAL

The Rad-5 and Rad-5v Operating Instructions intend to provide the necessary information for proper operation of all Rad-5 and Rad-5v pulse oximeter models. There may be information provided in this manual that is not relevant for your pulse oximetry system.

General knowledge of pulse oximetry and an understanding of the features and functions of the Rad-5 and Rad-5v Pulse Oximeter are prerequisites for proper use.

Do not operate the Rad-5 or Rad-5v Pulse Oximeter without completely reading and understanding these instructions.

NOTICE

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

CAUTION:

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

80 fk

Covered by one or more of the following U.S. Patents: RE38,492, RE38,476, 7,221,971, 7,215,986, 7,215,984, 6,850,787, 6,826,419, 6,816,741, 6,699,194, 6,684,090, 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, 6,236,872, 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.

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SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES

The Rad-5/5v Handheld Pulse Oximeter's software program is designed to minimize the possibility of hazards from errors 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.
- 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.
- 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 Pulse Oximeter is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
- Electric shock hazard. Do not open the pulse oximeter cover except to replace the batteries. 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 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 SpO₂ 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.
- The Rad-5v is not intended for continuous patient monitoring.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If sensor is exposed to the radiation, the reading might be inaccurate or the unit might read zero for the duration of the active radiation 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 muffled.

SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES

- 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 is damaged in any way, discontinue use immediately.
- 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 IEC 60601-1-2, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. 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.

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About this Manual

This manual explains how to set up and use the Rad-5/5v Handheld Pulse Oximeter. Important safety information relating to general use of the Rad-5/5v 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-5/5v Handheld Pulse Oximeter system and its functions and features.
- SECTION 3** SETUP describes how to setup the Rad-5/5v Handheld Pulse Oximeter for use.
- SECTION 4** OPERATION describes the operation of the Rad-5/5v Pulse Oximetry system.
- SECTION 5** ALARMS AND MESSAGES describes the alarm system messages.
- SECTION 6** TROUBLESHOOTING gives troubleshooting information.
- SECTION 7** SPECIFICATIONS gives the detailed specifications of the Rad-5/5v Handheld 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-5/5v Handheld Pulse Oximeter.
- SECTION 10** ACCESSORIES.

Warnings, Cautions and Notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels 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-5 family of Handheld Pulse Oximeters are noninvasive, arterial oxygen saturation and pulse rate monitors. The Rad-5 family features a multicolored LED display that continuously displays numeric values for SpO₂ and pulse rate, as well as LED indicator bars for Perfusion Index (PI) and Signal Identification and Quality Indicator (Signal IQ[®]).

The Rad-5 family consists of two models: the full-featured Rad-5 and the Rad-5v entry-level spot checker. Both devices are built on the same motion tolerant pulse oximetry technology, with the Rad-5 adding parameter alarming, three sensitivity settings and adjustable averaging times.

Features that apply to the Rad-5 only will be indicated with “(Rad-5)”.

FEATURES AND BENEFITS

These features are common to the Rad-5 family:

- Clinically proven Masimo SET[®] technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO₂, pulse rate, alarm, and perfusion index displays
- Signal I.Q. for signal identification and quality indication
- Lightweight, convenient handheld design
- Long battery life: over 30 hours on 4 “AA” alkaline batteries
- Audible Alarm for no sensor, sensor-off, interference detected and low battery

The Rad-5 adds these features:

- Alarms for High/Low saturation and High/Low pulse rate
- FastSat[®]
- SmartTone
- User definable alarm limit settings
- Sleep study mode
- Three sensitivity levels - Max, Normal and APOD[®]
- Stores up to 72 hours of trending memory
- Adjustable alarm volume
- Adjustable averaging 2 to 16 seconds

INDICATIONS FOR USE

Masimo SET® Rad-5 Pulse Oximeter

The Masimo SET® Rad-5 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor). The Masimo SET® Rad-5 Pulse Oximeter is indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

INDICATIONS FOR USE

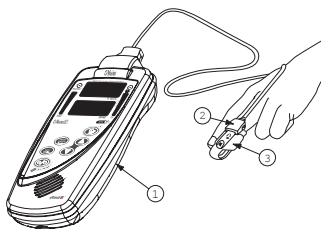
Masimo SET® Rad-5v Pulse Oximeter

The Masimo SET® Rad-5v Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor). The Masimo SET® Rad-5v Pulse Oximeter is indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Pulse Oximetry

GENERAL DESCRIPTION

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor connects to the pulse oximetry device with a patient cable. The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data in two ways: 1) as a percent value for arterial oxygen saturation (SpO₂), and 2) as a pulse rate (PR). The following figure shows the general monitoring setup.



1. Device
2. Patient Cable
3. Sensor

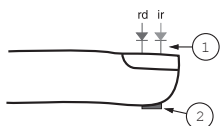
PRINCIPLE OF OPERATION

Pulse oximetry is governed by the following principles:

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

The Rad-5/5v Handheld 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, 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-5/5v utilizes a sensor with red and infrared light-emitting diodes (LEDs) that pass light through the site to a photodiode (detector). The detector receives the light, converts it into an electronic signal and sends it to the Rad-5/5v for calculation.



1. Light Emitting Diodes (LEDs)
2. Detector

Once the Rad-5/5v 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.

FUNCTIONAL VS. FRACTIONAL SATURATION

The Rad-5/5v is calibrated to measure and display functional saturation: the amount of oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. The Rad-5/5v does not measure fractional saturation: oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin. To convert fractional saturation to functional saturation, the fractional saturation measurements must be converted according to:

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

MEASURED VS. CALCULATED SATURATION

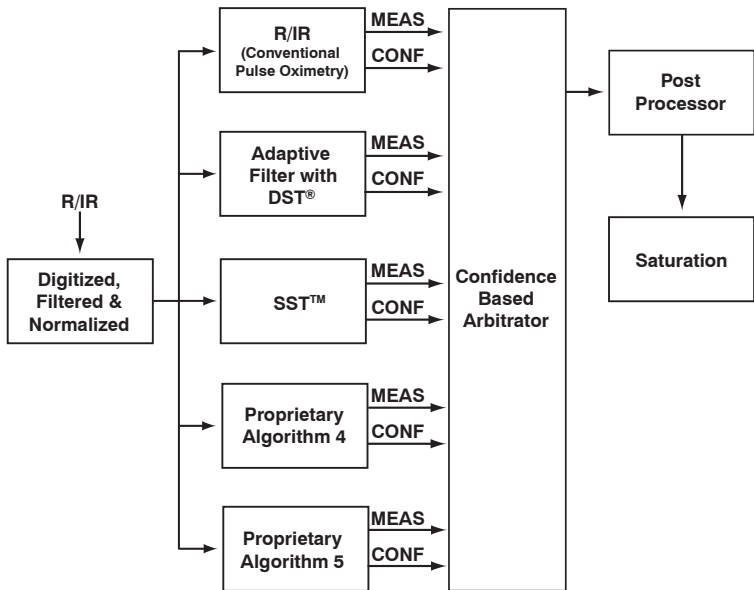
Oxygen saturation measurements obtained from a pulse oximeter are commonly compared to saturations calculated from the partial pressure of oxygen (PO₂) obtained from an arterial blood gas sample. When comparing the two measurements and interpreting values, caution should be used, as the calculated value obtained from the blood gas sample may differ from the SpO₂ 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 PO₂ and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO₂), 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

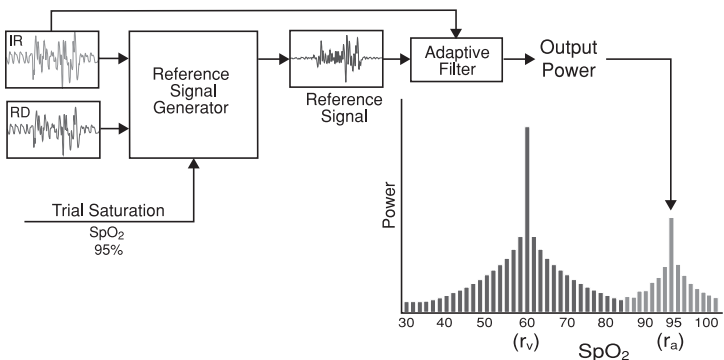
Masimo Signal Extraction Technology's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the non-arterial blood also moves, causing conventional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

MASIMO SET PARALLEL ENGINES



MASIMO SET DST



Introduction

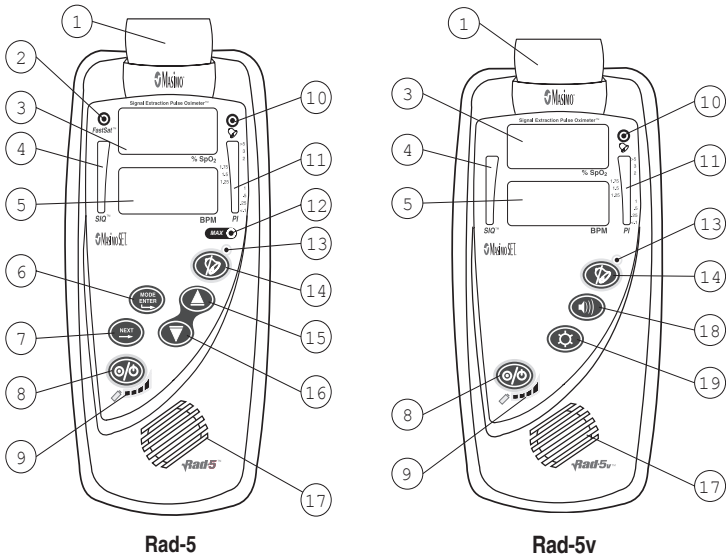
The Rad-5 family of Handheld Pulse Oximeters are full featured pulse oximeters designed for ease of operation. All pulse oximetry measurement information, as well as device status data, is displayed on the front panel of the device. All user input is handled by control buttons on the front panel and the sensor cable connection is located at the top edge of the device.

The Rad-5/5v are powered by 4 “AA” alkaline batteries, which provide over 30 hours of battery life.

- Rad-5 family offers full Masimo SET technology in a small, handheld device
- Rad-5 family supports the full line of Masimo sensors and patient cables (see Section 8, *sensors and patient cables*).
- Rad-5 family supports standardization of sensors and pulse oximetry technology throughout the hospital
- Rad-5v provides essential pulse oximetry features
- Rad-5 includes all the features of the Rad-5v, plus
 - High/Low saturation alarms
 - High/Low pulse rate alarms
 - User definable alarm limit settings
 - Sleep study mode
 - Stores up to 72 hours of trending memory
 - Adjustable averaging time
 - Three sensitivity levels - Max, Normal and APOD
 - FastSat[®]
 - SmartTone

A Red Direct Connect Spot Check Sensor or Masimo Patient Cable and Masimo sensor attach to the connector on the top of the Rad-5/5v. The Rad-5/5v can be used either for spot checks or continuous (Rad-5) SpO₂ monitoring.

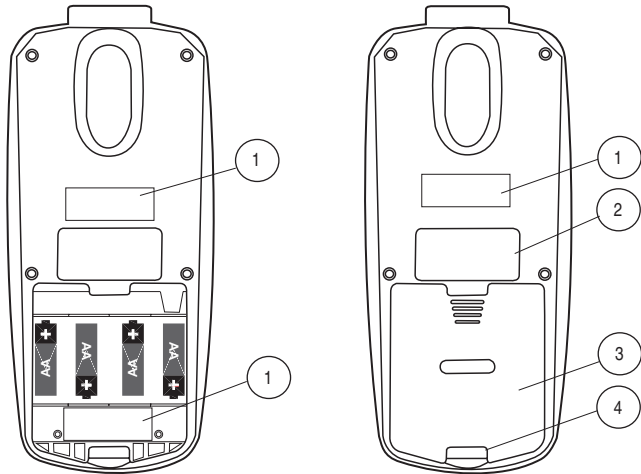
Rad-5/5v front Panel Controls



CONTROL / INDICATOR	DESCRIPTION
① Patient Cable Connector	Connects to Red Direct Connect Series Spot Check sensor or Masimo Patient Cable
② FastSat Indicator	Illuminates when the FastSat mode has been enabled. FastSat enables rapid tracking of arterial oxygen saturation changes
③ Saturation Display	The functional arterial hemoglobin oxygen saturation is displayed in units of SpO ₂ . When searching for a saturation and pulse, it will flash dashed lines.
④ 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.
⑤ Pulse Rate Display	The pulse rate in beats per minute (bpm). When searching for a saturation and pulse, it will flash dashed lines.
⑥ Mode / Enter Button	Used to enter the setup menus and to select/activate certain entries within the menu/setup system.
⑦ Next Button	Used within the menu/setup system to move through setup options. Not active during normal patient monitoring.

CONTROL / INDICATOR		DESCRIPTION
⑧	Power On / Off	Used to turn the unit on and off.
⑨	Battery Level Indicator	Four LEDs indicate the status of the battery. When the final indicator begins flashing, replace the batteries.
⑩	Visual Alarm Indicator	Illuminates when any alarm condition exists. This indicator may not be turned-off or otherwise over-ridden.
⑪	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.
⑫	MAX Sensitivity Indicator	Illuminates when the MAX Sensitivity mode has been enabled. Note: When using the Maximum Sensitivity setting, the SENSOR OFF detection performance may be compromised.
⑬	Alarm Silenced Indicator	Flashes to indicate the alarm is temporarily silenced (by pushing the Alarm Silence Button once) or is illuminated solid to indicate the alarms have been permanently muted (by pushing the Alarm Silence Button twice) .
⑭	Alarm Silence Button	Push once to temporarily silence the alarm for 120 seconds. Push a second time to temporarily mute (suspend) the alarm. A third push will return the device to standard alarm monitoring.
⑮	Up button	During saturation monitoring, use these buttons to adjust the volume of the pulse beep tone.
⑯	Down button	Within the menu/setup system, these buttons are used to select values within each menu option.
⑰	Speaker	Provides audible indication of alarm conditions, pulse tone and feedback for key-presses. Ensure the speaker is not covered or the device is placed face-down on bedding or other sound absorbing surface.
⑱	Pulse Tone Volume	Provides control of the pulse tone volume. Cycles through three volume levels, and mute. At the loudest level, pressing the Pulse Tone Volume button will return the volume to mute.
⑲	Display Brightness	Provides control of the front panel indicator brightness. Cycles through four brightness levels. At the brightest level, pressing the Display Brightness button will return the display to the lowest brightness setting.














Rad-5/5v rear panel



CONTROL / INDICATOR		DEFINITION
1	Serial Number Label	Located inside battery compartment and on back of device
2	Agency Approvals Label	
3	Battery Cover	
4	Battery Cover Release	Press down and slide the battery cover off the bottom of the oximeter

SYMBOLS

The following symbols are found on the Rad-5/5v or on the packaging and are defined below.

SYMBOLS	DEFINITION
	Consult accompanying documents
 (blue background)	Follow instructions for use
	WEEE compliant
	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
	Storage humidity range
	Storage temperature range Storage altitude range
	Keep dry
	Fragile/breakable, handle with care
EC REP	EU authorized representative
	Defibrillation Proof Type BF
	Caution
	Underwriter's Laboratory Inc. certification
	Manufacturer

Introduction

Before the Rad-5/5v Handheld Pulse Oximeter can be used in a clinical setting, it needs to be inspected, properly setup and the batteries need to be installed.

Unpacking and Inspection

Remove the device from the shipping carton and examine 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-5/5v Handheld Pulse Oximeter.

POWER REQUIREMENTS

The Rad-5 and Rad-5v are powered by 4 "AA" alkaline batteries. Do not use any other type of batteries or power source to run the device. The battery compartment is accessed from the back of the device. To install the batteries first remove the battery cover by depressing the small rectangular button at the bottom of the cover, and sliding the cover down off the bottom of the device. Install the batteries in the directions indicated by the battery icons inside the battery compartment. Replace the battery cover by sliding it back up from the bottom of the device until the rectangular locking button snaps back into position.

WARNING: USE ONLY ALKALINE BATTERIES. USE OF NON ALKALINE BATTERIES MAY AFFECT THE ACCURACY OF THE BATTERY LEVEL METER.

WARNING: USE OF BATTERIES WITH A CELL VOLTAGE OF MORE THAN 1.5V COULD CAUSE DAMAGE TO THE DEVICE.

WARNING: REMOVE BATTERIES IF UNIT IS NOT TO BE USED FOR SOME TIME.

Battery charge level is indicated by four LED indicators at the bottom of the front panel. All four indicators will be lit when the batteries are full, with fewer indicators being lit as the batteries lose their charge. When less than ten (10) percent battery life remains, the final battery indicator will begin to flash and an audible alarm will sound.

Monitor Setup

INITIAL SETUP

1. Inspect the oximeter case for damage.
2. Install 4 (four) new AA alkaline batteries.
3. Verify the device powers-up immediately after installing batteries.
4. Turn device off.
5. Turn the device on, verify all indicators illuminate and speaker sounds a brief tone.

No other setup is required. Refer to Section 4, *General Setup and Use* for additional steps to verify proper functioning of the device.

Introduction

To operate the Rad-5 or Rad-5v Pulse Oximeters 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. Ensure that the batteries are correctly installed.
3. Connect a Red Direct Connect Spot Check Sensor or patient cable to the Patient Cable connector of the oximeter. Make sure it is a firm connection and the cable is not twisted, sliced or frayed.
4. Select a sensor that is compatible with the oximeter 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. 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 detector.
5. Attach the sensor to the patient. Refer to the Directions for Use of the sensor.
6. Connect the sensor to the patient cable with the logos lining up; make sure it is a firm connection (does not apply for Red Direct Connect Spot Check Sensor).
7. Press the Power button to turn the oximeter on.
8. Verify all front-panel indicators momentarily illuminate and a one-second tone is heard.
9. Verify the display shows mode, SpO₂ Low Alarm Limit, SpO₂ High Alarm Limit, Pulse Rate Low Alarm Limit, Pulse Rate High Alarm Limit, Sensitivity and Averaging Time.
10. Verify the front panel display is free of alarm and system failure messages (see *Section 5, Alarms and Messages*) and the battery indicator shows sufficient charge (see *Section 4, Battery Level Indicator*)
11. 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).

GENERAL SETUP AND USE (CONTINUED)

12. Rad-5 only:
Verify that the patient alarms are functional by setting the high and low SpO₂ and pulse rate alarm limits beyond the patient readings.
 - An alarm tone sounds.
 - The violated alarm limit and reading flash on the display.
13. Verify the sensor alarms are functional by removing the sensor from the sensor site.
 - “SEn OFF” message appears on the display.
 - The alarm tone sounds.
 - The Visual Alarm Indicator flashes.
 - Disconnect the sensor from the patient cable or oximeter.
 - Confirm that “NO SEn” message appears on the display.

NOTE: “NO SEn” and “SEn OFF” will only generate an alarm if the Rad-5/5v was actively monitoring a patient when the sensor was disconnected.
14. Rad-5 only:
Verify parameter-violation alarm silence operation.
 - Create an alarm condition by lowering the SpO₂ or pulse rate high alarm limits beyond the patient readings.
 - Press the Alarm Silence button.
 - The alarm tone ceases for 120 seconds.
15. To begin patient monitoring:
 - Adjust the alarm limits (Rad-5 only).
 - Adjust the alarm volume (Rad-5 only).
 - Adjust the pulse beep volume.
16. Verify the sensor is applied correctly and that the measured data are appropriate, see Section 4, *Successful SpO₂ 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 governing rules. See the Directions for Use of the sensor. If trending is enabled, turn off.
19. Press and hold the Power/Standby Button for 2 seconds to turn the oximeter off.

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

DEFAULT SETTINGS

The Rad-5/5v 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 and will be remembered after a power cycle.

The following table outlines the default values that the Rad-5 and Rad-5v revert to after a power cycle:

OPTION	DEFAULT SETTING
Display brightness	Set to pre-power down setting
Pulse tone volume	Set to pre-power down setting

The following table outlines the default values that the Rad-5 revert to after a power cycle:

OPTION	DEFAULT SETTING
SpO ₂ high alarm limit	Set to Off
SpO ₂ low alarm limit	Set to 90%
Pulse rate high alarm limit	Set to 140 BPM
Pulse rate low alarm limit	Set to 50 BPM
Averaging Time	Set to pre-power down setting
FastSat	
Sensitivity*	
Display brightness	
Pulse tone volume	
Alarm Silence	
Alarm Volume	
Trending on/off	
Sleep Study Mode	Set to pre-power down setting

* Defaults to APOD and Normal only. High Sensitivity will default to normal.

Successful SpO₂ 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 LEDs and detector.
- Place the sensor on a site that has unrestricted blood flow.
- Do not constrict the monitoring site when securing a sensor with tape.
- Do not select a site near potential electrical interference (electrosurgical unit, for example).
- Read the sensor Directions for Use for proper sensor application.

NUMERIC DISPLAY - SpO₂

Stability of the SpO₂ 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 SpO₂ and PR.

MASIMO SENSORS

Before use, carefully read the sensor Directions for Use.

Use only Masimo oximetry sensors for SpO₂ 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 ANY 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. 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.

NUMERIC DISPLAY - PULSE RATE

The Pulse Rate displayed on the Rad-5/5v 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 devices 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.

SIGNAL IQ AND PULSE BAR

The Rad-5/5v 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-5/5v 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-5/5v 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%.

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-5/5v 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 an episode of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site is not interrupted. 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 CO-oximetry analysis may be considered to verify the oxygen saturation value.

LOW PERFUSION

The Rad-5/5v 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 saturation¹. 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 SpO₂ 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 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-5/5v Handheld Pulse Oximeters with integrated Masimo SET technology have 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-5 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 (Nor)** – 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 (APO)** – 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 (HI)** – 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 adaptive probe off detection 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 HI to the factory default or user configured default setting of APO or Nor.

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.

BATTERY LEVEL INDICATOR

Four LED indicators provide information on the remaining battery capacity. The operator should monitor these indicators periodically to determine remaining battery life and if the batteries should be replaced. Battery capacity is indicated in the following chart.

INDICATION	BATTERY CAPACITY
4 LEDs	100% to 75%
3 LEDs	75% to 50%
2 LEDs	50% to 25%
1 LED	25% to 10%
1 FLASHING LED WITH AUDIBLE ALARM	10% to 0%

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 by pressing the Alarm Silence Button.

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 replace the batteries.

WARNING: FAILURE TO REPLACE BATTERIES PROMPTLY AFTER A LOW BATTERY ALARM MAY RESULT IN THE OXIMETER SHUTTING DOWN, LEAVING THE PATIENT IN AN UN-MONITORED CONDITION.

WARNING: USE ONLY ALKALINE BATTERIES. USE OF NON ALKALINE BATTERIES MAY AFFECT THE ACCURACY OF THE BATTERY LEVEL METER.





WARNING: USE OF BATTERIES WITH A CELL VOLTAGE OF MORE THAN 1.5V COULD CAUSE DAMAGE TO THE DEVICE.

Normal Patient Monitoring






During normal operation, the Rad-5/5v Display shows oxygen saturation (as % SpO₂) on the upper number and Pulse Rate (in beats per minute) on the lower number.

The following sections describe the function of the Rad-5/5v front panel controls during normal patient monitoring.

RAD-5v FRONT PANEL CONTROL OPERATION

BUTTON	FUNCTION
	Power on/off. Press to turn Rad-5v on. Press-and-hold for 2 seconds to turn Rad-5v off.
	Front panel indicator brightness. Pressing this button will cycle the brightness through the full range, then back to the lowest setting to begin the cycle again.
	Alarm Silence. Pressing this button will acknowledge and permanently silence a 'sensor-off' and 'no-sensor' audible alarm (until power is cycled or patient monitoring begins). It will also suspend a low battery audible alarm if the Rad-5v 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.
	Pulse Tone Volume. Pressing this button will cycle the pulse tone volume through the full range, then back to the 'silence' setting to begin the cycle again.

RAD-5 FRONT PANEL CONTROL OPERATION

BUTTON	FUNCTION
	Power on/off. Press to turn Rad-5 on. Press-and-hold for 2 seconds to turn Rad-5 off.
	Enters the Rad-5 setup/menu system. See Section 4, <i>Setup menu</i> .
	No function during normal patient monitoring.
	Alarm Silence. Pressing this button one time will temporarily silence a saturation or pulse rate high/low limit violation for 120 seconds. A second press will permanently silence all audible alarms. Pressing this button will acknowledge and permanently silence a 'sensor-off' and 'no-sensor' audible alarm. It will also permanently silence a low battery audible alarm if the Rad-5 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.
	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.






Setup Menu (Rad-5 only)

This section gives an overview of available Rad-5 menu selections. These selections DO NOT apply to the Rad-5v. To navigate through the menus, use the *Mode/Enter*, *Next*, and *Up* and *Down* keys located on the front panel of the oximeter below the LED display. The following sub-sections describe each menu in more detail. The oximeter has options that allow user configuration to suit specific needs.

MENU NAVIGATION





The Rad-5 setup 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.

SETUP MENU LEVEL 1 – ALARM LIMITS AND ALARM VOLUME.

BUTTON	SETTING	
	Alarm Volume	Use <i>Up</i> or <i>Down</i> Arrow Keys to adjust parameter to desired setting. Note: The parameter is set/selected when the <i>Mode Enter</i> and <i>Next</i> are pressed.
	 SpO ₂ Low Alarm Limit	
	 SpO ₂ High Alarm Limit	
	 PR Low alarm Limit	
	 PR High alarm Limit	

SETUP MENU LEVEL 2 – AVERAGING, SENSITIVITY, FASTSAT AND SMARTTONE

Push the Mode/Enter button again to enter menu level 2.

BUTTON	SETTING	
 2X		Averaging. The signal averaging time of this device can be set to: 2 ² , 4 ² , 8, 10, 12, 14 or 16 seconds
		Sensitivity ¹ . Hi = Maximum Nor = Normal APO = APOD
		FastSat ² On, Off
		SmartTone ³ On, Off
		Use <i>Up</i> or <i>Down</i> Arrow Keys to adjust parameter to desired setting. Note: <i>The parameter is set/selected when the Mode Enter and Next are pressed.</i> Use the <i>Up</i> Arrow key to turn on SmartTone.

¹ Defaults to APOD and Normal only. High sensitivity will default to normal.

² FastSat is automatically enabled in 2 and 4 second averaging.







³ The SmartTone feature uses a proprietary algorithm that will provide pulse tones during excessive motion and low perfusion conditions. The pulse tone is based off of an averaged pulse rate measurement from the proprietary algorithm and may not identify irregular heart beat patterns when there is excessive artifact present.

SETUP MENU LEVEL 3 - TREND SETTINGS

Push the Mode/Enter button again to enter menu level 3.

To enable trending of patient data, the trend feature must be enabled (set to ON), and the current date and time must be set. See section 4, *Trend setup and use*.

The current date and time can only be set if the Trend is set to "ON". The date and time menu selections are not available if Trend is set to "OFF".

BUTTON	SETTING	
 3X		Trend ON / OFF
		Set Year
		Set Month
		Set Day
		Set Hour
		Set Minute
		Use <i>Up</i> key to turn Trend ON. Use <i>Down</i> key to turn Trend OFF Use <i>Up</i> or <i>Down</i> Arrow Keys to adjust parameter to desired setting.

SETUP MENU LEVEL 3 - TREND SETTINGS (CONTINUED)

A valid date must be entered. If an invalid date is entered (i.e., February 31), the trend will not turn on and “tnd off” will be displayed.

NOTE: Press and hold for rapid scrolling:




- SAT alarm keys up / down will scroll numbers.
- PR alarm keys up / down will scroll numbers.


NOTE: The date and time must be set before trending will be enabled. The Rad-5 will automatically ‘time out’ of the setup menu after 10 seconds with no key presses. If the Rad-5 should time-out to the Trend Settings menu, the trend will not be enabled.

NOTE: Enabling trend (setting Trend to “ON”) will erase all trend information in the Rad-5. Turn trending off prior to turning device off and storing.

SETUP MENU LEVEL 4 - LED BRIGHTNESS AND FACTORY DEFAULTS

Push the Mode/Enter button again to enter menu level 4.

BUTTON	SETTING	
 4X	LED Display Brightness (4 levels) Note: All LED indicators are illuminated while adjusting this setting.	Use Up or Down Arrow Keys to adjust parameter to desired setting.
	 Restore Factory Defaults Yes/No	
	 Save User Identified Default Settings (Password: next button, up arrow, down arrow, next button)	

Pressing  a fifth time returns the Rad-5 to patient monitoring in the Saturation/Pulse Rate Mode. Additionally, the Rad-5 will automatically return to patient monitoring display from any menu level/setting after 10 seconds with no key presses.

Trend Setup and Use (Rad-5 only)

INTRODUCTION

The Rad-5 can store 72 hours of SpO₂ and Pulse Rate and Perfusion Index trend data, captured at 2 second intervals. This trend data can then be transferred to a PC for evaluation.

Trend data is stored in non-volatile memory, so it is not erased when the device is shut off or when the batteries are replaced.

A special serial cable (see Section 10, *Accessories*) is required to connect the sensor connector of the Rad-5 to the PC. Patient monitoring is not possible while trend memory is being transferred to a PC.

A trend data download is initiated using the TrendCom utility which downloads the trend data and saves it to a space-delimited ASCII text (.out) file.

TRENDCOM UTILITY INSTALLATION

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

TRENDCOM UTILITY OPERATION

1. Disconnect patient sensor and/or cable from the Rad-5.
2. Connect the mini-D end of the Data Transfer Download cable to the Rad-5 patient cable connector (see Section 2, *Rad-5 front panel controls*) and connect the DB-9 end to a COM port on the PC.
3. Turn the Rad-5 on.
4. Start the TrendCom Utility.
5. Select the appropriate COM port number, if necessary.
6. Push the **RETRIEVE TREND** button on the TrendCom utility. Select the desired location and assign a filename for the trend file. Press **Save**.
7. The Rad-5 will display "dat out" while trend data are 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-5 functions are unavailable and the keypad is locked, except for the power button.

8. When trend data transfer is complete, close TrendCom and disconnect the Rad-5 from the Data Transfer Download cable.
9. Turn the Rad-5 off to exit the trend download mode.

NOTE: USB to serial port adapters are not supported for trend transfer.

NOTE: Enabling trend (setting Trend to "ON") will erase all trend information in the Rad-5.

ERASING TREND MEMORY

To erase (clear) the trend memory, turn the trend off and back on again. Enabling trend (setting Trend to "ON") will erase all trend data.

NOTE: Turning trend off will not erase trend memory. You may turn trending off and still retrieve the trend data using TrendCom.

Turning the Rad-5 off or replacing the batteries will not erase the trend data.

Turn trending off before storing the device for any length of time.

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.

PARAMETER	SPECIFICATION
Date	MM/DD\YY
Time	HH:MM:SS
SpO ₂	001 to 100, or "---" meaning parameter not available
Pulse Rate	001 to 240, or "---" meaning parameter not available
Perfusion Index	00.00 to 20.00
Exception Messages	<p>The exceptions are displayed as a 3 digit, ASCII encoded, hexadecimal value. The binary bits of the hexadecimal value are encoded as follows:</p> <p>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 in full SET mode. It requires a SET sensor and needs to acquire some clean data for this flag to be set</p>

SAMPLE TREND OUTPUT

```





07/21/04 09:56:08 SpO2=000 PR=000 PI=00.00 EXC=820:OffPat,SET
07/21/04 09:56:10 SpO2=000 PR=000 PI=00.00 EXC=828:Search,OffPat,SET
07/21/04 09:56:12 SpO2=097 PR=069 PI=04.69 EXC=800:SET
07/21/04 09:56:14 SpO2=096 PR=074 PI=02.28 EXC=C00:LowSigIQ,SET
07/21/04 09:56:16 SpO2=098 PR=078 PI=03.64 EXC=800:SET
07/21/04 09:56:18 SpO2=000 PR=000 PI=00.00 EXC=800:SET
07/21/04 09:56:20 SpO2=000 PR=000 PI=00.00 EXC=820:OffPat,SET
07/21/04 09:56:22 SpO2=096 PR=078 PI=02.68 EXC=800:SET
  
```

Special Menu

This section gives an overview of the Rad-5 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. These selections apply only to the Rad-5

STANDARD AND SLEEP MODE

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

BUTTONS	SETTINGS		
 + 	Standard Mode (STD)		
	 Sleep Mode (SLP)	 LED Display Brightness (4 levels) Note: Only available indicators are illuminated while adjusting setting.	

SLEEP MODE OPERATION

The Rad-5 can be placed into the Sleep Mode to allow the device to capture normal and abnormal data without triggering alarms. This mode will blank out the device display with the exception of the Battery Level Indicator and the Alarm Silenced Indicator and disable the alarms even after a power cycle. The keypad will be locked except for the power button. 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 parameters. 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.

Alarm Indication

An alarm condition is indicated by an audible alarm tone and visual alarm indicator. An out-of-limit parameter will flash on the Rad-5 only. “SEn OFF” and “nO SEn” will only generate an alarm condition after a pulse has been found.

Alarm Limits (Rad-5 only)

WARNING: 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 met or exceeded for greater than five seconds. Directions for alarm suspension are indicated below. When a sensor is not connected to a patient, or when a sensor is not connected to its cable, the display will read SEn OFF or NO SEn. An audible alarm will accompany the display unless the oximeter has been set to Alarm Suspend Mode.

SETTING	RANGE
SpO ₂ High Limit	The SpO ₂ high alarm limit can be set anywhere between 2% and 100%, 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 100%, with a 1% step size. Note: <i>The low alarm limit must always be set below the high alarm setting. When attempting to set the high alarm limit below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.</i>
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: <i>The low alarm limit must always be set below the high alarm setting. When attempting to set the high alarm limit below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.</i>

Alarm limits (Rad-5 only) (Continued)

The following table shows the potential result of failure to respond to the cause of the alarm condition:

PRIORITY	NEED OF RESPONSE	RESULT OF FAILURE	DESCRIPTION
High	Immediate	Death or irreversable injury/Reversible injury	Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.
	Prompt	Death or irreversible injury	Having the potential for the event to develop within a period of time usually sufficient for manual corrective action
Low	Delayed	Reversible injury/ Minor injury or discomfort	Having the potential for the event to develop within an unspecified time greater than that given under "Prompt".
	Prompt	Minor injury or discomfort	Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

ALARM SILENCE

Audible alarms may be suspended. There are three audible alarm suspension settings. All three settings are controlled by the Alarm Suspend Button. Repeated pressing of the Alarm Suspend button will cycle though all three alarm suspend options. Visual alarms are not suspended, except for the Sleep Mode.

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

Push Once – Alarm is suspended for 120 seconds and Alarm Suspended Indicator flashes.

Push Twice – Audible alarm is permanently suspended and Alarm Suspended Indicator is on solid.

Push 3rd time - Return to Audible Alarm Active.

ALARM SILENCED INDICATOR

The Alarm Silenced Indicator provides visual feedback when illuminated, the Rad-5 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 and the Alarm Silenced Indicator will flash. Pressing the Alarm Silence Button a second time (while the Alarm Silenced Indicator is still flashing) will permanently silence the audible alarm, and the Alarm Silenced Indicator will remain illuminated until the power is cycled or the Alarm Silence Button is pressed one more time.

While not monitoring a patient, acknowledging an alarm condition by pressing the Alarm Silence Button (one or more times) will permanently silence the alarm tone, and the Alarm Silenced Indicator will remain illuminated until the power is cycled or patient monitoring begins.

Should the alarm condition be created by low batteries, replace the batteries before monitoring begins.

MESSAGES

The Rad-5/5v will indicate other data or system errors.

Message conditions for the Rad-5 follow:

DISPLAY	TYPE	SOLUTION
SpO ₂ NUMBER FLASHES	Saturation limit alarm	Assess /address patient condition. Re-set alarm limits if indicated.
PULSE RATE NUMBER FLASHES	Pulse Rate limit alarm	Assess /address patient condition. Re-set alarm limits if indicated.
NO SEN	No Sensor Connected	Connect sensor to cable.
SEN OFF	Sensor off patient	1. Reattach sensor to patient. 2. Verify proper sensor placement.
LEDS FLASH HORIZONTAL BARS	Pulse Search	Wait for found pulse. (This Search should occur whenever a sensor is first applied to a patient).
PULSE BAR TURNS RED (Bottom two LEDs only)	Low Perfusion	1. Rule out occlusion of blood flow. 2. Verify placement of sensor.
PERFUSION BAR TURNS RED (Bottom two LEDs only)	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.
SINGLE BATTERY LEVEL INDICATOR FLASHES (WITH AUDIBLE ALARM)	Battery level too low	Replace batteries immediately.
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, <i>Service and Repair</i> .
bAd SEN	Defective sensor	Replace sensor
SEN (blinking)	Unrecognized sensor	Connect appropriate cable
int det (blinking)	Interference detected	Ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required.

Troubleshooting

The following chart describes what to do if the Rad-5/5v system does not operate properly or fails.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
DEVICE DOES NOT POWER ON	Low battery	Check / replace battery Verify that the trending feature is off, as it may deplete battery life at a faster rate than normal.
CONTINUOUS SPEAKER TONE	Internal Failure	Device requires service. Press the Alarm Silence button. If alarm continues to sound, power down the device and remove batteries.
NO SPEAKER TONE	Pulse tone set to "mute" Alarm Suspend Enabled	Press Up Arrow (Rad-5) or Alarm Volume Adjust (Rad-5v). Inspect Alarm Suspend Indicator. See Section 4, <i>Alarm Suspend</i> . Press Alarm Suspend button until Alarm Suspend Indicator is no longer illuminated or flashing.
BUTTONS DON'T WORK WHEN PRESSED	Internal Failure	Return for service.

Rad-5/5v Specifications

PERFORMANCE

Measurement Range

Arterial Oxygen Saturation (%SpO ₂):	1-100%
Pulse Rate:	25-240 beats per minute (bpm)
Perfusion Index	0.02% - 20%

ACCURACY

Arterial Oxygen Saturation Accuracy¹

Saturation	70% to 100%
<i>No Motion¹</i>	
Adults, Pediatrics	±2%
Neonate	±3%

Motion

Adults ² , Pediatrics ²	± 3%
Neonate	± 3%

Low Perfusion³

Adults, Pediatrics	± 2%
Neonate	± 3%

Pulse Rate Accuracy⁴

Pulse Rate:	25 - 240 (bpm)
<i>No Motion</i>	
Adults, Pediatrics, Neonates	± 3 bpm
<i>Motion²</i>	
Adults, Pediatrics, Neonates	± 5 bpm
<i>Low Perfusion³</i>	
Adults, Pediatrics, Neonates	± 3 bpm

Resolution

Arterial Oxygen Saturation (%SpO ₂)	1%
Pulse Rate (bpm)	1 bpm

ELECTRICAL

Batteries

Type:	4 "AA" Alkaline ⁵
Capacity: (battery life)	over 30 hours ⁶

ENVIRONMENTAL

Operating Temperature:	32°F to 122°F (0°C to 50°C)
Transportation/Storage Temperature:	-40°F to 158°F (-40°C to +70°C) ⁵
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)

PHYSICAL CHARACTERISTICS

Dimensions:	6.2" x 3.0" x 1.4" (15.8 cm x 7.6 cm x 3.6 cm)
Weight:	13oz. (0.32 kg)

Rad-5 Modes

Rad-5 Averaging mode:	2, 4, 8, 10, 12, 14 or 16 seconds ⁷
Rad-5 Sensitivity	Normal, Maximum, and APOD
Rad-5v Averaging mode:	8 seconds
Rad-5v Sensitivity:	Normal

Alarms

Sensor condition, system failure and low battery alarms

Rad-5 only: Audible and visual alarms for high low saturation and pulse rate (SpO₂ range 1-100%, pulse rate range 25-240 bpm)

High Priority:	799 Hz tone, 5 pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time: 10s
Low Priority:	432 Hz tone, 3 pulses, repeat time: 5s
Alarm Volume:	High Priority: 75 dB (max), Low Priority: 75 dB (max)

Display/Indicators

Data display: %SpO₂, pulse rate, alarm status, alarm silenced status, Signal IQ / pleth bar, perfusion index bar, battery status

Rad-5 only:	MAX, FastSat
Type:	LED

Compliance

EMC Classification:	IEC 60601-1-2, Class B
Equipment Classification:	IEC 60601-1-1 / UL 60601-1
Type of Protection:	Internally powered (on battery power)
Degree of Protection-Patient Cable:	Type BF-Applied Part
Rad-5 Mode of Operation:	Continuous
Rad 5v Mode of Operation:	Not Continuous (Spot Check)

- Masimo SET technology has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- Masimo SET technology has been validated for motion accuracy in human blood studies on healthy adult volunteers 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% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
- 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.
- 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.
- If alkaline batteries are to be stored for extended periods of time, it is recommended that they be stored between -0°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 the lifetime of the batteries may be shortened.
- This represents approximate run time at lowest indicator brightness and pulse tone turned off using new, fully charged batteries. Ensure trending is off to maximize battery life.
- 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.

Introduction

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

Masimo SpO₂ Sensors and Cables

Before use, carefully read the sensor Directions for Use.

Use only Masimo oximetry sensors for SpO₂ measurements. Other oxygen transducers or sensors may cause improper Rad-5/5v Handheld 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). UNLESS OTHERWISE SPECIFIED, DO NOT STERILIZE BY IRRADIATION, STEAM, AUTOCLAVE 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.
- CAREFULLY ROUTE PATIENT CABLES TO REDUCE THE POSSIBILITY OF PATIENT ENTANGLEMENT OR STRANGULATION.

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.

SENSOR APPLICATION SITE

Unless indicated otherwise in the directions for use, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.

RED DIRECT CONNECT REUSABLE SENSORS

(Red direct connect reusable sensors are connected directly to the device)

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	> 1 kg	± 2% Adult/Pediatric/Infant (> 3 kg) ± 3% Neonate (1-3 kg)		± 3%	± 3 bpm	± 5 bpm	± 2% Adult/ Pediatric/Infant ± 3% Neonate
LNOP TC-I	> 30 kg	± 3.5%	N/A	± 3 bpm	N/A	± 3.5%	± 3 bpm
LNOP DC-195	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP TF-I	> 30 kg	± 2%	N/A	± 3 bpm	N/A	± 2%	± 3 bpm

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

LNOP® ADHESIVE SENSORS

(LNOP 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
LNOP Adt	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Pdt	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Neo	< 10 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP NeoPt	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Neo-L	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
	> 40 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP NeoPt-L	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Inf-L	3-20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm

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)	3-10 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
	10 - 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
LNOP Pediatric (finger or toe)							
LNOP Newborn Neonatal (hand or foot)	< 3 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
LNOP Trauma (adult finger)	> 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

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

LNCS[®] REUSABLE SENSORS

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

SENSOR	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
LNCS DC-I	> 30 kg	± 2%		± 3%	± 3 bpm	± 5 bpm	± 2%
LNCS DC-IP	10 - 50 kg	± 2%		± 3%	± 3 bpm	± 5 bpm	± 2%
LNCS TC-I	> 30 kg	± 3.5%		N/A	± 3 bpm	N/A	± 3.5%
LNCS TF-I	> 30 kg	± 2%		N/A	± 3 bpm	N/A	± 2%
LNCS YI	> 1 kg	± 2% Adult/Pediatric/Infant (> 3 kg) ± 3% Neonate (1-3 kg)		± 3%	± 3 bpm	± 5 bpm	± 2% Adult/ Pediatric/Infant ± 3% Neonate

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

LNCS[®] ADHESIVE SENSORS

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

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

LNCS[®] SPECIALTY SENSORS

LNCS specialty sensors must be used in conjunction with Red LNC cables or Rainbow RC cables.

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

M-LNCS[™] REUSABLE SENSORS

(These sensors must be used in conjunction with Rainbow RC Patient cables)

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

M-LNCS[™] SERIES ADHESIVE SENSORS

(These sensors must be used in conjunction with Rainbow RC Patient cables)

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy	
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate
M-LNCS Adb/ Adbx-3	> 30 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS Pdb/ Pdbx-3	10 - 50 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS Inf/ Inf-3	3 - 20 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS Neo/ Neo-3	> 40 kg	± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm
M-LNCS NeoP/ NeoP-3t	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm
M-LNCS NeoPt- 500	< 1 kg	± 3%	± 3%	± 3 bpm	± 5 bpm	± 3%	± 3 bpm

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.

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.

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

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-5/5v handheld pulse oximeter performance.

Introduction

This chapter covers how to test the operation of the Rad-5/5v how to properly clean the Rad-5/5v pulse oximeter, how to replace the batteries and how to obtain service.

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

WARNING: BEFORE CLEANING THE OXIMETER, ALWAYS TURN IT OFF AND REMOVE THE BATTERIES.

Cleaning

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

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

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 REPLACEMENT

The Rad-5 and Rad-5v are powered by 4 "AA" alkaline batteries. Do not use any other type of batteries or power source to run the device. The battery compartment is accessed from the back of the device. To replace the batteries first remove the battery cover by depressing the small rectangular button at the bottom of the cover, and sliding the cover down off the bottom of the device. Remove the batteries and install new batteries in the directions indicated by the battery icons inside the battery compartment. Replace the battery cover by sliding it back up from the bottom of the device until the rectangular locking button snaps back into position.

BATTERY REPLACEMENT (CONTINUED)

Battery charge level is indicated by four LED indicators at the bottom of the front panel. All four indicators will be lit when the batteries are full, with fewer indicators being lit as the batteries lose their charge. When less than ten (10) percent battery life remains, the final battery indicator will begin to flash and an audible alarm will sound.

WARNING: USE ONLY ALKALINE BATTERIES. USE OF NON ALKALINE BATTERIES MAY AFFECT THE ACCURACY OF THE BATTERY LEVEL METER.

WARNING: USE OF BATTERIES WITH A CELL VOLTAGE OF MORE THAN 1.5V COULD CAUSE DAMAGE TO THE DEVICE.

Performance Verification

To test the performance of the Rad-5/5v pulse oximeter following repairs or during routine maintenance, follow the procedure outlined in this section. If the Rad-5/5v 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 or install new batteries into the Rad-5/5v Handheld. Also disconnect any patient cables or pulse oximetry probes or serial cables from the device.

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 (Rad-5 only):

1. With the monitor turned on, select the Menu Access key and enter the 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, next to the SpO₂ or pulse rate measurement 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. Rad-5: with the monitor turned on, select menu level 3 (see Section 4, *Setup Menu Level 3 - LED Brightness and Factory Defaults*) and use the Up and Down Arrow keys to cycle through all 4 brightness levels.
2. Rad-5v: push the Display Brightness key several times to cycle through all four brightness levels
3. Exit the Menu system by pressing the Mode/Enter key or waiting for the normal time-out.

Testing Rad-5 with Masimo SET Tester (Optional):

1. Turn the Oximeter off and then on again.
2. Connect the Masimo SET Tester to the Patient Cable Connector.
3. Verify that within 20 seconds a Signal IQ/pulse bar 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.

Testing Rad-5v with Masimo SET Tester (Optional):

1. Turn the Oximeter off and then on again.
2. Connect the Masimo SET Tester to the Patient Cable Connector.
3. Verify that within 20 seconds a Signal IQ/pulse bar 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. Press the Pulse Tone Volume button several times and verify that the loudness of the pulse beep tone increases, then is turned off, then repeats the cycle.
7. Disconnect the Masimo SET Tester from the Rad-5v.
8. Verify that an audible alarm occurs, that the front panel displays "nO SE" and the Alarm indicator is flashing.
9. Press the Alarm Silence button once and verify that the alarm is silenced and the Alarm Silence Indicator is 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 device 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-5/5v for service, please follow the Return Procedure.

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

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 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-5/5v pulse oximeter to the following shipping address:

For USA, Canada & Asia Pacific	For Europe	For Other Locations
Masimo Corporation	Masimo Europe Limited	Contact your local
40 Parker	304 RN5, Le Bois des Cotes 2	Representative
Irvine, California 92618	69760 Limones, France	
Tel: 949-297-7000	Tel: +33 (0) 472 17 93 70	
FAX: 949-297-7001	FAX: +33 (0) 478 35 78 08	

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 not under warranty.

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 the 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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Exclusions continued

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Rad-5 Accessories

PART NUMBER	DESCRIPTION
1908	TrendCom Software for trend download. Requires MS-Windows, Data Transfer Download cable, TrendCom software and PC with available COM port.
2063	Data Transfer Download cable. Requires TrendCom software and PC with available COM port.
1842	Rubber protective boot, grey
1980	Rubber protective boot, yellow
1981	Rubber protective boot, red
1982	Rubber protective boot, orange
2097	Rubber protective boot, royal blue
2098	Rubber protective boot, light blue
2099	Rubber protective boot, pink
13158	Nylon protective carrying case
1795	Masimo SET Tester (with modular plug and cable)
2367	Masimo SET Tester (with DB9 connector)
13017	Rad-5/5v Users Manual, English
13261	Rad-5/5v Users Manual, French
13262	Rad-5/5v Users Manual, German
13263	Rad-5/5v Users Manual, Italian
13264	Rad-5/5v Users Manual, Spanish
13265	Rad-5/5v Users Manual, Swedish
13266	Rad-5/5v Users Manual, Dutch
13267	Rad-5/5v Users Manual, Danish
13268	Rad-5/5v Users Manual, Portuguese
13427	Rad-5/5v Users Manual, Japanese
2368	Masimo SET tester (with Mini-D connector, 20-pin)

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



www.masimo.com

Devices and sensors containing Masimo SET technology are identified with the Masimo SET logo.



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